



Guidelines for Certification of a Physical Containment Level 1 Large Scale Facility

Version 2.1 – issued 1 September 2006

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

Certified PC1 Large Scale Facilities are to be used to contain **dealings** when there is greater than or equal to 25 litres of culture of any one GMO.

The Conditions of Certification detail the usual conditions that will apply to a PC1 Large Scale Facility pursuant to section 86 of the Act and are attached to this document.

The standards that are referenced in the requirements and conditions are also attached to this document.

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

The Office of the Gene Technology Regulator (OGTR) will inspect PC1 Large Scale facilities prior to any decision on an application for certification.

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Requirements for Certification

Physical Containment Level 1 Large Scale Facility Version 2.1 – issued 1 September 2006

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

Section 90 of the *Gene Technology Act 2000*

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

Definitions

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

Words in the singular include the plural and words in the plural include the singular.

Where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning.

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

The anteroom must not be used for performing any **procedures** on organisms.

The term **anteroom** is used only in relation to physical containment level 1 (PC1) and physical containment level 2 (PC2) facilities.

autoclave Pressure steam steriliser.

bunding Provision of a low wall around potential spillage areas.

competent person A person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skill enabling that person to perform a specified task.

dealings 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;

and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (g).

decontamination A physical or chemical process which kills or renders non-viable the organisms used in the **facility**, but does not necessarily result in sterility.

facility The whole of the space that is to be certified by the Regulator to a specific level of containment. A certified **facility** comprises the **work area** and any **anteroom** or **airlock** used to enter or leave the facility's **work area**.

procedures The meaning of **procedures** includes any activity involving work with organisms inside a **facility**.

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

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

General

1. To be granted certification a **facility** must meet each of the containment requirements for certification of a PC1 Large Scale Facility unless the **facility** receives an exemption from meeting a particular requirement from the Regulator or a delegate of the Regulator.

Facility requirements

2. The **facility** to be certified must be a fully enclosable space bounded by walls, doors, windows, floors and ceilings, to prevent the release of any genetically modified organisms.
3. Any openings in the walls, ceiling or roof, such as air vents, must be screened with insect proof mesh.
4. 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; and
 - (b) ceilings, and any other surfaces, where contamination can occur or where **decontamination** is required.

Facility furniture, including seating, must be able to be **decontaminated**.

NOTE: Australian Standard/New Zealand Standard (AS/NZS) 2243.3:2002 4.7.2(b) requires seats to be smooth and impervious to facilitate cleaning. While the Office of the Gene Technology Regulator (OGTR) would prefer the use of smooth and impervious seating, any seating that is not smooth and impervious must be able to be **decontaminated** in the event of a spill.

5. If the **facility** has floor drainage exits, all effluent from these drains must be **decontaminated** by heat treatment or chemical treatment before being discharged. If the **facility** has a sink, then all liquid effluent must be **decontaminated** prior to discharge down the sink.
6. Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.

NOTE: This is to allow for easier **decontamination** of spills and to reduce any persistence of genetically modified (GM) micro organisms on the floor.

7. The **facility** must contain either a wash basin fitted with hands-free tap(s) and supplied with potable water, or some other means of **decontaminating** hands.

NOTE: Alternatives to wash basins, such as dispensers filled with **decontaminant** solutions, are considered suitable, provided the dispensers can be operated without using the hands.

8. 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 provides information on eyewash equipment. The OGTR does not require the placement of more than one piece of eyewash equipment for the purposes of flushing micro organisms out of the eyes.

9. Potable water supplied to the **facility** must be provided with backflow prevention by a registered testable device for protection against both back-pressure and back-siphonage in accordance with the requirements of AS/NZS 3500.1.

NOTE: This includes any water supplied to the **facility**, eg. supply to **autoclave**.

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

NOTE: This is so that contaminated protective clothing will not cross-contaminate other surfaces and items.

Containment equipment requirements

11. Secondary containment, such as **bundling**, must be provided to retain any leakage from the primary vessel or closed system. It must be of sufficient capacity to retain:

- (a) the maximum volume of fluid in the closed system; and
- (b) the volume of any disinfectant that might be used,

with additional capacity to prevent any expected general fluid movement from breaching the secondary containment.

Capacity to comply with certification conditions

12. To be granted certification a **facility** must be able to comply with the conditions of certification that will be applied to a certified PC1 Large Scale Facility, as attached to these requirements, unless the **facility** receives an exemption from meeting a particular condition from the Regulator or a delegate of the Regulator.

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 condition clauses in this section are the ones that can be expected, in most cases, to be included on the certification instrument as the conditions of certification for a Physical Containment Level 1 (PC1) Large Scale Facility.

Definitions

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* (the Regulations).

Words in the singular include the plural and words in the plural include the singular.

Where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning.

aerosol	Particulate matter, solid or liquid, small enough to remain suspended in air.
anteroom	<p>An area or room between a pair of doors through which access is had to the work area inside a facility.</p> <p>The anteroom must not be used for performing any procedures on organisms.</p> <p>The term anteroom is used only in relation to PC1 and PC2 facilities.</p>
autoclave	Pressure steam steriliser.
bunding	Provision of a low wall around potential spillage areas.
competent person	A person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skill enabling that person to perform a specified task.

dealings or deal with	<p>In relation to a GMO, means the following:</p> <ul style="list-style-type: none"> (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO; (d) propagate the GMO; (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO; <p>and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (g).</p>
decontamination	A physical or chemical process which kills or renders non-viable the organisms used in the facility , but does not necessarily result in sterility.
facility	The whole of the space that is to be certified by the Regulator to a specific level of containment. A certified facility comprises the work area and any anteroom or airlock used to enter or leave the facility's work area .
procedures	The meaning of procedures includes any activity involving work with organisms inside a facility .
work area	Any area inside a facility that is not performing the function of an anteroom .
	Procedures on GMOs may take place in the work area and any procedures in the work area are subject to the conditions on the certification instrument.

Work not permitted in this facility

- 1 The following work must not be conducted in this **facility**:
 - (a) work with any GMO that under the Act, or under the conditions of a licence, requires containment in any physical containment level higher than PC1;
 - (b) the housing/keeping/rearing of any animals or aquatic organisms; or
 - (c) the growing of any plants.

Compliance with certification conditions

- 2 All the conditions listed under the heading of ‘Facility Conditions’, ‘Containment Equipment’ and ‘Facility Management’ must be complied with at all times whether or not the **facility** is being used for a **dealing** with a GMO. The certification holder must notify the Regulator in writing when the **facility** is no longer able to meet these conditions. This notification may include an application for a variation to the conditions and must also include an alternative, effective strategy to manage any risks associated with **dealings** with GMOs in the **facility**.

The conditions listed under ‘Personal Protective Clothing and Equipment’ and ‘Work Practices’ must be complied with at all times if a **dealing** with a GMO is being conducted in a **facility**. This condition applies whether or not work with a non-GMO is occurring in the **facility** at the same time.

NOTE: A GMO dealing includes possession, supply, use, transport and disposal of a GMO for the purposes of a **dealing**. Storage of a GMO, for example, constitutes a **dealing** with a GMO.

Facility conditions

- 3 The **facility** must be labelled with the following adhesive signs:
 - (a) a PC1 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 PC1 **facility**.

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.

NOTE: Signs do not need to be displayed on or next to the outside of emergency exits (which are not to be used to enter the **facility**).

- 4 The **facility** must be maintained as a fully enclosable space contained within walls, doors, windows, floors and ceilings. Doors and windows must be maintained so they are lockable.

Any changes to the physical structure of a **facility** must not affect compliance with these conditions of certification. Prior to any structural changes that will affect the containment of GMOs, the applicant must cease all **dealings** with GMOs and request a suspension of the certification, in writing, from the Regulator.

Following any structural changes, the **facility** must be inspected to ensure compliance with the conditions for certification before any suspension can be lifted. **Dealings** with GMOs may not commence until the Regulator has lifted the suspension by approval in writing.

- 5 Any openings in the walls, ceiling or roof, such as air vents, must be screened with insect proof mesh.
- 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; and
 - (b) ceilings, and any other surfaces, where contamination can occur or where **decontamination** is required.

Facility furniture, including seating, must be able to be **decontaminated**.

NOTE: AS/NZS 2243.3:2002 4.7.2(b) requires seats to be smooth and impervious to facilitate cleaning. While the OGTR would prefer the use of smooth and impervious seating, any seating that is not smooth and impervious must be able to be **decontaminated** in the event of a spill.

- 7 Open spaces between and under benches, cabinets and equipment must be accessible for cleaning at all times.
- 8 The **facility** must contain either a wash basin fitted with hands-free tap(s) and supplied with potable water, or some other means of **decontaminating** hands.
- 9 Eyewash facilities (either a plumbed eyewash facility or single-use packs of sterile eye irrigation fluids) must be provided within the **facility** at all times. If plumbed facilities are installed, they must be used and maintained in accordance with the manufacturer's instructions.
- 10 Where any device or system that may cause contamination of a potable water supply is connected directly or indirectly to any part of a water service, backflow prevention must be enabled via a registered testable device that has an appropriate hazard rating for protection against both back-pressure and back-siphonage in accordance with the requirements of AS/NZS 3500.1.
- 11 If the **facility** is fitted with any testable water supply backflow prevention devices (in accordance with AS/NZS 3500.1), these devices must pass a test every 12 months. These tests must be conducted in accordance with AS 2845.3 by a licensed plumber accredited to test backflow prevention devices.

Documentation of the most recent test results must be made available to the Regulator, if requested.

- 12 Designated storage or hanging provisions for protective clothing must be available within the **facility** at all times.
- 13 A supply of disinfectants effective against the GMOs used in the **facility** must be available in the **facility** for **decontamination** purposes. Containers of disinfectants must be clearly labelled with the contents and, where relevant, the expiry date.

Containment equipment conditions

- 14 Where any biological safety cabinets are installed and used for **procedures** with GMOs, they must be inspected and tested in accordance with the requirements of Clause 7.10 of AS/NZS 2647. This testing is required at least every 12 months, or after relocation of a cabinet, after mechanical or electrical maintenance and after high efficiency particulate air (HEPA) filters are replaced.

The cabinets must pass tests 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** involving GMOs.

The inspection and testing of cabinets must be carried out by a **competent person**.

- 15 All cultures of GMOs, with the exception of inocula and samples taken during production, must be contained within a primary container or closed vessel.

Any closed system must be maintained so that it is capable of being **decontaminated *in situ***.

Inspection and testing of the integrity of any closed system must be undertaken before each use and following modification or replacement of the equipment. Records of the inspections and testing and any repairs, including the date, must be kept and made available to the OGTR if requested.

- 16 Secondary containment, such as **bundling**, must be maintained in the **facility** to retain any leakage from the closed system. It must be of sufficient capacity to retain:
- (a) the maximum volume of fluid in the primary container or closed system; and
 - (b) the volume of any disinfectant that might be used,
- with additional capacity to prevent any expected general fluid movement from breaching the secondary containment.

Facility management

- 17 Access to the **facility** must be restricted to authorised persons and/or authorised classes of persons.

NOTE: The intention of this condition is to prevent access to the **facility** by persons, especially the general public, who may be unaware of any potential hazards. Access can be restricted by means such as: keys, key cards or combination locks for entry to the **facility**; controlled access to the building where the certified **facility** is only a part of a larger building; or simply by **procedural** means where the certification holder can disseminate information that effectively limits who may enter the **facility**.

It is the certification holder's responsibility to decide who may enter the **facility**. Authorisation can take any form that is effective and may apply to specific individuals or to a class of persons, such as students of a faculty that need to access a person who works in the **facility**, or a group of colleagues who may be working on collaborative projects.

- 18 The **facility** must have **procedures** and the means in place to clean up any spills in the **facility**, including large spills, involving GMOs.
- 19 All **facility** personnel must be trained in the use of equipment present in the **facility** and also in the **procedures** to be used in the **facility**. Records of this training must be kept and made available to the Regulator if requested.

NOTE: The required training should include transport, disposal, identification of hazards associated with the GMO and emergency procedures, certification requirements and licence conditions.

- 20 The **facility** must be kept free of pests. A record of any pest prevention strategies or pest control activities must be kept and made available to the Regulator if requested, along with the dates and details of any pest control and/or eradication activities.
- 21 The **facility** must be inspected at least once every 12 months. The inspection report must detail the extent of compliance with the conditions of certification and a copy of the most recent inspection report must be provided to the Regulator if requested.

NOTE: The certification holder can arrange for any **competent person** to inspect the **facility** to assess compliance with these conditions of certification. Proforma inspection checklists are available on the OGTR web site <www.ogtr.gov.au> but their use is not mandatory for annual inspections. Inspection reports should not be sent to the Regulator unless requested. An annual inspection is not required in any year coinciding with an OGTR inspection of the **facility**.

Personal protective clothing and equipment

22 The following personal protective clothing must be worn by personnel performing **procedures** in the **facility**:

- (a) laboratory coat or gown, or equivalent, to protect the arms and front part of the body from spills or any other source of contamination.

NOTE: Assessment should be made of the need to wear face shields when working with GMOs.

23 Laboratory coats, gowns or equivalent and equipment must be removed before leaving the **facility** and stored in designated storage or hanging provisions or disposed of.

Work practices

24 **Facility** doors must remain closed when laboratory **procedures** are in progress and must be locked when the **facility** is unattended.

25 Windows must remain closed while **procedures** are in progress.

NOTE: Where practicable any **dealings** involving GMOs should be conducted in a manner to prevent or limit the production of **aerosols** or contamination of surfaces.

26 Work benches, surfaces and equipment where **procedures** involving GMOs have taken place must be **decontaminated** when the **procedures** are completed.

27 All work surfaces and equipment where maintenance is to be carried out must be **decontaminated** prior to maintenance taking place.

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

28 If a spill of GMOs occurs in the **facility**, a spills **procedure** (as required in Condition 18) must be implemented to **decontaminate** the spill.

29 **Decontamination** of contaminated items or material must be performed as follows:

- (a) Process waste, including that from floor drains, must be **decontaminated** before discharge using a method approved by the Regulator in writing. Details of the treatment method and evidence of its effectiveness must be provided to the Regulator.
- (b) for all other contaminated items or material:
 - (i) GMOs and organisms infected with GMOs must be rendered non-viable prior to disposal.
 - (ii) Liquid and solid wastes containing GMOs must be **decontaminated** prior to disposal.
 - (iii) Equipment must be **decontaminated** prior to use in another location that does not at least meet the Regulator's requirements for PC1 containment.
 - (iv) Personal protective clothing and equipment contaminated with GMOs must be taken off as soon as practicable and **decontaminated** prior to reuse.

Decontamination can take place in the **work area** of the **facility**, or at another location (except for volumes of culture greater than 25 litres) providing the organisms or waste are transported to the **decontamination** site in accordance with any transport guidelines and other relevant guidelines, as in force from time to time, issued by the Regulator.

30 **Decontamination** can be effected by: pressure steam sterilisation (**autoclaving**) or other heat treatment; chemical treatment; incineration; or by any other method approved in writing by the Regulator.

Any heat treatment other than **autoclaving** must be performed using a combination of temperature and time that has been validated as effective against the organisms being rendered non-viable.

Chemical disinfectant treatment must be effective against the organisms being rendered non-viable.

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

NOTE: AS/NZS 2243.3 is a recommended source of information on the selection and use of chemical disinfectant agents.

Retention of process waste from floor drains could be collected, for example, in a holding tank and treated with chemical disinfectant or heat treatment.

31 Where use of a pressure steam steriliser (**autoclave**) is required for sterilisation purposes:

- (a) Loads must be packed and loaded to allow for the penetration of steam into the material being sterilised in accordance with Clauses 6.6.3 or 6.6.4 of AS/NZS 2243.3:2002.
- (b) The coldest part of the load must be exposed to a minimum temperature of 121° C for at least 15 minutes in accordance with Clause 6.6.5 of AS/NZS 2243.3:2002.
- (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).

The efficacy of the sterilisation treatment must be validated at least monthly by the use of:

- (d) thermocouples or resistance thermometers, to ensure that the sterilisation temperature has been achieved; or
- (e) chemical indicators which progressively change colour with the time exposed at the specified temperature; or
- (f) biological indicators such as spore strips; or
- (g) enzyme indicators; or
- (h) other methods approved in writing by the Regulator.

Calibration of the **autoclave** thermometer and timers, and pressure testing of the vessel, must be performed annually by a **competent person**. The results of the autoclave tests, including evidence of the calibration of the equipment used, must be kept for the previous 5 years and made available to the Regulator, if requested.

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

32 Organisms that are not GMOs must not be removed from the **facility** while a **dealing** with a GMO is occurring in a **facility** unless:

- (a) **procedures** are implemented to ensure that **dealings** with GMOs do not mix with or contaminate work with any other organisms that are not part of the **dealing**;
- (b) the above **procedures** are documented; and
- (c) all primary containers and transport containers are **decontaminated** prior to removal from the **facility**.

If mixing or cross-contamination of any other work by GMOs occurs, or is suspected to have occurred, then the other work must be handled and disposed of in accordance with the conditions of certification, as if it were **dealing** with a GMO.

NOTE: Means of preventing cross-contamination of other work by GMO **dealings** could include physical separation of the work, or separation by working at different times and ensuring any contaminated surfaces are **decontaminated** prior to commencing different work.

- 33 Volumes greater than 25 litres of culture containing GMOs must not be removed from the **facility**.
- Volumes less than or equal to 25 litres of culture containing GMOs must not be removed from the **facility** unless:
- (a) they are to be transported to a containment **facility** that at least meets the Regulator's requirements for PC1 level containment;
 - (b) they are to be transported to another location for storage;
 - (c) they are to be transported for disposal or **decontamination** prior to disposal; or
 - (d) written permission has been given by the Regulator for transport to another destination.
- 34 All GMOs, and waste contaminated with GMOs, being transported out of the **facility** must be transported in accordance with any transport guidelines and other relevant guidelines, as in force from time to time, issued by the Regulator.
- 35 Volumes less than or equal to 25 litres of cultures containing GMOs may be stored outside the **facility** in a storage unit (freezer, fridge, controlled temperature room or other controlled temperature container). A biohazard symbol must be posted on the storage unit and it must be locked when not in use, unless access is restricted to the room or area where the storage unit is located.
- 36 GMOs or organisms infected with GMOs being stored outside the certified **facility** must be double-contained. The primary container must be sealed and leak proof. The primary container must be clearly labelled so it can be identified and 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.
- 37 Transport of GMOs between the certified **facility** and the storage unit must be in accordance with any transport guidelines and other relevant guidelines, as in force from time to time, issued by the Regulator. Any spills of GMOs that occur outside the certified **facility** must be reported to the Regulator as soon as practicable. The spilt material and any contaminated surfaces must be **decontaminated**.
- 38 All cultures of viable material must be clearly identified and labelled.
- 39 Any unintentional release or suspected unintentional release of GMOs from the **facility** must be reported to the Regulator as soon as practicable.
- 40 Persons who have been performing **procedures** in the **work area** must remove gloves and/or **decontaminate** their hands before leaving the **work area**. This can be achieved by washing, or use of appropriate chemical **decontaminant**.

Standards referenced in this document

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

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

AS/NZS 2243.3	Safety in laboratories Part 3: Microbiological aspects and containment facilities
AS/NZS 2647	Biological safety cabinets Installation and use
AS 2845.3	Water supply - Backflow prevention devices Part 3: Field testing and maintenance
AS/NZS 2982.1	Laboratory design and construction Part 1: General requirements
AS/NZS 3500.1	Plumbing and drainage Part 1: Water services