



Guidelines for Certification of a Physical Containment Level 2 Plant Facility

Version 3.1– Effective 1 July 2007

The guidelines (Part A) contain the requirements for certification of a Physical Containment Level 2 (PC2) Plant 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 Plant 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>.

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Requirements for Certification

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CONTAINMENT REQUIREMENTS THAT MUST BE MET IN ORDER FOR A
PHYSICAL CONTAINMENT LEVEL 2 (PC2) PLANT 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 Plant 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 Plant 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 Plant 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**.

dealing or deal with	In relation to a GMO , means the following: (a) conduct experiments with the GMO ; (b) make, develop, produce or manufacture the GMO ; (c) breed the GMO ; (d) propagate the GMO ; (e) use the GMO in the course of manufacture of a thing that is not the GMO ; (f) grow, raise or culture the GMO ; (g) import the GMO ; (h) transport the GMO ; (i) dispose of the GMO ; and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (i).
decontamination	A physical or chemical process which removes, kills or renders non-viable the GMOs being dealt with in the facility , but does not necessarily result in sterility.
environment	Includes: (a) ecosystems and their constituent parts; (b) natural and physical resources; and (c) the qualities and characteristics of locations, places and areas.
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.
micro-organism	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.
OGTR	Office of the Gene Technology Regulator.
PC2	Physical Containment Level 2.
the Regulator	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. Walls, doors and ceilings may be partially or completely made of transparent material.

NOTE: The walls, doors, windows, floors and ceilings, including any transparent sections, 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. All boundaries of the **facility** must be rigid and durable, must be suitable for the environmental conditions they are exposed to, and must withstand expected wear and tear without loss of containment. Any transparent sections of a **facility** must be made of glass, polycarbonate sheeting, or other similar durable material. All boundaries must be impact resistant or 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 machinery such as lawnmowers.

3. The **facility** must be designed to prevent the entry of surface run-off water.
4. 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.
5. The **facility** must contain either a wash basin or some other means of **decontaminating** hands.

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

6. 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, animals or any plants from moving into the **facility** via the drains and to prevent the escape of arthropods or animals, or loss of containment of **GM** plants or **GM** propagative plant material, from the **facility**.

7. 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, including arthropods used for pollination of plants involved in **dealings**.

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:

8. 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.
9. 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.

10. If the **facility** has drainage exits, they must be fitted with liquid traps permanently filled with an appropriate **decontaminant** to ensure that any liquid waste is **decontaminated** prior to being released from the **facility**. Alternatively, all liquid entering the drains must be contained and treated as waste.
11. 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.

12. 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>.

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

13. 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 Plant 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) Plant Facility.

Definitions and acronyms

Unless defined otherwise in these conditions, words and phrases used in the conditions 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 .
autoclave	Pressure steam steriliser.

dealing or deal with	In relation to a GMO , means the following: (a) conduct experiments with the GMO ; (b) make, develop, produce or manufacture the GMO ; (c) breed the GMO ; (d) propagate the GMO ; (e) use the GMO in the course of manufacture of a thing that is not the GMO ; (f) grow, raise or culture the GMO ; (g) import the GMO ; (h) transport the GMO ; (i) dispose of the GMO ; and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (i).
decontamination	A physical or chemical process which removes, kills or renders non-viable the GMOs being dealt with in the facility , but does not necessarily result in sterility.
environment	Includes: (a) ecosystems and their constituent parts; (b) natural and physical resources; and (c) the qualities and characteristics of locations, places and areas.
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.
micro-organism	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.
NLRD	Notifiable Low Risk Dealing.
OGTR	Office of the Gene Technology Regulator.
PC2	Physical Containment Level 2.
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 seeds), including under 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.
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.

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) work with any **GM micro-organisms** unless they are integral to the **dealing** being contained in the **facility**;
 - (c) the housing/keeping/rearing of any animals, arthropods, or aquatic organisms unless they are integral to the **dealing** being contained in the **facility**;
 - (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, including any transparent sections.
 - 2.2. All boundaries of the **facility** must be maintained to be rigid and durable, suitable for the environmental conditions they are exposed to, and able to withstand expected wear and tear without loss of containment. Any transparent sections of a **facility** must continue to be made of glass, polycarbonate sheeting, or other similar durable material. All boundaries must continue to be impact resistant or protected from impact.
 - 2.3. The **facility** must be maintained to prevent the entry of surface run-off water.

- 2.4. 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.
- 2.5. The **facility** must continue to contain either a wash basin or some other means of **decontaminating** hands.
- 2.6. 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, animals or any plants from moving into the **facility** via the drains and to prevent the escape of arthropods or animals, or loss of containment of **GM** plants, or **GM** propagative plant material from the **facility**.
- 2.7. 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, including arthropods used for pollination of plants involved in **dealings**.
- 2.8. Prior to any significant structural changes that will affect the containment of **GMOs** in the **facility**, the applicant must either:
 - 2.8.1. request a suspension of the certification, in writing, from **the Regulator**; or
 - 2.8.2. 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.
- 2.9. Before the suspension of the certification can be lifted, the **facility** must be inspected by a suitably qualified 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.
- 2.10. **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:

- 2.11. 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.
- 2.12. 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.
- 2.13. If the **facility** has drainage exits, they must remain fitted with liquid traps permanently filled with an appropriate **decontaminant** to ensure that any liquid waste is **decontaminated** prior to being released from the **facility**, or, all liquid entering the drains must continue to be contained and treated as waste.
- 2.14. 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.
- 2.15. 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.
- 2.16. 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**.

- 2.17. 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.

- 2.18. 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.

- 2.19. 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.

- 2.20. 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 Policy on Backflow Prevention in Certified Facilities** on the **OGTR** website <www.ogtr.gov.au>.

- 2.21. 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:

- 2.21.1. 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

- 2.21.2. 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.
- 2.22. 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.
- 2.23. Any new or reviewed backflow prevention risk assessments must be kept and made available to **the Regulator** if requested.
- 2.24. 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** Plant Facilities is available on the **OGTR** web site <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

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Doors

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 except in emergencies.

Handling of plants

2. The **GM** plants or plants containing **GM micro-organisms** must be handled in a way to ensure that plants and any **GM** propagative material are contained within the **facility**. Special care should be given to ensuring that **GM** propagative material is not taken out of the **facility** on clothing and shoes.

NOTE: The **facility** physical boundaries alone may not be sufficient for containment. For example, under Schedule 3, Part 1 of the *Gene Technology Regulations 2001*, an **NLRD** involving a **GM** flowering plant requires that before flowering, all inflorescences are wholly enclosed in bags designed to prevent escape of viable pollen and seed.

3. All **GM** plants, plants containing **GM micro-organisms** or other **GM** material must be clearly labelled to indicate their identity. This may be achieved by labelling plants, containers or trays as relevant. 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**.

Non-GMOs in the facility

4. 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 the non-**GMO** work is not mixed with **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 non-**GMO** work by **GMO dealings** could include physical separation of the work, use of selfing bags, ensuring plants with pollination potential are separated whilst flowering or separation by working at different times and ensuring any contaminated surfaces are **decontaminated** prior to commencing work with non-**GMOs**.

Personal protective clothing

5. The following personal protective clothing must be worn by personnel undertaking **dealings** with **GM** pollen, **GM** seeds or **GM micro-organisms** in the **facility**:
 - (a) protective clothing to afford protection to the front part of the body; and
 - (b) gloves, when **dealing** with **GMOs** which fit into the classification of Risk Group 2 or higher, as described in AS/NZS 2243.3:2002 Section 3.2.
6. 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.

Decontamination

7. All **decontamination** procedures must be carried out by trained personnel.
8. **GMOs** or viable **GM** plant material must be rendered non-viable prior to disposal.
9. Soil or other growth media must be **decontaminated** prior to re-use.

NOTE: This may be achieved by physical removal of all **GM** plant material, including **GM** roots and any **GM** propagative material.

10. Wastes containing **GMOs** or viable **GM** plant material must be **decontaminated** prior to disposal.
11. Work benches, surfaces and equipment where procedures involving **GM** pollen, **GM** seeds or **GM micro-organisms** have taken place must be **decontaminated** when the **dealings** are completed.
12. Equipment, pots, bags, soil or soil substitutes contaminated with **GM** plant material, **GM** pollen, **GM** seeds or **GM micro-organisms** must be **decontaminated** before being removed from the **facility**.
13. Protective clothing contaminated with or suspected to be contaminated with **GM** pollen, **GM** seeds or **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** pollen, **GM** seeds or **GM micro-organisms** may be washed using normal laundry methods. Gloves must be disposed of.

14. Any effluent waste containing **GM** pollen, **GM** seeds or **GM micro-organisms**, including run off, must be **decontaminated** prior to release.
15. **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.

16. 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).

If superheated (non-pressurised) steam is used for **decontamination**:

- (a) provision must be made to allow for the penetration of steam into the load;
- (b) the coldest part of the load must be exposed to a minimum temperature of 98°C for at least 2 hours, or a minimum temperature and time approved in writing by **the Regulator**; and
- (c) measures must be taken to ensure that loads that have been processed can be differentiated from loads that have not.

17. 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.
18. Any chemical disinfectant 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 disinfectant agents.

19. **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**.

20. Persons who have been performing procedures with **GM pollen, GM seeds or 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.

Removal, storage and escape/spills of GMOs

21. **GMOs or GM propagative material** 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.
22. All **GMOs or GM propagative material** being transported out of the **facility** must be transported in accordance with any transport guidelines and other relevant guidelines issued by **the Regulator**.
23. Whole live **GM plants** (excepting **GM pollen, GM seeds, GM tubers, GM bulbs, GM corms or dormant GM stems**) cannot be stored outside of the **facility**.
24. All **GM material** being stored within the **facility**, including cultures of **GM micro-organisms**, 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 organism being stored.

25. **GM pollen, GM seeds, GM tubers, GM bulbs, GM corms, dormant GM stems or material 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 unintentional release of **GM propagative material** into the **environment**.
26. **GM pollen, GM seeds, GM tubers, GM bulbs, GM corms or dormant GM stems or material 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 **GM propagative 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.

27. In the case of **NLRDs**, the notifying organisation must authorise the storage of **GMOs** or **GM** propagative material outside of the **facility**.
28. Documented procedures must be in place to **decontaminate** any unintentional release or spill involving **GM** plants, plants containing **GM micro-organisms**, or other **GM** material inside or outside the **facility**. The procedures must be made available to **the Regulator** if requested.
29. If a spill of **GM** pollen, **GM** seeds or **GM micro-organisms** occurs inside the **facility**, the spills procedures must be implemented to **decontaminate** the spill as soon as reasonably possible.
30. If an unintentional release or spill of **GM** plants, plants containing **GM micro-organisms**, or other **GM** material occurs outside the **facility**, the spills procedures must be implemented to ensure that all **GM** material is recovered and any contaminated surfaces are **decontaminated**.
31. 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:

Containment equipment

32. Any **dealings** 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

33. Non-viable plant material containing **GM micro-organisms** must be **decontaminated** once **dealings** are complete by **autoclaving**, incineration, superheated (non-pressurised steam) or any other method approved in writing by **the Regulator**.

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**.

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 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