Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

# Guidelines for Certification
## of a
# Physical Containment Level 1 Facility

### Version 1.1– issued 30 March 2007

These guidelines contain the requirements for certification of a Physical Containment Level 1 (PC1) Facility issued pursuant to section 90 of the *Gene Technology Act 2000* (the Act).

These guidelines apply to facilities containing dealings that are required to be conducted in a PC1 facility certified by the Gene Technology Regulator (the Regulator).

Once a facility is certified, the certification instrument imposes conditions on the facility pursuant to section 86 of the Act.

The conditions of certification, attached to this document, detail the usual conditions that will apply to a PC1 Facility. Individual certification conditions may differ from these in some respect but generally an applicant can expect that their conditions will closely follow those published here.

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

A separate document - *Explanatory Information on Guidelines for Certification of Physical Containment Facilities* - contains details about the process of certification.

# Contents

# Requirements for Certification

**Physical Containment Level 1 Facility**
**Version 1.1 – issued 30 March 2007**

CONTAINMENT REQUIREMENTS THAT MUST BE MET IN ORDER FOR A PHYSICAL CONTAINMENT LEVEL 1 (PC1) FACILITY TO BE CERTIFIED BY THE GENE TECHNOLOGY REGULATOR (THE REGULATOR).

Section 90 of the *Gene Technology Act 2000*

These are the requirements for the certification of a PC1 Facility issued under section 90 of the *Gene Technology Act 2000* (the Act) and, as applicable, corresponding State legislation. These requirements apply to applications for certification of PC1 Facilities received on or after the day on which these guidelines take effect.

To be granted certification, a facility must meet each of the requirements for certification of a PC1 Facility, unless the facility receives a written exemption from meeting a particular requirement from the Regulator or a delegate of the Regulator.

## Definitions

Unless defined otherwise in these guidelines, words and phrases used in the guidelines have the same meaning as in the Act and the *Gene Technology Regulations 2001*.

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).

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| **aerosol** | Particulate matter, solid or liquid, small enough to remain suspended in air. |
| **autoclave** | Pressure steam steriliser. |

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| **dealing or deal with** | In relation to a **GMO**, means the following:<br>(a) conduct experiments with the **GMO**;<br>(b) make, develop, produce or manufacture the **GMO**;<br>(c) breed the **GMO**;<br>(d) propagate the **GMO**;<br>(e) use the **GMO** in the course of manufacture of a thing that is not the **GMO**;<br>(f) grow, raise or culture the **GMO**;<br>(g) import the **GMO**;<br>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). |
| **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:<br>(a) ecosystems and their constituent parts;<br>(b) natural and physical resources; and<br>(c) the qualities and characteristics of locations, places and areas. |
| **facility** | The whole of the space that is to be certified by **the Regulator** to a specific level of containment. |
| **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. |
| **secondary container** | The container immediately surrounding the **primary container**. |
| **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. |

# General requirements

1. The applicant must be able to demonstrate a capacity to comply with the conditions of certification that will be generally applied to a certified PC1 Facility. These conditions are attached to this document.

# Facilities and fittings requirements

### What 'Facilities and fittings requirements' must be met?

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| If the **facility** will contain **dealings** with **GM** animals only, the **facility** must comply with the requirements in the following sections: | Facilities and fittings (A) & (B) |
| If the **facility** will contain **dealings** with **GM** micro-organisms only, the **facility** must comply with the requirements in the following sections: | Facilities and fittings (A) & (C) |
| If the **facility** will contain **dealings** with **GM** micro-organisms within an animal(s), the **facility** must comply with the requirements in the following sections:<br>*Note: if the **dealing** involves **GM** micro-organisms within a non-**GM** animal, the animal must be treated as if it were **GM.*** | Facilities and fittings (A), (B) & (C) |
| If the **facility** will contain **dealings** with non-**GM** plants that contain or host **GMOs**, the **facility** must comply with the requirements in the following sections: | Facilities and fittings (A), (C) & (D) |

### A) Requirements for all facilities containing dealings with GMOs

2. The **facility** to be certified must be 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 **dealings** with **GMOs** will be conducted.

### B) Requirements for facilities containing dealings with GM animals

3. 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.

4. 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.

5. The **facility** boundaries (doors, walls, floors, ceilings etc.) must be designed to prevent the escape of the **GM** animals being contained.

6. Any openings in the **facility** walls, ceiling or roof, such as air vents, must be screened with rodent proof mesh.

7. If the **facility** has drainage exits, they must be fitted with barriers (e.g. floor wastes or mesh) to prevent rodents or any other animals from entering the **facility** via the drains and to prevent the escape of animals from the **facility**. Where a **dealing** being conducted in the **facility** involves animals containing a **GMO** capable of being transmitted by arthropods, the drains must also be designed to prevent arthropods from entering or leaving the **facility** via the drains (e.g. by use of liquid traps permanently filled with water, or by a mesh that acts as a barrier to both arthropods and rodents).

## C) Requirements for facilities containing dealings with GM micro-organisms

8. 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**.

9. 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.

10. Designated storage or hanging provisions for protective clothing must be available within the **facility**.

## D) Requirements for facilities containing dealings with non-GM plants that contain or host GMOs

11. Transparent sections may be used in walls, doors and ceilings if required.

12. All boundaries of the **facility** must be rigid and durable, must be suitable for the **environment** in which the **facility** is located, and must withstand expected wear and tear without risking loss of containment. Any transparent sections of the **facility** boundary must made of glass, polycarbonate sheeting or other similar durable material. All boundaries must be impact resistant or must be protected from impact.

> NOTE: 'Impact resistant' or 'protected' refers to the ability of the boundaries to withstand exposure to events such as hailstones, wind-borne debris, birds and objects displaced by equipment or machinery such as lawnmowers.

13. The **facility** must be designed to prevent the entry of surface run-off water.

14. Any openings in the walls, ceiling or roof, such as windows, vents and air-conditioning or ventilation inlets and outlets, must be screened or filtered at the containment boundary to prevent entry or exit of arthropods and, where applicable, the escape of any arthropod vectors used for pollination. The screening material must be of a material mechanically strong enough to withstand the airflow load, remain undamaged with regular cleaning, and resist corrosion.

15. If the **facility** has drainage exits, they must be fitted with a barrier such as mesh, grilles or floor wastes, to prevent entry of rodents and arthropods.

# General conditions of certification

## Facilities and fittings conditions

1. The certification holder must ensure that the physical attributes of the **facility** and fittings are maintained so that the relevant 'Facilities and fittings requirements' for certification continue to be met.

   NOTE: If the type of **dealings** change, the certification holder must ensure the 'Facilities and fittings requirements' applicable to the new **dealings** are met. For example, if the **facility** was originally used for **dealings** with micro-organisms and will now be used for **dealings** with animals, then any unlockable doors would need to be modified so they are lockable.

2. If the certification holder is not the owner of the **facility** and does not have the authority to maintain the **facility** and fittings, the certification holder must notify **the Regulator** in writing if the owner of the **facility** is incapable of carrying out, or refuses to carry out, or otherwise does not carry out, any maintenance required to continue to meet the 'Facilities and fittings requirements'.

3. Each access door to the **facility** must be labelled with a **PC1** sign as supplied by the **OGTR** so that persons entering the **facility** are able to clearly see they are entering a certified **PC1 facility**. Emergency only exits must not be used except in emergencies.

   NOTE: Signs do not need to be displayed on or next to the outside of dedicated "emergency only" exits. Signs may be stuck onto removable fixtures, such as backing boards or plastic frames, which must be secured to the door or adjacent wall and must not be transferred to any other location.

## Obligations of the holder of certification in respect of users of the facility

4. While any **dealings** with **GMOs** are being conducted in the **facility**, the certification holder must ensure that access to the **facility** is restricted to authorised persons.

5. For purposes of the previous condition, an authorised person is:
   (a) A person who:
      (i) intends to undertake **dealings,** and has been notified of and trained in the **PC1** behavioural conditions listed below, and
      (ii) has agreed to comply with those behavioural conditions, and
      (iii) has not been excluded from the **facility** by the certification holder on the direction of **the Regulator**; or
   (b) An individual, or class of person, who does not intend to undertake **dealings** and has the permission of the certification holder, its representative or the **facility** manager, to enter the **facility**.

6. If **the Regulator** directs the certification holder to exclude a person or class of person from entry to the **facility**, the certification holder must exclude that person or class of person from the **facility** unless and until otherwise directed by **the Regulator**.

7. If **the Regulator** directs the certification holder to admit a person or class of person to the **facility** subject to conditions, the certification holder must only admit the person or class of person subject to those conditions.

8. Before admitting a person or class of person subject to conditions, the certification holder must notify the person of any conditions that would apply to them.

9. **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 **facility** and any **dealings** being conducted in it.

# Behavioural conditions relating to dealings conducted in the facility

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| If the **facility** will contain **dealings** with **GM** animals *not* containing micro-organisms, the conditions in the following sections must be complied with: | Behavioural conditions (A) & (B) |
| If the **facility** will contain **dealings** with **GM** micro-organisms, the conditions in the following sections must be complied with: | Behavioural conditions (A) & (C) |
| If the **facility** will contain **dealings** with **GM** micro-organisms within an animal(s), the conditions in the following sections must be complied with:<br>*Note: if the **dealing** involves **GM** micro-organisms within a non-**GM** animal, the animal must be treated as if it were **GM.*** | Behavioural conditions (A), (B) & (C) |
| If the **facility** will contain **dealings** with non-**GM** plants that contain or host **GMOs**, the conditions in the following sections must be complied with: | Behavioural conditions (A), (C) & (D) |

### A) Conditions for all dealings with GMOs

10. Non-**GMOs** used in the **facility** while a **GMO dealing** is occurring are subject to these conditions unless:
    (a) procedures are implemented to ensure that **dealings** with **GMOs** do not result in the unintentional cross-contamination of non-**GM** work;
    (b) the above procedures are documented; and
    (c) prior to removal from the **facility,** all **primary containers** and any **secondary containers** are **decontaminated**.

    NOTE: Means of preventing cross-contamination of other work by **GMO dealings** could include physical separation of the work, or separation by

working at different times and ensuring any contaminated surfaces are **decontaminated** prior to commencing work with non-**GMOs**.

11. **GMOs** requiring **PC1** containment must not be removed from the **facility** unless:
    (a) they are to be transported to another containment **facility** certified by **the Regulator** to at least **PC1**;
    (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.

12. **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.

13. 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.

14. **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**.

15. In the case of Notifiable Low Risk Dealings, the notifying organisation must authorise the storage of **GMOs** outside of the **facility**.

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 dealings involving animals

18. Except during the entry and exit of personnel, supplies, or equipment, doors of the **facility** must be closed while **dealings** involving animals are contained there. Windows and doors must be locked when **facility** personnel are not in attendance.

19. When not being handled, the animals involved in **dealings** must 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.

20. All animal cages or containers must be labelled to enable identification of the animals being contained and to indicate the number of animals in the containers. Large 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 animals in the **facility** must be used.

21. Handling of the animals involved in **dealings** and any experimental procedures conducted on the animals must be carried out in a way that minimises the chance of escape.

22. If an animal involved in **dealings** 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 dealings with GM micro-organisms (including plants and animals containing GMOs)

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 before leaving the **facility** and disposed of or stored in the designated storage or hanging provisions. This condition does not apply if moving directly to another containment **facility**, certified to at least **PC1** by **the Regulator**, that is directly connected to the **facility** or is connected by a corridor that is not a public thoroughfare and in which there is negligible risk of cross-contamination should other personnel be encountered or contacted in the corridor.

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.

## D) Conditions for all dealings with non-GM plants that contain or host GMOs

37. Any effluent waste containing **GMOs**, including run off, must be **decontaminated** prior to release from the **facility**.

38. All plants and containers containing **GMOs** or **GM** material must be labelled. This may be achieved by labelling plants, containers or trays as relevant.

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

# 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.

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|---|---|
| AS/NZS 2243.3 | Safety in laboratories<br>Part 3: Microbiological aspects and containment facilities |