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

Guidelines for Certification
of a
Physical Containment Level 2 Constant Temperature Room

Version 2.1– Effective 9 August 2011

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

Certification of PC2 Constant Temperature Rooms is intended to apply to standalone constant temperature rooms where genetically modified organisms (GMOs) that require containment in a PC2 facility are cultured or grown in controlled temperature conditions, either constant or fluctuating.

If a constant temperature room is part of another PC2 facility, currently or proposed to be, certified by the Gene Technology Regulator (the Regulator) to PC2, then it is not necessary to separately certify the constant temperature room.

The scope of dealings to be conducted with GMOs in facilities certified under these guidelines is also intended to be limited to procedures which produce no aerosols containing GMOs. Therefore, conditions generally will be applied to the certification of PC2 Constant Temperature Rooms specifying that all GMOs requiring containment in a PC2 facility certified by the Regulator, must remain within primary containment at all times, except for:

- Genetically modified (GM) animal tissue cultures which do not contain any GM micro-organisms
- GM multi-cellular plant tissue cultures which do not contain any GM micro-organisms
- whole GM plants which:
  - do not contain any GM micro-organisms;
  - do not contain any pollen, seed or other propagule; or
  - are contained within a plant growth cabinet that is screened to prevent the escape of seeds and pollen.

Liquid cultures of GM micro-organisms must be kept in primary containers of less than 25 litres of GM culture per vessel.

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 Constant Temperature Room. 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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Part A

Requirements for Certification

Physical Containment Level 2 Constant Temperature Room
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CONTAINMENT REQUIREMENTS THAT MUST BE MET IN ORDER FOR A PHYSICAL CONTAINMENT LEVEL 2 (PC2) CONSTANT TEMPERATURE ROOM 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 Constant Temperature Room 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 Constant Temperature Rooms 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 Constant Temperature Room, 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 this document, words and phrases used in this document 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.

aerosol	Suspension in air of finely dispersed solids and/or liquids.
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 or decontaminate	A physical or chemical process which removes, kills or renders non-viable the GMOs used. In the case of micro-organisms this may 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.
OGTR	Office of the Gene Technology Regulator.
PC2	Physical Containment Level 2.
personal protective equipment (PPE)	Any devices or equipment, including clothing, designed to be worn or held by a person on its own, or part of a system, to protect against one or more health safety hazards.
pest	An unwanted organism that could cause cross-contamination within the facility or compromise containment of the GMO.
primary container	A container directly surrounding the GMO.

sealed	Able to contain all GMOs or the reproductive material of GM plants or GM aquatic organisms (including pollen or gametes) being transported or stored, and able to remain closed during all reasonably expected conditions of transport and storage.
the Regulator	The Gene Technology Regulator.

Facility and fittings requirements

1. The facility to be certified must be a fully enclosable space bounded by walls, doors, windows, floors and ceilings. The facility doors and windows must be lockable or otherwise able to be secured.

   NOTE: The walls, doors, windows, floors and ceilings form the physical containment barrier of the facility where dealings with GMOs will be conducted. This barrier protects all spaces outside the facility, including internal spaces of buildings in which a certified facility is located, and the environment.

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

3. Open spaces between and under benches, cabinets and equipment in the facility must be accessible for decontamination.

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

Capacity to comply with certification conditions

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

Information required with application forms

5. The floor plans for the facility submitted with the application must clearly indentify rooms or spaces that are lifts, toilets, bathrooms, kitchens, lunch rooms and offices with carpets.

   NOTE: The Regulator would not usually certify the above rooms as part of the certified facility.

Part B

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) Constant Temperature Room.

Where a specific condition in this document conflicts with a condition of a licence, the *Gene Technology Regulations 2001*, or any applicable guidelines issued under Section 27(d) of the Act, then the condition of a licence, the Regulations or applicable guidelines prevails.

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

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

2. For purposes of condition 1, an authorised person is a person who:
   (a) intends to undertake dealings, and has been trained in accordance with the Behavioural Requirements listed at Part C of this document;
   (b) has signed, dated and provided to the certification holder a record of the training referred to in paragraph 2(a) above; and
   (c) has not been excluded from the facility by the certification holder on the direction of the Regulator;

   or

   (d) is an individual, or class of person, who does not intend to undertake dealings and has the permission of the certification holder, the facility manager or other representative of the certification holder, to enter the facility.

3. If the Regulator requests the certification holder to provide a signed and dated record of the training provided to a particular authorised person, or class of person, the signed and dated record of that training must be available to the Regulator within a time period stipulated by the Regulator.

4. If the Regulator directs the certification holder to exclude a person, or class of person, from entry to the facility on the grounds that the person, or class of person:
   (a) has behaved, or is behaving, in a manner which has caused, or which may cause, GMOs to escape from the facility; or

(b) has behaved, or is behaving, in a manner which has exposed, or exposes, other persons in the facility to a GMO in circumstances where the exposure causes, or is capable of causing, a threat to the health and safety of those other persons;

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

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

6. For the purposes of condition 5, before admitting a person, or class of person, subject to conditions, the certification holder must notify the person(s) of any conditions that apply to them.

7. If the Regulator invites the certification holder to make a submission on whether or not a person, or class of person, should:
   (a) be excluded from entry to the facility; or
   (b) be admitted to the facility subject to conditions;

   the certification holder may make such a submission within a time period stipulated by the Regulator.

8. If the certification holder is not the owner of the facility and does not have the authority to admit and exclude persons from the premises, the certification holder must not allow dealings in the facility until such authority is obtained in writing from the owner of the facility. If the certification holder does not have the capacity to prevent dealings from occurring, the certification holder must notify the Regulator of this in writing as soon as reasonably practicable.

9. The Regulator or a person authorised by the Regulator must, at all reasonable times, be allowed to enter the facility for the purposes of auditing or monitoring the conditions applying to the facility and any dealings being conducted in it.

Dealings not permitted in this facility type

10. Unless otherwise agreed to in writing by the Regulator the following dealings must not be conducted in this facility:
   (a) dealings with any GMO that under the conditions of a licence or legislation requires containment in any physical containment level higher than PC2;
   (b) the housing of any animals including invertebrates and aquatic animals (except animals that are in diapause or another form of dormancy);
   (c) any dealing with a GMO outside of a primary container or where the primary container is opened, except for:
      - GM animal tissue cultures which do not contain any GM micro-organisms
      - GM multi-cellular plant tissue cultures which do not contain any GM micro-organisms

- whole GM plants which do not contain any GM micro-organisms and:
  - do not contain any pollen, seed or other propagule; or
  - are contained within a plant growth cabinet that is screened to prevent the escape of seeds and pollen.

(d) dealings producing 25 litres or more of liquid culture of GMOs in each vessel; and
(e) any other work notified in writing by the Regulator.

General conditions

11. If the certification holder is not the owner of the facility, fittings or containment equipment and does not have the authority to maintain the facility**,** fittings or containment equipment, the certification holder must notify the Regulator in writing if the owner of the facility, fittings 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.

12. The facility must be inspected at least once every 12 months by a person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skill enabling that person to assess the facility's compliance with the conditions listed under Part B 'Facility and fittings conditions' and 'General conditions'. An inspection report which records the extent of compliance with those conditions must be made. A copy of the last five years' inspection reports must be kept and made available to the Regulator if requested.

    NOTE: A checklist which may be used for annual inspections of PC2 Constant Temperature Rooms is available on the OGTR web site <www.ogtr.gov.au> – but its use is not mandatory. Annual inspection reports should <u>not</u> be sent to the Regulator unless requested.

13. 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 (as detailed in AS/NZS 2243.3).

    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.

14. A supply of decontamination agents effective against the GMOs being dealt with in the facility must be available in or near the facility for decontamination purposes. All containers of decontamination agents, including any solutions for decontaminating hands, must be labelled with the contents and the expiry date. Decontamination agents must not be used after the expiry date.

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

Facility and fittings conditions

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

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

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

    17.2. 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.

18. Before a suspension of the certification can be lifted, the facility must be inspected by a person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skill enabling that person to assess the facility's compliance with the conditions listed under 'Facility and fittings conditions' and 'General conditions' to ensure that the facility meets the conditions of certification. Dealings with GMOs, with the exception of storage, must not recommence in a facility which has its certification suspended until the Regulator has lifted the suspension by notice in writing. Storage of GMOs in a suspended facility must be in accordance with the requirements listed in the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as in force from time to time.

19. Dealings, with the exception of storage, 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.

20. The effectiveness of any autoclave, or any other heat-based equipment, used in decontaminating GMOs must be monitored, and the results documented, in accordance with Section 3.1 of the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as in force from time to time.

21. Any autoclave, or any other heat-based equipment, must be calibrated, and the results documented, in accordance with Section 3.1 of the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as in force from time to time.

22. 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. Defective decontamination equipment must be decontaminated prior to maintenance or repair.

Part C

Behavioural Requirements

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Persons undertaking work in the facility on GMO's requiring PC2 containment must comply with these Behavioural Requirements.

Non-GMOs, Exempt GMOs and PC1 dealings in the facility

1. Persons undertaking work in the facility on non-GMOs, exempt dealings or dealings which may be undertaken in a PC1 facility, must comply with these Behavioural Requirements unless:
   (a) procedures are implemented to ensure that non-GMOs, exempt dealings or dealings which may be undertaken in a PC1 facility, are not cross-contaminated with GMO dealings requiring containment in a PC2 facility;
   (b) the above procedures are documented; and
   (c) the outermost container used to transport any organism out of the facility must be free of contamination with GMOs prior to being transported out of the facility.

   Dealings which may be undertaken in a PC1 facility, and where subclauses (a) to (c) above are met, may be conducted in accordance with the Behavioural Requirements in this document or the *Guidelines for Certification of a Physical Containment Level 1 Facility*.

   NOTE: Means of preventing cross-contamination could include physical separation of the work, or separation by working at different times and ensuring any contaminated surfaces are decontaminated prior to working with a different organism.

Doors & windows

2. 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, or the facility must be otherwise secured, when facility personnel are not in attendance. Dedicated "emergency only" exits must not be used to enter or exit the facility except in an emergency.

3. Windows must remain closed and locked, or otherwise secured, while procedures with GMOs are being conducted or when facility personnel are not in attendance.

Containment equipment

4. Any GMOs must remain in a sealed primary container while in the facility, except for:.
   - GM animal tissue cultures which do not contain any GM micro-organisms
   - GM multi-cellular plant tissue cultures which do not contain any GM micro-organisms.

NOTE: Whole GM plants which do not contain any GM micro-organisms and do not contain any pollen, seed or other propagule may be contained in pots which will function as a primary container.

Personal protective equipment

5. Any personal protective equipment must be removed before leaving the facility and disposed of or stored in a designated storage or hanging space. With the exception of gloves, this does not apply if moving directly to another containment facility, certified to at least PC2 by the Regulator, that is directly connected to the facility or is connected by a corridor, stairs or other space that is not a public thoroughfare and in which there is negligible risk of cross-contamination should other personnel be encountered or contacted in the corridor.

Decontamination

6. Decontamination must take place in the facility, or at another location, providing the GMOs, equipment, waste or personal protective equipment are transported to the decontamination site in accordance with the Regulator's *Guidelines for the, Storage and Disposal of GMOs*, as in force from time to time, and other relevant guidelines issued by the Regulator.

7. All decontamination procedures conducted inside the facility must be carried out by authorised personnel.

8. GMOs, or non-GM organisms containing GMOs, must be decontaminated prior to disposal if the method of disposal is not also the method of decontamination.

9. Any wastes containing GMOs must be decontaminated prior to disposal if the method of disposal is not also the method of decontamination.

10. Work benches, surfaces and equipment, where procedures involving GMOs have taken place, that are known to be contaminated with or suspected to be contaminated with GMOs must be decontaminated immediately after each procedure and/or at the end of each working day.

11. Equipment contaminated with or suspected to be contaminated with GMOs must be decontaminated before being removed from the facility, except if the equipment is being transported in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*, as in force from time to time, and other relevant guidelines issued by the Regulator.

12. Personal protective equipment contaminated with or suspected to be contaminated with GMO**s** must be taken off as soon as practicable and decontaminated prior to reuse or disposal. Protective clothing that is known to be not contaminated with GMOs may be washed using normal laundry methods. Gloves must be disposed of.

13. Decontamination may be undertaken in accordance with Section 3.1 of the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as in force from time to

time. Any alternative method of decontamination to be undertaken inside the facility must be approved in writing by the Regulator.

14. Persons who have contaminated their hands with GMOs in the facility must decontaminate their hands before leaving the facility.

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

Spills

15. Documented procedures must be in place to decontaminate any spills involving GMOs inside the facility. The procedures must be made available to the Regulator if requested.

16. If a spill of GMOs or any material containing GMOs occurs inside the facility, the spills procedures must be implemented to decontaminate the spill as soon as reasonably practicable.

Labelling

17. All containers of GMOs must be labelled in a manner capable of notifying the handler that the item contains a GMO. Any unlabelled viable material must be treated as a GMO and handled in accordance with these requirements.

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

Removal and storage of GMOs

18. GMOs which require containment in a PC2 facility, and any other organism potentially cross-contaminated with GMOs requiring PC2 containment (see Behavioural Requirement 3), 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 or disposed of where the method of disposal is also the method of decontamination;
    (d) written permission has been given by the Regulator for transport to another destination within Australia; or
    (e) subject to obtaining any required permits, they are to be transported to the Australian border for export.

19. Transport, storage and disposal of all GMOs being transported out of the facility, must be conducted in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*, as in force from time to time, and other relevant guidelines issued by the Regulator.

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.

Refer to the most recent issue of the standards.

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