



# **Guidelines for Certification of a Physical Containment Level 2 Culture Facility**

**Version 2.1– Effective <Day> <Month> 2010**

The guidelines (Part A) contain the requirements for certification of a Physical Containment Level 2 (PC2) Culture Facility issued pursuant to section 90 of the *Gene Technology Act 2000* (the Act) and, as applicable, corresponding State legislation.

Once a facility is certified, the certification instrument imposes conditions on the facility pursuant to section 86 of the Act. The conditions of certification (Part B), detail the usual conditions that will apply to a PC2 Culture 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. Once issued, the conditions may be varied by the Gene Technology Regulator as necessary and appropriate.

A list of the Australian/New Zealand Standards that are referenced throughout this document is also attached.

A separate document - *Explanatory Information on Guidelines for Certification of Physical Containment Facilities* - contains details about the process of certification. This document can be downloaded from the OGTR website <[www.ogtr.gov.au](http://www.ogtr.gov.au)>.

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## Requirements for Certification

### Physical Containment Level 2 Culture Facility Version 2.1– Effective <Day> <Month> 2010

CONTAINMENT REQUIREMENTS THAT MUST BE MET IN ORDER FOR A PHYSICAL CONTAINMENT LEVEL 2 (PC2) CULTURE 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 PC2 Culture 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 PC2 Culture 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 PC2 Culture Facility, unless the facility receives a written exemption from meeting a particular requirement from the Regulator or a delegate of the Regulator.

### Definitions and acronyms

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

**aerosol**                      Suspension in air of finely dispersed solids and liquids.

**autoclave**                    Pressure steam steriliser.

<b>dealing or deal with</b>	In relation to a <b>GMO</b> , means the following: (a) conduct experiments with the <b>GMO</b> ; (b) make, develop, produce or manufacture the <b>GMO</b> ; (c) breed the <b>GMO</b> ; (d) propagate the <b>GMO</b> ; (e) use the <b>GMO</b> in the course of manufacture of a thing that is not the <b>GMO</b> ; (f) grow, raise or culture the <b>GMO</b> ; (g) import the <b>GMO</b> ; (h) transport the <b>GMO</b> ; (i) dispose of the <b>GMO</b> ; and includes the possession, supply or use of the <b>GMO</b> for the purposes of, or in the course of, a <b>dealing</b> mentioned in any of the paragraphs (a) to (i).
<b>decontamination</b>	A physical or chemical process which removes, kills or renders non-viable the <b>GMOs</b> being <b>dealt</b> with in the <b>facility</b> , but does not necessarily result in sterility.
<b>environment</b>	Includes: (a) ecosystems and their constituent parts; (b) natural and physical resources; and (c) the qualities and characteristics of locations, places and areas.
<b>facility</b>	The whole of the space that is to be certified by <b>the Regulator</b> to a specific level of containment.
<b>GM</b>	Genetically Modified.
<b>GMO</b>	Genetically Modified Organism.
<b>NLRD</b>	Notifiable Low Risk Dealing.
<b>OGTR</b>	Office of the Gene Technology Regulator.
<b>PC2</b>	Physical Containment Level 2.
<b>primary container</b>	The container directly surrounding the <b>GMO</b> .
<b>sealed</b>	Able to contain and prevent the escape/release of all <b>GMOs</b> or <b>GM</b> reproductive material, including under standard transport conditions.
<b>secondary container</b>	The container immediately surrounding the <b>primary container</b> .
<b>the Regulator</b>	The Gene Technology Regulator.

**unbreakable**                   Able to maintain integrity under all reasonably expected conditions of transport such as pressures, forces, impacts, temperatures and moisture.

## Facility and fittings requirements

1. 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 of the **facility** where **dealings** with **GMOs** will be conducted. This barrier protects all spaces outside the **facility**, including internal spaces of buildings in which a certified **facility** is located, and the **environment**.

2. The following surfaces in the **facility** must be smooth, impermeable to water, easily cleanable, and resistant to damage by the cleaning agents and/or **decontamination** agents that will be used in the **facility**:
  - (a) walls, floors, doors, windows, and benches;
  - (b) furniture, including seating; and
  - (c) any other surfaces, where contamination is likely to occur or where **decontamination** is required.
3. Open spaces between and under benches, cabinets and equipment in the **facility** must be accessible for **decontamination**.

NOTE: The requirement for access to open spaces is to allow for easier **decontamination** of spills and to reduce any persistence of **GMOs** on the floor.

## Capacity to comply with certification conditions

4. The applicant must be able to demonstrate a capacity to comply with the conditions of certification that will generally be applied to a certified **PC2** Culture Facility. These conditions are found in Part B of this document.

## Conditions of Certification

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Conditions are imposed on facilities by the Regulator at the time of certification pursuant to section 86 of the *Gene Technology Act 2000* (the Act) and, as applicable, corresponding State legislation. The condition clauses in this section are the ones that can be expected, in most cases, to be included in the certification instrument as the conditions of certification for a Physical Containment Level 2 (PC2) Culture Facility.

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

1. 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.
2. For purposes of condition 1, an authorised person is a person who:
  - (a) intends to undertake **dealings**, and has been trained in accordance with the Behavioural Requirements listed at Part C of this document;
  - (b) has signed, dated and provided to the certification holder a record of the training referred to in paragraph 2(a) above; and
  - (c) has not been excluded from the **facility** by the certification holder on the direction of **the Regulator**;or
  - (d) is an individual, or class of person, who does not intend to undertake **dealings** and has the permission of the certification holder, the **facility** manager or other representative of the certification holder, to enter the **facility**.
3. If **the Regulator** requests the certification holder to provide a signed and dated record of the training provided to a particular authorised person, or class of person, the signed and dated record of that training must be available to **the Regulator** within a time period stipulated by **the Regulator**.
4. If **the Regulator** directs the certification holder to exclude a person, or class of person, from entry to the **facility** on the grounds that the person, or class of person:
  - (a) has behaved, or is behaving, in a manner which has caused, or which may cause, **GMOs** to escape from the **facility**; or
  - (b) has behaved, or is behaving, in a manner which has exposed, or exposes, other persons in the **facility** to a **GMO** in circumstances where the exposure causes, or is capable of causing, a threat to the health and safety of those other persons;

the certification holder must exclude that person, or class of person, from the **facility** unless and until otherwise directed by **the Regulator**.

5. 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.
6. For the purposes of condition 5, before admitting a person, or class of person, subject to conditions, the certification holder must notify the person(s) of any conditions that apply to them.
7. If **the Regulator** invites the certification holder to make a submission on whether or not a person, or class of person, should:
  - (a) be excluded from entry to the **facility**; or
  - (b) be admitted to the **facility** subject to conditions;the certification holder may make such a submission within a time period stipulated by **the Regulator**.
8. If the certification holder is not the owner of the **facility** and does not have the authority to admit and exclude persons from the premises, the certification holder must not allow **dealings** in the **facility** until such authority is obtained in writing from the owner of the **facility**. If the certification holder does not have the capacity to prevent **dealings** from occurring, the certification holder must notify **the Regulator** of this in writing as soon as reasonably possible.
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.

## Work not permitted in this facility type

10. The following work must not be conducted in this **facility**:
  - (a) **dealings** with any **GMO** that under the conditions of a licence or legislation requires containment in any physical containment level higher than **PC2**;
  - (b) the growing of any plants (except those in tissue culture or other containment device approved in writing by **the Regulator**);
  - (c) the housing of any animals (except animals that are in diapause or another form of dormancy);
  - (d) any dealing with a **GMO** where the primary containment for the **GMO** is broken or opened;
  - (e) **dealings** producing more than 25 litres of **GMO** culture in each vessel containing the resultant culture; and
  - (f) any other work notified in writing by **the Regulator**.

## Facility and fittings conditions

11. The certification holder must ensure that the physical attributes of the **facility** and fittings are maintained so that the relevant 'Facility and fittings requirements' listed in Part A of this document continue to be met.

11.1. Prior to any structural changes that will affect the containment of **GMOs** in the **facility**, the applicant must either:

11.1.1. request a suspension of the certification, in writing, from **the Regulator**; or

11.1.2. request a variation to the conditions of certification in writing, from **the Regulator**, to allow **dealings** to continue in a part of the **facility** unaffected by the structural changes.

NOTE: For example, it may be possible to temporarily partition the **facility** to provide containment for **GMOs** at one end while the other end is being modified.

11.2. Before a suspension of the certification can be lifted, the **facility** must be inspected by a person qualified to assess the **facility's** compliance with the conditions listed under 'Facility and fittings conditions' and 'General conditions' to ensure that the **facility** meets the conditions of certification. **Dealings** with **GMOs** must not recommence in a **facility** which has its certification suspended until **the Regulator** has lifted the suspension by notice in writing.

11.3. **Dealings** must not be conducted in a part of the **facility** that has been excluded from the **facility** by variation, until **the Regulator** approves a further variation to allow the resumption of **dealings** in that part of the **facility**.

11.4. The physical parameters or efficacy of any heat-based equipment used to **decontaminate GMOs** must be validated monthly and the results of each month's testing kept for the previous 12 months and made available to **the Regulator** if requested.

If an **autoclave** is used to **decontaminate GMOs**, the **autoclave** must be validated by the use of:

- (a) thermocouples or resistance thermometers, to ensure that the required temperature has been achieved; or
- (b) chemical indicators which use a combination of moisture, heat and time and which progressively change colour with the time exposed at the specified temperature; or
- (c) biological indicators such as spore strips; or
- (d) enzyme indicators; or
- (e) other methods approved in writing by the Regulator.

11.5. Any heat-based equipment used to **decontaminate GMOs** must be calibrated annually by a person competent to do so and the results of each year's

calibration must be kept for the previous 5 years and made available to **the Regulator** if requested. When an **autoclave** is used for **decontamination**, calibration means verification that the autoclave actually runs at the temperature indicated on the temperature gauge of the autoclave. Autoclave pressure safety valves must also be tested annually to ensure they are working correctly. If the autoclave has been fitted with fail-safe pressure safety valves, it is sufficient to record this at the time of the annual temperature calibration.

- 11.6. If any **decontamination** equipment is found to be defective and the defect has not been corrected, the equipment must be clearly marked to show that it is defective and must not be used for **decontaminating GMOs**, waste or equipment associated with **dealings** with **GMOs** until the defect has been corrected.

## General conditions

12. If the certification holder is not the owner of the **facility**, fittings and/or containment equipment and does not have the authority to maintain the **facility**, fittings and/or containment equipment, the certification holder must notify **the Regulator** in writing if the owner of the **facility**, fittings and/or containment equipment is incapable of carrying out, or refuses to carry out, or otherwise does not carry out, any maintenance required in order for the certification holder to continue to comply with the conditions of certification.
13. The **facility** must be inspected at least once every 12 months by a person qualified to assess the **facility's** compliance with the conditions listed under Part B 'Facility and fittings conditions' and 'General conditions'. An inspection report which records the extent of compliance with those conditions must be made. A copy of the last five years' inspection reports must be kept and made available to **the Regulator** if requested.

NOTE: A checklist which may be used for annual inspections of **PC2** Culture Facility is available on the **OGTR** web site <[www.ogtr.gov.au](http://www.ogtr.gov.au)> – but its use is not mandatory. Annual inspection reports should not be sent to **the Regulator** unless requested.

14. Each access door to the **facility** must be labelled with the following adhesive signs:
  - (a) a **PC2** sign, as supplied by the **OGTR**; and
  - (b) a biohazard symbol.

The signs must be placed on or next to each access door to the **facility** so that persons entering the **facility** are able to clearly see they are entering a certified **PC2 facility**.

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 wall and must not be transferred to any other location.

15. A supply of **decontamination** agents effective against the **GMOs** being **dealt** with in the **facility** must be available in the **facility** for **decontamination** purposes. All

containers of **decontamination** agents, including any solutions for **decontaminating** hands, must be labelled with the contents and, where necessary, the expiry date. **Decontamination** agents must not be used after the expiry date.

16. A strategy to control pests in the **facility** must be implemented and maintained.

# Behavioural Requirements

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### Doors & windows

1. Except during the entry and exit of personnel, supplies, and/or equipment, doors of the **facility** must be closed while procedures with **GMOs** are being conducted. Dedicated “emergency only” exits must not be used to enter or exit the **facility** except in an emergency.
2. Windows must remain closed while dealings with **GMOs** are being conducted.

### Non-GMOs and Exempt GMOs in the facility

3. Persons undertaking work in the **facility** on non-**GMOs** or Exempt **GMOs** while a non-Exempt **GMO dealing** is occurring are subject to these requirements unless:
  - (a) procedures are implemented to ensure that non-**GMOs** or Exempt **GMOs**, are not cross-contaminated with non-Exempt **GMOs**;
  - (b) the above procedures are documented; and
  - (c) the outermost container used to transport any organisms out of the **facility** must be free of contamination with **GMOs**.

NOTE: Means of preventing cross-contamination of non-**GMOs** or Exempt **GMOs** by non-Exempt **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** or Exempt **GMOs**.

### Containment equipment

4. Any **GMOs** must remain in a sealed primary container while in the facility.

### Personal protective clothing

5. Any personal protective clothing must be removed before leaving the **facility** and disposed of or stored in a designated storage or hanging space. This does not apply if moving directly to another containment **facility**, certified to at least **PC2** by **the Regulator**, that is directly connected to the **facility** or is connected by a corridor, stairs, or other space 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.

## Decontamination

6. All **decontamination** procedures must be carried out by trained personnel.
7. **GMOs** must be **decontaminated** prior to disposal.
8. Wastes containing **GMOs** must be **decontaminated** prior to disposal.
9. Work benches, surfaces and equipment, where procedures involving **GMOs** have taken place, that are known to be contaminated with or suspected to be contaminated with **GMOs** must be **decontaminated** immediately after each procedure and/or at the end of each working day.
10. Equipment contaminated with or suspected to be contaminated with **GMOs** must be **decontaminated** before being removed from the **facility**, except if the equipment is being transported to a **decontamination** site in accordance with any transport guidelines and other relevant guidelines issued by **the Regulator**.
11. **Decontamination** can be effected by **autoclaving** or other heat treatment, incineration, chemical treatment, or by any other method approved in writing by **the Regulator**.

NOTE: **Autoclaving** is the most reliable means of **decontamination**, however this method may not be applicable in all situations.

12. Any heat-based treatment must be performed using a combination of temperature and time that has been validated as effective in rendering the **GMOs** non-viable.

NOTE: If an **autoclave** is used for **decontamination**:

- (a) loads must be packed and loaded to allow for the penetration of steam into the material being **decontaminated** in accordance with AS/NZS 2243.3:2002;
  - (b) the coldest part of the load must be exposed to a minimum temperature of 121°C and 103 kPa for at least 15 minutes or at 134°C and 203 kPa for at least 3 minutes in accordance with AS/NZS 2243.3:2002; and
  - (c) measures must be taken to ensure that loads that have been processed can be differentiated from loads that have not (e.g. by use of **autoclave** tape).
13. 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.
  14. Any chemical **decontamination** treatment must be effective in rendering the **GMO** non-viable.

NOTE: AS/NZS 2243.3:2002 is a recommended source of information when selecting and using chemical **decontamination** agents.

15. **Decontamination** can take place in the **facility**, or at another location, providing the **GMOs**, equipment, waste or clothing are transported to the **decontamination** site in

accordance with any transport guidelines and other relevant guidelines issued by **the Regulator**.

### **Labelling**

16. All cultures of **GMOs** must be clearly labelled. Any unlabelled viable material must be treated as a **GMO** and handled in accordance with these conditions.

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

### **Removal and storage of GMOs**

17. **GMOs** and any material containing **GMOs** which require containment in a **PC2 facility** 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 **PC2**;
  - (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.
18. All **GMOs** being transported out 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**.
19. All cultures of **GMOs** being stored inside the **facility** must be **sealed** during storage to prevent dissemination of the **GMOs**.

NOTE: The type of container necessary to prevent the **GMOs** from escaping will vary depending on the type of organisms being stored.

20. **GMOs** or organisms containing **GMOs** may be stored outside the **facility** in a storage unit (freezer, fridge or other container). A biohazard symbol must be posted on the storage unit. The storage unit must be locked when not in use, unless access is restricted to the room or area where the storage unit is located. Access to the storage unit must be restricted or controlled to prevent unintentional release of **GMOs** into the **environment**.
21. **GMOs** or organisms containing **GMOs** being stored outside the **facility** must be double-contained. The **primary container** must be **sealed** to prevent the escape or release of the **GMOs** and must be labelled. The **primary container** must be stored in an **unbreakable secondary container**. In the case of a small storage unit such as a fridge, freezer or liquid nitrogen container, the **secondary container** may be the storage unit.

22. In the case of **NLRDs**, approval from the notifying organisation must be obtained prior to the storage of **GMOs** outside of the **facility**.

### **Spills**

23. Documented procedures must be in place to **decontaminate** any spills involving **GMOs** inside or outside the **facility**. The procedures must be made available to **the Regulator** if requested.
24. If a spill of **GMOs** or any material containing **GMOs** occurs inside the **facility**, the spills procedures must be implemented to **decontaminate** the spill as soon as reasonably possible.
25. If a spill of **GMOs** occurs outside the **facility**, the spills procedures must be implemented to ensure that all spilt material is recovered and any contaminated surfaces are **decontaminated**.
26. Any known or suspected unintentional release of **GMOs** outside the **facility**, including spills, must be reported to **the Regulator** as soon as reasonably possible.

## 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.

AS/NZS 2243.3:2002 Safety in laboratories  
Part 3: Microbiological aspects and containment facilities

AS/NZS 2982.1:1997 Laboratory design and construction  
Part 1: General requirements