



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

Guidelines for Certification of a Physical Containment Level 3 Animal Facility

Version 2.1 – Effective 28 June 2010

The guidelines (Part A) contain the requirements for certification of a Physical Containment Level 3 (**PC3**) Animal **Facility** issued pursuant to section 90 of the *Gene Technology Act 2000* (the Act) and, as applicable, corresponding State legislation.

These guidelines are intended for **PC3** Animal Facilities in which animals are housed within primary containment devices that contain both the animal and any **micro-organisms** they may be infected with.

Once a **facility** is certified, the Regulator imposes conditions on the **facility** pursuant to section 86 of the Act. The conditions of certification outlined in this document (Part B) detail representative conditions that may apply to a **PC3** Animal **Facility**. Individual certification conditions may differ from these depending upon the design, construction and proposed **dealings** to be conducted in the **facility**. Once issued, the conditions may be varied by the Gene Technology Regulator (**the Regulator**) as necessary and appropriate.

A list of the Australian/New Zealand Standards that are referred to throughout this document is also attached.

A separate document - *Explanatory Information on Guidelines for Certification of Physical Containment Facilities* - contains details about obtaining and maintaining certification. This document can be downloaded from the Office of the Gene Technology Regulator (OGTR) website <www.ogtr.gov.au>.

A **PC3** Animal **Facility** should be constructed so that it achieves upon commissioning an air leakage rate, at a differential pressure of 200 Pa, of no more than 120L/min. After commissioning, and in accordance with the Australian/New Zealand Standard AS/NZS 2243.3, it is recommended that the air leakage rate of the **facility** is retested at least once every 5 years and that an air leakage rate of no more than 1200L/min should be maintained.

The OGTR will inspect **PC3** Facilities prior to any decision on an application for certification.

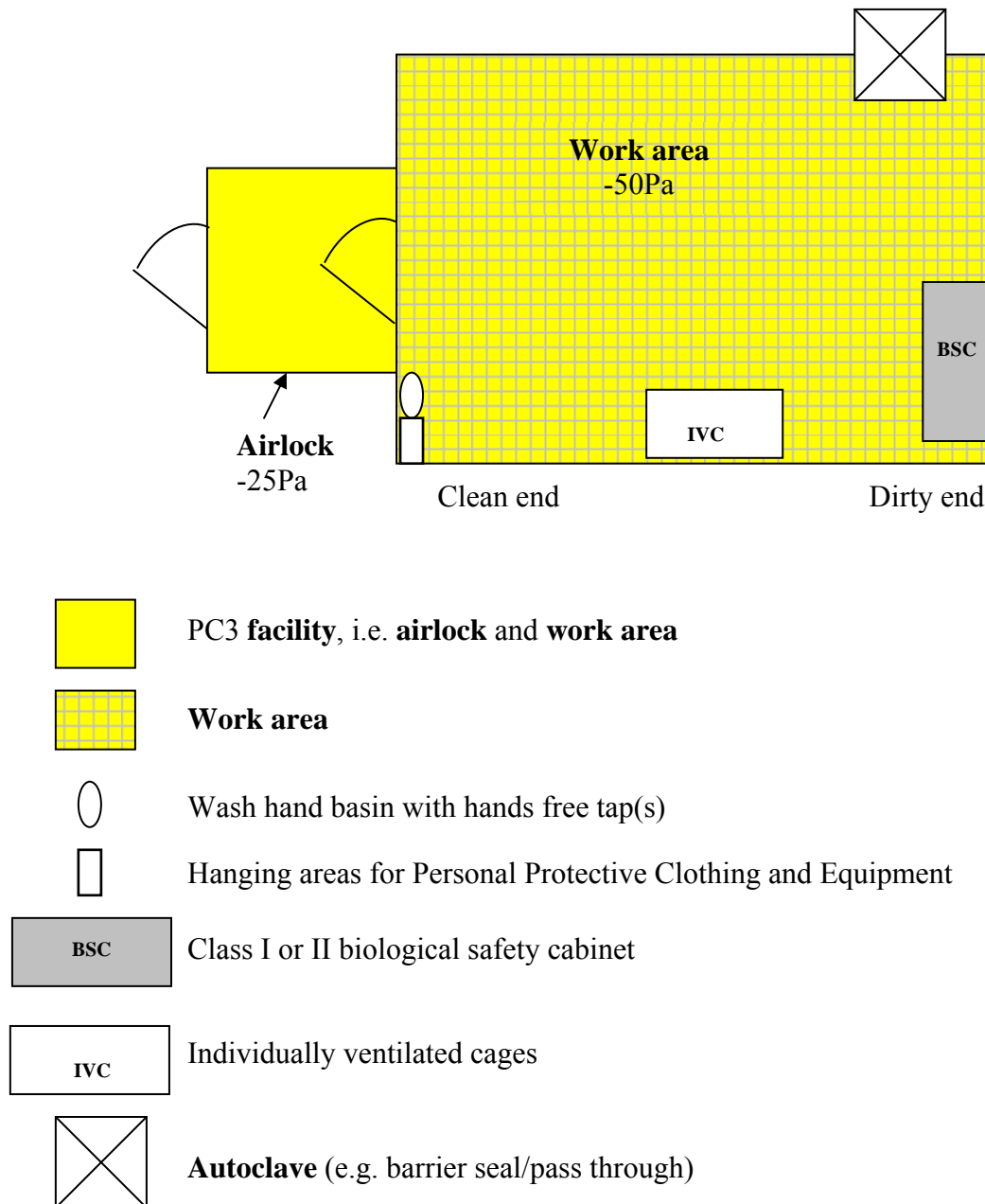
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Representative layouts of PC3 Facilities

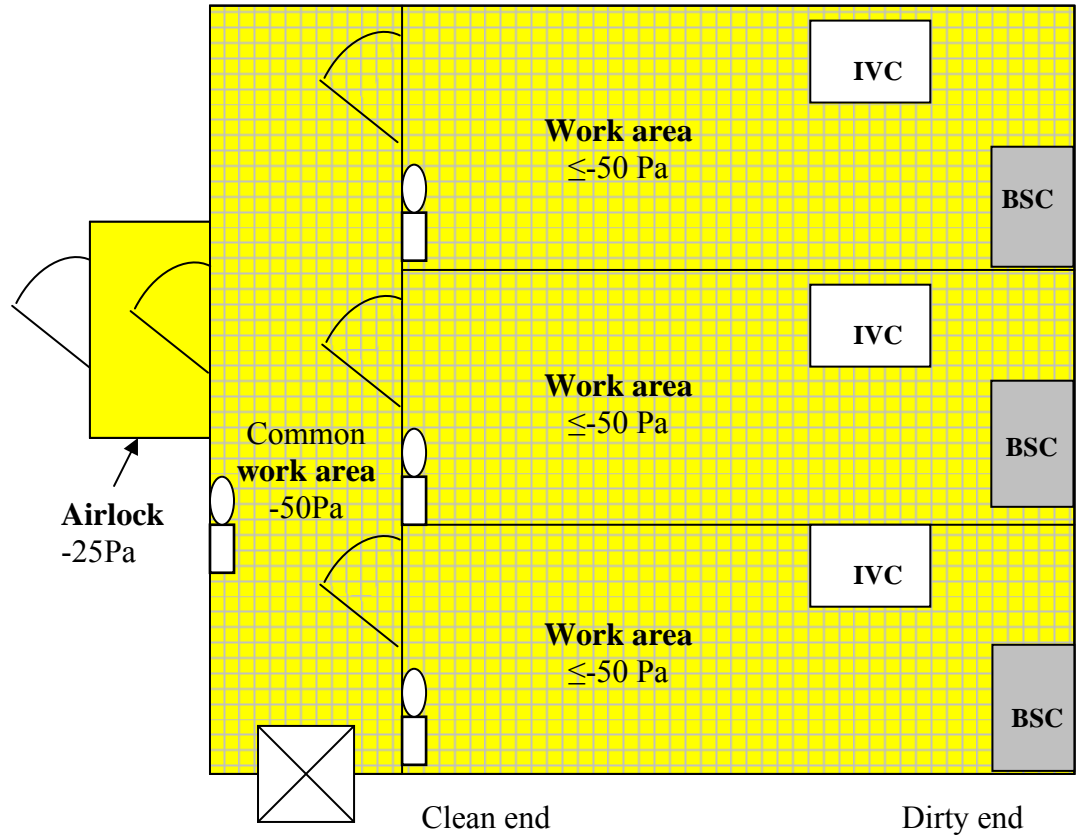
For the purposes of these **PC3 Animal Facility** guidelines, a **PC3 facility** includes a **work area** separated from other areas by a dedicated **airlock** and may include other support rooms, corridors, etc. within the physical containment barrier as certified by **the Regulator**. Representations of typical **PC3** facilities are shown below (Figures 1 to 3).






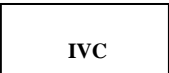

Figure 1: Representation of a **PC3 facility** with a single **work area**



NOTE: These diagrams are indicative only

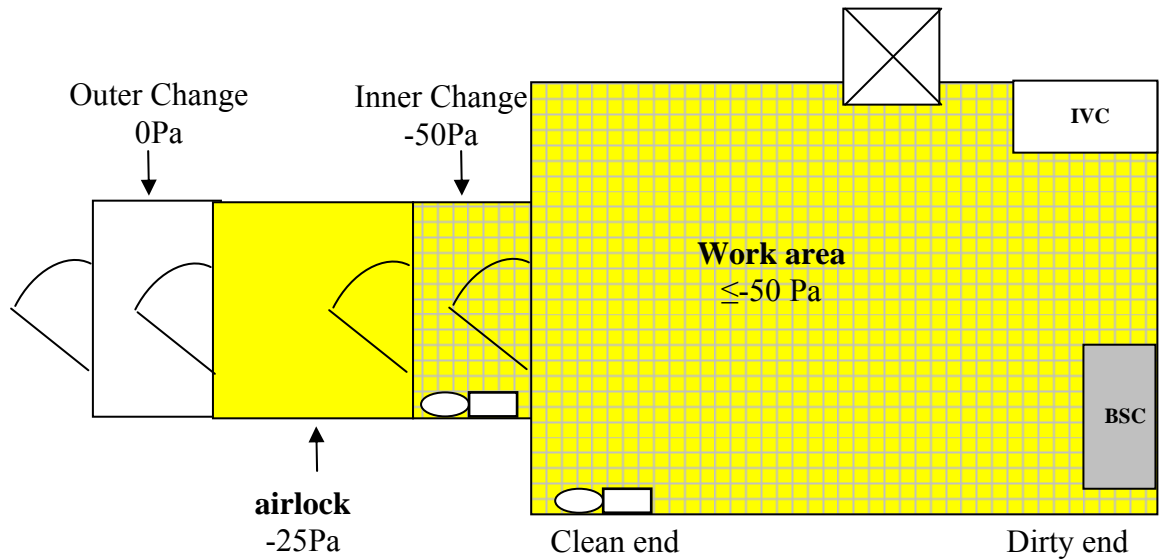
Figure 2: Representation of a **PC3 facility** with multiple **work areas**






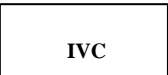
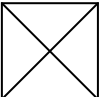


-  **PC3 facility**, i.e. **airlock** and **work areas**
-  **Work area**
-  Wash hand basin with hands free tap(s)
-  Hanging areas for Personal Protective Clothing and Equipment
-  **BSC** Class I or II biological safety cabinet
-  **IVC** Individually ventilated cages
-  **Autoclave** (e.g. barrier seal/pass through)

NOTE: These diagrams are indicative only

Figure 3: Representation of a **PC3 facility with inner and outer change rooms**



-  **PC3 facility**, i.e. **airlock**, **work area** (inner change room and animal holding area)
-  **Work area**, i.e. containment **facility** minus the **airlock**
-  Wash hand basin with hands free tap(s)
-  Hanging areas for Personal Protective Clothing and Equipment
-  **BSC** Class I or II biological safety cabinet
-  **IVC** Individually ventilated cages
-  **Autoclave** (e.g. barrier seal/pass through)

NOTE: These diagrams are indicative only

Part A

Requirements for Certification

Physical Containment Level 3 Animal Facility Version 2.1 – Effective 28 June 2010

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

Section 90 of the *Gene Technology Act 2000*

These are the requirements for the certification of a **PC3** Animal Facility issued under section 90 of the *Gene Technology Act 2000* (the Act) and, as applicable, corresponding State legislation. These requirements apply to applications for certification of **PC3** Animal Facilities received on or after the day on which these guidelines take effect.

To be granted certification, a **facility** must meet each of the requirements for certification of a **PC3** Animal Facility, unless the **facility** receives a written exemption from meeting a particular requirement from **the Regulator** or a delegate of **the Regulator**. Additional conditions may also be imposed on the **facility** by **the Regulator** or a delegate of **the Regulator**.

Definitions and acronyms

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

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

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

Where a word in the text is **bolded**, it indicates that the word has been defined (see below).

aerosol	Suspension in air of finely dispersed solids and liquids.
airlock	A separate, fully-enclosable space with two doors designed to limit pressure fluctuations during entry and exit. The airlock must remain a clean area. No dealings with GMOs are permitted in the airlock .
autoclave	Pressure steam steriliser.

dealings or deal with	<p>In relation to a GMO, means the following:</p> <ul style="list-style-type: none"> (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO; (d) propagate the GMO; (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO; (h) transport the GMO; (i) dispose of the GMO; <p>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).</p>
decontamination	<p>A physical or chemical process which removes, kills or renders non-viable the GMOs being dealt with in the facility, but does not necessarily result in sterility.</p>
facility	<p>The whole of the space that is to be certified by the Regulator to a specific level of containment. A certified facility comprises the work area (including the inner change room, where present) and the airlock.</p>
GMO	<p>Genetically Modified Organism.</p>
HEPA filter	<p>A High-Efficiency Particulate Air filter corresponding to one of the following two types:</p> <ul style="list-style-type: none"> (a) Type 1, Class A filters as specified in AS 1324.1 with separators and elastomeric compression seals or gel seals that do not support microbiological growth, which meet all the requirements of AS 4260 with a minimum performance of Grade 2. (b) Separatorless filters that meet all the requirements of AS 4260 with a minimum performance of Grade 2 provided accredited data is available demonstrating full compliance with AS 4260 and, in particular, the requirements for filter efficiency, leak testing, fire performance, structural strength and resistance to vibration.
inner change room	<p>A separate, fully-enclosable space within the facility used by authorised persons for donning facility clothing and PPE on entry and for removing it on exit.</p>
micro-organism	<p>An organism too small to be viewed by the unaided eye, including bacteria, fungi, viruses and some multicellular organisms. For the purposes of these guidelines, this definition includes viral vectors.</p>

outer change room	Space used by authorised persons to remove personal clothing prior to entry and to don personal clothing on exit from airlock . The outer change room is not part of the certified space of the facility .
PC3	Physical Containment Level 3.
the Regulator	The Gene Technology Regulator.
work area	Any area inside a facility that is not performing the function of an airlock . Procedures on GMOs must only take place in the work area .

Facility construction and access requirements

1. The **facility** must be a fully enclosable space, bounded by walls, doors, windows, floors and ceilings, which permits operation of the **facility** under negative pressure.
2. The **facility** must be constructed to enable gaseous **decontamination** of the whole **facility** to be achieved.
3. All **facility** penetrations must be fitted with seals to limit air leakage.
4. The **facility** boundaries (walls, windows, doors, floors, ceilings etc.) must be constructed to prevent the escape of the animals being contained and to prevent the incursion of pests.
5. Entry of authorised persons into the **work area** must be through an **airlock**. **Airlock** doors must be self-closing, fitted with seals at the top, bottom and both sides of the door, and contain a viewing panel. The outer **airlock** door must be lockable. Physical mechanisms (e.g. interlocking or alarm system) must be in place to ensure that only one door can be opened at any time.

NOTE: The use of interlocks requires the provision of manual overrides in case of emergencies.

6. Provision must be made for viewing of **work areas** from outside the **facility**.

NOTE: This may include the use of windows, viewing panels in doors, or video cameras.

7. All windows in the **facility** must be closed and sealed.
8. The following surfaces in the **facility** must be smooth, impermeable to water, easily cleanable, and resistant to damage by the cleaning agents, chemical and gaseous **decontaminants** that will be used in the **facility**:
 - (a) walls, floors, doors, windows and benches;

- (b) furniture, including seating; and
 - (c) ceilings.
9. Benches, cupboards, and other fittings and services must be installed to enable **decontamination**, including gaseous **decontamination**, of all spaces in the **facility**. Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.
 10. Any openings in the walls or ceiling, such as ventilation inlets and outlets, must be screened. The screens must be fixed and sealed against their mounting. The apertures of the screen must be sufficiently small as to prevent entry or exit of invertebrates or other animals.

NOTE: Where **HEPA filters** are external to the **facility** and connected to it by ducting then the screens should be mounted as close as practicable to the junction of the ducting with the **facility** boundary.

11. Where present, liquid drainage exits must be protected against entry or exit of invertebrates or other animals by the use of screens, liquid traps or an equivalent effective method. The apertures of the screen must be sufficiently small as to prevent entry or exit of invertebrates or other animals.
12. The **facility** must have two alternative, independent communication systems for contact between persons inside and outside the **facility**. Two-way communication must be able to be conducted on at least one system.

NOTE: Suitable alternative independent communication systems may include a normal telephone service and a dedicated mobile telephone that is kept charged and does not leave the **facility**. A networked computer can also be used provided it is connected to an attended location outside the **PC3 facility**.

13. Designated storage or hanging areas for personal protective clothing and equipment must be available within the **work area**. Storage for personal effects and non-laboratory clothing must be provided outside the **facility**.

Containment equipment requirements

14. Animals in the **facility** must be housed in primary containment devices within the **work area**.
15. Primary containment devices for animals must be fitted with exhaust **HEPA filters**, either as individually ventilated cages (IVC) or within **HEPA-filtered** ventilated enclosures.

Exhaust systems on the primary containment devices must be sealed to prevent escape of **GMOs**. In normal operation, all exhaust air from the cages must be contained and filtered to a standard that is equivalent to HEPA filtration. Air must be drawn through the primary containment devices to remove **aerosols**.

On removal and in transit to a BSC or change station, the primary containment devices must maintain a seal integrity equal to HEPA filtration or 0.2µm membrane filtration. The arrangement of cage or enclosure HEPA-filtration must ensure that the **work area** is not exposed to **GMOs** during normal operation and routine maintenance of cages, racks or other equipment.

Safety mechanisms must be in place that prevent the primary containment devices and exhaust air paths from becoming positively pressured relative to the surrounding area in the event of failure of the exhaust fan. The system must also be alarmed to indicate when operational malfunctions occur.

16. The **work area** of the **facility** must contain a biological safety cabinet (BSC), or other **aerosol** containment equipment approved in writing by **the Regulator** (e.g. cage change stations), appropriate for the **dealings** which are to be undertaken in the **facility**. Installation, use, **decontamination** and testing of Class I and Class II BSC must be in accordance with the requirements of AS 2252.4.

Aerosol containment equipment must also be installed in accordance with the manufacturer's instructions and the requirements of the relevant AS/NZS, where available. Such containment equipment must be tested, commissioned and results documented before use.

NOTES:

The type of BSC or other **aerosol** containment equipment will need to accommodate the changing of animal cages, bedding, feed and water without compromising containment of **GMOs**.

Consideration should be given to the installation of an uninterruptible power supply to the primary containment equipment.

Laboratory services and equipment requirements

17. The **facility** must contain an **autoclave** that is suitable for the load size and type of material to be **decontaminated**. The **autoclave** must not be located in the **airlock**.

NOTES:

The **autoclave** should preferably be of double-ended type with interlocked doors, with the inner door opening into the **facility** and the outer door opening externally to the **facility**.

For existing facilities, where the location of the **autoclave** in the **facility** would affect the welfare of the animals housed in the **facility** (e.g. due to heat, humidity or noise generated during operation), an exemption to this requirement may be requested from **the Regulator**.

18. The following water supplied to the **facility** must be protected against backflow by registered testable devices that have a high hazard rating for protection against both back-pressure and back-siphonage in accordance with the requirements of AS/NZS 3500.1:

- (a) laboratory sink outlets;
- (b) outlets within a class II BSC; and
- (c) direct connection to an **autoclave**.

Backflow prevention must isolate the **facility** to the exclusion of all other areas.

19. 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 **work areas**, each **work area** must contain a dedicated hand wash basin or some other means of **decontaminating** hands, at or near the exit of that **work area**.

NOTE: Alternatives to wash basins, such as dispensers filled with **decontaminant** solutions are considered suitable, provided the **decontaminant** solution is appropriate for the organisms being used in the **facility**.

20. The **work area** of the **facility** must contain eyewash equipment (either plumbed eyewash equipment or single-use packs of sterile eye irrigation fluids).

NOTE: AS/NZS 2982 provides information on eyewash equipment. If the **facility** contains multiple **work areas**, consideration should be given to providing eyewash equipment in each **work area**.

21. Any reticulated vacuum services must contain liquid disinfectant traps. Air drawn through the liquid disinfectant trap must be filtered with a filter with pore size of less than or equal to 0.2 µm prior to connection to the vacuum pump.

NOTE: Unused vacuum points do not require liquid traps provided they are closed with tamper-proof fittings that prevent accidental use.

22. Piped gas supplies to the **facility** must have reverse flow prevention on outlets located within the BSC.

NOTE: A filter with pore size of less than or equal to 0.2 µm is appropriate.

Ventilation requirements

23. The **facility** must have a ventilation system that establishes a negative air pressure gradient in the **facility** and directional airflow into a **work area**. All exhaust air from the **facility** must be filtered. Where **facilities** have a supply air system, the supply and exhaust air systems must be interlocked to prevent positive pressurisation of the **facility** in the event of failure of the exhaust system.

NOTES:

Failure of a single component, such as an exhaust fan or a supply fan, can result in extremely high positive or negative pressures in the **facility**. Alarms and failure mode operations of ventilation systems must address this risk to ensure that interlocks operate rapidly to stop systems.

Where separate animal rooms are provided within the **facility**, consideration should be given to the need for common or individual air exhaust systems, **HEPA filters** and duct isolation valves to facilitate gaseous **decontamination** of all or part of the **facility**.

An automatic changeover emergency power source, emergency lighting and communication systems should be considered. The emergency power source should be adequate to operate the ventilation systems, primary containment equipment, and **facility** access.

Ventilation equipment should be located to ensure a flow of incoming air from the vicinity of the entry door towards the highest risk microbiological **work areas**.

Ventilation inlets and outlets should be located to minimise the disturbance to the operation of any Class I and Class II BSC installed.

24. 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 of the **PC3** containment barrier.

NOTE: The **facility** ventilation system should be able to accommodate fluctuations due to wind and other building ventilation systems in maintaining the **facility** pressure gradient.

25. 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 gaseous **decontamination** 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.

NOTE: A variable speed drive on the exhaust fan is preferred to facilitate room pressure control adjustments.

26. The **work area** must be equipped to measure and display the pressure difference between the **facility** and areas adjacent to the **facility**. The display must be located so that it can be read immediately before entering the **facility**.
27. The **facility** must be equipped with an alarm that will alert people both inside and outside the **facility**, and be activated when the pressure in the **facility** is more than 25 Pa above the set point.

NOTES:

The purpose of the alarm is to indicate a malfunction of the air system and therefore the alarm should not be triggered during the course of normal opening and closing of the doors.

The selection of alarm type and the provision of mute switches should be considered to address animal welfare concerns associated with sudden or prolonged noises.

28. The **facility** must have an emergency stop button for the ventilation system, which is easily accessible in case of an emergency. The emergency stop button must operate independently of the main ventilation control and main **facility** pressure control system such that emergency isolation of the ventilation can be implemented in event of central control system malfunction.
29. Supply or replacement air to the **facility** must have 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. Where replacement air is drawn from adjacent areas, adjustable dampers must be provided in the transfer aperture to assist in setting up the reduced room pressure. This aperture and filter must not be mounted in the door.
30. The exhaust filter must be a **HEPA filter** as specified in the definitions to this document, or another filter that meets all requirements of AS 4260 with a minimum performance of Grade 2. An exhaust pre-filter of the same or higher standard as the supply filter must be installed and mounted upstream of the **HEPA filter**. Filters must be selected to meet the expected quantity and type of animal debris, e.g. animal dander, hair, dusts and down.

NOTE: Pre-filters should be located within the **work area** for ease of replacement.

31. Each exhaust **HEPA filter** must be mounted in a gas-tight housing, with sealed access doors, and the ductwork between the **facility** and the **HEPA filter** housing must also be gas-tight. The design and location of the filter housing must allow for access to and integrity testing of the **HEPA filter**.
32. Filter housings must incorporate the following features:
 - (a) a gas-tight isolating valve on the air outlet duct (and supply duct if present). If gaseous **decontamination** of the filter is to be performed separately from **decontamination** of the **facility**, isolating valves 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 0.2µm hydrophobic membrane type filters that are protected from physical impact.

Capacity to comply with certification conditions

33. The applicant must be able to demonstrate a capacity to comply with the conditions of certification that will generally be applied to a certified **PC3 Animal Facility**. These conditions are found in Part B of this document.

Documentation to be supplied with the application

34. The following documentation must be submitted with the application for certification of the **PC3 Animal Facility**:
- (a) results of testing and commissioning of backflow prevention devices installed on water pipes supplied to the **facility**;
 - (b) results of testing and commissioning of **HEPA filters** installed in the **facility**;
 - (c) results of testing and commissioning of biological safety cabinets or other containment equipment (e.g. change stations, IVC) installed in the **facility**;
 - (d) results of testing and commissioning of the **autoclave**, or other heat-based **decontamination** equipment, installed in the **facility**; and
 - (e) a copy of the **facility** manual.

Part B

Conditions of Certification

Physical Containment Level 3 Animal Facility Version 2.1 – Effective 28 June 2010

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 3 (**PC3**) Animal **Facility**.

The definitions and acronyms found in Part A of this document also apply to this Part.

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

1. The certification holder must have the authority to admit persons to the **facility** and exclude persons from the **facility**.
2. 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.
3. For the purposes of condition 2, an authorised person is a person who:
 - (f) intends to undertake **dealings**, and has been trained in accordance with the conditions of certification that apply to the **PC3 Animal Facility**; and
 - (g) has signed, dated and provided to the certification holder a record of the training referred to in paragraph 3(a) above; and
 - (h) has not been excluded from the **facility** by the certification holder on the direction of **the Regulator**;
or
 - (i) is an individual, 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**.
4. While the **facility** is in operation, any person covered by Condition 3(i) who enters the **facility** must be supervised by persons trained in accordance with the conditions of certification that apply to the **PC3 Animal Facility**.
5. If **the Regulator** requests the certification holder to provide a signed and dated record of the training provided to a particular authorised person, the signed and dated record of that training must be made available to **the Regulator** within a time period stipulated by **the Regulator**.

6. If **the Regulator** directs the certification holder to exclude a person, from entry to the **facility** on the grounds that the person:
 - (a) has behaved, or is behaving, in a manner which contravenes the Work Practices; or
 - (b) has behaved, or is behaving, in a manner which has caused, or which may cause, **GMOs** to escape from the **facility**; or
 - (c) 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 from the **facility** unless and until otherwise directed by **the Regulator**.
7. If **the Regulator** directs the certification holder to admit a person, to the **facility** subject to conditions, the certification holder must only admit the person, subject to those conditions.
8. For the purposes of Condition 7, before admitting a person, subject to conditions, the certification holder must notify the person(s) of any conditions that apply to them.
9. If **the Regulator** invites the certification holder to make a submission on whether or not a 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**.
10. **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.

Work not permitted in this facility

11. 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 PC level higher than **PC3** or any **GMO** that is a Risk Group 4 organism as specified in AS/NZS 2243.3;
 - (b) unless otherwise authorised by **the Regulator**, **dealings** with animals infected with **GMOs** where the **work area** of the **facility** forms the primary containment measure;
 - (c) the housing/keeping/rearing of any invertebrates, or aquatic organisms other than those integral to the **dealings** with **GMOs** being conducted in the **facility**;
 - (d) the growing of any plants other than those integral to the **dealings** with **GMOs** being conducted in the **facility**; or
 - (e) any other work prohibited by notification in writing by **the Regulator**.

General conditions

12. 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.
13. The **facility** must be inspected at least once every 12 months by a person approved by the certification holder and qualified to assess the **facility's** compliance with the conditions listed under:
 - (a) Work not permitted in the **facility**;
 - (b) General conditions;
 - (c) **Facility** construction and access conditions;
 - (d) Containment equipment conditions;
 - (e) Laboratory services and equipment conditions;
 - (f) Ventilation conditions;
 - (g) Testing conditions;
 - (h) Work Practices
 - (i) **Facility** Management;
 - (j) **Facility** Manual; and
 - (k) Training.

An inspection report which records the extent of compliance with those conditions must be made. A copy of the last three years' inspection reports must be kept and made available to **the Regulator** if requested.

NOTES:

A checklist suitable for use during annual inspections of **PC3** Animal Facilities is available on the **OGTR** web site <www.ogtr.gov.au> – but its use is not mandatory. Annual inspection reports should not be sent to **the Regulator** unless requested.

Inspections are not required in the same year as an OGTR inspection for recertification.

14. Each access door to the **facility** must be labelled with the following adhesive signs:
 - (a) a current **PC3** sign, supplied by the OGTR;
 - (b) a biohazard symbol; and
 - (c) emergency contact numbers (e.g. 24-hour contacts for medical emergency and for alarm response);

The signs identified in (a) to (c) must be placed so that persons entering the **facility** are able to clearly see that they are entering a certified **PC3 facility**.

NOTE: For security reasons, signs do not have to be placed on the outside wall of the **facility**, however, they must be visible prior to entering the **airlock**.

15. Emergency contact numbers (e.g. 24-hour contacts for medical emergency and for alarm response) must also be visible within the **work area** of the **facility**.
16. A supply of **decontamination** agents effective against the **GMOs** being **dealt** with in the **facility** must be available in the **work area** of the **facility** for **decontamination** purposes. All containers of **decontamination** agents must be labelled with the contents, concentration and, where appropriate, the expiry date. **Decontamination** agents must not be used after the expiry date.
17. The **facility** must be kept free of pests. A record of any pest prevention strategies or pest control activities must be kept and made available to **the Regulator** if requested, along with the dates and details of any pest control and/or eradication activities.

Facility construction and access conditions

18. The certification holder must ensure that the physical attributes of the **facility** and fittings are maintained so that the relevant ‘**Facility** construction and access requirements’ listed in Part A of this document continue to be met.
19. Prior to any structural changes that will affect the containment of **GMOs** in the **facility**; the applicant must request a suspension of the certification, in writing, from **the Regulator**. 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:
 - (a) General conditions;
 - (b) **Facility** construction and access conditions;
 - (c) Containment equipment conditions;
 - (d) Laboratory services and equipment conditions;
 - (e) Ventilation conditions; and,
 - (f) Testing conditions;

to ensure that the **facility** meets the conditions of certification. An inspection report which records the extent of compliance with these conditions must be made and provided to **the Regulator** with the request to lift the suspension. **Dealings** with **GMOs** may not commence until **the Regulator** has lifted the suspension by notice in writing.

NOTE: Before suspension can be lifted an inspection by OGTR may be required. A variation to the conditions of certification may also be required and would be assessed on a case-by-case basis.

Containment equipment conditions

20. The certification holder must ensure that the physical attributes of the **facility** and fittings are maintained so that the relevant ‘Containment equipment requirements’ listed at Part A of this document continue to be met.
21. Use and **decontamination** of Class I and Class II BSC must be in accordance with the requirements of AS 2252.4.

Laboratory services and equipment conditions

22. The certification holder must ensure that the physical attributes of the **facility** and fittings are maintained so that the relevant 'Laboratory services and equipment requirements' listed in Part A of this document continue to be met.
23. All services and equipment must be used and maintained in accordance with the manufacturer's instructions or the relevant AS/NZS.
24. All services or equipment added to the **facility** after certification is issued must be tested, commissioned and found to meet the conditions of certification.

Ventilation conditions

25. The certification holder must ensure that the physical attributes of the **facility** and fittings are maintained so that the relevant 'Ventilation requirements' listed in Part A of this document continue to be met.
26. Any failure of the ventilation 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 reasonably possible.

Testing conditions

27. Biological safety cabinets must be inspected and tested in accordance with the requirements of AS 2252.4. This testing is required at least annually and additionally after relocation of a cabinet, after mechanical or electrical maintenance and after **HEPA filters** are replaced. The inspection and testing of cabinets must be carried out by a qualified person.

The cabinet(s) 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 defective and must not be used for procedures involving **GMOs** until the defect has been corrected.

Records of the annual tests for the last 3 years must be kept and made available to **the Regulator** if requested.

28. Other containment equipment installed in the **facility** (e.g. IVC, change stations) must be inspected and tested at least annually. Testing must include **HEPA filter** integrity testing and the containment equipment 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 **HEPA filter** integrity are not met and the defect has not been corrected, the equipment must be clearly marked to show that it is unsafe and must not be used for procedures involving **GMOs** until the defect has been corrected.

Records of the annual tests for the last 3 years must be kept and made available to **the Regulator** if requested.

29. Testing and maintenance of **facility** ventilation systems must be carried out at least annually and must include:

- (a) testing of the pressure differentials;
- (b) integrity testing of all **HEPA filters** in accordance with AS 1807.6 or AS 1807.7, as applicable, by a qualified 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 (i.e. an over-pressure or under-pressure response);
- (f) calibration of pressure gauges;
- (g) the air handling control system; and
- (h) if applicable, the building management system.

Records of the tests in items (a) to (h), and of any maintenance conducted, must be kept for 3 years and made available to **the Regulator** if requested.

If any failures occur, **dealings** involving **GMOs** in the **facility** must cease until the failures are rectified and the ventilation system must be re-tested until compliance is achieved.

30. If the **facility** contains a liquid effluent **decontamination** system, it must be tested and maintained by a competent person at least annually and must include:

- (a) calibration of all instruments that control or monitor critical process parameters;
- (b) confirmation that all parameters of the system are operating within the specified limits (e.g. temperature, time, pH, concentration of chemical);
- (c) checking and maintenance of equipment to ensure effective operating condition;
- (d) checking of all safety and relief equipment.

Records of the tests in items (a) to (d), and of any maintenance conducted, must be kept for 3 years and made available to **the Regulator** if requested.

31. The physical parameters and efficacy of the **autoclave**, or other heat-based equipment used to **decontaminate GMOs**, must be validated monthly.

The physical parameters 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) other methods approved in writing by **the Regulator**.

The efficacy of the **autoclave** must be validated by the use of:

- (a) biological indicators such as spore strips; or
- (b) bacterial enzyme indicators; or
- (c) other methods approved in writing by **the Regulator**.

The results of each month's testing must be kept for the previous 12 months and made available to **the Regulator**, if requested.

- 32. Any heat-based equipment used to **decontaminate GMOs** must be calibrated annually by a person competent to do so. The results of the annual calibration for the previous 3 years must be kept and made available to **the Regulator**, if requested. When an **autoclave** is used for **decontamination**, annual calibration of the thermometer, timers, thermocouple and safety valves must be performed.
- 33. 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.
- 34. All testable water supply backflow prevention devices must pass an annual test, conducted in accordance with AS 2845.3, by a licensed plumber accredited to test backflow prevention devices. A record of the annual test for the last 3 years must be kept and made available to **the Regulator** if requested.

Work Practices

Entry and exit

- 35. The outer door of the **facility** must be kept locked at all times, except when authorised persons are entering or exiting the **facility**.
- 36. **Airlock** doors must remain closed at all times, except when authorised persons are entering or exiting the **facility**.
- 37. Persons must enter and exit the **work area** only through the **airlock**.
- 38. Emergency exits must only be opened in the event of an emergency.
- 39. Procedures with **GMOs** and/or animals must only take place in the **work area**.
- 40. The following personal protective clothing and equipment must be worn by all authorised persons in 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;
- (c) gloves; and
- (d) eye protection.

NOTE: The use of disposable overshoes should also be considered.

- 41. When exiting the **work area** and prior to entering the **airlock**, personal protective clothing and equipment must be removed and disposed of, or stored in designated storage or hanging spaces. If a **facility** contains multiple **work areas**, personal protective clothing and equipment should be removed before exiting each **work area**.
- 42. When exiting the **work area** and immediately prior to entering the **airlock** all persons must wash or **decontaminate** their hands. If a **facility** contains multiple **work areas**, all persons must wash or **decontaminate** their hands immediately before exiting each **work area**.

Containment equipment

- 43. Any procedures that may generate **aerosols** containing **GM micro-organisms**, such as opening of any animal primary containment devices, surgical procedures, post-mortem dissection, and animal inoculation, must be conducted in a BSC, or other specialised containment equipment approved in writing by **the Regulator**.
- 44. If centrifugation is undertaken, it must be carried out in sealed containers (tubes, buckets or rotors). Centrifuge containers must only be opened in a BSC.

Animal Handling

- 45. Procedures with animals must only be undertaken by authorised persons who have been trained to do so.
- 46. Handling of the animals containing **GMOs**, and any experimental procedures conducted on the animals, must be carried out in a way that minimises the possibility of escape of the animals and exposure of people to the **GMOs**.
- 47. When not being handled in the BSC or other specialised containment equipment, animals containing **GMOs** must be kept in ventilated cages or enclosures.
- 48. If an animal containing **GMOs** escapes within the **facility**, trapping devices must be used to capture the animal and the animal must be returned to its container or cage or euthanased.

Decontamination

- 49. Work benches, surfaces and equipment where procedures involving **GMOs** have taken place must be **decontaminated** immediately after each procedure and/or at the end of each working day.
- 50. **Decontamination** of the **facility** must take place:

- (a) in the event of a spill of viable organisms occurring outside of primary containment (e.g. BSC) that cannot be effectively **decontaminated** by another means;
- (b) prior to suspension, surrender, expiry or cancellation of certification; and
- (c) prior to re-certification of the **facility** at a lower containment level, if stipulated by **the Regulator**.

NOTES:

For **facilities** that contain multiple **work areas**, an individual **work area** may be **decontaminated** without the need for the whole **facility** to be **decontaminated**.

Facilities may also require **decontamination** in the event of escape of an animal containing **GMOs** within the **facility**.

- 51. With the exception of transport of viable **GMOs** (in accordance with Conditions 60 and 61) to another certified **PC3 facility**, all items, including equipment, personal protective clothing, and waste, that are contaminated or potentially contaminated with **GMOs**, must be **decontaminated** prior to removal from the **facility**.
- 52. 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.
- 53. **Decontamination** can be effected by **autoclaving** or other heat treatment, 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.

- 54. 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**;
 - (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;
 - (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); and
 - (d) all displaced or evacuated air, steam and liquid must be filtered or **decontaminated** before discharge.
- 55. If a double-ended **autoclave** is installed across the barrier, it must have a mechanism in place such that it cannot be opened on the clean side without a complete **decontamination** cycle being undertaken.
- 56. Any other heat-based treatment used for **decontamination** must be performed using a combination of temperature and time that has been validated as effective in rendering the **GMOs** non-viable.

57. Any chemical **decontamination** agent must be validated as effective in rendering the **GMOs** non-viable.

NOTE: AS/NZS 2243.3 is a recommended source of information when selecting and using chemical disinfectant agents.

Spills

58. If any spill occurs in the **facility**, the spills procedure (see Conditions 66(r)(i)) must be implemented to **decontaminate** the spill as soon as reasonably possible.
59. Any known or suspected unintentional release of **GMOs** outside the **facility** must be reported to **the Regulator** as soon as reasonably possible.

Removal and Storage of GMOs

60. **GMOs** and material containing or potentially containing **GMOs**, including carcasses, blood, organs and tissues must not be removed from the **facility** unless:
- (a) it is to be transported to another containment **facility** certified by **the Regulator** to at least **PC3**; or
 - (b) written permission has been given by **the Regulator**.
61. **GMOs** and material containing or potentially containing **GMOs** being transported out of the **facility** must be transported in accordance with any Transport Guidelines and other relevant guidelines issued by **the Regulator**.
62. **GMOs** must be stored within the **work area** of a **PC3 facility**.

GMOs must be stored in a sealed primary container, which has been surface **decontaminated** prior to enclosure within a sealed secondary container.

NOTE: Where this is not practicable, due to space constraints or availability of appropriate storage devices within the **PC3 facility work area**, an exemption to this condition may be requested from **the Regulator**.

Personal effects

63. Non-essential personal effects, including handbags, personal mobile phones, personal organisers and other non-essential electronic equipment, which will not remain within the **work area**, must not be taken into the **airlock**.

Facility management

64. A **facility** manager must be appointed by the certification holder. The **facility** manager, or his or her delegate(s), must be capable of demonstrating an understanding of the technical aspects of **facility** design, operation and maintenance.
65. The certification holder must ensure that the **facility** manager or his or her delegate(s) is capable of undertaking the following functions:

- (a) developing and maintaining documented policies and documented procedures for the safe operation of the **facility**;
- (b) ensuring that access to the **facility** is restricted to authorised persons;
- (c) ensuring that access to voids around the perimeter of the **facility** and the ventilation system of the **facility** is restricted to authorised persons;
- (d) facilitating delivery of appropriate training to all persons as per the training conditions;
- (e) development, documentation, implementation and annual review of a **facility** manual, as stipulated in condition 66 and 67;
- (f) development, documentation, implementation and validation of **decontamination** procedures effective for all organisms and equipment used in the **facility**;
- (g) provision of information to all authorised persons on changes to all **facility** operating procedures (e.g. entry and exit procedures, work practices, **decontamination** procedures and emergency plans);
- (h) ensuring that successful **decontamination** of the **facility** is carried out;
- (i) retention of documentation relating to the maintenance and testing of the **facility** equipment and services, including the air handling system, primary containment equipment (e.g. BSC, IVC), **autoclave(s)** and gaseous **decontamination** of the **facility**;
- (j) co-ordination of immunisation of persons working within the **facility**, where appropriate;
- (k) ensuring that current emergency contact numbers are clearly visible from inside and outside the **facility** (e.g. 24-hour contacts for medical emergency and for alarm response);
- (l) ensuring that a record of all organisms (GM and non-GM) used in the **facility** since the most recent gaseous **decontamination** 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**.

Facility Manual

66. A **facility** manual must be readily available to all authorised users of the **facility**. The **facility** manual must document the following elements:
- (a) the **facility** manager's contact details;
 - (b) a list of persons authorised to enter the **facility**;
 - (c) the persons to contact in case of emergency;
 - (d) copies of conditions imposed under the Gene Technology Legislation that must be followed, including:
 - i. conditions of certification of the **facility**;
 - ii. conditions imposed by any licences for **dealings** with **GMOs**;
 - iii. any relevant clauses of the Guidelines for the Transport of **GMOs**; and
 - iv. details of any other authorisations granted to **deal with GMOs** in the **facility** (e.g. NLRDs);
 - (e) the structure and operation (including design limits) of the **facility**;
 - (f) details of all organisms and animals being handled within the **facility**, the risks associated with the use of these organisms and animals, and the management strategies for these risks;
 - (g) the procedures for the handling of animals within the **facility**;

- (h) the procedures that must be followed by all persons entering and exiting the **facility**, and the use of personal protective clothing and equipment and the order in which these are removed;
- (i) the procedures for the operation and use of BSC, IVC, and other specialised containment equipment approved in writing by **the Regulator**;
- (j) the procedures for the use of normal and emergency communication systems;
- (k) the procedures for the movement of all equipment into and out of the **facility**, including **decontamination** of that equipment;
- (l) the procedures for **decontamination**, including operation and use of the **autoclave**;
- (m) the procedures and circumstances for gaseous **decontamination** of the **facility**;
- (n) the procedures for waste and effluent disposal, including transport procedures;
- (o) the procedures for the transport of viable material inside the **facility**, including transport for storage of **GMOs**;
- (p) the procedures for the transport of viable material outside the **facility** (e.g. transport to another **PC3 facility**);
- (q) the circumstances or events which must be notified to **the Regulator**;
- (r) the emergency response plans, including the procedures and use of specialised equipment required for responding to:
 - (i) spills in the **facility** (both inside and outside BSC) and spills while transporting viable material outside the **facility**;
 - (ii) accidental exposure to organisms used within the **facility**, including procedures for the management and treatment of persons suspected to be infected or contaminated with/exposed to Risk Group 3 organisms;
 - (iii) escape of animals containing **GMOs** within the **facility**;
 - (iv) alarms for fire or loss of pressure;
 - (v) loss, theft or unintentional release of **GMOs** from the **facility**;
 - (vi) failure of power or ventilation systems;
 - (vii) fire and natural disasters;
 - (viii) serious injury or medical emergencies to persons within the **facility**;
 - (ix) security threats; and
 - (x) other life-threatening situations.

67. The **facility** manual must be reviewed at least annually and updated as necessary.

Training

- 68. Training, as identified in Condition 3 (a) of this Part, must include familiarisation with the elements of the **facility** manual (Condition 66).
- 69. Training must include theoretical instruction, and where applicable, supervised practical experience and assessment of competence.
- 70. Training of authorised persons must be reviewed at least annually and updated where necessary and whenever:
 - (a) licence conditions or certification conditions related to the **facility** change;
 - (b) the *Guidelines for Certification of a PC3 Animal Facility* change;
 - (c) there are new risks associated with **GMOs dealt** with in the **facility**;

- (d) procedures or equipment used in the **facility** changes; or
 - (e) new **GMOs** or **animals** are used in the **facility**.
71. Training records must be updated at least annually and kept for a period of at least three years.

Health Monitoring

72. If the **GMOs** being or likely to be used are human pathogens, then consideration must be given to providing authorised persons with any available immunisation against the **GMOs** being used or likely to be used in the **facility**.
73. Where a zoonotic agent or human pathogen is in use, a documented system must be set up for reporting accidents and exposures to the **micro-organisms**, for monitoring employee absenteeism, and for the medical surveillance of illnesses that are potentially **facility**-associated. **The Regulator** must be informed of any such incidents as soon as reasonably possible.

Non-compliance

74. Any non-compliance with the conditions set out in these *Guidelines for Certification of a Physical Containment Level 3 Animal Facility*, including any unintentional release of **GMOs** from the **facility**, must be reported to **the Regulator** as soon as reasonably possible.

Attachment 1

Standards referred to in this document

‘AS’ followed by a number or other identification is a reference to the Australian Standard so numbered or identified.

‘AS/NZS’ followed by a number or other identification is a reference to the Australian New Zealand Standard so numbered or identified.

AS 1324.1	Air filters for use in general ventilation and air conditioning Part 1: Application, performance and construction
AS 1324.2	Air filters for use in general ventilation and air conditioning 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 safety and containment
AS 2252.4	Controlled environments Part 4: Biological safety cabinets Classes I and II - Installation and use
AS 2845.3	Water supply - Backflow prevention devices Part 3: Field testing and maintenance
AS/NZS 2982	Laboratory design and construction
AS/NZS 3500.1	Plumbing and drainage Part 1: Water services
AS 4260	High efficiency particulate air (HEPA) filters Classification, construction and performance