



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

**Version 3.1– issued 1 July 2007**

The guidelines (Part A) contain the requirements for certification of a Physical Containment Level 2 (PC2) Animal Facility issued pursuant to section 90 of the *Gene Technology Act 2000* (the Act).

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 Animal 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 Animal Facility Version 3.1 – issued 1 July 2007

CONTAINMENT REQUIREMENTS THAT MUST BE MET IN ORDER FOR A PHYSICAL CONTAINMENT LEVEL 2 (PC2) ANIMAL 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 Animal 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 Animal 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 Animal 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** Particulate matter, solid or liquid, small enough to remain suspended in air.

**anteroom** An area or room between a pair of doors through which access is gained to the **work area** inside a **facility**.

The **anteroom** must not be used for performing any procedures with **GMOs**.

<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>micro-organism</b>	An organism too small to be viewed by the unaided eye, including bacteria, fungi, viruses and some multicellular organisms. For the purposes of these guidelines, this definition includes replication defective viral vectors.
<b>OGTR</b>	Office of the Gene Technology Regulator.
<b>PC2</b>	Physical Containment Level 2.
<b>the Regulator</b>	The Gene Technology Regulator.

**work area** Any area inside a **facility** that is not performing the function of an **anteroom**.

Procedures with **GMOs** may only take place in the **work area** and any procedures with **GMOs** in the **work area** are subject to the conditions on the certification instrument.

## Facility and fittings requirements

1. The **facility** to be certified must be a fully enclosable space bounded by walls, doors, windows, floors and ceilings. Doors must be lockable. If windows are able to be opened, they must be lockable.

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 **facility** must have an **anteroom**. Entry to the **facility** must be through the **anteroom**. Where **dealings** in the **facility** have the potential to be disseminated via arthropods, the **anteroom** must have strategies in place to prevent the entry or exit of arthropods.
3. The **facility** boundaries (walls, doors, floors, ceilings etc.) must be designed to prevent the escape of the animals being contained.
4. If the **facility** has drainage exits, they must be fitted with barriers (e.g. liquid traps permanently filled with water, or fine mesh) to prevent arthropods or animals from entering the **facility** via the drains and to prevent the escape of arthropods or animals from the **facility**.

## Dealings involving GM micro-organisms

If any of the **dealings** proposed to be conducted in the **facility** will involve **GM micro-organisms**, the **facility** must meet the following requirements in addition to all other requirements listed:

5. Any openings in the walls, ceiling or roof must be filtered at the boundary or screened with fine mesh screens capable of preventing the entry or exit of arthropods and animals. The filter or mesh must be of a material mechanically strong enough to withstand any airflow load, remain undamaged with regular cleaning and resist corrosion and penetration by arthropods and animals.
6. The following surfaces in the **facility** must be smooth, impermeable to water, cleanable, and resistant to damage by the cleaning agents and/or disinfectants that will be used in the **facility**:
  - (a) walls, floors, and benches;

- (b) furniture, including seating; and
- (c) any other surfaces, where contamination is likely to occur or where **decontamination** is required.

7. 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 **GM micro-organisms** on the floor.

8. The **facility** must contain either a wash basin fitted with taps of the hands-free operation type or some other means of **decontaminating** hands.

NOTE: **Decontamination** of hands is considered an important means of preventing unintentional release of **GM micro-organisms** and of protecting the health of **facility** personnel. If wash basins are to be used, the provision of hand-operated taps is not acceptable, as they are a ready source of contamination.

Alternatives to wash basins, such as dispensers filled with **decontaminant** solutions, are considered suitable.

9. Eyewash equipment (either plumbed eyewash equipment or single-use packs of sterile eye irrigation fluids) must be provided within the **facility**.

NOTE: AS/NZS 2982.1:1997 provides information on eyewash equipment. **The Regulator** does not require the placement of more than one piece of eyewash equipment in the **facility** for the purposes of flushing **GM micro-organisms** out of the eyes.

10. If any proposed **dealings** in the **facility** with **GM micro-organisms** that require **PC2** containment will produce **aerosols** containing **GM micro-organisms**, then the **facility** must contain a biological safety cabinet, or other equipment specifically approved in writing by **the Regulator** that is designed to contain **aerosols**.

Where a Class I or Class II biological safety cabinet is installed, it must be installed in accordance with the requirements of AS/NZS 2647:2000.

11. Where any device or system that may cause contamination of a potable water supply with **GM micro-organisms** that require **PC2** containment will be connected directly or indirectly to any part of a water service, a risk assessment of the **GM micro-organisms** that will be **dealt** with in the **facility** must be undertaken to determine whether backflow prevention on the water supplied to the **facility** is necessary. The backflow prevention risk assessment must be provided with the application for certification.

If backflow prevention is necessary, then backflow prevention measures must be implemented in accordance with the requirements of Section 4 of AS/NZS 3500.1:2003.

NOTE: More information on the risk assessment can be found in the **OGTR's** operational *Policy on Backflow Prevention in Certified Facilities* on the **OGTR** website <[www.ogtr.gov.au](http://www.ogtr.gov.au)>.

Section 4 of AS/NZS 3500.1:2003 specifies the requirements and methods for the prevention of contamination of potable water within the water service and the water main, and provides for the selection and installation of backflow prevention devices.

## **Capacity to comply with certification conditions**

12. 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 Animal Facility**. These conditions are found in Part B of this document.

# Conditions of Certification

## Physical Containment Level 2 Animal Facility Version 3.1 – issued 1 July 2007

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). 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) Animal Facility.

### Definitions and acronyms

Unless defined otherwise in these conditions, words and phrases used in the conditions have the same meaning as 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** Particulate matter, solid or liquid, small enough to remain suspended in air.

**anteroom** An area or room between a pair of doors through which access is gained to the **work area** inside a **facility**.

The **anteroom** must not be used for performing any procedures with **GMOs**.

**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>micro-organism</b>	An organism too small to be viewed by the unaided eye, including bacteria, fungi, viruses and some multicellular organisms. For the purposes of these guidelines, this definition includes replication defective viral vectors.
<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 gametes), 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.
<b>unbreakable</b>	Able to maintain integrity under all reasonably expected conditions of transport such as pressures, forces, impacts, temperatures and moisture.
<b>work area</b>	Any area inside a <b>facility</b> that is not performing the function of an <b>anteroom</b> .  Procedures with <b>GMOs</b> may only take place in the <b>work area</b> and any procedures with <b>GMOs</b> in the <b>work area</b> are subject to the conditions on the certification instrument.

## Work not permitted in this facility type

1. The following work must not be conducted in this **facility**:
  - (a) **dealings** with any **GMO** that under the conditions of a licence requires containment in any physical containment level higher than **PC2**;
  - (b) the housing/keeping/rearing of any arthropods, or aquatic organisms, for longer than the minimum time required to complete procedures on them;
  - (c) the growing of any plants;
  - (d) **dealings** with **GMO** cultures greater than 25 litres; or
  - (e) any other work notified in writing by **the Regulator**.

## Facility and fittings conditions

2. The certification holder must ensure that the physical attributes of the **facility** and fittings are maintained so that the relevant 'Facility and fittings requirements' continue to be met, in particular:
  - 2.1. The **facility** must be maintained so that it is a fully enclosable space bounded by walls, doors, windows, floors and ceilings. Doors and any windows which are able to be opened must be maintained so they are lockable.
  - 2.2. The **facility** must continue to have an **anteroom**. Entry to the **facility** must be through the **anteroom**. Where **dealings** in the **facility** have the potential to be disseminated via arthropods, the **anteroom** must keep strategies in place to prevent the entry or exit of arthropods.
  - 2.3. The **facility** boundaries (walls, doors, floors, ceilings etc.) must be maintained to continue to prevent the escape of the animals being contained.
  - 2.4. If the **facility** has drainage exits, they must continue to be fitted with barriers (e.g. liquid traps which must remain filled with water, or fine mesh which must remain intact) to prevent arthropods or animals from entering the **facility**

via the drains and to prevent the escape of arthropods or animals from the **facility**.

- 2.5. Prior to any significant structural changes that will affect the containment of **GMOs** in the **facility**, the applicant must either:
- 2.5.1. request a suspension of the certification, in writing, from **the Regulator**; or
  - 2.5.2. 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.

- 2.6. 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' 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.
- 2.7. **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**.

## Dealings involving GM micro-organisms

Where any of the **dealings** conducted in the **facility** involve **GM micro-organisms**, the **facility** must meet the following conditions in addition to all other conditions listed:

- 2.8. Any openings in the walls, ceiling or roof must continue to be filtered at the boundary or screened with fine mesh screens capable of preventing the entry or exit of arthropods and animals. The filter or mesh must be maintained to withstand any airflow load, regular cleaning, corrosion and penetration by arthropods and animals.
- 2.9. The following surfaces in the **facility** must be maintained so they continue to be smooth, impermeable to water, cleanable, and resistant to damage by the cleaning agents and/or disinfectants that will be used in the **facility**:
- (a) walls, floors, and benches;
  - (b) furniture, including seating; and
  - (c) any other surfaces, where contamination is likely to occur or where **decontamination** is required.

- 2.10. The **facility** must be operated so that open spaces between and under benches, cabinets and equipment in the **facility** can be accessed for **decontamination** when required.
- 2.11. The **facility** must continue to contain either a wash basin fitted with taps of the hands-free operation type or some other means of **decontaminating** hands.

NOTE: Alternatives to wash basins, such as dispensers filled with **decontaminant** solutions, are considered suitable.

- 2.12. Eyewash equipment (either plumbed eyewash equipment or single-use packs of sterile eye irrigation fluids) must be maintained within the **facility**.
- 2.13. Where **dealings** in the **facility** with **GM micro-organisms** that require **PC2** containment produce **aerosols** containing **GM micro-organisms**, then the **facility** must continue to contain a biological safety cabinet, or other equipment specifically approved in writing by **the Regulator** that is designed to contain **aerosols**.

NOTE: Procedures with **GM micro-organisms** such as centrifuging and vortexing that use **sealed** tubes need not be carried out in a biological safety cabinet, provided that the tubes are opened in a biological safety cabinet.

- 2.14. Where any Class I or Class II biological safety cabinet is installed and used for procedures with **GM micro-organisms**, it must be used and **decontaminated** in accordance with the requirements of AS/NZS 2647:2000.
- 2.15. Where any Class I or Class II biological safety cabinet is installed and used for procedures with **GM micro-organisms**, it must be inspected and tested in accordance with the requirements of AS/NZS 2647:2000. This testing is required at least every 12 months, and additionally after relocation of a cabinet, after mechanical or electrical maintenance, and after high efficiency particulate air (HEPA) filters are replaced. The inspection and testing of cabinets must be carried out by a qualified person.

The cabinets must be tested for containment efficiency and a certificate, summarising the test results and the date of the next test, must be affixed to the cabinet.

Where testing has shown that the performance requirements for inward air velocity or HEPA filter integrity (Class I), or air barrier containment or exhaust HEPA filter integrity (Class II) are not met and the defect has not been corrected, the cabinet must be clearly marked to show that it is unsafe and must not be used for procedures that produce **aerosols** containing **GM micro-organisms**.

- 2.16. The effectiveness 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 effectiveness of 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.
- 2.17. Any heat-based equipment used to **decontaminate GMOs** must be calibrated annually by a qualified person 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**, this must include calibration of the thermocouple and safety valves.
- 2.18. 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.
- 2.19. Any backflow prevention measures in place either at the time of certification or installed at a later time must be maintained until a change in the measures is indicated by a review of the risk assessment.

NOTE: More information on the risk assessment can be found in the **OGTR's** operational *Policy on Backflow Prevention in Certified Facilities* on the **OGTR** website <[www.ogtr.gov.au](http://www.ogtr.gov.au)>.

- 2.20. Where no backflow prevention device was installed at the time of certification of the **facility**, the need for installation of a backflow prevention device must be reviewed when:
- 2.20.1. any device or system that may cause contamination of a potable water supply is connected directly or indirectly to any part of the water service to the **facility** where no such connections were made prior to the certification of the **facility**; or
  - 2.20.2. previous connections were made prior to certification and were assessed as not requiring backflow prevention measures, but a new **GM micro-organism** is to be **dealt** with in the **facility** that presents different risks from the **GM micro-organisms** assessed at the time of certification.

- 2.21. If installation of backflow prevention becomes necessary, then backflow prevention measures must be implemented in accordance with the requirements of Section 4 of AS/NZS 3500.1:2003.

NOTE: Section 4 of AS/NZS 3500.1:2003 specifies the requirements and methods for the prevention of contamination of potable water within the water service and the water main, and provides for the selection and installation of backflow prevention devices.

- 2.22. Any new or reviewed backflow prevention risk assessments must be kept and made available to **the Regulator** if requested.
- 2.23. If the **facility** is fitted with any testable water supply backflow prevention devices (in accordance with AS/NZS 3500.1:2003), these devices must pass a test every 12 months. These tests must be conducted in accordance with AS 2845.3:1993 by a licensed plumber accredited to test backflow prevention devices. Any failures must be rectified and the device re-tested until compliance is achieved. Documentation of the last five years' test results must be kept and made available to **the Regulator** if requested.

## General conditions

3. 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.
4. 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 the 'Facility and fittings 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** Animal Facilities 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.

5. 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.

6. A supply of disinfectants effective against the **GM micro-organisms** being **dealt** with in the **facility** must be available in the **facility** for **decontamination** purposes. All containers of disinfectants, including any solutions for **decontaminating** hands, must be labelled with the contents and, where necessary, the expiry date. Solutions must not be used after the expiry date.
7. A strategy must be in place to control pests in the **facility**.

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

8. 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.
9. For the purposes of condition 8, 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 9(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**.
10. 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**.
11. 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**.

12. 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.
13. For the purposes of condition 12, 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.
14. 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**.
15. 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.
16. **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 Requirements

## Physical Containment Level 2 Animal Facility Version 3.1 – issued 1 July 2007

### 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. Entrance doors into the **facility** must remain locked when **facility** personnel are not in attendance. Dedicated “emergency only” exits must not be used except in emergencies.
2. Windows must be closed and locked while **GM** animals or animals containing **GM micro-organisms** are in the **facility**.

### Handling of animals

3. Handling of the **GM** animals or animals containing **GM micro-organisms**, and any experimental procedures conducted on the animals, must be carried out in a way that minimises the chance of escape of the animals.
4. When not being handled, the **GM** animals or animals containing **GM micro-organisms** 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.

5. All animals or cages/containers of animals must be labelled. 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 clearly marked so they can be readily identified (e.g. with a tattoo, permanent tag, microchip or permanent brand). Some documented system of accounting for the number of animals in the **facility** must be used. The documentation must be made available to **the Regulator** if requested.

### Non-GMOs in the facility

6. Persons undertaking work on non-**GMOs** in the **facility** while a **GMO dealing** is occurring are subject to these requirements unless:
  - (a) procedures are implemented to ensure that animals involved in non-**GMO** work are not mixed with animals involved in **GMO dealings**;
  - (b) the above procedures are documented; and
  - (c) the outermost container must be free of contamination with **GMOs** prior to being transported out of the **facility**.

NOTE: Means of preventing mixing of animals involved in non-**GMO** work with animals involved in **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**.

## Decontamination

7. All **decontamination** procedures must be carried out by trained personnel.
8. **GMOs** must be rendered non-viable prior to disposal.
9. Wastes containing **GMOs** must be **decontaminated** prior to disposal.
10. **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 is not applicable in all situations.

11. 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 2243.3:2003;
  - (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 2243.3:2003; 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).
12. 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.
  13. Any chemical disinfectant treatment must be effective in rendering the **GMO** non-viable.

NOTE: AS/NZS 2243.3:2003 is a recommended source of information when selecting and using chemical disinfectant agents.

14. **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**.

## Removal, storage and escape/spills of GMOs

15. **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, such as a licence, 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.
16. All **GMOs**, animals containing **GM micro-organisms**, **GM sperm**, **GM ova**, **GM embryos** or animal tissue containing **GM micro-organisms** being transported out of the **facility** must be transported in accordance with any transport guidelines and other relevant guidelines issued by **the Regulator**.
17. Whole live **GM** animals (excepting **GM sperm**, **GM ova** and **GM embryos**) cannot be stored outside of the **facility**.
18. **GM sperm**, **GM ova**, **GM embryos**, **GM micro-organisms** or animal tissue containing **GM micro-organisms** may be stored outside the **facility** in a storage unit (freezer, fridge, controlled temperature room 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 the unintentional release of propagative **GM** material into the **environment**.
19. **GM sperm**, **GM ova**, **GM embryos**, **GM micro-organisms** or animal tissue containing **GM micro-organisms** being stored outside the **facility** must be double-contained. The **primary container** must be **sealed** to prevent the escape or release of the propagative **GM** material 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.
20. In the case of **NLRDs**, the notifying organisation must authorise the storage of **GM sperm**, **GM ova**, **GM embryos**, **GM micro-organisms** or animal tissue containing **GM micro-organisms** outside of the **facility**.
21. If a **GM** animal or animal containing **GM micro-organisms** 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.
22. Documented procedures must be in place to **decontaminate** any spills involving **GM sperm**, **GM ova**, **GM embryos**, **GM micro-organisms** or animal tissue containing **GM micro-organisms** inside or outside the **facility**. The procedures must be made available to **the Regulator** if requested.

23. If a spill of **GM sperm, GM ova, GM embryos, GM micro-organisms** or animal tissue containing **GM micro-organisms** occurs inside the **facility**, the spills procedures must be implemented to **decontaminate** the spill as soon as reasonably possible.
24. If a spill of **GM sperm, GM ova, GM embryos, GM micro-organisms** or animal tissue containing **GM micro-organisms** occurs outside the **facility**, the spills procedures must be implemented to ensure that all spilt material is recovered and any contaminated surfaces are **decontaminated**.
25. Any real or suspected unintentional release of **GMOs** outside the **facility**, including spills, must be reported to **the Regulator** as soon as reasonably possible.

## Dealings involving GM micro-organisms

If any of the **dealings** proposed to be conducted in the **facility** will involve **GM micro-organisms**, the behavioural training must encompass the following requirements in addition to all other requirements listed:

### Personal protective clothing

26. The following personal protective clothing must be worn by personnel undertaking **dealings** with **GM micro-organisms** in the **facility**:
  - (a) protective clothing to afford protection to the front part of the body; and  
  
NOTE: A rear-fastening gown is preferable.
  - (b) gloves, when **dealing** with **GM micro-organisms** which fit into the classification of Risk Group 2 or higher, as described in AS/NZS 2243.3:2003 Section 3.2.
27. Personal protective clothing must be removed before leaving the **facility**. 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 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.

NOTE: **The Regulator** recommends the provision and use of coat hooks or similar for the storage of personal protective clothing.

### Containment equipment

28. Any procedures in the **facility** with **GM micro-organisms** that require **PC2** containment that produce **aerosols** containing **GM micro-organisms** must be performed in the biological safety cabinet or other **aerosol** containment equipment approved in writing by **the Regulator**.

## Decontamination

29. Work benches, surfaces and equipment where procedures involving **GM micro-organisms** have taken place must be **decontaminated** when the **dealings** are completed.
30. Equipment, pens, cages or bedding contaminated with **GM micro-organisms** must be **decontaminated** before being removed from the **facility**.
31. Carcasses of animals containing **GM micro-organisms** must be **decontaminated** once **dealings** are completed by **autoclaving**, incineration or any other method approved in writing by **the Regulator**.
32. Protective clothing contaminated with or suspected to be contaminated with **GM micro-organisms** must be taken off as soon as practicable and **decontaminated** prior to reuse. Protective clothing that has not been contaminated with **GM micro-organisms** may be washed using normal laundry methods. Gloves must be disposed of.
33. Persons who have been performing procedures with **GM micro-organisms** in the **facility** must **decontaminate** their hands before leaving the **facility**.

NOTE: This may include the use of soap and water, if appropriate. If wash basins are to be used, the use of hand operated taps is not acceptable, as they are a ready source of contamination.

## Labelling

34. All cultures of **GM micro-organisms** 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**.

## Storage

35. All cultures of **GM micro-organisms** 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.

# Attachment 1

## 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 2243.3:2003 Safety in laboratories  
Part 3: Microbiological aspects and containment facilities

AS/NZS 2647:2000 Biological safety cabinets  
Installation and use

AS 2845.3:1993 Water supply - Backflow prevention devices  
Part 3: Field testing and maintenance

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

AS/NZS 3500.1:2003 Plumbing and drainage  
Part 1: Water services