



# Guidelines for Certification of a Physical Containment Level 3 Laboratory

## Version 2.1 – issued 1 September 2006

These guidelines contain the requirements for certification of a Physical Containment Level 3 (PC3) Laboratory pursuant to section 90 of the *Gene Technology Act 2000* (the Act).

The Conditions of Certification detail the usual conditions that will apply to a PC3 Laboratory 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 obtaining and maintaining certification.

A PC3 laboratory should be constructed so that it achieves upon commissioning an air leakage rate, at a differential pressure of 200Pa, of no more than 120L/min. At all times after commissioning an air leakage rate of no more than 1200L/min should be maintained.

The Office of the Gene Technology Regulator (OGTR) will inspect PC3 Laboratories prior to any decision on an application for certification.

## Contents

<b>Definitions.....</b>	<b>2</b>
<b>Requirements for certification .....</b>	<b>4</b>
<b>Conditions of certification.....</b>	<b>10</b>
<b>Standards referenced in this document .....</b>	<b>22</b>

## Indicative layouts of PC3 facilities

For the purposes of these PC3 Laboratory guidelines, a PC3 **facility** includes a laboratory or **work area** separated from other areas by a dedicated **airlock** and may include other support rooms, corridors, etc. within the physical containment barrier certified by the Regulator. Diagrams of typical PC3 **facilities** are shown below (Figures 1 and 2).

Figure 1: Typical layout of a single laboratory PC3 facility

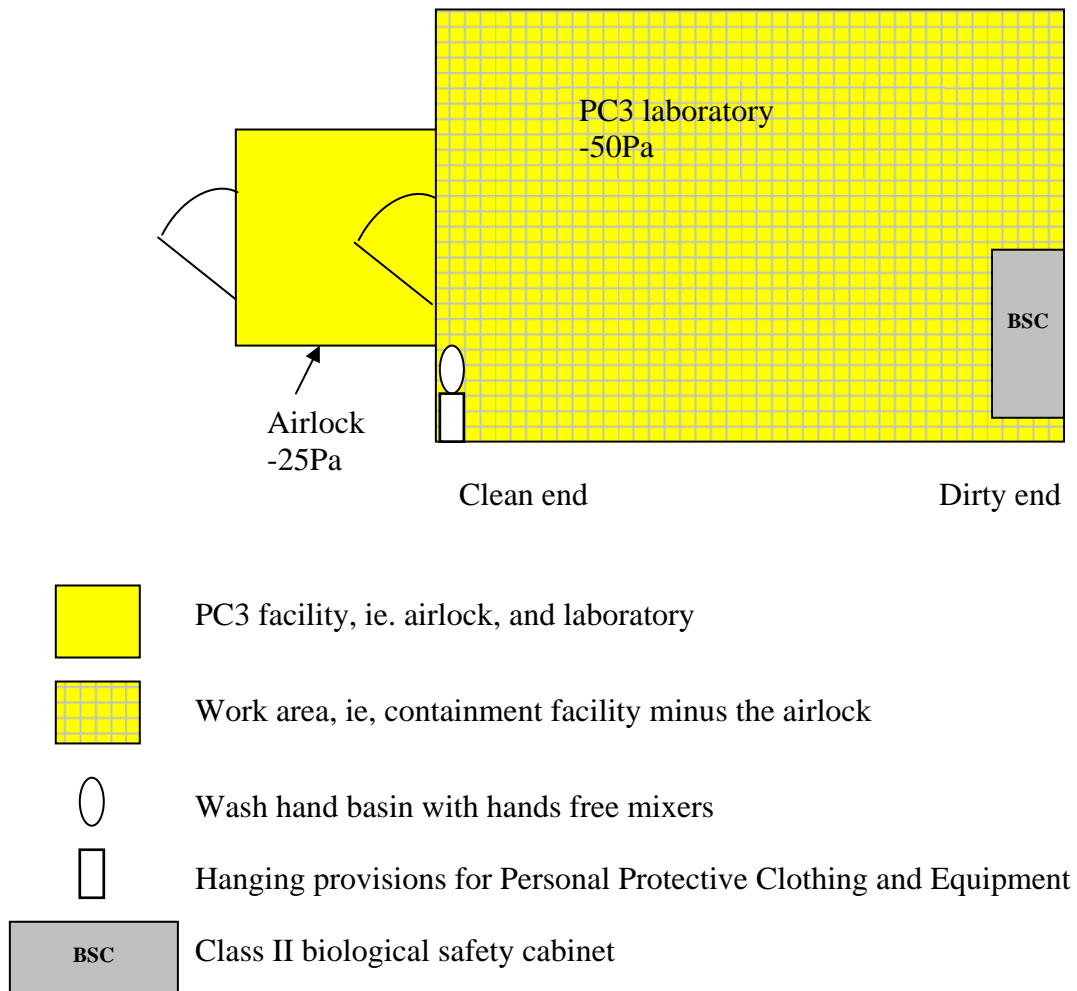
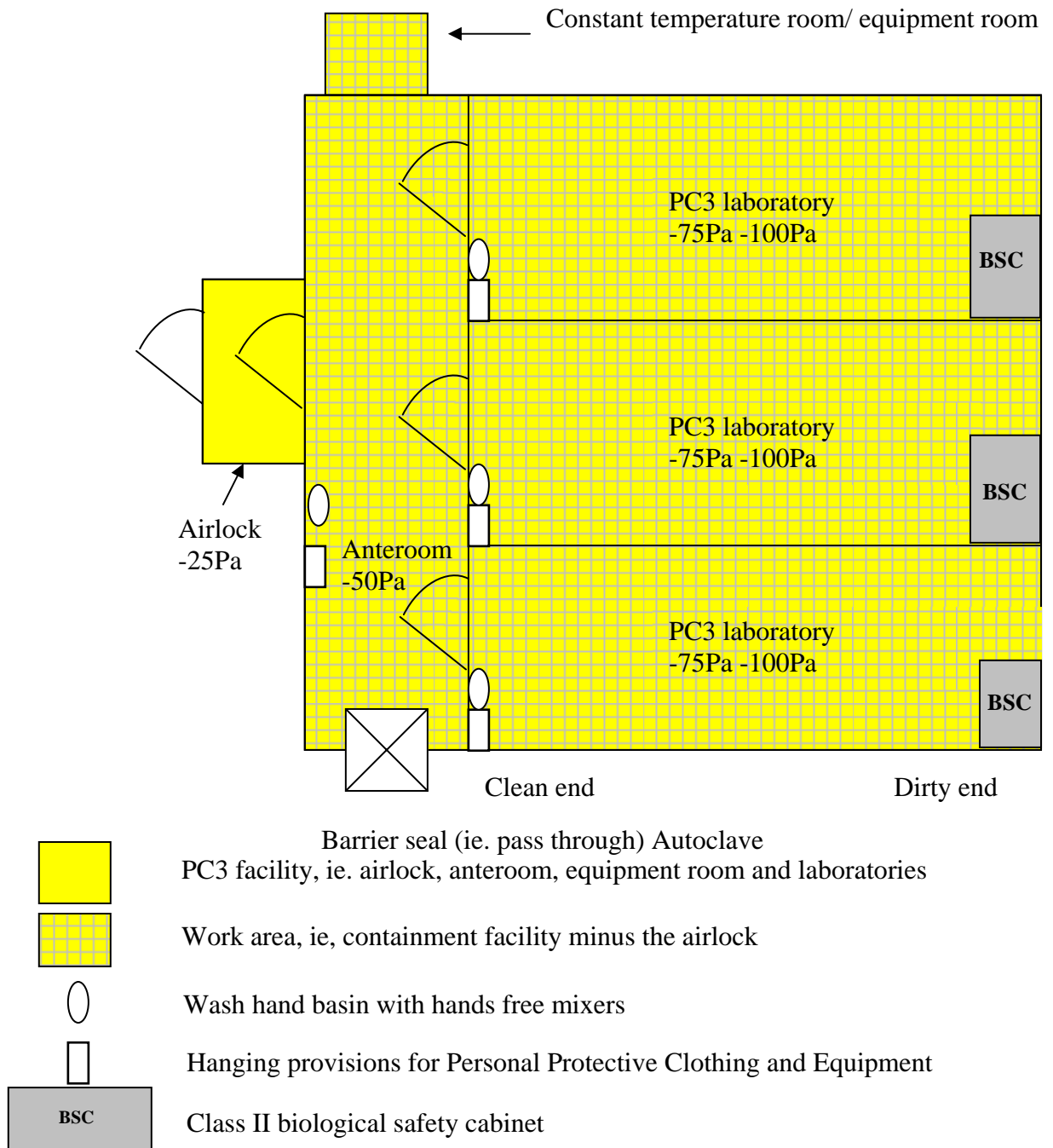


Figure 2: Typical layout of a multi-laboratory PC3 facility



# Requirements for Certification

## Physical Containment Level 3 Laboratory Version 2.1 – issued 1 September 2006

CONTAINMENT REQUIREMENTS THAT MUST BE MET IN ORDER FOR A PHYSICAL CONTAINMENT LEVEL 3 (PC3) LABORATORY TO BE CERTIFIED BY THE GENE TECHNOLOGY REGULATOR.

These are the requirements for the certification of PC3 Laboratory issued under section 90 of the *Gene Technology Act 2000* (the Act) and corresponding State legislation. These requirements apply to applications for certification of PC3 Laboratories 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.

**airlock** An area or room between a pair of doors that separates the **work area** inside a **facility** from access corridors, other laboratories, or other spaces outside the **facility**.

The **airlock** permits the movement of equipment and personnel without affecting the inward flow of air into the **work area**, since at least one door is kept closed at all times.

The **airlock** can function as a clothes change room (showers may be included), but must not be used for performing any **procedures** on organisms.

**autoclave** Pressure steam steriliser.

**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.

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

## General

1. To be granted certification a **facility** must meet each of the containment requirements for certification of a PC3 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** must be a fully enclosable space bounded by walls, doors, windows, floors and ceilings and must be designed and constructed to allow the operation of the **facility** under negative pressure, as required in requirement 16.
3. Entry to the **work area** must be through an **airlock**. **Airlock** doors must remain closed when not in normal use (eg. persons entering or exiting the **facility**). **Airlock** doors must be self-closing, fitted with seals and must contain at least one glass viewing panel. The outer door must be lockable. Physical mechanisms (eg. interlocking or alarm system) must be in place to ensure that only one door can be opened at any time.

NOTE: In order to maintain the required pressure in the **facility**, **airlock** doors must be self-closing, fitted with seals and only one door can be opened at any time. If interlocking is employed as the mechanism used to ensure that only one door is open at any time, consideration must be given to having an interlocking device separate from the building management system (BMS). Therefore, if the BMS fails, interlocking doors can still operate at all times. Viewing panels allow persons entering or exiting the **airlock** to check whether other persons are in the **airlock** or about to enter/leave the **airlock**, thus minimising the risk of accidents.

4. Windows in the **facility** must be closed and sealed.
5. All walls, floors, ceilings, benches and furniture surfaces must be smooth, impermeable to water, cleanable and resistant to damage by the cleaning agents, disinfectants and **fumigants** used in the **facility**.
6. 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.
7. The **facility** must be constructed to enable **fumigation** of the whole **facility** to take place. Benches, cupboards and services must be constructed to enable **decontamination**, including **fumigation**, of all spaces in the **facility**. Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.
8. A communication system and a backup system must be provided inside the **facility**.

NOTE: A suitable communication and backup communication system may include a normal telephone service and a dedicated mobile telephone that is kept charged and does not leave the **facility**.

9. The **facility** must contain an **autoclave**.

NOTE: A double-door barrier seal **autoclave** installed in the barrier wall of the **facility** is preferable.

10. The **work area** of the **facility** must contain either a dedicated hand wash basin fitted with tap(s) of the hands-free operation type and supplied with potable water, or some other means of **decontaminating** hands at or near the exit of the **work area**. If the **facility** contains multiple laboratories, each laboratory must contain a dedicated hand wash basin or some other means of **decontaminating** hands at or near the exit of that laboratory.

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

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

NOTE: Eyewash equipment should be positioned within the **work area** rather than in the **airlock**. AS/NZS 2982.1 provides information on eyewash equipment. If the **facility** contains multiple laboratories, consideration should be given to providing eyewash equipment in each laboratory.

12. Potable water supplied to the **facility** must be provided with backflow prevention by a registered testable device that has a high hazard rating for protection against both back-pressure and back-siphonage in accordance with the requirements of AS/NZS 3500.1. Backflow prevention must isolate the certified PC3 **facility** or a group of certified PC3 **facilities** to the exclusion of all other areas.

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

13. Where a central reticulated vacuum system or portable vacuum pumps are used, 0.2 µm hydrophobic membrane-type filters or liquid disinfectant traps must be employed to prevent escape of organisms into the system.
14. Designated storage or hanging provisions for personal protective clothing and equipment must be available within the **work area**. Storage for personal effects, coats, etc must be provided outside the **facility**.

## Ventilation requirements

15. A ventilation system that establishes a negative air pressure gradient in the **facility** must be provided. Where **facilities** have supply air fans, the supply and exhaust airflow must be interlocked to prevent positive pressurisation of the **facility** in the event of failure of the exhaust fan. Directional airflow must be established in the **facility** to move air from the least to the most contaminated areas in the **facility** (usually away from the **airlock**).

NOTE: The negative pressure gradient is required so that there is a directional airflow into the **work area**. It is recommended that proper directional airflow into the laboratory be verified by airflow tests (eg. smoke pencil, pressure gauge).

Consideration must be given to establishing interlocking that is independent of the building management system (BMS). Therefore if the BMS fails, the interlocking mechanisms can still engage when necessary and prevent positive pressurisation.

16. The **work area** must be able to be maintained at an air pressure of at least 50 Pa below the pressure of adjacent areas outside the **facility** when both doors of the **airlock** are closed. When either door is open, the **work area** pressure must remain at least 25 Pa below that of the adjacent areas outside the **facility**.
17. The **facility** must be equipped to measure and display the pressure difference between the **facility** and adjacent areas. The display must be able to be read before entering the **facility**.

18. The **facility** must be equipped with an alarm that is audible inside and outside the **facility**, and activated when the pressure in the laboratory is more than 25 Pa above the set point.

NOTE: The purpose of the alarm is to indicate a malfunction of the air system and therefore the alarm should not go off during the course of normal opening and closing of the doors.

19. The pressure differential must be able to be achieved by means of an independent room exhaust fan located downstream of a high efficiency particulate air (HEPA) filter and discharging to the outside atmosphere. All exhaust air and **decontaminating** gases used during **fumigation** of the **facility**, must be able to be purged to the atmosphere in such a manner that it is dispersed away from occupied buildings and air intakes.
20. Supply or replacement air to the **facility** must have filters that are Type 1 Class A or Class B filters complying with AS 1324.1 and having a minimum arrestance efficiency of 90% when tested in accordance with AS 1324.2 with Test Dust No. 4.
21. An exhaust pre-filter of the same or higher standard as the air intake filter must be installed. The exhaust filter must be a HEPA filter as specified in Clause 1.3.15 of AS/NZS 2243.3:2002, or another filter that meets all requirements of AS 4260 with a minimum performance of Grade 2.
22. The exhaust HEPA filter(s) must be mounted in air-tight housing, with sealed access doors, and the ductwork between the **facility** and the HEPA filter housing must also be air-tight. The design and location of the filter housing must allow for access to and integrity testing of the HEPA filter.
23. Filter housings must incorporate the following features:
  - (a) a gas-tight isolating valve on the air outlet duct (and supply duct if present). In order to enable **fumigation** of the filter to be performed separately from **decontamination** of the **facility**, an isolating valve on the air inlet duct and upstream and downstream valved ports are also required;
  - (b) secure filter element clamping and mounting tracks; and
  - (c) if the housing contains upstream and downstream valved pressure tappings to permit monitoring and display of the filter air flow pressure drop, the tapping on the **facility** side of the HEPA filter must be fitted with a 0.2 µm hydrophobic membrane type filter that is protected from physical impact.
24. The exhaust HEPA filter must be tested after installation and prior to use by a **competent person** in accordance with AS 1807.6 or AS 1807.7 as applicable.

## Containment equipment requirements

25. The **facility** must contain a biological safety cabinet. Installation of Class I and Class II biological safety cabinets must be in accordance with the requirements of AS/NZS 2647:2004.

NOTE: For further information on biological safety cabinets Class I and Class II, refer to Section 6.7 of AS/NZS 2243.3:2002.

## Documentation to be supplied with application

26. The following documentation must be submitted with the application for certification of a PC3 Laboratory **facility**:
- (a) evidence of installation of backflow prevention for any water supplied to the **facility** (in accordance with certification requirement 12);
  - (b) evidence of installation of all HEPA filters (in accordance with requirement 24);
  - (c) evidence of installation of biological safety cabinets (in accordance with certification requirement 25);
  - (d) a copy of the **facility** manual (in accordance with condition 34 of the Conditions of Certification); and
  - (e) evidence of **autoclave** calibration (in accordance with condition 50 of the Conditions of Certification).

## Capacity to comply with certification conditions

27. To be granted certification a facility must be able to comply with the conditions of certification that will be applied to a certified PC3 Laboratory 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

## Physical Containment Level 3 Laboratory Version 2.1 – issued 1 September 2006

Conditions that must be met to retain ongoing certification of a Physical Containment Level 3 (PC3) Laboratory are imposed on **facilities** by the Regulator at the time of certification pursuant to section 86 of the *Gene Technology Act 2000* (the Act). The condition clauses in this section are the ones that can be expected, in most cases, to be included on the certification instrument as the conditions of certification for a PC3 Laboratory.

### 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.

**airlock** An area or room between a pair of doors that separates the **work area** inside a **facility** from access corridors, other laboratories, or other spaces outside the **facility**.

The **airlock** permits the movement of equipment and personnel without affecting the inward flow of air into the **work area**, since at least one door is kept closed at all times.

The **airlock** can function as a clothes change room (showers may be included), but must not be used for performing any **procedures** on organisms.

**autoclave** Pressure steam steriliser.

**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.

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

## 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 PC3; or
  - (b) the containment of animals and plants for longer than the minimum time necessary to complete laboratory **procedures**.

## Compliance with certification conditions

2. All the conditions listed under the heading of 'Facility Conditions', 'Ventilation 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 by personnel working in the **facility**. This condition applies whether or not work with a GMO is occurring in the **facility**.

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 Physical Containment Level 3 (PC3) sign, as supplied by the Office of the Gene Technology Regulator (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 PC3 **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.

4. The **facility** must be maintained as a fully enclosable space bounded by walls, doors, windows, floors and ceilings and must allow the operation of the **facility** under negative pressure, as required in Condition 21.

Prior to any structural changes that will affect the maintenance of containment, the applicant must cease all **dealings** with GMOs and request a suspension of the certification, in writing, from the Regulator.

In order to lift the suspension, the **facility** must be inspected after the structural changes are completed to ensure that the **facility** meets the requirements for certification. **Dealings** with GMOs may not commence until the Regulator has lifted the suspension by approval in writing.

5. Entry to the **work area** must be through an **airlock**. **Airlock** doors must remain closed when not in normal use (eg. persons entering or exiting the **facility**). **Airlock** doors must be self-closing, fitted with seals and must contain at least one glass viewing panel. The outer door must be lockable. Physical mechanisms (eg. interlocking or alarm system) must be in place to ensure that only one door can be opened at any time.

NOTE: In order to maintain the required pressure in the **facility**, **airlock** doors must be self-closing, fitted with seals and only one door can be opened at any time. If interlocking is employed as the mechanism used to ensure that only one door is open at any time, consideration must be given to having an interlocking device separate from the building management system (BMS). Therefore, if the

BMS fails, interlocking doors can still operate at all times. Viewing panels allow persons entering or exiting the **airlock** to check whether other persons are in the **airlock** or about to enter/leave the **airlock**, thus minimising the risk of accidents.

6. Windows in the **facility** must be closed and sealed.
7. All walls, floors, ceilings, benches and furniture surfaces must be smooth, impermeable to water, cleanable and resistant to damage by the cleaning agents, disinfectants and **fumigants** used in the **facility**.
8. 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.

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

9. The **facility** must be constructed to enable **fumigation** of the whole **facility** to take place. Benches, cupboards and services must be constructed to enable **decontamination**, including **fumigation**, of all spaces in the **facility**. Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.
10. A communication system and a backup system must be provided inside the **facility**.

NOTE: A suitable communication and backup communication system may include a normal telephone service and a dedicated mobile telephone that is kept charged and does not leave the **facility**.

11. The **facility** must contain an **autoclave**.

NOTE: A double-door barrier seal **autoclave** installed in the barrier wall of the **facility** is preferable.

12. The **work area** of the **facility** must contain either a dedicated hand wash basin fitted with hands-free tap(s) and supplied with potable water, or some other means of **decontaminating** hands. If the **facility** contains multiple laboratories, each laboratory must contain a dedicated hand wash basin or some other means of **decontaminating** hands at or near the exit of each laboratory.

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

13. Eyewash equipment (either plumbed eyewash equipment or single-use packs of sterile eye irrigation fluids) must be provided within the **facility**. Eyewash equipment must be used and maintained in accordance with the manufacturer's instructions.

NOTE: Eyewash equipment should be positioned within the **work area** rather than in the **airlock**. AS/NZS 2982.1 provides information on eyewash equipment. If the **facility** contains multiple laboratories, consideration should be given to providing eyewash equipment in each laboratory.

14. Potable water supplied to the **facility** must be provided with backflow prevention by a registered testable device that has a high hazard rating for protection against both back-pressure and back-siphonage in accordance with the requirements of AS/NZS 3500.1. Backflow prevention must isolate the certified PC3 **facility** or a group of certified PC3 **facilities** to the exclusion of all other areas.

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

15. All testable backflow devices must pass a test every 12 months, 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**, when requested.
16. Where a central reticulated vacuum system or portable vacuum pumps are used, 0.2 µm hydrophobic membrane-type filters, and liquid disinfectant traps must be installed at the point of use.
17. Designated storage or hanging provisions for personal protective clothing and equipment must be available within the **facility**, adjacent to the **work area** access door. Storage for personal effects, coats, etc must be provided outside the **facility**.
18. A supply of disinfectants effective against the organisms 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 necessary, the expiry date.

## Ventilation conditions

19. A ventilation system that establishes a negative air pressure gradient in the **facility** must be provided. Where **facilities** have supply air systems, the supply and exhaust airflow must be interlocked to prevent positive pressurisation of the **facility** in the event of failure of the exhaust fan. Directional airflow must be established in the **facility** to move air from the least to the most contaminated areas in the **facility** (usually away from the **airlock**).

NOTE: A ventilation system establishing negative pressure is required so that there is a directional airflow into the **work area**. It is recommended that proper directional airflow into the laboratory be verified by airflow tests (eg. smoke pencil, pressure gauge).

Consideration must be given to establishing interlocking that is independent of the BMS. Therefore if the BMS fails, the interlocking mechanisms can still engage when necessary and prevent positive pressurisation.

20. Any failure of the air handling system (exhaust air fan or interlocked supply/exhaust system) that results in loss of the negative air pressure gradient or produces a positive air pressure must be reported to the Regulator as soon as practicable.
21. The **work area** must be maintained at an air pressure of at least 50 Pa below the pressure of adjacent areas outside the **facility** when both doors of the **airlock** are closed. When either door is open, the **work area** pressure must remain at least 25 Pa below that of the adjacent areas outside the **facility**.
22. The **facility** must be equipped to measure and display the pressure difference between the **facility** and adjacent areas. The display must be able to be read before entering the **facility**.
23. The **facility** must be equipped with an alarm that is audible inside and outside the **facility** and activated when the pressure in the laboratory is more than 25 Pa above the set point.

NOTE: The purpose of the alarm is to indicate a malfunction of the air system and therefore the alarm should not go off during the course of normal opening and closing of the doors.

24. The pressure differential must be achieved by means of an independent room exhaust fan located downstream of a HEPA filter and discharging to the outside atmosphere. All exhaust air and **decontaminating** gases used during **fumigation** of the **facility**, must be purged to the atmosphere in such a manner that it is dispersed away from occupied buildings and air intakes.
25. Supply or replacement air to the room must be filtered using Type 1 Class A or Class B filters complying with AS 1324.1 and having a minimum arrestance efficiency of 90% when tested in accordance with AS 1324.2 with Test Dust No. 4.
26. An exhaust pre-filter of the same or higher standard as the air intake filter must be installed. The exhaust filter must be a HEPA filter as specified in Clause 1.3.15 of AS/NZS 2243.3:2002, or another filter that meets all requirements of AS 4260 with a minimum performance of Grade 2.
27. The exhaust HEPA filter(s) must be mounted in air-tight housing, with sealed access doors, and the ductwork between the **facility** and the HEPA filter housing must also be air-tight. The design and location of the filter housing must allow for access to and integrity testing of the HEPA filter.
28. Filter housings must incorporate the following features:
  - (a) a gas-tight isolating valve on the air outlet duct (and supply duct if present). If **fumigation** of the filter is to be performed separately from **decontamination** of the **facility**, an isolating valve on the air inlet duct and upstream and downstream valved ports are also required;
  - (b) secure filter element clamping and mounting tracks; and
  - (c) if the housing contains upstream and downstream valved pressure tappings to permit monitoring and display of the filter air flow pressure drop, the tapping on

the **facility** side of the HEPA filter must be fitted with a 0.2 µm hydrophobic membrane type filter that is protected from physical impact.

29. Annual testing of the **facility's** ventilation system must be carried out and must include:
- (a) testing of the pressure differentials to ensure compliance with these requirements;
  - (b) integrity testing of all HEPA filters in accordance with AS 1807.6 or AS 1807.7 by a **competent person**. The HEPA filter must be **decontaminated** prior to testing;
  - (c) checking directional airflow;
  - (d) verifying that the alarms operate when the air pressure in the **facility** is raised;
  - (e) calibration of transducers fitted to the air-handling system and validation of air-handling performance (ie. an over-pressure or under-pressure response);
  - (f) calibration of pressure gauges; and
  - (g) a record of the tests in items (a) to (f) and of any maintenance conducted must be kept and made available to the Regulator, if requested.

## Containment equipment conditions

30. The **facility** must contain a biological safety cabinet. Installation, use and **decontamination** of Class I and Class II biological safety cabinets must be in accordance with the requirements of AS/NZS 2647.

NOTE: For further information on biological safety cabinets Class I and Class II, refer to Section 6.7 of AS/NZS 2243.3:2002.

31. Biological safety cabinets must be inspected and tested in accordance with the requirements of Clause 7.10 of AS/NZS 2647:2004. This testing is required at least every 12 months, or after relocation of a cabinet, after mechanical or electrical maintenance and after 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**.

## Facility management

32. A **facility** manager must be appointed. The **facility** manager must understand the technical aspects of **facility** design, operation and maintenance including but not limited to the use and maintenance of the air-handling system, **autoclaves** and monitoring and alarm systems.

33. The **facility** manager must be responsible for establishing and maintaining policies and **procedures** for the safe operation of the **facility**.

The responsibilities of the **facility** manager must include:

- (a) authorisation of access to the **facility** for staff, visitors and contractors;
  - (b) conduct or facilitation of appropriate training to all staff, visitors and contractors as per Conditions 36 and 37;
  - (c) development, documentation and implementation of emergency response plans, which must include, as a minimum, responses to accidental exposure to pathogenic organisms, spills, failure of the power or ventilation systems, security threats and fire or other life-threatening situations;
  - (d) development, documentation and implementation of **decontamination** procedures effective for all organisms and equipment used in the **facility**;
  - (e) provision of information to all authorised users on changes to all **facility** operating procedures (e.g. entry and exit procedures, work practices, **decontamination** procedures and emergency plans);
  - (f) compilation of a **facility** manual and review and if necessary update of the manual at least annually or more frequently if required;
  - (g) ensuring that successful **decontamination** of the **facility** or the relevant area in the **facility** is carried out before any maintenance procedures occur;
  - (h) retention of documentation relating to the maintenance of the **facility** ventilation system, **autoclave(s)** and **fumigation** of the **facility**;
  - (i) co-ordination of immunisation of personnel working within the **facility**;
  - (j) ensuring that emergency contact numbers are clearly visible from inside and outside the **facility** (eg. 24 hours contacts for medical emergency and for alarm response);
  - (k) ensuring that access to voids, such as roof spaces, around the perimeter of the **facility** is restricted to persons authorised by the **facility** manager;
  - (l) ensuring that a record of all organisms (GM and non-GM) used in the **facility** since the most recent **fumigation** is kept and is made available to the Regulator, if requested; and
  - (m) coordination of all work in the **facility** where multiple projects or work on different organisms is taking place in the **facility**.
34. Access to the **facility** must be restricted to trained people authorised by the Institutional Biosafety Committee (IBC) and then only after they have been advised of any hazards and meet all specific requirements such as immunisation.
35. A **facility** manual must be readily available to all authorised users of the PC3 **facility**. The manual must include:
- (a) the **facility** manager's contact details;
  - (b) a list of persons authorised to enter the **facility**;
  - (c) a copy of the certification instrument for the **facility**;
  - (d) a copy of all licences and Notifiable Low-Risk Dealings for work with GMOs conducted in the **facility**, a list of all organisms being used in the **facility** and the risks associated with the use of these organisms;
  - (e) **procedures** that must be followed by all persons entering and exiting the **facility**;

- (f) **procedures** for the movement of all equipment into and out of the **facility**, including **decontamination** of that equipment;
  - (g) **decontamination** procedures for work surfaces;
  - (h) **procedures** for waste disposal, including transport, **decontamination** and **autoclave** usage;
  - (i) **procedures** for the transport of viable material from the **facility** (e.g. when sending samples to another PC3 **facility**);
  - (j) procedures for **fumigation** of the **facility** (this may include contact details of a company contracted to undertake the work);
  - (k) the emergency response plans, including procedures for responding to:
    - (i) spills in the **facility** (both inside and outside biological safety cabinets) and spills while transporting viable material outside the **facility**;
    - (ii) accidental exposure to organisms used within the **facility**;
    - (iii) fire and loss of pressure alarms;
    - (iv) loss, theft or unintentional release of GMOs from the **facility**;
    - (v) power failure;
    - (vi) fire and natural disasters;
    - (vii) serious injury or medical emergencies to personnel within the **facility**;
    - and
    - (viii) security threats;
  - (l) the method of **decontaminating** and testing of biological safety cabinets; and
  - (m) if present, the procedure for **decontamination** and testing of liquid effluent.
36. Training must include theoretical instruction, supervised practical experience and assessment of competence in the **facility**. The training must include familiarisation with the **facility** manual (see Condition 35), in particular:
- (a) **procedures** that must be followed by persons entering and exiting the **facility**, including the use of personal protective clothing and equipment;
  - (b) familiarisation with the hazards posed by the organisms being used in the **facility**;
  - (c) **decontamination** procedures;
  - (d) **procedures** for waste disposal;
  - (e) **procedures** for the transport of material inside and outside the **facility**;
  - (f) communication systems - normal and emergency;
  - (g) procedures for responding to accidents and emergencies;
  - (h) **procedures** for dealing with spills inside and outside the biological safety cabinet and outside the **facility**;
  - (i) licence conditions;
  - (j) conditions of the certification instrument for the **facility**;
  - (k) out of hours procedures in case of emergency; and
  - (l) structure and operation of the PC3 **facility**.
37. Training of staff must be updated at least annually. Trained persons must indicate to the certification holder that they fully understand their training by signing a record of their training or re-training after completion. The trainer must also sign the record to indicate that the trained person is competent to work in the **facility**. The training records must be made available to the Regulator, if requested.

38. The **facility** must be kept free of pests. A record of any pest control activities must be kept and made available to the Regulator when requested, along with the dates and details of any pest control and/or eradication activities.
39. The **facility** must be inspected at least once every 12 months by a person approved by the certification holder. 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. Any non-compliance issues must be notified to the Regulator as soon as practicable.

## Personal protective clothing and equipment

40. The following personal protective clothing and equipment must be worn by all personnel entering the **work area**:
  - (a) protective clothing to protect the front part of the body (e.g. long-sleeved, back-fastening, tight-wristed protective clothing);
  - (b) closed footwear; and
  - (c) gloves.

NOTES: Consideration should be given to wearing safety glasses or face shields when the facility contains organisms that can infect humans by the mucosal route.

Some method to prevent the release of organisms from the **facility** via footwear (eg. dedicated closed footwear for use only within the **facility** or shoe covers for footwear that will be worn outside the **facility**) should be considered.

41. Personal protective clothing and equipment must be removed and stored in designated storage or hanging provisions before leaving the **work area** and before entering the **airlock**. If a **facility** contains multiple laboratories, personal protective clothing and equipment should be removed before exiting each laboratory.

## Work practices

42. Access to the **facility** must be restricted by a lockable door which must be locked when no-one is present in the **facility**.
43. Any **procedures** that involve the use of pathogenic organisms requiring PC3 containment must be performed in a biological safety cabinet.
44. If centrifugation is undertaken, it must be carried out in sealed containers (tubes, buckets or rotors). Centrifuge containers that may contain pathogenic organisms must be capable of being detached from the centrifuge and opened in a biological safety cabinet.
45. Work benches, surfaces and equipment, including centrifuge containers, where **procedures** involving viable organisms have taken place must be **decontaminated** with an appropriate **decontaminant** when the **procedures** are completed.
46. If any spill occurs in the **facility**, a spills procedure (as required in Condition 35) must be implemented to **decontaminate** the spill.

47. **Fumigation** of the **facility** must take place:
- (a) in the event of a spill of viable organisms occurring outside of primary containment (eg. biological safety cabinet), that cannot be effectively **decontaminated** by another means;
  - (b) prior to surrender or cancellation of certification; and
  - (c) prior to re-certification of the **facility** at a lower containment level, if stipulated by the Regulator.

NOTE: For **facilities** that contain multiple laboratories, an individual laboratory may be **decontaminated** without the need for the whole **facility** to be **decontaminated**.

48. All work surfaces and equipment where maintenance is to be carried out must be **decontaminated** prior to maintenance taking place.
49. All waste material other than effluent from floor drains must be **decontaminated** by autoclaving prior to removal from the **facility**.

NOTE: Other methods of **decontamination** may be permissible where required (eg. radioactive wastes).

50. Equipment or protective clothing must be **decontaminated** by autoclaving or chemical treatment (eg. fire extinguisher) prior to removal from the **facility**. The chemical **decontamination** treatment must take place within the **facility**.

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

51. Where 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 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 **decontamination** treatment must be validated at least monthly by the use of:

- (d) thermocouples or resistance thermometers, to ensure that the required 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 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.

52. Viable material must not be removed from the **facility** unless:
- (a) it is to be transported for the purpose of work to another containment **facility** certified by the Regulator to at least PC3; or
  - (b) written permission has been given by the Regulator.

Any viable waste material must be **decontaminated** before being removed from the **facility**.

53. All viable materials 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. The surface of the secondary container must be chemically **decontaminated** prior to removal from the **facility**.
54. All cultures must be sealed during storage to prevent dissemination of the organism.
55. Any unintentional release or suspected unintentional release of GMOs from the **facility**, or unintended exposure to GMOs, must be reported to the Regulator as soon as practicable.
56. Non-essential personal effects, including handbags, personal mobile phones, personal organisers and other non-essential electronic equipment, which will not remain within the **facility**, must not be taken into the **facility**. The above does not include other personal effects that will be covered by personal protective equipment at all times.
57. Reading and writing material must not be used inside a biological safety cabinet and must be **decontaminated** before removal from the **facility**.

NOTE: the use of a scanner or fax machine to enable documents to be sent outside the **facility** should be considered.

58. All persons must remove gloves and wash or **decontaminate** their hands immediately before leaving the **work area**.

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

## 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 1324.1	Air filters for use in general ventilation and airconditioning Part 1: Application, performance and construction
AS 1324.2	Air filters for use in general ventilation and airconditioning Part 2: Methods of test
AS 1807.6	Cleanrooms, workstations, safety cabinets and pharmaceutical isolators - Methods of test Method 6: Determination of integrity of terminally mounted HEPA filter installations
AS 1807.7	Cleanrooms, workstations, safety cabinets and pharmaceutical isolators - Methods of test Method 7: Determination of integrity of HEPA filter installations not terminally mounted
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
AS 4260	High efficiency particulate air (HEPA) filters Classification, construction and performance