



Guidance Notes for the Containment of Exempt Dealings

These notes are provided as guidance only to persons conducting exempt dealings pursuant to regulation 6 of the *Gene Technology Regulations 2001* (the Regulations) and, as applicable, corresponding State legislation.

Exempt dealings are dealings described in Schedule 2, Part 1 of the regulations. The only further legislative requirement for exempt dealings is that they do not involve an intentional release of the GMO into the environment.

Note that a dealing with a GMO listed as an exempt dealing will cease to be exempt from licensing if the GMO is intentionally released.

These Guidance Notes, which are effectively equivalent to those for facilities certified by the Regulator to Physical Containment Level 1 (PC1), may be of assistance to organisations or persons in determining how to undertake exempt dealings to satisfy themselves with regard to avoiding intentional release. Please note that these Guidance Notes are not Guidelines for Certification of a PC1 Facility.

A list of the Australian/New Zealand standards that are referenced in the Guidance Notes is also attached to this document.

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Explanatory Information

Guidance Notes for the Containment of Exempt Dealings

This document comprises Guidance Notes for the containment of exempt dealings as described in regulation 6 of the Regulations.

The Guidance Notes are only applicable to exempt dealings conducted under the *Gene Technology Act 2000* (the Act). They do not provide comprehensive guidance for laboratory safety, good laboratory practice or broader occupational health and safety issues, nor do they provide comprehensive guidance for laboratory design and construction. For these purposes, refer to AS/NZS 2243.3 and AS/NZS 2982.1.

Containment of Exempt Dealings

Definitions and acronyms

Unless defined otherwise in these Guidance Notes, words and phrases used have the same meaning as in the Act and the Regulations.

Words in the singular include the plural and words in the plural include the singular.

Where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning.

aerosol	Suspension in air of finely dispersed solids and/or liquids.
dealing or deal with	<p>In relation to a GMO, means the following:</p> <ul style="list-style-type: none">(a) conduct experiments with the GMO;(b) make, develop, produce or manufacture the GMO;(c) breed the GMO;(d) propagate the GMO;(e) use the GMO in the course of manufacture of a thing that is not the GMO;(f) grow, raise or culture the GMO;(g) import the GMO;(h) transport the GMO;(i) dispose of the GMO; <p>and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (i).</p>
Decontamination	A physical or chemical process which removes, kills or renders non-viable the GMOs used. In the case of micro-organisms this may not necessarily result in sterility.
environment	<p>Includes:</p> <ul style="list-style-type: none">(a) ecosystems and their constituent parts;(b) natural and physical resources; and(c) the qualities and characteristics of locations, places and areas.
exempt dealing	A dealing conducted pursuant to regulation 6 of the Regulations.
facility	The laboratory or other work area within which exempt dealings are contained.

GM	Genetically modified.
GMO	Genetically modified organism.
sealed	Able to contain all GMOs or the reproductive material of GM plants or GM aquatic organisms (including pollen or gametes) being transported or stored, and able to remain closed during all reasonably expected conditions of transport and storage.

Which parts of these Notes are applicable?

If you are conducting exempt dealings with GM micro-organisms or tissue cultures only, you should refer to:	Part 1 (A) and Part 2 (A)
If you are conducting exempt dealings with animals containing GM micro-organisms, you should refer to:	Parts 1 (A) & (B) and Parts 2 (A) & (B)

Part 1 – Facility and fitting requirements

1. Exempt dealings with GMOs should be conducted in a facility that is a fully enclosable space bounded by walls, doors, windows, floors and ceilings.

NOTE: The walls, doors, windows, floors and ceilings form the physical containment barrier around the area where exempt dealings with GMOs will be conducted.

2. Floors and benches in the facility should be cleanable, easily decontaminated and resistant to damage by the cleaning agents and/or decontamination agents that will be used in the facility.
3. The facility should contain either a wash basin or some other means of decontaminating hands.

NOTE: Decontamination of hands is considered an important means of preventing unintentional release of GMOs. Alternatives to wash basins, such as dispensers filled with decontamination agents, are considered suitable.

4. If the facility has drainage exits, they should be fitted with barriers (e.g. fine mesh). This is to prevent the movement, either in or out of the facility, of animals, including invertebrates, via the drains.

Additional facility and fitting requirements for Exempt Dealings with animals containing GMOs

5. Doors and windows that are able to be opened should be lockable or otherwise able to be secured. Windows that are able to be opened should be screened to prevent the entry or exit of animals, including invertebrates.
6. The facility boundaries (doors, walls, floors, ceilings etc.) should be designed to prevent the escape of the animals containing GMOs.
7. Any openings in the facility walls, ceiling or roof, such as air vents, should be screened with rodent-proof mesh.

Part 2 – Work practices

8. Access to the facility should be restricted to persons authorised to enter.
9. Dedicated “emergency only” exits should not be used except in emergencies.
10. Persons performing procedures with GMOs in the facility should wear protective clothing to protect the front part of the body from exposure to the GMOs.
11. Personal protective equipment should be removed and disposed of, or stored, before leaving the facility.

NOTE: Consideration should be given to the provision of hooks or other storage for personal protective equipment.

12. Personal protective equipment contaminated with or suspected to be contaminated with GMOs should be removed as soon as practicable and decontaminated prior to reuse or disposal. Protective clothing that has not been contaminated with GMOs may be washed using normal laundry methods.
13. Precautions should be taken to minimise the production of aerosols where procedures involving GMOs are carried out on an open bench.
14. All cultures of GMOs should be labelled.

NOTE: Labelling assists the separation of GM work from non-GM work and enhances the control of GMOs within the facility.

15. GMOs, or non-GM organisms containing GMOs, should be rendered non-viable prior to disposal if the method of disposal is not also the method of decontamination.
16. Any wastes containing GMOs should be decontaminated prior to disposal if the method of disposal is not also the method of decontamination.

17. Work benches and surfaces where procedures involving GMOs have taken place should be decontaminated when the dealings are completed. Equipment directly used in procedures involving GMOs and equipment suspected to be contaminated should be decontaminated when the dealings are completed.

NOTE: This is to minimise any persistence of GMOs inside the facility and minimise cross-contamination with any other work.

18. Equipment contaminated with or suspected to be contaminated with GMOs should be decontaminated before being removed from the facility.
19. Decontamination can be achieved by any method effective in rendering the GMO non-viable.

NOTES: Decontamination can take place in the facility or at another location. Readers may like to refer to Section 3.1 of the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as in force from time to time, for guidance in decontamination methods.

20. A supply of decontamination agents effective against the GMOs used in the facility should be available in the facility for decontamination purposes. Containers of decontamination agents, including any solutions for decontaminating hands, should be labelled with the contents and the expiry date. Decontamination agents should not be used after the expiry date.

NOTES: AS/NZS 2243.3 is a recommended source of information when selecting chemical decontamination agents.

21. All cultures of GMOs being stored inside the facility should be sealed during storage to prevent dissemination of the GMOs.

NOTE: The type of containment necessary to prevent the GMOs from escaping will vary depending on the type of GMO being stored.

22. Persons who have been performing procedures with GMOs in the facility should decontaminate their hands before leaving the facility.

NOTE: This may include the use of soap and water, if appropriate.

23. Transport, storage and disposal of all GMOs outside of the facility should be conducted in such a way to prevent intentional release of GMOs into the environment.

Additional work practices for exempt dealings with animals containing GMOs

24. Except during the entry and exit of personnel, supplies and/or equipment, doors of the facility should be closed while procedures with animals containing GMOs are being conducted. Windows and doors should be locked when facility personnel are not in attendance.
25. Handling of and any experimental procedures conducted on the animals containing GMOs should be carried out in a way that minimises the chance of escape of the animals.
26. When not being handled, the animals containing GMOs should be kept in containers or cages designed to prevent the escape of the animals being contained.

NOTE: The facility physical boundaries alone are not sufficient for containment.

27. All animal cages or containers should be labelled. Cages or containers should be labelled to enable identification of the animals containing GMOs and to indicate the number of animals in the containers. Large animals containing GMOs should be clearly marked so that they can be readily identified (eg. with a tattoo, permanent tag, microchip or permanent brand). Some documented system of accounting for the number of animals containing GMOs in the facility should be used.
28. If an animal containing GMOs escapes within the facility, the animal should be captured and returned to its container of cage, or euthanised.

Standards referenced in this document

‘AS’ followed by a number or other identification is a reference to the Australian Standard so numbered or identified.

‘AS/NZS’ followed by a number or other identification is a reference to the Australian/New Zealand Standard so numbered or identified.

Refer to the most recent issue of the Australian or Australian/New Zealand Standards.

AS/NZS 2243.3 Safety in laboratories
Part 3: Microbiological aspects and containment facilities

AS/NZS 2982.1 Laboratory design and construction
Part 1: General requirements