



Conditions of Certification

Physical Containment Level 2 Laboratory Version 3.1 – Effective 1 July 2007

Work not permitted in this facility type

1. The following work must not be conducted in this **facility**:
 - (a) **dealings** with any **GMO** that under the conditions of a licence requires containment in any physical containment level higher than **PC2**;
 - (b) the housing/keeping/rearing of any animals, arthropods, or aquatic organisms for longer than the minimum time required to complete laboratory procedures on them;
 - (c) the growing of any plants (except those in tissue culture, or contained in a plant growth cabinet or other containment device approved in writing by **the Regulator**);
 - (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.
 - 2.2. Prior to any significant structural changes that will affect the containment of **GMOs** in the **facility**, the applicant must either:
 - 2.2.1. request a suspension of the certification, in writing, from **the Regulator**; or
 - 2.2.2. 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.

- 2.3. Before a suspension of the certification can be lifted, the **facility** must be inspected by a person qualified to assess the **facility's** compliance with the conditions listed under 'Facility and fittings conditions' to ensure that the **facility** meets the conditions of certification. **Dealings** with **GMOs** must not recommence in a **facility** which has its certification suspended until **the Regulator** has lifted the suspension by notice in writing.
- 2.4. **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**.
- 2.5. 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.
- 2.6. 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.
- 2.7. The **facility** must continue to contain either a wash basin fitted with taps of the hands-free operation type or some other means of **decontaminating** hands.
- NOTE: Alternatives to wash basins, such as dispensers filled with **decontaminant** solutions, are considered suitable.
- 2.8. Eyewash equipment (either plumbed eyewash equipment or single-use packs of sterile eye irrigation fluids) must be maintained within the **facility**.
- 2.9. Where **dealings** in the **facility** with **GMOs** that require **PC2** containment produce **aerosols** containing **GMOs**, 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 **GMOs** 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.
- 2.10. Where any Class I or Class II biological safety cabinet is installed and used for procedures with **GMOs**, it must be used and **decontaminated** in accordance with the requirements of AS/NZS 2647:2000.
- 2.11. Where any Class I or Class II biological safety cabinet is installed and used for procedures with **GMOs**, 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 **GMOs**.

- 2.12. 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.

- 2.13. 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.

- 2.14. 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.

- 2.15. Any backflow prevention measures in place either at the time of certification or installed at a later time must be maintained until a change in the measures is indicated by a review of the risk assessment.

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

- 2.16. 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:
- 2.16.1. 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
 - 2.16.2. previous connections were made prior to certification and were assessed as not requiring backflow prevention measures, but a new **GMO** is to be **dealt** with in the **facility** that presents different risks from the **GMOs** assessed at the time of certification.
- 2.17. 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.
- 2.18. Any new or reviewed backflow prevention risk assessments must be kept and made available to **the Regulator** if requested.
- 2.19. 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** Laboratories 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 **GMOs** 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**.

Behavioural Requirements

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Doors & windows

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

Non-GMOs in the facility

3. 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 cross-contaminated 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 cross-contamination of non-**GMO** 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 work with non-**GMOs**.

Containment equipment

4. Any procedures in the **facility** with **GMOs** requiring containment in a **PC2 facility** that produce **aerosols** containing **GMOs** must be performed in the biological safety cabinet or other **aerosol** containment equipment approved in writing by **the Regulator**.

Personal protective clothing

5. The following personal protective clothing must be worn by personnel undertaking **dealings** in the **facility**:
 - (a) protective clothing to afford protection to the front part of the body; and

NOTE: A rear-fastening gown is preferable.

- (b) gloves, when **dealing** with **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** must be rendered non-viable prior to disposal.
9. Wastes containing **GMOs** must be **decontaminated** prior to disposal.
10. Work benches, surfaces and equipment where procedures involving **GMOs** have taken place must be **decontaminated** when the **dealings** are completed.
11. Equipment must be **decontaminated** before being removed from the **facility**.
12. Protective clothing contaminated with or suspected to be contaminated with **GMOs** must be taken off as soon as practicable and **decontaminated** prior to reuse. Protective clothing that has not been contaminated with **GMOs** may be washed using normal laundry methods. Gloves must be disposed of.
13. **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.

14. 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).
15. 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.

16. 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.

17. **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**.
18. Persons who have been performing procedures 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.

Labelling

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

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

Removal and storage of GMOs

20. **GMOs** which require containment in a **PC2 facility** must not be removed from the **facility** unless:
 - (a) they are to be transported to another containment **facility** certified by **the Regulator** to at least **PC2**;
 - (b) they are to be transported to another location for storage;
 - (c) they are to be transported to another location to be **decontaminated** prior to disposal;
 - (d) written permission, such as a licence, has been given by **the Regulator** for transport to another destination within Australia; or
 - (e) subject to obtaining any required permits, they are to be transported to the Australian border for export.
21. All **GMOs** being transported out of the **facility**, including transport to storage outside the **facility**, must be transported in accordance with any transport guidelines and other relevant guidelines issued by **the Regulator**.
22. All cultures of **GMOs** being stored inside the **facility** must be **sealed** during storage to prevent dissemination of the **GMOs**.

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

23. **GMOs** or organisms containing **GMOs** 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 **GMOs** into the **environment**.
24. **GMOs** or organisms containing **GMOs** being stored outside the **facility** must be double-contained. The **primary container** must be **sealed** to prevent the escape or release of the **GMOs** and must be labelled. The **primary container** must be stored in an **unbreakable secondary container**. In the case of a small storage unit such as a fridge, freezer or liquid nitrogen container, the **secondary container** may be the storage unit.
25. In the case of **NLRDs**, the notifying organisation must authorise the storage of **GMOs** outside of the **facility**.

Spills

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