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

Guidelines for Certification

of a

Physical Containment Level 3 Laboratory

Version 3.1 – Effective 28 May 2012

These guidelines for certification of a Physical Containment Level 3 (PC3) Laboratory have been issued pursuant to section 90 of the *Gene Technology Act 2000* (the Act) and, as applicable, corresponding State legislation.

Part A of these guidelines contains the requirements that must be met for certification of a PC3 Laboratory by the Gene Technology Regulator (the Regulator) under section 84 of the Act. The requirements apply to all applications for certification of PC3 Laboratories received on or after the day on which these guidelines take effect.

Part B outlines representative conditions of certification that the Regulator may impose on a PC3 Laboratory pursuant to section 86 of the Act.

Notes within the document are intended to provide information, and are not mandatory conditions or requirements.

Wherever possible, equipment should be independently tested by an entity other than the equipment supplier.

A list of the Australian/New Zealand Standards that are referred to throughout this document is 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 facility should be constructed so that upon commissioning it achieves an air leakage rate of no more than 120 L/min, at a differential pressure of 200 Pa. 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, or whenever any modifications take place that could affect the integrity of the seal. An air leakage rate of no more than 1200 L/min should be maintained.

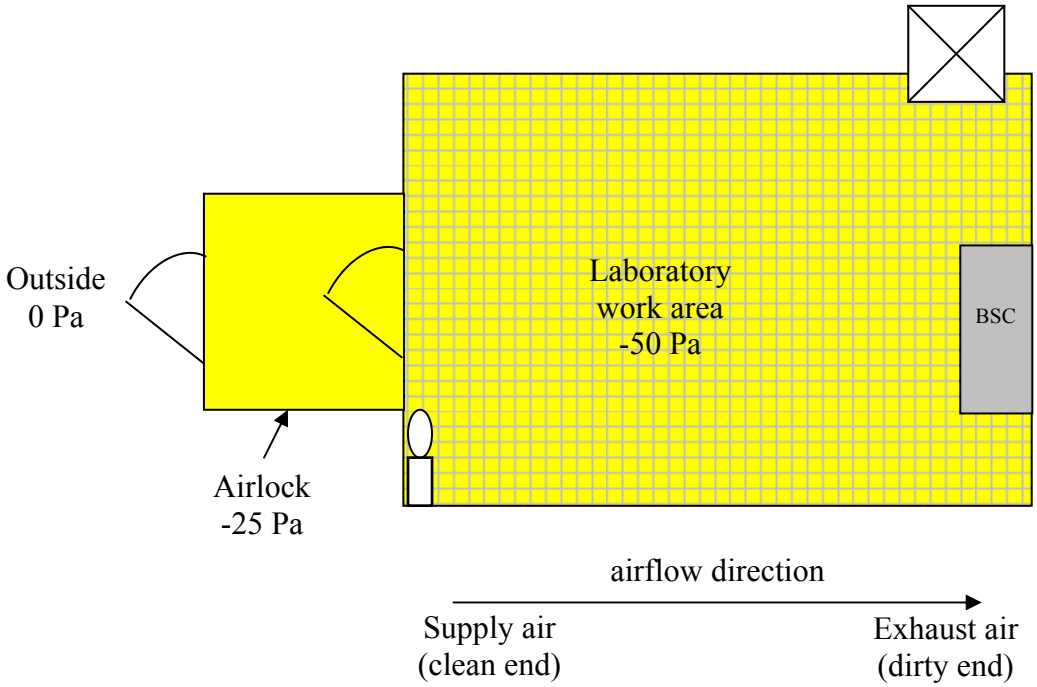
Staff from the OGTR will inspect PC3 facilities prior to any decision being made on an application for certification. Prior to entering a facility, staff from the OGTR must be informed of any Workplace Health and Safety risks that they may be exposed to within the facility, including any chemical or microbiological risks, and of any vaccinations that may be required prior to entering the facility.

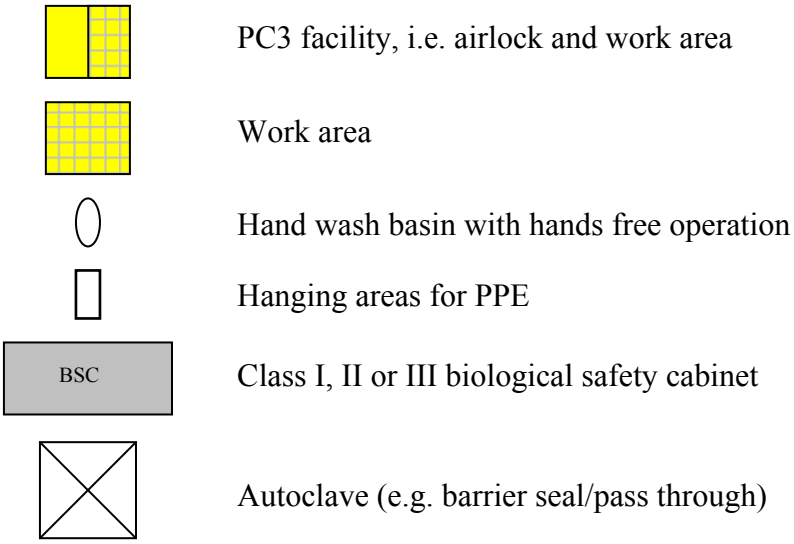
Contents

Representative layouts of PC3 Facilities

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

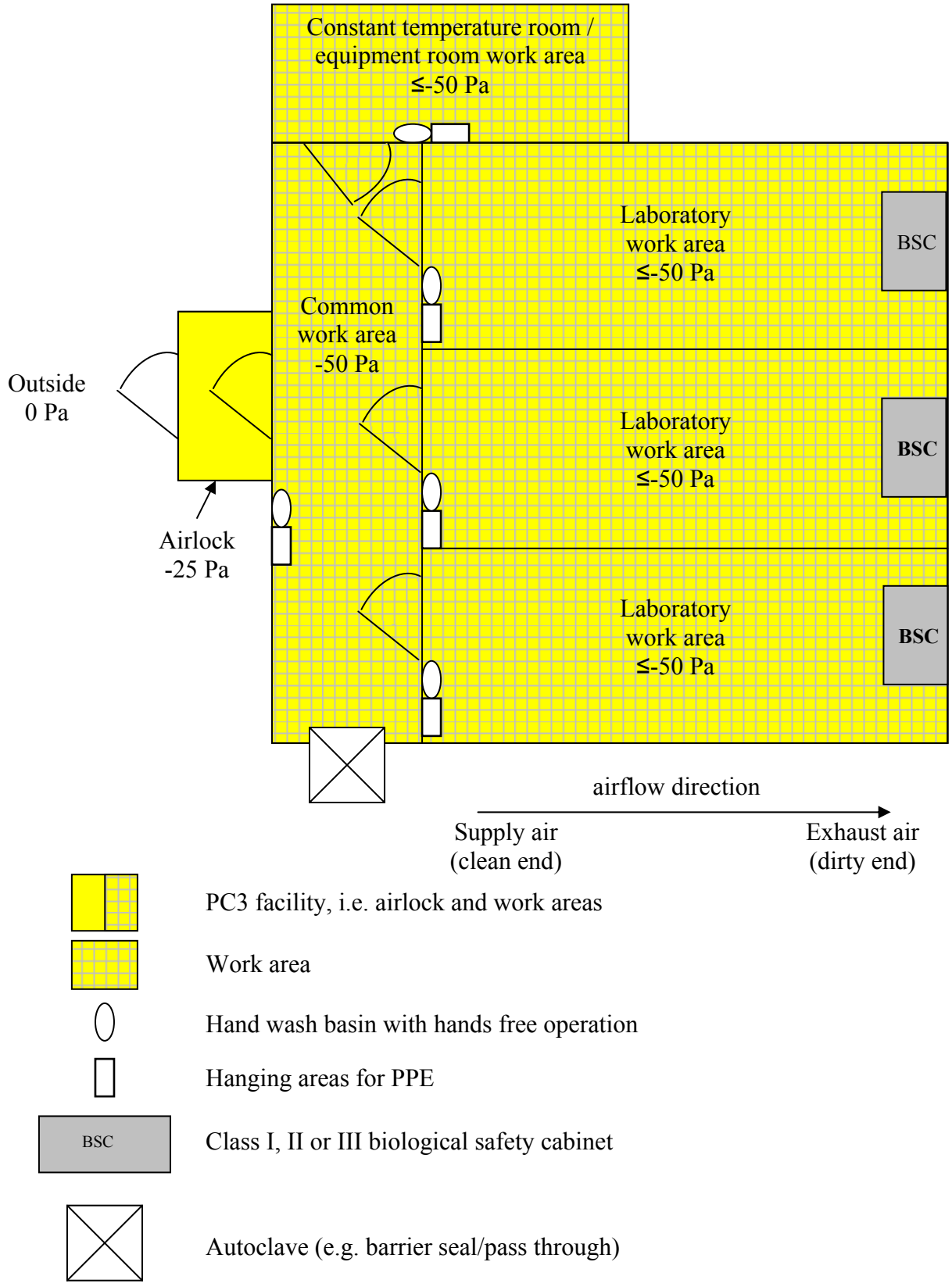
Figure 1: Representation of a PC3 laboratory with a single work area





NOTE: These diagrams are indicative only.

Figure 2: Representation of a PC3 laboratory with multiple work areas



NOTE: These diagrams are indicative only.

Part A

Requirements for Certification

Physical Containment Level 3 Laboratory
Version 3.1 – Effective 28 May 2012

CONTAINMENT REQUIREMENTS THAT MUST BE MET IN ORDER FOR A PC3 LABORATORY TO BE CERTIFIED BY THE REGULATOR.

To be granted certification, a facility must meet each of the requirements for certification of a PC3 Laboratory, unless the facility receives a written exemption from meeting a particular requirement from the Regulator. Additional requirements may also be imposed on the facility by the Regulator depending upon the design, construction and proposed dealings to be conducted in the facility.

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.

aerosol	Suspension in air of finely dispersed solids and/or 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. With the exception of transport, no dealings with GMOs are permitted in the airlock.
arrestance	A measure of the ability of an air filter to remove test dust from the test air, expressed as a mass percentage.
AS/NZS	Australian/New Zealand Standard
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 (including the inner change room, where present) and the airlock.
GMO	Genetically Modified Organism
High-Efficiency Particulate Air (HEPA) filter	An 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 requirements of AS 4260 with a minimum performance of Grade 2; or (b) Separator-less 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.
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.
PPE	Personal Protective Equipment (includes clothing)
PC3	Physical Containment Level 3.
PC3 GMOs	A GMO required to be contained in a PC3 facility, in accordance with Regulation 13 and Schedule 3 Part 2.2 of the Regulations, or by a licence issued by the Regulator; or otherwise specified in writing by the Regulator.

the Regulator	The Gene Technology Regulator or a delegate of the Gene Technology Regulator.
Work area	Any area inside a facility that is not performing the function of an airlock. With the exception of transport, dealings with 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.

3. All facility penetrations must be fitted with seals to minimise air leakage.

   NOTE: Consideration should be given to minimising the number of facility penetrations where possible.

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

5. The facility boundaries (walls, windows, doors, floors, ceilings etc.) must be constructed to prevent the incursion of pests.

6. Where the facility shares an airlock with a PC3 animal or invertebrate facility, or if animals or invertebrates are handled within the facility, 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 small enough 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.

7. Where present, liquid drainage exits must be protected against entry and exit of invertebrates or other animals by the use of screens, liquid traps or an equivalent effective method. Where a screen is used, the apertures of the screen must be small enough to prevent entry or exit of invertebrates or other animals.

8. The surfaces of walls, floors, doors, windows, ceilings, benches and furniture, including seating, must be smooth, impermeable to water, easily cleanable and resistant to damage by the cleaning agents and the chemical and gaseous decontaminants that will be used in the facility.

9. Benches, cupboards, and other fittings and services must be installed to enable decontamination, including gaseous decontamination, of all spaces in the facility. Open

10. Entry into the work area must be through an airlock. Airlock doors must be self-closing and fitted with seals at the top, bottom and both sides of the door. Airlock doors must contain a viewing panel unless the airlock functions as a shower airlock. The outer airlock door must have a mechanism in place to restrict access to the facility. Mechanisms (e.g. interlocking or alarm system) must be in place to ensure that only one door is open at any time.

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

11. Designated storage or hanging areas for PPE must be available within each work area.

12. 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/CCTV/web cameras (e.g. video, CCTV or web cameras).

13. 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.

Containment equipment requirements

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

15. BSCs must be tested, commissioned and results documented before use. Installation, use and decontamination of Class I and Class II BSCs must be in accordance with AS 2252.4. Testing of Class I and Class II BSCs must be in accordance with the requirements of AS 2252.1 and AS 2252.2.

    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.

Laboratory services and equipment requirements

16. 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.

    Other decontamination equipment may be used if approved in writing by the Regulator (e.g. gaseous decontamination chamber, other heat-based decontamination equipment, liquid effluent decontamination system).

17. All autoclaves and other decontamination equipment must be tested and commissioned and the results documented before use.

    NOTE:
    If applicants are planning to use non-standard forms of decontamination, they are encouraged to contact the OGTR as early as possible in the planning process. This will help the OGTR provide advice about what testing and commissioning data should be supplied with the application, and also if any additional requirements will apply to the proposed equipment.

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 and equipment outlets (including autoclaves); and
    (b) outlets within a BSC or other aerosol containment equipment.

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

19. Each work area of the facility must contain either a dedicated hand wash basin, or some other means of decontaminating hands, at or near the exit of the work area. All means of decontaminating hands must be able to be operated in a hands-free manner.

    NOTE: Alternatives to dedicated hand wash basins, such as dispensers filled with decontaminant solutions, are considered suitable provided the decontaminant solution is effective against the GMOs being dealt with 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. 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 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.

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

    The use of Bunsen burners inside BSCs is not recommended as they disrupt the airflow and may affect containment within the BSC.

Ventilation requirements

23. 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. 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.

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

    Where multiple work areas are present in a PC3 facility, consideration should be given to the need for individual ventilation systems for each work area, to facilitate gaseous decontamination of the individual work areas independent of the rest 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 inlets and outlets should be located to minimise disturbance to the operation of any BSC or other aerosol containment equipment approved by the Regulator.

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 of the airlock is open, the work area pressure must remain at least 25 Pa below that of 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 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.

26. The pressure differential must be achieved by means of an independent room exhaust fan located downstream of an exhaust pre-filter and HEPA filter that discharge 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 such that they are 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.

27. Supply or replacement air to the facility must have Type 1 Class A or Class B filters complying with AS 1324.1 with 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 a door.

28. The exhaust filter must be a HEPA filter as defined in this document. After installation, the HEPA filter must be tested by a qualified person in accordance with AS 1807.6 or 1807.7, as applicable, and the results documented. An exhaust pre-filter of the same or higher standard as the supply filter must be installed and mounted on the facility side of the HEPA filter.

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

29. 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.

30. 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; and
    (c) if the housing contains upstream and downstream valved pressure tappings to permit monitoring and display of the filter air flow pressure drop, the tapping on the facility side of the HEPA filter must be fitted with a 0.2 μm hydrophobic membrane filter that is protected from physical impact.

31. The facility must be equipped with an alarm that will alert relevant persons both inside and outside the facility, and be immediately 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.

    Relevant persons include staff working in the vicinity of the facility and the persons responsible for incident response.

32. 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 the event of central control system malfunction.

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 Laboratory. 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 Laboratory:

    (a) results of testing and commissioning of backflow prevention devices installed on pipes supplying water to the facility;
    (b) results of testing and commissioning of HEPA filters;
    (c) results of testing and commissioning of BSCs installed in the facility;
    (d) results of testing and commissioning of autoclaves and any other decontamination equipment installed in the facility;
    (e) an electronic or paper copy of the facility manual (as detailed in Condition 65); and
    (f) a floor plan of the facility including locations of laboratory services, containment equipment, ventilation systems, and decontamination equipment.

Part B

Conditions of Certification

Physical Containment Level 3 Laboratory
Version 3.1 – Effective 28 May 2012

CONTAINMENT CONDITIONS THAT MUST BE MET IN ORDER FOR A PC3 LABORATORY TO REMAIN CERTIFIED BY THE REGULATOR.

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 section are those that can be expected, in most cases, to be included in the certification instrument as the conditions of certification for a PC3 Laboratory. Individual certification conditions may differ from these representative conditions depending upon the design, construction and proposed dealings to be conducted in the facility. Once issued, the conditions may be varied by the Regulator as necessary and appropriate.

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

Obligations of the certification holder

1. The certification holder must have the authority to admit persons to the facility and exclude persons from the facility.

2. A facility manager must be appointed by the certification holder.

3. Any delegate of the facility manager must be appointed by the certification holder.

4. The certification holder must ensure that the facility manager or their delegate has an understanding of the technical aspects of facility design, operation and maintenance.

5. The certification holder must ensure that the facility manager, or their delegate(s), undertake the following functions:
   (a) ensure that access to voids around the perimeter of the facility (if applicable) and the ventilation system of the facility is restricted to authorised persons;
   (b) develop and maintain documented policies and documented procedures for the safe operation of the facility (e.g. entry and exit procedures, work practices, decontamination procedures and emergency plans);
   (c) facilitate training to all persons as per the Training conditions (Conditions 67 & 68);
   (d) provide information to all authorised persons on changes to facility operating policies and procedures;
   (e) develop, document, and undertake an annual review of a facility manual, as stipulated in Conditions 65 and 66;
   (f) develop, document, implement and validate decontamination procedures effective for all organisms and equipment used in the facility;

(g) ensure that successful decontamination of the facility, equipment or work area is carried out when required;
(h) retain documentation relating to gaseous decontamination and to the maintenance and testing of the facility equipment and services, including the air handling system, primary aerosol containment equipment (e.g. BSC) and autoclave(s);
(i) co-ordinate immunisation of persons working within the facility, where appropriate;
(j) ensure 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);
(k) ensure 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
(l) coordinate all work in the facility where multiple projects or work on different organisms is taking place in the facility.

6. 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.

7. For the purposes of Condition 6, an authorised person is:

(a) the facility manager or their delegate; or
(b) another person who:

i. intends to undertake dealings, and has been trained in accordance with conditions 67 to 69; and
ii. has signed, dated and provided to the certification holder a record of the training referred to in paragraph 7(i) above; and
iii. has not been excluded from the facility by the certification holder on the direction of the Regulator; or

(c) is an individual who does not intend to undertake dealings and has the permission of the certification holder to enter the facility.

NOTE: A person who is authorised under 7(a) may also be authorised under 7(b); and subject to those training conditions that apply to persons authorised under 7(b).

8. While the facility is in operation, any person covered by Condition 7(c) who enters the facility must be supervised by persons trained in accordance with conditions 67 to 69.

9. 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 which may expose, 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.

10. 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.

11. For the purposes of Condition 10, before admitting a person subject to conditions, the certification holder must notify the person of any conditions that apply to them.

12. 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.

13. 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

14. The following work must not be conducted in this facility:

    (a) dealings with any GMO that, under the conditions of a licence, requires containment in any physical containment level higher than PC3;
    (b) dealings with any GMO that is a Risk Group 4 organism as specified in AS/NZS 2243.3
    (c) the housing/keeping/rearing of any animals, including invertebrates and aquatic organisms, beyond the minimum time that they are required for conducting the dealings with GMOs;
    (d) the growing of any plants beyond the minimum time that they are required for conducting the dealings with GMOs; or
    (e) any other work prohibited by notification in writing by the Regulator.

General conditions

15. If the certification holder is not the owner of and does not have the authority to maintain the facility, fittings and/or containment equipment, the certification holder must notify the Regulator in writing, as soon as reasonably possible, if the owner of the facility, fittings and/or containment equipment is incapable of carrying out, 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.

16. 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 this 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 that records the extent of compliance with these conditions must be made. Inspection reports must be kept for 3 years, and made available to the Regulator if requested.

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

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

17. 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 they can be clearly seen by all persons entering the facility.

NOTE: Signs do not have to be placed on the outside wall of the facility. However, they must be visible prior to entering the airlock.

18. 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.

19. 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. 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.

20. 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

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

22. Prior to any structural changes that will affect the containment of GMOs in the facility, the applicant must request, in writing, a suspension of the certification 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 that 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 a suspension can be lifted, an inspection by the 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.

23. The airlock must not be used to conduct dealings (other than transport) with GMOs.

    The airlock must not contain laboratory equipment or used PPE. Storage of small supplies of clean PPE is permissible. The airlock must not be used for long term storage of laboratory supplies.

    > NOTE: The purpose of the airlock is to maintain negative pressure within the PC3 facility and prevent airflow between the PC3 facility and areas external to the facility. The airlock should not contain handwash basins or safety showers.

Containment equipment conditions

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

25. Use and decontamination of Class I and Class II BSC must be in accordance with the requirements of AS 2252.4. Use and decontamination of other aerosol containment equipment must be in accordance with the manufacturer's instructions and the requirements of the relevant AS/NZS, where applicable.

Laboratory services and equipment conditions

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

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

28. All services or equipment added to the facility after certification must be tested, commissioned and found to meet the conditions of certification prior to use with GMOs.

Ventilation conditions

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

30. While the facility is operational, 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

31. Biological safety cabinets must be inspected and tested in accordance with the requirements of AS 2252.1 (class I) or AS 2252.2 (class II). 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 must be decontaminated prior to testing.

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

32. Other aerosol containment equipment installed in the facility must be inspected and tested by a qualified person at least annually and additionally after relocation of the equipment, after mechanical or electrical maintenance and after HEPA filters are

replaced. Testing must include HEPA filter integrity and containment efficiency testing and a certificate summarising the test results and the date of the next test must be affixed to the equipment.

Where testing has shown that the performance requirements for HEPA filter integrity or containment efficiency 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 all tests must be kept for 3 years and made available to the Regulator if requested.

33. Testing and maintenance of facility ventilation systems must be carried out at least annually by a qualified person. This 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. 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 re-testing has shown that compliance with these Conditions has been achieved. Storage of GMOs in the facility is permitted when failures occur provided containment of the GMOs is not compromised.

34. The physical parameters of the autoclave, or other heat-based equipment used to decontaminate GMOs, must be validated either at least monthly (if it is in frequent use) or before or with each decontamination cycle (if it is in intermittent use) with:

(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, or other heat-based equipment used for decontamination, must be validated either at least monthly (if it is in frequent use) or before or with each decontamination cycle (if it is in intermittent use) with:

(i) biological indicators such as spore strips; or
(ii) bacterial enzyme indicators; or
(iii) other methods approved in writing by the Regulator.

Indicators that determine the efficacy of the autoclave must be placed in locations that are least likely to encounter the physical conditions required for effective decontamination (e.g. at the centre of the load or coldest part of the autoclave).

35. The results of testing of physical parameters and efficacy of the autoclave or other heat-based decontamination equipment (as specified in Condition 34 above) must be kept for 12 months and made available to the Regulator if requested.

36. Any equipment (heat, chemical or other) used to decontaminate GMOs must be tested and maintained annually by a person qualified or trained to do so. The results of the annual maintenance for the previous 3 years must be kept and made available to the Regulator, if requested. Annual maintenance must include, but may not be limited to:
    (a) calibration of all instruments that control or monitor critical process parameters. For autoclaves this includes calibration of thermometers, timers, and thermocouples;
    (b) confirmation that all parameters of the system are operating within the specified limits (e.g. temperature, time, pH, concentration of chemical);
    (c) testing and maintenance of equipment to ensure effective operating conditions; and
    (d) testing of all safety and relief equipment, including the autoclave safety valves.

37. If any autoclave or other 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.

38. 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

39. The outer door of the facility must be kept locked when the room is unoccupied by personnel.

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

41. Under normal operation of the facility, persons must enter and exit the work area through the airlock.

42. Where present, dedicated emergency exits must only be opened in the event of an emergency.

43. With the exception of transport, dealings with GMOs must only take place in the work area(s).

44. The following PPE must be worn by all authorised persons in the work area(s):

    (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;
    (d) eye protection; and
    (e) waterproof dressings on all broken skin.

    NOTE: The use of disposable overshoes or dedicated facility footwear should also be considered.

45. When exiting the work area and prior to entering the airlock, PPE must be removed and disposed of, or stored in designated storage or hanging spaces. If a facility contains multiple work areas in which different GMOs are being dealt with, gloves and gowns worn at the BSC must be removed before exiting each work area.

46. 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

47. Any dealings that may generate aerosols containing GMOs must be conducted in a BSC or other aerosol containment equipment approved in writing by the Regulator.

48. Any centrifugation of GMOs must be carried out in sealed containers (tubes, buckets or rotors). Centrifuge containers must only be opened in a BSC or other aerosol containment equipment approved in writing by the Regulator.

Use of sharps

49. Sharps must not be used in direct connection with GMOs unless no alternatives are available. An assessment of the need to use sharps and the procedures for safe handling must be documented in the facility manual (Condition 65(i)).

Decontamination

50. Work benches, surfaces and equipment where procedures involving viable GMOs have taken place must be decontaminated immediately after each procedure and/or at the end of each working day.

    NOTE: It is recommended that procedures with different GMOs be separated in space or time, with decontamination of work benches, surfaces, PPE and other equipment being undertaken before commencing work with each different GMO.

51. Gaseous decontamination of the facility must take place:

    (a) after a spill of viable GMOs outside primary containment (e.g. BSC) and that cannot be decontaminated by another means;
    (b) prior to suspension, surrender, expiry or cancellation of certification;
    (c) prior to re-certification of the facility at a lower containment level, if stipulated by the Regulator; and
    (d) prior to maintenance work on equipment in the facility that cannot be decontaminated by another means.

    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. All contaminated liquid effluent must be decontaminated by heat or chemical treatment before being discharged to sewer.

    NOTE: This does not include effluent from handwash stations, eyewash stations or safety showers.

53. All items, including equipment, PPE and waste, must be decontaminated prior to removal from the facility. An exception is permitted for the transport of GMOs to another certified PC3 facility, or for export, in accordance with Condition 61.

    This includes all reading and writing material, computers, communication devices including phones, and other items such as radios or other audio equipment.

    NOTE: It is recommended that a networked computer and/or fax machine be provided to enable documents to be electronically sent outside the facility.

54. Decontamination can be effected by autoclaving or other heat treatment, by chemical or gas 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.

55. 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 (e.g. 0.22μm) or decontaminated before discharge.

56. If a double-ended autoclave is installed across the facility barrier, it must have a mechanism in place such that it cannot be opened on the clean side without completion of a successful decontamination cycle.

57. Any other heat-based treatment used for decontamination must be performed using a combination of pressure, temperature and time that has previously been validated as effective in rendering the GMOs non-viable.

58. Any chemical decontamination agent must have been validated, prior to use, as being 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. Other peer-reviewed literature may be consulted.

59. Any gaseous decontamination agent must be validated as effective in rendering the GMOs non-viable. When gaseous decontamination of the facility, part of the facility or selected laboratory equipment is conducted, validation of successful decontamination must be achieved by use of appropriate indicators (e.g. spore strip tests) placed throughout the space to be decontaminated. Records of the tests must be kept for 3 years and made available to the Regulator if requested.

    Gaseous decontamination is only considered effective if confirmed by all indicators employed. The type, number and location of indicators must be appropriate for the nature of the gaseous decontamination agent used and the space being decontaminated.

Spills

60. If any spill occurs in the facility, the spills procedure (see Condition 65(r)(i)) must be implemented to decontaminate the spill as soon as reasonably possible.

> NOTE: The Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* cover spills outside of the facility.

Transport and Storage of GMOs

61. Viable PC3 GMOs and/or material containing or potentially containing such GMOs must not be removed from the facility unless:

    (a) they are to be transported to another containment facility certified by the Regulator to at least PC3; or
    (b) they are to be transported for the purpose of export; or
    (c) written permission has been given by the Regulator.

62. Transport of the GMOs must be in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*.

63. PC3 GMOs must be stored within the work area of a PC3 facility. GMOs must be stored in a sealed, unbreakable primary container, which has been surface decontaminated prior to enclosure within a sealed, unbreakable secondary container. The secondary container can then be placed in a fridge or freezer (the tertiary container).

NOTES:
A written exemption to this condition may be requested from the Regulator, e.g. where it is not practicable to store PC3 GMOs within the work area due to space constraints or availability of appropriate storage devices.

GMOs that are not PC3 GMOs may be transported and stored outside of the facility in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* provided they are not contaminated with PC3 GMOs.

Personal effects

64. Non-essential personal effects, including handbags, mobile phones, portable music devices, and other non-essential electronic equipment must not be taken into the facility.

Facility Manual

65. A facility manual (either paper or electronic) must be readily available to all authorised users from within 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) conditions imposed by other relevant guidelines issued by the Regulator, such as those concerning transport, storage or 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 organisms being handled in the facility, the risks associated with the use of these organisms, and the management strategies for these risks;
    (g) the procedures that must be followed by all persons entering and exiting the facility, including the use of PPE and the order in which it is removed;
    (h) the procedures for the operation and use of the BSC (if applicable) and any other specialised aerosol containment equipment approved in writing by the Regulator;
    (i) the assessment of and the procedures for the use of sharps (Condition 49);
    (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 of GMOs, 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 within the facility, including for storage of GMOs;
(p) the procedures for the transport of GMOs outside the facility (e.g. transport to another PC3 facility) as outlined in 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 of GMOs in the facility (both inside and outside BSCs) and spills while transporting GMOs outside the facility;
(ii) accidental exposure to GMOs used within the facility, including procedures for the management and treatment of persons suspected to be infected or contaminated with or exposed to Risk Group 3 organisms, as outlined in Condition 70;
(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) medical emergencies or serious injury to persons within the facility;
(ix) security threats; and
(x) other life-threatening situations.

66. The facility manual must be reviewed at least annually and updated as necessary by the facility manager or their delegate(s).

Training

67. All authorised persons as defined by Condition 7(b) must undertake training that includes:

(a) all information contained in the facility manual (Condition 65);
(b) theoretical instruction; and
(c) where applicable, supervised practical experience and assessment of competence;

prior to commencing dealings with GMOs.

68. All authorised persons as defined by Condition 7(b) must undertake re-training at least annually. Re-training must assess ongoing ability to comply with the requirements specified in Condition 67. Training material and procedures 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 are used in the facility.

69. Training records of all authorised persons described in Conditions 7(b) must be kept by the certification holder for a period of at least 3 years and made available to the Regulator if requested.

Health Monitoring

70. Where a zoonotic agent or human pathogen is in use, a documented system must be in place to:

    (a) report accidents and exposures to micro-organisms;
    (b) monitor employee absenteeism; and
    (c) provide medical surveillance of illnesses that are potentially associated with the dealings conducted in the facility.

    The Regulator must be informed of any accidents and exposures to GMOs or illnesses associated with these events as soon as reasonably possible.

    NOTES:
    If the GMOs being or likely to be used are human pathogens, then consideration should be given to providing authorised persons with any available immunisation against the relevant parent organisms.

    Contingency plans in the event of a laboratory exposure should also be developed and discussed with local public health authorities.

Non-compliance

71. Any non-compliance with the conditions applying to the certified facility (usually these *Guidelines for Certification of a Physical Containment Level 3 Laboratory*), including any unintentional release of GMOs from the facility, must be reported to the Regulator as soon as reasonably possible.

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. Refer to the most recent issue of the Standards.

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