



Guidelines for the Containment of Exempt Dealings

Guidelines for the purpose of regulation 6(1)(c) of the *Gene Technology Regulations 2001*

Version 1.1 – issued 30 March 2007

These guidelines are issued by the Gene Technology Regulator (the Regulator) under section 27(d) of the *Gene Technology Act 2000* and, as applicable, corresponding State legislation.

These guidelines apply to exempt dealings conducted pursuant to regulation 6(1)(c) of the *Gene Technology Regulations 2001* (the regulations) as in force from 31 March 2007 and/or pursuant to any applicable corresponding law. Any subsequent reference in this document to ‘the regulations’ will be a reference to the regulations as applicable under Commonwealth and/or corresponding State law.

It is not a requirement of these guidelines that exempt dealings take place in a certified facility. Where dealings are conducted that are required to be contained in a certified PC1 facility, then the Regulator’s *Guidelines for Certification of a Physical Containment Level 1 Facility* apply.

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

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Explanatory Information

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This document comprises the guidelines for the conduct of exempt dealings pursuant to regulation 6(1)(c) of the *Gene Technology Regulations 2001* as in force from 31 March 2007.

The conditions are based on a Physical Containment (PC) Level equivalent to PC1 in AS/NZS 2243.3.

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

Compliance with these guidelines will satisfy the Regulator's requirements with respect to exempt dealings but this does not imply that a facility is compliant with AS/NZS 2243.3.

The primary function of these guidelines is to assist the broad objectives of the Act, that is, the protection of the health and safety of people and the environment. The Regulator considers that achievement of these objectives will be achieved if exempt dealings with GMOs are properly contained within a facility that meets the conditions in these guidelines.

Conditions for the Containment of Exempt Dealings

Exempt Dealings Version 1.1 – issued 30 March 2007

THESE TECHNICAL AND PROCEDURAL GUIDELINES ARE ISSUED UNDER SECTION 27(d) OF THE *GENE TECHNOLOGY ACT 2000* (THE ACT) AND, AS APPLICABLE, CORRESPONDING STATE LEGISLATION.

EXEMPT DEALINGS WITH GMOs MUST BE CONDUCTED IN ACCORDANCE WITH THESE GUIDELINES.

Definitions

Unless defined otherwise in these guidelines, words and phrases used in the guidelines 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.

Where a word in the text is **bolded**, it indicates that the word has been defined (see below).

aerosol	Particulate matter, solid or liquid, small enough to remain suspended in air.
autoclave	Pressure steam steriliser.
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; <p>and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (g).</p>
decontamination	A physical or chemical process which kills or renders non-viable the GMOs being dealt with in the facility , but does not necessarily result in sterility.

environment	Includes: (a) ecosystems and their constituent parts; (b) natural and physical resources; and (c) the qualities and characteristics of locations, places and areas.
exempt	A dealing conducted pursuant to regulation 6 of the regulations.
facility	The non-certified laboratory or other work area within which exempt dealings are contained.
GM	Genetically Modified.
GMO	Genetically Modified Organism.
PC1	Physical Containment Level 1.
primary container	The container directly surrounding the GMO .
sealed	Able to contain and prevent the escape/release of all GMOs or GM reproductive material (including pollen or gametes), including during standard transport conditions.
the Regulator	The Gene Technology Regulator.
unbreakable	Able to maintain integrity under all reasonably expected conditions of transport such as pressures, forces, impacts, temperatures and moisture.

What requirements and conditions are applicable?

If you are conducting exempt dealings with GM animals only, you will need to refer to:	Parts 1 (A) & (B) and Parts 2 (A) & (B)
If you are conducting exempt dealings with GM micro-organisms only, you will need to refer to:	Parts 1 (A) & (C) and Parts 2 (A) & (C)
If you are conducting exempt dealings with GM micro-organisms within an animal(s) , you will need to refer to: <i>Note: if the exempt dealing involves GM micro-organisms within a non-GM animal, the animal must also be treated as if it were GM.</i>	Parts 1 (A), (B) & (C) and Parts 2 (A), (B) & (C)

Part 1 – Facilities and fittings

A) Requirements for all exempt dealings with GMOs

1. **Exempt dealings** with **GMOs** must 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** are being or will be conducted.

B) Requirements for exempt dealings with GM animals

2. Doors, and windows that are able to be opened, must be lockable. Windows that are able to be opened must be screened to prevent the entry or exit of arthropods.
3. Except when persons are entering or exiting the **facility**, doors of the **facility** must be closed while **GM** animals are contained there. Windows and doors must be locked when **facility** personnel are not in attendance.
4. The **facility** boundaries (doors, walls, floors, ceilings etc.) must be designed to prevent the escape of the **GM** animals being contained.
5. Any openings in the **facility** walls, ceiling or roof, such as air vents, must be screened with rodent proof mesh.
6. If the **facility** has drainage exits, they must be fitted with barriers (e.g. floor wastes or mesh) to prevent rodents or any other animal from entering the **facility** via the drains and to prevent the escape of **GM** animals from the **facility**.

C) Requirements for exempt dealings with GM micro-organisms

7. Floors and benches in the **facility** must be cleanable, easily **decontaminated** and resistant to damage by the cleaning agents and/or disinfectants that will be used in the **facility**.
8. The **facility** must 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 **GM** micro-organisms. Alternatives to wash basins, such as dispensers filled with **decontaminant** solutions, are considered suitable.

Part 2 – Behavioural conditions

A) Conditions for all exempt dealings with GMOs

9. Access to the **facility** must be restricted to persons authorised to enter.
10. Emergency only exits must not be used except in emergencies.
11. **The Regulator** or a person authorised by **the Regulator** must, at all reasonable times, be allowed to enter the **facility** for the purposes of auditing or monitoring the conditions applying to the certified **facility** and any **dealings** being conducted in it.
12. **GMOs** must not be removed from the **facility** unless:
 - (a) they are to be transported to another **facility** that meets at least these Guidelines for the Containment of Exempt Dealings;
 - (b) they are to be transported to another location for storage;
 - (c) they are to be transported to another location to be **decontaminated** prior to disposal;
 - (d) written permission has been given by **the Regulator** for transport to another destination within Australia; or
 - (e) subject to obtaining any required permits, they are to be transported to the Australian border for export.
13. **Decontamination** can be effected by: **autoclaving** or other heat treatment; chemical treatment; incineration; or by any other method approved in writing by **the Regulator**.

Incineration must be performed in a high temperature, high efficiency incinerator that has been approved by the relevant government authority in the jurisdiction where the incinerator is located.

NOTES: **Decontamination** can take place in the **facility** or at another location.

AS/NZS 2243.3 is a recommended source of information when selecting chemical disinfectant agents.

14. All **GMOs** and waste contaminated with **GMOs** being transported outside of the **facility**, including transport to storage outside the **facility**, must be transported in accordance with any transport guidelines and other relevant guidelines, issued by **the Regulator** and as in force from time to time.
15. **GMOs** or organisms containing **GMOs** may be stored outside the **facility** in a storage unit (freezer, fridge, controlled temperature room or other container). Access to the storage unit must be restricted or controlled to prevent unintentional release of **GMOs** into the **environment**.
16. **GMOs** or organisms containing **GMOs** being stored outside the **facility** must be stored in a labelled, **sealed, unbreakable primary container** to prevent the escape or release of the **GMO**.

17. Any real or suspected unintentional release of **GMOs** from the **facility**, including a spill or escape, must be reported to **the Regulator** as soon as reasonably possible.

B) Conditions for all exempt dealings with GM animals

18. Except during the entry or exit of personnel, supplies or equipment, doors of the **facility** must be closed while **GM** animals are contained there. Windows and doors must be locked when **facility** personnel are not in attendance.
19. When not being handled, the **GM** animals must be kept in containers or cages designed to prevent the escape of the **GM** animals being contained.

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

20. All animal cages or containers must be labelled to enable identification of the **GM** animals being contained and to indicate the number of **GM** animals in the containers. Large **GM** animals must be marked so that they can be identified (eg. with a tattoo, permanent tag, microchip or permanent brand). A system of accounting for the **GM** animals in the **facility** must be used.
21. Handling of the **GM** animals and any experimental procedures conducted on the **GM** animals must be carried out in a way that minimises the chance of escape.
22. If an animal escapes within the **facility**, trapping devices must be used to capture the animal and the animal must be returned to its container or cage or euthanased.

C) Conditions for all exempt dealings with GM micro-organisms

23. Precautions must be taken to minimise the production of **aerosols** where procedures involving **GMOs** are carried out on an open bench.
24. All cultures of **GMOs** must be labelled.

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

25. All cultures of **GMOs** being stored inside the **facility** must 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.

26. If any spills of **GMOs** occur outside the **facility**, the contaminated surfaces must be **decontaminated** as soon as reasonably possible.
27. A supply of disinfectants effective against the **GMOs** used in the **facility** must be available in the **facility** for **decontamination** purposes. Containers of disinfectants, including any solutions for **decontaminating** hands, must be clearly labelled with the contents and, where necessary, the expiry date. Solutions must not be used after the expiry date.

28. Persons performing procedures with **GMOs** in the **facility** must wear protective clothing to protect the front part of the body from exposure to the **GMOs**.
29. Protective clothing must be removed and disposed of or stored before leaving the **facility**. This condition does not apply if moving directly to another equivalent or higher level physical containment area that is directly connected to the **facility**, or is connected by a corridor that has no public access and in which there is negligible risk of cross-contamination should other personnel be encountered or contacted in the corridor.

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

30. Protective clothing contaminated or suspected to be contaminated with **GMOs** must be removed as soon as reasonably possible and **decontaminated** prior to reuse. Protective clothing that has not been contaminated with **GMOs** may be washed using normal laundry methods.
31. Work benches, surfaces and equipment where procedures involving **GMOs** have taken place must be **decontaminated** when the procedures are completed.

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

32. **GMOs** must be **decontaminated** prior to disposal.
33. Carcasses of animals containing **GMOs** must be **decontaminated** by **autoclaving**, incineration or any other method approved in writing by **the Regulator**.
34. Liquid and solid wastes potentially containing **GMOs** must be **decontaminated** prior to disposal.
35. Any equipment that is, or may be, contaminated with **GMOs** must be **decontaminated** prior to being removed from the **facility**.
36. Persons who have been performing procedures with **GMOs** in the **facility** must **decontaminate** their hands before leaving the **facility**.

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

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 in force or existing from time to time.

‘AS/NZS’ followed by a number or other identification is a reference to the Australian New/Zealand Standard so numbered or identified, as in force or existing from time to time.

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