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

Guidelines for Certification
of a
Physical Containment Level 3 Invertebrate Facility

Version 2.1 – Effective 21 September 2011

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

Once a facility is certified, the certification instrument imposes conditions on the facility pursuant to section 86 of the Act. The conditions of certification (Part B) detail the representative/standard conditions that can apply to a PC3 Invertebrate 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 (AS/NZS) 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 Invertebrate Facility 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. After commissioning, and in accordance with 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.

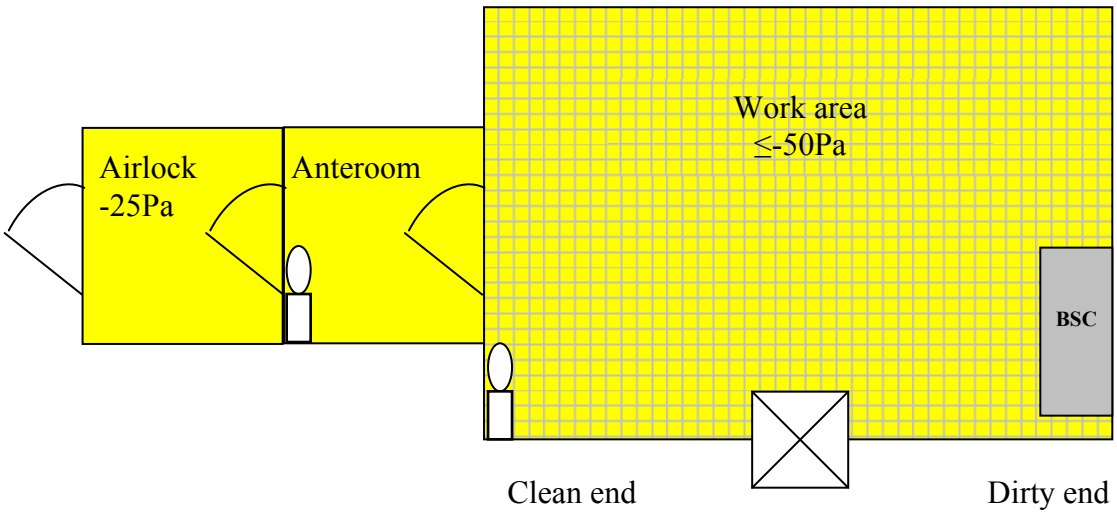
The OGTR will inspect PC3 Facilities prior to any decision on an application for certification.

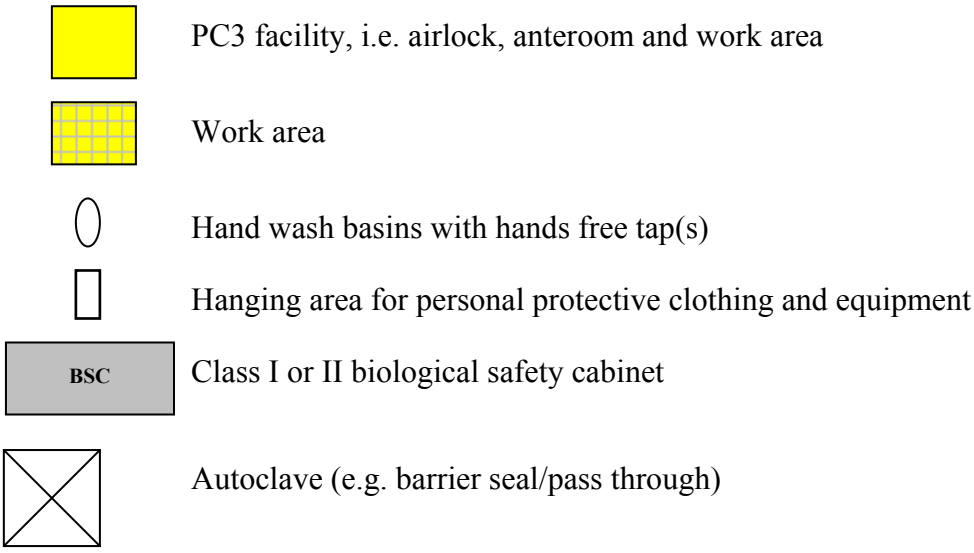
Contents

Representative layouts of PC3 Invertebrate Facilities

Representations of typical PC3 Invertebrate facilities are shown below (Figures 1 and 2).

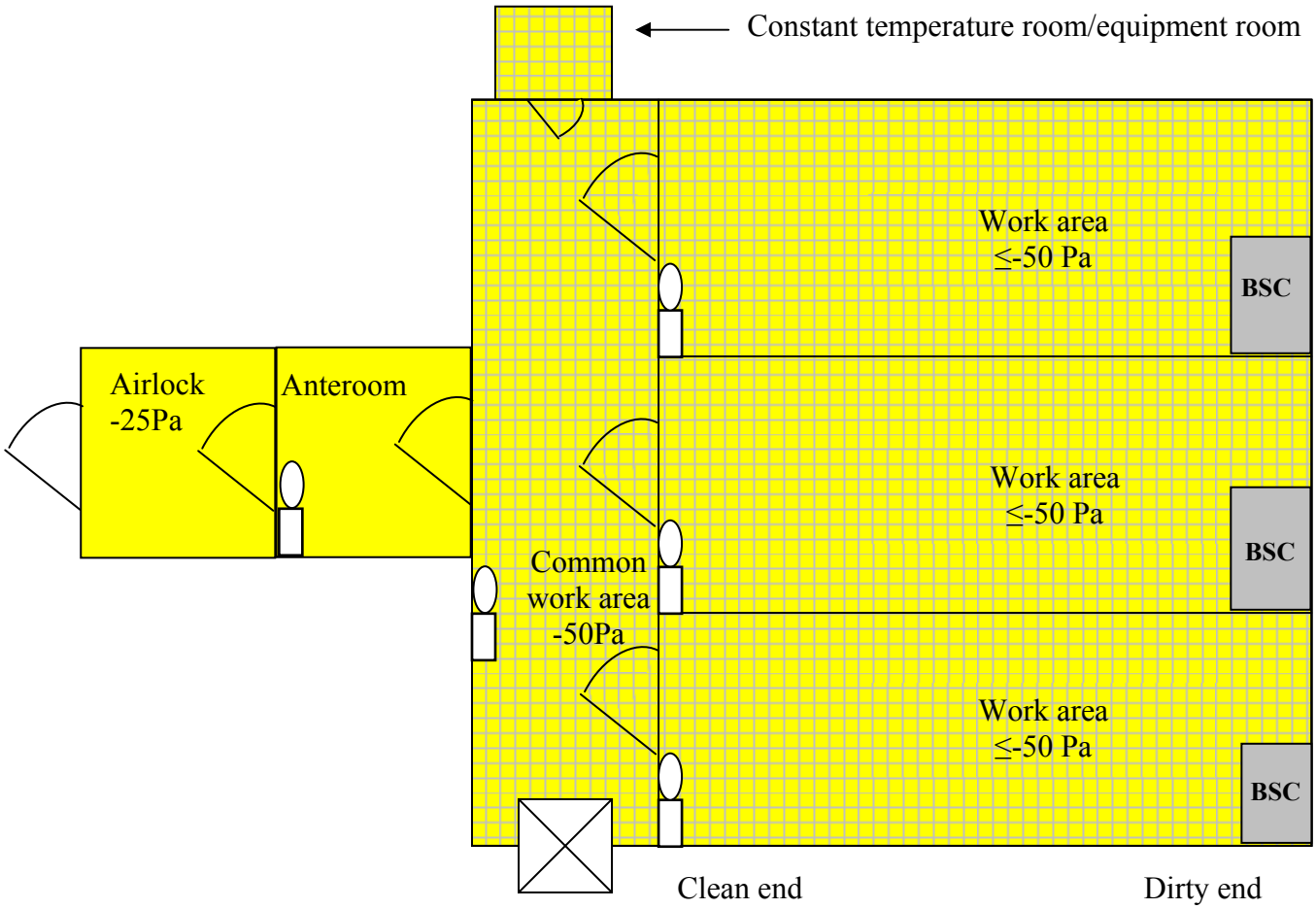
Figure 1: Representation of a PC3 Invertebrate facility with a single work area

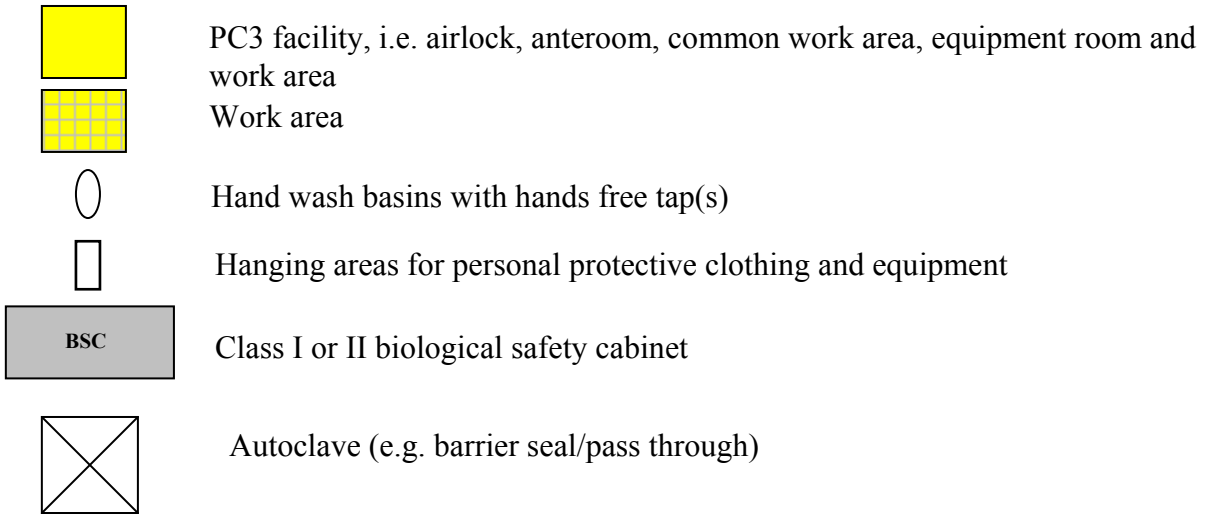




NOTE: These diagrams are indicative only

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





NOTE: These diagrams are indicative only

Part A

Requirements for Certification

Physical Containment Level 3 Invertebrate Facility
Version 2.1 – Effective 21 September 2011

CONTAINMENT REQUIREMENTS THAT MUST BE MET IN ORDER FOR A PHYSICAL CONTAINMENT LEVEL 3 (PC3) INVERTEBRATE 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 Invertebrate 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 Invertebrate Facilities received on or after the day on which these guidelines are issued.

To be granted certification, a facility must meet each of the requirements for certification of a PC3 Invertebrate 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 the Act and the Gene Technology Regulations 2001.

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

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

aerosol	Suspension in air of finely dispersed solids and liquids.
airlock	A separate, fully enclosable space with two doors designed to limit pressure fluctuations during entry and exit. No dealings with GMOs, except for transport, are permitted in the airlock.

anteroom	A separate, fully enclosable space used during entry and exit that has specific containment functions. No dealings with GMOs, except for transport, are permitted in the anteroom.
autoclave	Pressure steam steriliser.
dealings or deal with	In relation to a GMO, means the following: (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO; (d) propagate the GMO; (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO; (h) transport the GMO; (i) dispose of the GMO; and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (i).
decontamination	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.
facility	The whole of the space that is to be certified by the Regulator to a specific level of containment. A certified facility comprises the work area, the airlock and the anteroom.
GMO	Genetically Modified Organism.
HEPA filter	A High-Efficiency Particulate Air filter corresponding to one of the following two types: (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.

invertebrate	For the purposes of these guidelines invertebrates are all multi-cellular animal species without backbones that are land based as adults. This includes relevant species of annelids, flatworms, nematodes, molluscs and arthropods. Protozoans are not included due to their microscopic size and single cellular nature.
micro-organism	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.
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 or anteroom.

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, doors, floors, windows, ceilings etc.) must be constructed and maintained to prevent the escape of the organisms being contained and to prevent the incursion of pests.

   NOTES:
   Recapture of loose invertebrates may be facilitated if the boundaries are of a contrasting colour to that of the invertebrates being contained in the facility. Depending on type of invertebrate, other methods for recapturing loose invertebrates may also be acceptable, such as traps.

   The facility boundaries should be constructed such that the ability of loose invertebrates to hide or remain undetected is minimised (e.g. if the facility contains false ceilings they should be sealed against their mounting).

5. Entry of authorised persons into the work area must be through an airlock and an anteroom.

6. Airlock doors must be self-closing and each door must be fitted with seals to limit air leakage, and contain a viewing panel. The outer airlock door must have a mechanism in place to restrict access to the facility. Mechanisms (e.g. interlocking or an alarm system) must also be in place to ensure that only one airlock door can be opened at any time.

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

7. The facility must contain an anteroom located between the airlock and work area. The anteroom doors must be self-closing.

    NOTE: If the invertebrate facility connects via its anteroom to another PC3 facility, an airlock is not required between the two PC3 facilities.

8. A mechanism must be in place in the anteroom to effectively prevent invertebrates from traversing the boundary of anteroom/airlock.

    NOTE: Mechanisms could be insect traps, cold lock systems, or door seals.

9. A device for inspection and removal of invertebrates from persons exiting the facility must be provided in the anteroom.

    NOTE: Examples of such devices are an appropriately sized and positioned mirror and vacuum aspiration device.

10. 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.

11. All windows in the facility must be closed and sealed.

12. The following surfaces in the facility must be smooth, impermeable to water, easily cleanable, and resistant to damage by the cleaning agents, decontamination agents and gaseous decontaminants that will be used in the facility:

    (a) walls, floors, ceilings, doors, windows and benches; and
    (b) furniture, including seating.

13. 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.

    NOTE: Water collected under equipment (e.g. freezers) may provide a place for loose invertebrates to hide or breed. Water collection trays should also be accessible for cleaning or decontamination.

14. 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.

    NOTES:
    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.

    Internal facility apertures (e.g. light fixtures, pipes, ducting) should be minimal since these may provide hiding places for loose invertebrates. Surface mounting of services to the facility will minimise the number of penetrations to be sealed.

15. 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. Where screens are fitted the apertures of the screen must be sufficiently small as to prevent entry or exit of invertebrates or other animals.

    NOTE: This includes any hand wash basins and plumbed eyewash equipment.

16. 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.

17. Designated storage or hanging areas for personal protective clothing and equipment must be available within the anteroom and/or work area.

Containment equipment requirements

18. The work area of the facility must contain a biological safety cabinet (BSC), or other aerosol containment equipment approved in writing by the Regulator, appropriate for the dealings which are to be undertaken in the facility.

    Installation, use, decontamination and testing of Class I, Class II and Class III BSC must be in accordance with the requirements of AS 2252.1, AS 2252.2, AS 2252.3 and AS 2252.4.

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

NOTES:
Consideration should be given to the installation of an uninterruptible power supply to aerosol containment equipment.

BSCs and other approved aerosol containment equipment should be located to ensure that airflow from the facility ventilation inlet to outlet does not compromise the correct functioning of the BSC or other approved aerosol containment equipment.

The type of BSC or other aerosol containment equipment will need to accommodate the handling and manipulation of invertebrates, without compromising containment of GMOs.

Laboratory services and equipment requirements

19. 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 within the airlock or anteroom.

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

    If the invertebrate facility connects via its anteroom to another PC3 facility that contains an autoclave, a separate autoclave is not required.

20. The following water supplied to the facility must be protected against backflow 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:

    (a) laboratory sink outlets and other equipment supplied with non-potable water, e.g. humidifiers ;
    (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.

21. Autoclave and backflow prevention devices in, or connected to, the facility must be installed in accordance with the requirements of the relevant AS/NZS and/or manufacturer's instructions where available. Such equipment/devices must be tested, commissioned and results documented before use.

22. The anteroom and work area of the facility must contain either a dedicated hand wash basin fitted with tap(s) of the hands-free operation type, or some other means of decontaminating hands at or near the exit of the anteroom and 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 GMOs being dealt with in the facility.

23. The work area 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.

24. Where a central reticulated vacuum system or portable vacuum pump is used, 0.2 μm hydrophobic membrane filters and liquid disinfectant traps must be installed on the facility side of the vacuum line.

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

25. Piped gas supplies to the facility must have reverse flow prevention on outlets located within a BSC or other approved aerosol containment equipment.

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

Ventilation requirements

26. The facility must have a ventilation system that establishes a negative air pressure gradient in the facility and directional airflow into the 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 or 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 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.

27. 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 airlock doors 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.

28. The pressure differential must be able to 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 gases used during 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.

29. 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.

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

30. Each exhaust HEPA filter must be mounted in a gastight 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(s) must allow for access to and integrity testing of the HEPA filter.

31. HEPA filter housings must incorporate the following features:
    (a) a gas-tight isolating valve on the air outlet duct (and air inlet 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;
    (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 0.2µm hydrophobic membrane type filter that is protected from physical impact; and
    (d) where separate supply ducts are not fitted, HEPA filter gaseous decontamination would require decontamination of the facility as well.

32. 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 it can be read immediately before entering the facility.

33. 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.

    NOTE: 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.

34. 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.

35. Supply or replacement air to the facility must be filtered with 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.

Documentation to be supplied with the application

36. The following documentation must be submitted with the application for certification of the PC3 Invertebrate 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 BSCs, or other approved aerosol containment equipment, installed in the facility;
    (d) results of testing and commissioning of the autoclave, or any other decontamination equipment, installed in the facility;
    (e) an electronic or paper copy of the facility manual; and
    (f) a floor plan for the facility, including the locations of laboratory services, containment equipment, ventilation systems, and decontamination equipment.

Capacity to comply with certification conditions

37. 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 Invertebrate Facility. These conditions are found in Part B of this document.

Part B

Conditions of Certification

Physical Containment Level 3 Invertebrate Facility
Version 2.1 – Effective 21 September 2011

Conditions are imposed on facilities by the Regulator at the time of certification pursuant to Section 86 of the Act and, as applicable, corresponding State legislation. The condition clauses in this Part are the ones that can be expected, in most cases, to be included in the certification instrument as the conditions of certification for a PC3 Invertebrate Facility.

The definition 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:
   (a) intends to undertake dealings, and has been trained in accordance with conditions 70 to 73
   (b) has signed, dated and provided to the certification holder a record of the training referred to in paragraph 3(a) above; and
   (c) has not been excluded from the facility by the certification holder on the direction of the Regulator;
   or
   (d) is an individual 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(d) who enters the facility must be supervised by persons trained in accordance with the conditions 70 to 73.

5. If the Regulator requests the certification holder to provide a signed and dated record of the training provided to a particular authorised person, it must be 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 at a higher level 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 any aquatic organism, except for the aquatic life stage of invertebrates that are necessary for dealings being conducted in the facility;
   (c) the growing of any plants, beyond the minimum time that they are required for conducting the dealings with GMOs;
   (d) the housing/keeping/rearing of terrestrial vertebrates, beyond the minimum time that they are required for conducting the dealings with GMOs;
   (e) dealing with invertebrates smaller than the aperture size of the screens fitted on the facility openings as per requirement 14; or
   (f) 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.

    > NOTE: A checklist which may be used for annual inspections of a PC3 Invertebrate Facility 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 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 clearly able to 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 facility, for decontamination purposes and to deal with spills. All containers of decontamination agent must be labelled with the contents, concentration and, where appropriate, the expiry date. Decontamination agents must not be used after the expiry date.

    NOTE: Consideration should also be given to having insecticidal agents effective against the invertebrates being handled in the facility either in the facility, or in an accessible location close to the facility.

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 may affect the containment of GMOs or invertebrates 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.

Laboratory services and equipment conditions

21. 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.

22. All services and equipment must be used and maintained in accordance with the relevant AS/NZS or the manufacturer's instructions.

23. All services or equipment added to the facility after certification is finalised must be tested, commissioned and found to meet the conditions of certification before undertaking dealings with GMOs.

24. All effluent from the work area must be decontaminated before being discharged.

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 at Part A of this document continue to be met.

26. If any failure of the air handling system occurs (exhaust air fan or interlocked supply/exhaust system) that results in loss of the negative air pressure gradient or produces a positive air pressure, then:
    (a) dealings involving GMOs in the facility must cease until the failures are rectified;
    (b) the air handling system re-tested until compliance is achieved; and
    (c) the failure must be reported to the Regulator as soon as practicable.

Testing conditions

27. Biological safety cabinets must be inspected and tested in accordance with the requirements of AS 2252.1 (class I), AS 2252.2 (class II) or AS 2252.3 (class III). This testing is required at least annually and additionally after relocation of a cabinet, or 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 have not been 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 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 aerosol containment equipment installed in the facility must be inspected and tested for containment capability at least annually. Where equipment is fitted with HEPA filters, testing must include filter integrity testing. 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;
    (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 device re-tested until compliance is achieved.

30. If the facility contains a liquid effluent decontamination system, it must be tested and maintained annually by a competent person. Testing must include but may not be limited to:
    (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; and
    (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.

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

32. Any heat-based equipment used to decontaminate GMOs, including autoclaves, 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 decontamination of 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 when the room is unoccupied by personnel.

36. Airlock doors must remain closed at all times, except when persons are entering or exiting the facility.

37. Emergency exits must only be opened in the event of an emergency.

38. Persons must enter and exit the work area only through the airlock.

39. With the exception of transport (in accordance with Conditions 62 and 63), dealings with GMOs and/or invertebrates must only take place in the work area.

40. The following personal protective clothing and equipment (PPCE) must be worn by all authorised persons 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;
    (c) eye protection;
    (d) gloves, and
    (e) waterproof dressings on all broken skin not covered by other PPCE.

    NOTES:
    Where relevant, consideration should be given to selecting personal protective clothing that offers protection against invertebrates and readily enables the detection of invertebrates on the clothing.

    Consideration should also be given to the use of hairnets to help prevent the unintentional removal of invertebrates from the facility in hair.

41. Before entering the airlock from the anteroom, authorised persons must check to ensure they are not inadvertently carrying invertebrates on their persons.

42. Upon exit from the facility 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 in the work area and/or anteroom.

    NOTE: If a facility contains multiple work areas, personal protective clothing and equipment should be removed before exiting each work area.

43. Immediately prior to entering the airlock, all persons must wash or decontaminate their hands.

NOTE: If a facility contains multiple work areas, all persons should also wash or decontaminate their hands immediately before exiting each work area.

Containment equipment

44. All life stages of invertebrates used in the facility must be contained in primary containers that are designed to prevent the escape of the invertebrates.

    NOTES:
    The facility physical boundaries alone are not sufficient for containment of invertebrates. While working with small invertebrates, consideration should be given to contain the invertebrates in containment equipment (e.g. Mesh cages, plastic isolator with sleeve openings etc) or in a designated area (e.g. a cage-like room constructed of fine mesh).

    Access to primary containers for research, feeding and cleaning etc should also be designed to minimise the possibility of escape.

    For aquatic life stages, in the event of a breach of the primary container, consideration should be given to additional containment measures, such as trays or bunding.

45. Any dealings involving GM micro-organisms that may generate aerosols must be performed in a BSC or in specialised aerosol containment equipment that has been approved in writing by the Regulator.

    NOTES:
    Aerosol containment equipment should be selected on the basis of a risk assessment that determines the potential for aerosol generation during the dealings with GMOs (including invertebrates containing GMOs), and the transmissibility of GMOs via aerosols.

    Purpose designed aerosol containment equipment is recommended to be used while dealing with small invertebrates containing GM micro-organisms as manipulations in a BSC can be extremely difficult, the airflow can blow small invertebrates around the cabinet, into the filters, and other inaccessible locations.

46. If centrifugation is undertaken, it must be carried out in sealed containers (tubes, buckets or rotors). Centrifugation containers must only be opened in a BSC or other aerosol containment equipment approved by the Regulator.

Invertebrate handling

47. Procedures with invertebrates must only be undertaken by authorised persons who have been trained to do so.

48. Handling of the invertebrates containing GMOs, and any experimental procedures conducted on GM invertebrates, must be carried out in a way that minimises the possibility of escape of the invertebrates and exposure of people to the GMOs and invertebrates containing the GMOs.

49. If invertebrates containing GMOs escape within the facility, trapping devices must be used to capture the invertebrates and either return them to their container or cage or euthanase them.

Decontamination

50. 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.

51. Decontamination of the facility must take place:
    (a) after a spill of GMOs, or escape of GM invertebrates or invertebrates containing GMOs, from primary containment that cannot be effectively decontaminated by another means;
    (b) prior to maintenance work on equipment installed in the facility that cannot be decontaminated by another means;
    (c) prior to suspension, surrender, expiry or cancellation of certification; and
    (d) prior to re-certification of the facility at a lower containment level, if stipulated by the Regulator.

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

52. With the exception of transport of viable GMOs (in accordance with conditions 62 and 63) to another certified PC3 facility all items, including equipment, personal protective clothing and waste, contaminated or potentially contaminated with GMOs, must be decontaminated prior to removal from the facility.

53. If the facility has floor drainage exits, all effluent from these drains must be decontaminated by heat treatment or chemical treatment before being discharged to sewer. If the facility has a sink, then all liquid effluent must be decontaminated prior to discharge to sewer.

54. Prior to discharge of decontaminated liquid effluent, the parameters of the decontamination process (e.g. temperature, time, pH etc) must be verified to have met the validated requirements.

55. 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.

56. 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.

57. 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.

58. Any other heat-based treatment must be performed using a combination of temperature and time that has been validated as effective in rendering the GMOs non-viable.

59. Any chemical decontamination agent treatment must be validated as effective in rendering the GMOs and/or invertebrates containing GMOs non-viable.

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

Spills

60. If any spill occurs in the facility, the spill procedure (as outlined in Condition 68 (r)) must be implemented to decontaminate the spill as soon as reasonably possible.

61. 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

62. GMOs and material containing GMOs or potentially containing GMOs must not be removed from the facility unless:
(a) it is to be transported to another containment facility of an appropriate type certified by the Regulator to at least PC3; or
(b) written permission has been given by the Regulator.

63. GMOs and material containing GMOs or potentially containing GMOs being transported out of the facility must be transported in accordance with any transport guidelines issued by the Regulator in force at the time.

64. 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 and condition 62 may be requested from the Regulator.

Personal effects

65. 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, should not be taken into the airlock.

Facility management

66. 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.

67. The certification holder must ensure that the facility manager, or his or her delegate(s), is/are 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 conditions 70-73;
    (e) development, documentation, implementation and annual review of a facility manual, as stipulated in conditions 68 and 69;
    (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), 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 (GMOs, invertebrates containing GM micro-organisms and non-GM micro-organisms) used in the facility since the most recent facility 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

68. 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 applying to the facility;
  (ii) conditions imposed by any licences for dealings with GMOs;
  (iii) any relevant clauses of the *Guidelines for the Transport Storage and Disposal 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 GMOs and invertebrates being dealt with in the facility, including the risks associated with the use of these GMOs and invertebrates and management strategies for these risks.
(g) the procedures for the handling of invertebrates 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 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 GMOs inside the facility, including transport for storage of GMOs;
(p) the procedures for the transport of GMOs outside the facility (e.g. transport to another PC3 facility), in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*;
(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)
  (ii) spills while transporting GMOs outside the facility, in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*;
  (iii) 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;
  (iv) escape of invertebrates containing GMOs, or GM invertebrates, within the facility;
  (v) loss, theft or unintentional release of GMOs from the facility;
  (vi) alarms for fire or loss of pressure;
  (vii) failure of power or ventilation systems;
  (viii) fire and natural disasters;
  (ix) serious injury or medical emergencies to persons within the facility;
  (x) security threats; and
  (xi) other life-threatening situations.

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

Training

70. Training must include familiarisation with the elements of the facility manual (Condition 68).

71. Training must include theoretical instruction, and where applicable, supervised practical experience and assessment of competence.

72. Training of authorised persons and training records must be updated whenever:
    (a) licence conditions or certification conditions related to the facility change;
    (b) any applicable guidelines issued by the Regulator change (e.g. *Guidelines for the Transport, Storage and Disposal of GMOs*);
    (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 invertebrates are used in the facility.

73. Training records must be updated at least annually and kept for a period of at least three years.

Health monitoring

74. If the GMOs being or likely to be used in the facility are human pathogens, then consideration must be given to providing authorised persons with any available immunisation against such GMOs.

75. Where a zoonotic agent or human pathogen is being used in the facility, 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

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

Standards referred 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 2252.1	Controlled environments Part 1: Biological safety cabinets (Class I) for personnel and environment protection
AS 2252.2	Controlled environments Part 2: Biological safety cabinets Class II – Design
AS 2252.3	Controlled environments Part 3: Biological safety cabinets Class III – Design
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