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

Guidelines for Certification
of a
Physical Containment Level 4 Facility

Version 2.1 – Effective 1 July 2007

The guidelines (Part A) contain the requirements for certification of a Physical Containment Level 4 (PC4) Facility issued pursuant to section 90 of the *Gene Technology Act 2000* (the Act).

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 usual conditions that will apply to a PC4 Facility. Individual certification conditions may differ from these in some respect but generally an applicant can expect that their conditions will closely follow those published here. Once issued, the conditions may be varied by the Gene Technology Regulator as necessary and appropriate.

A list of the Australian/New Zealand Standards that are referenced 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>.

The OGTR will inspect PC4 Facilities prior to any decision on an application for certification.

Contents

Representative layouts of PC4 Facilities

For the purposes of these PC4 Facility guidelines, a PC4 Facility includes a laboratory or work area separated from other areas by a dedicated airlock and may include other support rooms, corridors, etc. within the physical containment barrier certified by the Regulator. Representations of typical PC4 Facilities are shown below (Figures 1 and 2).

Figure 1: Representation of a non-suit area PC4 Facility

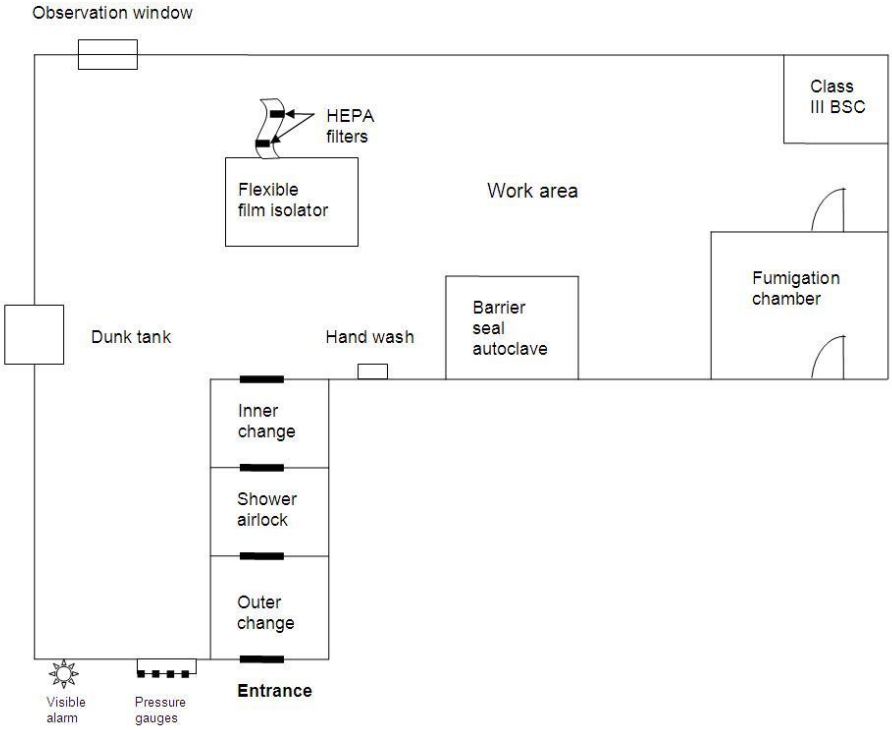
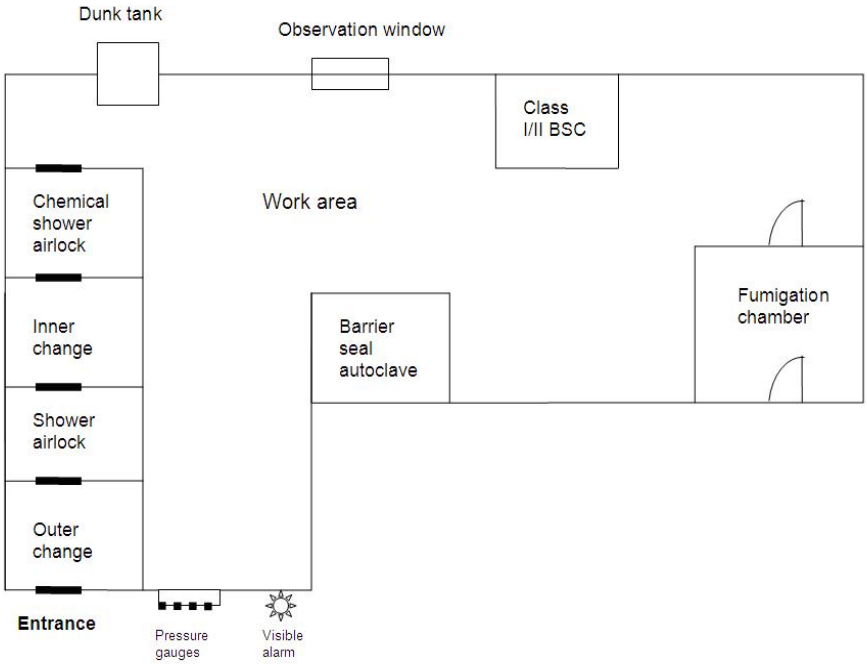


Figure 2: Representation of a suit area PC4 Facility



Part A

Requirements for Certification

Physical Containment Level 4 Facility
Version 2.1 – Effective 1 July 2007

CONTAINMENT REQUIREMENTS THAT MUST BE MET IN ORDER FOR A PHYSICAL CONTAINMENT LEVEL 4 (PC4) 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 PC4 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 PC4 Facilities received on or after the day on which these guidelines take effect.

To be granted certification, a facility must meet each of the requirements for certification of a PC4 Facility, unless the facility receives a written exemption from meeting a particular requirement from the Regulator or a delegate of the Regulator.

Definitions and acronyms

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

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

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

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

airlock	An area or rooms between a pair of doors that separates the **work area** inside a **facility** from access corridors, other laboratories, or other spaces outside the **facility**. The **airlock** permits the movement of equipment and personnel without affecting the inward flow of air into the **work area**, since at least one door is kept closed at all times.
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.
envelope walls	Walls that form the external perimeter of a building.
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** and any **airlock** or change room used to enter or leave the **work area**.
GMO	Genetically Modified Organism.
PC4	Physical Containment Level 4.
the Regulator	The Gene Technology Regulator.
work area	Any area inside a **facility** that is not performing the function of an **airlock** or change room. Procedures on **GMOs** must take place in the **work area** and any procedures in the **work area** are subject to the conditions on the certification instrument.

Facility location, construction and access requirements

1. The **facility** to be certified must be housed in a separate building or form an isolated part of a building. The **facility** must be located close to mechanical service areas and away from **envelope walls** to provide an interstitial space that can be maintained at a positive pressure with respect to the **facility** boundary. Full access to all exterior surfaces of the **facility** and service penetrations must be provided to facilitate periodic integrity testing.

2. The **facility** must be a sealed internal shell bounded by walls, doors, windows, floors and ceilings, which allow gaseous **decontamination** and the operation of the **facility** under negative pressure. Seals at all **facility** surfaces and junctions must be continuous. Interior surfaces must be gastight to prevent transfer of any gases. All penetrations must be sealed. Doors must be lockable.

3. The **facility** must be constructed so that it achieves upon commissioning an air leakage rate, at a differential pressure of 200 Pa, of no more than 120L/min.

4. The entrance to the **work area** must be through an outer and inner change room, separated by a shower **airlock**. The shower **airlock** doors must be interlocked to prevent simultaneous opening of both doors. **Airlock** doors must be airtight and fitted with inflatable or compression seals to the full perimeter. Entry and exit door controls must operate in the event of power failure or building management system failure.

5. Windows positioned on the containment barrier are to be sealed in place. Any window glazing material must be of laminated security glass selected to withstand the maximum pressure differential imposed during all operating conditions, including all possible failure modes, and during testing.

6. The **facility** must be constructed to permit visual monitoring of all activities from outside the **facility**.

   NOTE: Visual monitoring could be achieved by a viewing panel, CCTV, or video/web-based monitoring.

7. All surfaces in the **facility** must be smooth; impermeable to water, chemicals and gases; easily cleanable; and resistant to damage by the cleaning agents, disinfectants and gaseous **decontaminants** that will be used in the **facility**, including but not limited to:
   (a) walls, doors, floors, and benches (bench tops must not have open seams);
   (b) furniture, including seating; and
   (c) ceilings.

8. **Facility** equipment and fixtures, such as benches, doors, drawers and handles, must be designed to prevent the possibility of snagging, catching, puncturing or tearing protective clothing.

9. Two alternative independent communication systems must be provided for contact between persons inside and outside the **facility**. At least one of these systems must operate in the event of power failure.

10. All cables and conduits must be permanently and durably sealed at the **facility** containment barrier. Permanent support and protection must be provided to minimise the risk of accidental disturbance of seals.

11. If drainage traps exist, the drainage seal depth of the drainage traps must be designed so that a seal is able to be maintained under all expected operating air pressures.

12. Any drainage and sewer vents, and vents from the effluent **decontamination** system, must be provided with a filter with pore size of less than or equal to 0.2 µm. These vents must also be able to be isolated and **decontaminated**.

Laboratory services and equipment requirements

13. All services must be tested and results documented before the **facility** is commissioned.

14. Water supplied to the **facility** must be provided with backflow prevention by a registered testable device that has a high hazard rating for protection against both back-pressure and back-siphonage in accordance with the requirements of AS/NZS 3500.1:2003. Backflow prevention must isolate the **facility** to the exclusion of all other areas. There must be an isolation valve immediately outside the **facility**.

    NOTE: This includes water supplied to equipment directly associated with the operation of the **facility**, such as **autoclaves**.

15. Any reticulated services supplied to the **facility**, such as piped gases, must be fitted with backflow prevention or alarms to advise persons of a low pressure condition. Potentially hazardous gases (flammable, combustible or other special hazard) must be provided with leak detection and alarms to warn persons of a leak.

16. An **autoclave** must be provided within the **work area**. It must be of double-ended type with interlocked doors. The inner door must open into the **facility** and the outer door must open externally to the **facility**. A barrier, sealed to the chamber of the **autoclave**, must be provided and this barrier must be sealed to the **facility** perimeter to maintain the **facility** airtight seal. The interlock must prevent simultaneous opening of both doors, and must prevent opening of the outer door once the inner door has been opened unless a full sterilization cycle has taken place. Maintenance must be achievable from outside the **facility** to the maximum extent practicable. Connections and equipment associated with the **autoclave** must be designed and installed to minimise the risk of escape of viable **GMOs**. This must include the use of bursting discs before pressure relief valves with interstitial pressure monitoring and an alarm, adequate retention of condensate during warm up, and prevention of contamination of vacuum pumps.

17. A pass-through dunk-tank, gaseous **decontamination** chamber or equivalent **decontamination** equipment must be provided, so that materials and equipment that cannot be **decontaminated** in the **autoclave** can be rendered safe for removal from the **facility**.

    17.1. If a dunk tank is to be provided, it must be capable of being sealed.

    17.2. If a gaseous **decontamination** chamber is to be provided, the inner and outer doors must be interlocked to prevent simultaneous opening at any time.

18. A system must be in place to effect the **decontamination** of all effluent from the **work area**, shower and inner change room before being discharged. An alarm must be provided to alert persons of any **decontamination** system malfunction.

19. Vacuum services must be provided with liquid disinfectant traps at each point of use in the **facility**. Air drawn through the liquid disinfectant trap must be filtered with a filter with pore size of less than or equal to 0.2 µm prior to connection to the vacuum pump.

NOTE: Central vacuum systems are not recommended for use in **PC4 facilities**.

20. The **facility** must have an automatic changeover emergency power source that is activated in the event of power failure. The emergency power source must ensure continuing operation of the ventilation systems, biosafety cabinets, flexible film isolators, room access shower controls, emergency lighting, emergency communication systems, and control systems associated with ventilation, effluent and waste management. Uninterruptible Power Supplies (UPS) must be provided to any services that do not automatically restore correct control functions following changeover between normal power and emergency power, including personal breathing air sources in a suit area.

21. The **facility** must be provided with a duress alarm system that, when triggered, raises an alert with at least one person external to the **facility**.

22. High performance respiratory equipment must be available outside the **work area**.

Containment equipment requirements

23. The **facility** must contain a biological safety cabinet (BSC) appropriate to the **dealings** which are to be undertaken in the **facility**.

Heating, ventilation and air conditioning requirements

24. A non-recirculating ventilation system that establishes a negative air pressure gradient in the **facility** must be provided to establish a directional airflow into the **work area**. The supply and exhaust airflow must be separate and interlocked to prevent positive pressurisation of the **facility** in the event of failure of the exhaust fan. Interlocking that is independent of the building management system must be provided.

25. There must be a pressure differential of at least 25 Pa between each room to achieve air flow direction towards the **work area**.

26. The pressure differential must be achieved by means of an independent room exhaust fan located downstream of the HEPA filter(s) and discharging to the outside atmosphere. All exhaust air and **decontaminating** gases used during gaseous **decontamination** of the **facility** and in the gaseous **decontamination** chamber must be purged to the atmosphere in such a manner that it is dispersed away from occupied buildings and air intakes.

27. The **facility** must be equipped to measure and display the pressure difference between the **work area** and areas adjacent to the **facility**. The display must be located so it can be read before entering the **facility**.

28. If a manometer/differential pressure gauge is used to sense the pressure differentials between adjacent areas, any differential pressure monitoring lines must be fitted with a filter with pore size of less than or equal to 0.2 µm.

29. The **facility** must be equipped with an alarm that is visible and audible inside and outside the **facility** and activated when the pressure in the **work area**, inner change room or shower **airlock** is more than 15 Pa above the set point for more than 2 minutes.

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

30. Supply and exhaust ductwork between the connection to the **facility** and the HEPA filter housings must be gastight. Gastight valves and HEPA filters must be located as close to the perimeter of the **facility** as practicable to minimise the lengths of potentially contaminated ducts.

31. Supply or replacement air to the **facility** must be HEPA filtered.

32. The supply and exhaust filters must be HEPA filters as specified in Clause 1.3.15 of AS/NZS 2243.3:2002, or another filter that meets all requirements of AS 4260:1997 with a minimum performance of Grade 2.

    NOTE: Consideration should be given to preceding each HEPA filter by a suitable pre-filter to prolong the life of the HEPA filter element. Pre-filters must be Type 1 Class A or B in accordance with AS 1324.1:2001, with a minimum efficiency of 90% when tested to AS 1324.2:1996 with test dust No. 4.

    Where animals that create dust, dander or other airborne particulate contamination are used, consideration should be given to fitting appropriate roughing filters to exhaust air grilles in the animal rooms to prolong the life of the exhaust filter against rapid clogging.

33. The exhaust HEPA filters(s) must be mounted in gastight housing, with sealed access doors, and the ductwork between the **facility** and the HEPA filter housing must also be gastight. The design and location of the filter housing must allow for access to, and integrity testing of, the HEPA filters. Exhaust air is to be dedicated to the **facility** and completely separate from other areas.

34. Filter housings must incorporate the following features:
    (a) a gastight isolating valve on the air outlet duct (and supply duct if present). If **decontamination** of the filters is to be performed separately from **decontamination** of the **facility**, an isolating valve on the air inlet duct and upstream and downstream valved ports is also required;
    (b) secure filter element clamping and mounting tracks;
    (c) filter chambers designed to allow gaseous **decontamination** before filters are removed;
    (d) 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 filter with pore size of less than or equal to 0.2 µm that is protected from physical impact; and

(e) ability to withstand pressure of 2,500 Pa.

Suit area requirements

For certain circumstances, a specially designed suit area may be provided within the **facility**. Where this is the case, the **facility** must meet the following requirements in addition to all other requirements listed:

35. The entrance to the suit area must be through a chemical shower **airlock** fitted with gastight interlocked doors. The chemical shower must incorporate a disinfectant that is effective against the micro-organisms **dealt** with in the suit area.

36. Persons who enter the suit area must wear a one-piece positive pressure suit that is ventilated by a life support system that includes an alarm and emergency back-up breathing air system.

    NOTE: Consideration must be given to the provision of a suit storage room to facilitate testing of the suit prior to entering the **work area**.

37. An automatic second exhaust fan must be provided to re-establish the negative pressure of the suit area in the minimum time possible in the event of exhaust fan failure. Supply and exhaust fan systems must be interlocked or provided with rapidly acting mechanisms to ensure positive pressures cannot occur in the suit area at any time. The exhaust air must be filtered through two HEPA filters installed in series.

38. The personal breathing air source must be connected to an Uninterruptible Power Supply (UPS) in accordance with requirement 20.

39. An automatic changeover emergency power source that is activated in the event of power failure must be provided. Essential control equipment must monitor and re-establish room pressure conditions during operation on emergency power. Sufficient uninterruptible power must be provided to ensure this occurs.

Capacity to comply with certification conditions

40. The applicant must be able to demonstrate a capacity to comply with the conditions of certification that will generally be applied to a certified **PC4 Facility**. These conditions are found in Part B of this document.

Part B

Conditions of Certification

Physical Containment Level 4 Facility
Version 2.1 – Effective 1 July 2007

Conditions are imposed on facilities by the Regulator at the time of certification pursuant to section 86 of the *Gene Technology Act 2000* (the Act), and, as applicable, corresponding State legislation. The condition clauses in this section are the ones that can be expected, in most cases, to be included in the certification instrument as the conditions of certification for a Physical Containment Level 4 (PC4) Facility.

Definitions and acronyms

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

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

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

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

airlock	An area or rooms between a pair of doors that separates the **work area** inside a **facility** from access corridors, other laboratories, or other spaces outside the **facility**. The **airlock** permits the movement of equipment and personnel without affecting the inward flow of air into the **work area**, since at least one door is kept closed at all times.
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.
DIR	A **dealing** involving the intentional release of **GMOs** into the **environment**.
DNIR	A **dealing** *not* involving the intentional release of **GMOs** into the **environment**.
envelope walls	Walls that form the external perimeter of a building.
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** and any **airlock** or change room used to enter or leave the **work area**.
GM	Genetically Modified.
GMO	Genetically Modified Organism.
licensed dealing	A **dealing** conducted under the conditions of a licence for either a **DIR** or **DNIR** issued by **the Regulator**.
NLRD	Notifiable Low Risk Dealing.
OGTR	Office of the Gene Technology Regulator.
PC4	Physical Containment Level 4.
the Regulator	The Gene Technology Regulator.

work area	Any area inside a **facility** that is not performing the function of an **airlock** or change room. Procedures on **GMOs** must take place in the **work area** and any procedures in the **work area** are subject to the conditions on the certification instrument.

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 a **licensed dealing**, or an **NLRD** which is integral to the **licensed dealings** to be undertaken in the **facility**, and has been trained in implementing the Mandatory Behavioural Requirements listed at Part C of this document;
   (b) has signed, dated and provided to the certification holder a record of the training referred to in condition 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, or class of person, 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. If **the Regulator** requests the certification holder to provide a signed and dated record of the training provided to a particular authorised person, or class of person, the signed and dated record of that training must be made available to **the Regulator** within a time period stipulated by **the Regulator**.

5. If **the Regulator** directs the certification holder to exclude a person, or class of person, from entry to the **facility** on the grounds that the person, or class of person:
   (a) has behaved, or is behaving, in a manner which contravenes the Mandatory Behavioural Requirements listed at Part C of this document; 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, or class of person, from the **facility** unless and until otherwise directed by **the Regulator**.

6. If **the Regulator** directs the certification holder to admit a person, or class of person, to the **facility** subject to conditions, the certification holder must only admit the person, or class of person, subject to those conditions.

7. For the purposes of condition 6, before admitting a person, or class of person, subject to conditions, the certification holder must notify the person(s) of any conditions that apply to them.

8. If **the Regulator** invites the certification holder to make a submission on whether or not a person, or class of 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**.

9. **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.

General conditions

10. 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.

11. The **facility** must be inspected at least once every 12 months by a person qualified to assess the **facility's** compliance with the conditions listed under:
   (a) Facility location, construction and access conditions;
   (b) Laboratory services and equipment conditions;
   (c) Containment equipment conditions;
   (d) Heating, ventilation and air conditioning conditions;
   (e) Testing conditions; and, when applicable,
   (f) Suit area conditions;
   (g) Animal control conditions; and/or
   (h) Plant control conditions.

   An inspection report which records the extent of compliance with these conditions must be made. A copy of each inspection report must be forwarded to **the Regulator** in years where the **facility** is not being inspected by the **OGTR**.

12. The **facility** must be labelled with the following adhesive signs:
   (a) a Physical Containment Level 4 (**PC4**) sign, as supplied by the **OGTR**;
   (b) a biohazard symbol;
   (c) a sign listing the name and phone number of the **facility** manager; and
   (d) an alternative emergency contact telephone number.

The signs must be placed so that persons entering the **facility** are able to clearly see they are entering a certified **PC4 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**.

13. A supply of disinfectants effective against the **GMOs** being **dealt** with in the **facility** must be available in the **facility** for **decontamination** purposes. All containers of disinfectants must be labelled with the contents and, where necessary, the expiry date. Solutions must not be used after the expiry date.

Facility location, construction and access conditions

14. The certification holder must ensure that the physical attributes of the **facility** and fittings are maintained so that the relevant 'Facility location, construction and access requirements' listed in the Requirements for Certification at Part A of this document continue to be met, as follows:

    14.1. The **facility** must continue to be housed in a separate building or form an isolated part of a building. The **facility** must continue to be located close to mechanical service areas and away from **envelope walls** to provide an interstitial space that can be maintained at a positive pressure with respect to the **facility** boundary. Full access to all exterior surfaces of the **facility** and service penetrations must continue to be provided to facilitate periodic integrity testing.

    14.2. The **facility** must be maintained as a sealed internal shell bounded by walls, doors, windows, floors and ceilings, which allow gaseous **decontamination** and the operation of the **facility** under negative pressure. Seals at all **facility** surfaces and junctions must be continuous. Interior surfaces must be gastight to prevent transfer of any gases. All penetrations must continue to be sealed. Doors must be maintained to be lockable.

    14.3. At all times after commissioning, an air leakage rate of no more than 1200L/min should be maintained in the **facility**.

    14.4. The entrance to the **work area** must be through an outer and inner change room, separated by a shower **airlock**. The shower **airlock** doors must continue to be interlocked to prevent simultaneous opening of both doors. **Airlock** doors must continue to be airtight and fitted with inflatable or compression seals to the full perimeter. Entry and exit door controls must operate in the event of power failure or building management system failure.

    14.5. Windows positioned on the containment barrier are to remain sealed in place. Any window glazing material must continue to be of laminated security glass selected to withstand the maximum pressure differential imposed during all operating conditions, including all possible failure modes, and during testing.

14.6. Prior to any significant structural changes that will affect the containment of **GMOs** in the **facility**, the applicant must request a suspension of the certification, in writing, from **the Regulator**. Before a suspension of the certification can be lifted, the **facility** must be inspected by a person qualified to assess the **facility's** compliance with the conditions listed under:

(a) Facility location, construction and access conditions;
(b) Laboratory services and equipment conditions;
(c) Containment equipment conditions;
(d) Heating, ventilation and air conditioning conditions;
(e) Testing conditions; and, when applicable,
(f) Suit area conditions;
(g) Animal control conditions; and/or
(h) Plant control 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** must not recommence in a **facility** which has its certification suspended until **the Regulator** has lifted the suspension by notice in writing.

14.7. The ability to visually monitor all activities from outside the **facility** must be maintained.

14.8. All surfaces in the **facility** must be maintained to be smooth; impermeable to water, chemicals and gases; easily cleanable; and resistant to damage by the cleaning agents, disinfectants and gaseous **decontaminants** that will be used in the **facility**, including but not limited to:

(a) walls, doors, floors, and benches (bench tops must not have open seams);
(b) furniture, including seating; and
(c) ceilings.

14.9. **Facility** equipment and fixtures, such as benches, doors, drawers and handles, must be maintained to prevent the possibility of snagging, catching, puncturing or tearing protective clothing.

14.10. Two alternative independent communication systems must continue to be provided for contact between persons inside and outside the **facility**. At least one of these systems must operate in the event of power failure.

14.11. All cables and conduits must be permanently and durably sealed at the **facility** containment barrier. Permanent support and protection must be maintained to minimise the risk of accidental disturbance of seals.

14.12. If drainage traps exist, a seal must be maintained under all expected operating air pressures.

14.13. Any drainage and sewer vents, and vents from the effluent **decontamination** system, must be maintained to have a filter with pore size of less than or equal to 0.2 µm. These vents must also be able to be isolated and **decontaminated**.

Laboratory services and equipment conditions

15. 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 the Requirements for Certification at Part A of this document continue to be met, as follows:

    15.1. Any services added to the **facility** after certification is finalised must be tested and results documented before being commissioned.

    15.2. Water supplied to the **facility** must continue to be provided with backflow prevention by a registered testable device that has a high hazard rating for protection against both back-pressure and back-siphonage in accordance with the requirements of AS/NZS 3500.1:2003. Backflow prevention must isolate the **facility** to the exclusion of all other areas. There must be an isolation valve immediately outside the **facility**.

    15.3. Any reticulated services supplied to the **facility**, such as piped gases, must continue to be fitted with backflow prevention or alarms to advise persons of a low pressure condition. Potentially hazardous gases (flammable, combustible or other special hazard) must continue to be provided with leak detection and alarms to warn persons of a leak.

    15.4. An **autoclave** must continue to be provided within the **work area**. It must be of double-ended type with interlocked doors. The inner door must open into the **facility** and the outer door must open externally to the **facility**. A barrier, sealed to the chamber of the **autoclave**, must be provided and this barrier must be sealed to the **facility** perimeter to maintain the **facility** airtight seal. The interlock must prevent simultaneous opening of both doors, and must prevent opening of the outer door once the inner door has been opened unless a full sterilization cycle has taken place. Maintenance must be achievable from outside the **facility** to the maximum extent practicable. Connections and equipment associated with the **autoclave** must be maintained to minimise the risk of escape of viable **GMOs**. This must include the maintenance of bursting discs before pressure relief valves with interstitial pressure monitoring and an alarm, continued adequate retention of condensate during warm up, and continued prevention of contamination of vacuum pumps.

    15.5. A pass-through dunk-tank, gaseous **decontamination** chamber or equivalent **decontamination** equipment must continue to be provided, so that materials and equipment that cannot be **decontaminated** in the **autoclave** can be rendered safe for removal from the **facility**.

        15.5.1. If a dunk tank has been provided, it must continue to be capable of being sealed.

        15.5.2. If a gaseous **decontamination** chamber has been provided, the inner and outer doors must continue to be interlocked to prevent simultaneous opening at any time.

15.6. A system must continue to be in place to effect the **decontamination** of all effluent from the **work area**, shower and inner change room before being discharged. An alarm must continue to be provided to alert persons of any **decontamination** system malfunction.

15.7. Vacuum services must continue to be provided with liquid disinfectant traps at each point of use in the **facility**. Air drawn through the liquid disinfectant trap must be filtered with a filter with pore size of less than or equal to 0.2 µm prior to connection to the vacuum pump.

15.8. The **facility** must continue to have an automatic changeover emergency power source that is activated in the event of power failure. The emergency power source must continue to ensure continuing operation of the ventilation systems, biosafety cabinets, flexible film isolators, room access shower controls, emergency lighting, emergency communication systems, and control systems associated with ventilation, effluent and waste management. Uninterruptible Power Supplies (UPS) must be provided to any services that do not automatically restore correct control functions following changeover between normal power and emergency power, including personal breathing air sources in a suit area.

15.9. The **facility** must continue to be provided with a duress alarm system that, when triggered, raises an alert with at least one person external to the **facility**.

15.10. High performance respiratory equipment must continue to be available outside the **work area**.

Containment equipment conditions

16. The certification holder must ensure that the physical attributes of the **facility** and fittings are maintained so that the relevant 'Containment equipment requirements' listed in the Requirements for Certification at Part A of this document continue to be met, as follows:

16.1. The **facility** must continue to contain a biological safety cabinet (BSC) appropriate to the **dealings** being undertaken in the **facility**.

16.1.1. If a Class II BSC is used as the primary means of containment, then all persons in the **facility** must wear a positive pressure suit and follow the conditions listed in the section 'Suit area conditions' (see page 19).

16.1.2. Class III BSCs, including Flexible Film Isolators (FFIs), must be operated at negative pressure at all times and exhausted from the building with a minimum of 2 HEPA filters in series.

16.1.3. Installation, use and **decontamination** of all classes of BSC must be in accordance with the requirements of the relevant AS/NZS. The

inspection and testing of cabinets must be carried out by a qualified person.

Heating, ventilation and air conditioning conditions

17. The certification holder must ensure that the physical attributes of the **facility** and fittings are maintained so that the relevant 'Heating, ventilation and air conditioning requirements' listed in the Requirements for Certification at Part A of this document continue to be met, as follows:

    17.1. A non-recirculating ventilation system that establishes a negative air pressure gradient in the **facility** must continue to be provided to maintain a directional airflow into the **work area**. The supply and exhaust airflow must be separate and interlocked to prevent positive pressurisation of the **facility** in the event of failure of the exhaust fan. Interlocking that is independent of the building management system must be maintained.

    17.2. A differential pressure of at least 25 Pa between each room must be maintained to achieve air flow direction towards the **work area**.

    17.3. The pressure differential must be maintained by means of an independent room exhaust fan located downstream of the HEPA filter(s) and discharging to the outside atmosphere. All exhaust air and **decontaminating** gases used during gaseous **decontamination** of the **facility** and in the gaseous **decontamination** chamber must continue to be purged to the atmosphere in such a manner that it is dispersed away from occupied buildings and air intakes.

    17.4. The **facility** must continue to be equipped to measure and display the pressure difference between the **work area** and areas adjacent to the **facility**. The display must be located so it can be read before entering the **facility**.

    17.5. If a manometer/differential pressure gauge is used to sense the pressure differentials between adjacent areas, any differential pressure monitoring lines must continue to be fitted with a filter with pore size of less than or equal to 0.2 μm.

    17.6. The **facility** must continue to be equipped with an alarm that is visible and audible inside and outside the **facility** and activated when the pressure in the **work area**, inner change room or shower **airlock** is more than 15 Pa above the set point for more than 2 minutes.

    17.7. Supply and exhaust ductwork between the connection to the **facility** and the HEPA filter housings must continue to be gastight. Gastight valves and HEPA filters must continue to be located as close to the perimeter of the **facility** as practicable to minimise the lengths of potentially contaminated ducts.

    17.8. Supply or replacement air to the **facility** must continue to be HEPA filtered.

17.9. The supply and exhaust filters must continue to be HEPA filters as specified in Clause 1.3.15 of AS/NZS 2243.3:2002, or another filter that meets all requirements of AS 4260:1997 with a minimum performance of Grade 2.

17.10. The exhaust HEPA filters(s) must continue to be mounted in gastight housing, with sealed access doors, and the ductwork between the **facility** and the HEPA filter housing must also be gastight. The filter housing must be maintained to allow for access to, and integrity testing of, the HEPA filters. Exhaust air is to continue to be dedicated to the **facility** and completely separate from other areas.

17.11. Filter housings must have the following features maintained:

(a) a gastight isolating valve on the air outlet duct (and supply duct if present). If **decontamination** of the filters is to be performed separately from **decontamination** of the **facility**, an isolating valve on the air inlet duct and upstream and downstream valved ports is also required;
(b) secure filter element clamping and mounting tracks;
(c) filter chambers designed to allow gaseous **decontamination** before filters are removed;
(d) 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 filter with pore size of less than or equal to 0.2 µm that is protected from physical impact; and
(e) ability to withstand pressure of 2,500 Pa.

17.12. Any failure of the air handling 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.

Suit area conditions

18. When applicable, the certification holder must ensure that the physical attributes of the **facility** and fittings are maintained so that the relevant 'Suit area requirements' listed in the Requirements for Certification at Part A of this document continue to be met, as follows:

18.1. The entrance to the suit area must be through a chemical shower **airlock** fitted with gastight interlocked doors. The chemical shower must continue to incorporate a disinfectant that is effective against the micro-organisms **dealt** with in the suit area.

18.2. Persons who enter the suit area must wear a one-piece positive pressure suit that is ventilated by a life support system that includes an alarm and emergency back-up breathing air system.

18.3. An automatic second exhaust fan must be maintained to re-establish the negative pressure of the suit area in the minimum time possible in the event of exhaust fan failure. Supply and exhaust fan systems must continue to be

interlocked or provided with rapidly acting mechanisms to ensure positive pressures cannot occur in the suit area at any time. The exhaust air must be filtered through two HEPA filters installed in series.

18.4. The personal breathing air source must be connected to an Uninterruptible Power Supply (UPS) in accordance with condition 15.8.

18.5. An automatic changeover emergency power source that is activated in the event of power failure must be maintained. Essential control equipment must monitor and re-establish room pressure conditions during operation on emergency power. Sufficient uninterruptible power must continue to be provided to ensure this occurs.

Testing conditions

19. Inspections of all containment parameters (e.g. directional airflow) and life support systems must be completed daily before work is initiated.

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

    The cabinet(s) must pass tests for containment efficiency and a certificate, summarising the test results and the date of the next test, must be affixed to the cabinet.

    Where testing has shown that the performance requirements for air barrier containment or exhaust HEPA filter integrity are not met and the defect has not been corrected, the cabinet must be clearly marked to show that it is unsafe and must not be used for procedures involving **GMOs** until the defect has been corrected.

    A record of the annual test must be forwarded to **the Regulator** upon completion.

21. Annual testing and certification of the **facility** ventilation system must be carried out and must include:
    (a) testing of the pressure differentials to ensure compliance with conditions 17.1 & 17.2;
    (b) integrity testing of all HEPA filters in accordance with AS 1807.6:2000 or AS 1807.7:2000, as applicable, by a qualified person. The HEPA filter must be **decontaminated** prior to testing;
    (c) checking directional airflow;
    (d) verifying that the alarms operate when the air pressure in the **facility** is raised;
    (e) calibration of transducers fitted to the air-handling system and validation of air-handling performance (i.e. an over-pressure or under-pressure response);
    (f) calibration of pressure gauges;
    (g) the building management system; and
    (h) the air handling control system.

If any failures occur, **dealings** in the **facility** must cease until the failures are rectified and the device re-tested until compliance is achieved.

A record of the tests in items (a) to (h), and of any maintenance conducted, must be forwarded to **the Regulator** upon completion.

22. Air leakage testing of the **facility** must be undertaken every 3 years to coincide with recertification of the **facility**. Records must be forwarded to **the Regulator** upon completion.

23. Annual testing must be undertaken to ensure monitoring and communication arrangements result in the emergency procedures being initiated in a timely manner, and to ensure that the procedures are adequate.

24. Annual testing of the effectiveness of the effluent treatment and **decontamination** system must be carried out by a qualified person. Any failures must be rectified and the system(s) re-tested until compliance is achieved. Records must be forwarded to **the Regulator** upon completion.

25. The effectiveness of the **autoclave** must be validated monthly by the use of:
    (a) thermocouples or resistance thermometers, to ensure that the required temperature has been achieved; or
    (b) chemical indicators which use a combination of moisture, heat and time and which progressively change colour with the time exposed at the specified temperature; or
    (c) biological indicators such as spore strips; or
    (d) enzyme indicators; or
    (e) other methods approved in writing by **the Regulator**.

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

26. Calibration of the **autoclave** thermometer, timers, thermocouple and safety valves must be performed annually by a qualified person. The results of the annual **autoclave** tests, including evidence of calibration of the equipment used, must be forwarded to **the Regulator** upon completion.

    If an **autoclave** is found to be defective and the defect has not been corrected, the **autoclave** must be clearly marked to show that it is defective and must not be used for **decontaminating GMOs**, waste or equipment associated with **dealings** with **GMOs** until the defect has been corrected.

27. All testable water supply backflow prevention devices must pass an annual test, conducted in accordance with AS 2845.3:1993 by a licensed plumber accredited to test backflow prevention devices. Backflow test liquid must be treated as if contaminated. Any failures must be rectified and the device re-tested until compliance is achieved. A record of the annual test must be forwarded to **the Regulator** upon completion.

Health monitoring

28. Consideration must be given to providing persons entering the **facility** with any available immunisation against the organisms being used or likely to be used in the **facility**.

29. A documented system must be set up for reporting accidents and exposures to **GM** micro-organisms, for monitoring employee absenteeism, and for the medical surveillance of illnesses that are potentially **facility**-associated. Persons infected or suspected of being infected by organisms being used in the **facility** must be managed or treated in accordance with those systems, and **the Regulator** must be informed of each incident as soon as reasonably possible.

Facility management

30. A **facility** manager must be appointed. A **facility** manager must not be appointed unless the person so appointed understands, and is capable of demonstrating an understanding of, the technical aspects of **facility** design, operation and maintenance, including but not limited to the use and maintenance of the air-handling system, **autoclaves** and monitoring and alarm systems.

31. The certification holder must ensure that the **facility** manager is capable of undertaking the following functions:
    (a) developing and maintaining documented policies and documented procedures for the safe operation of the **facility**;
    (b) ensuring that access to the **facility** is restricted to authorised persons;
    (c) facilitating delivery of appropriate training to all persons, including training in animal and plant handling where appropriate;
    (d) development, documentation, implementation and annual review of a **facility** manual, as stipulated in condition 32;
    (e) development, documentation and implementation of **decontamination** procedures effective for all organisms and equipment used in the **facility**;
    (f) 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);
    (g) ensuring that successful **decontamination** of the **facility** is carried out before any maintenance procedures occur;
    (h) retention of documentation relating to the maintenance and testing of the **facility** equipment and services, including the air handling system, biosafety cabinets, **autoclave(s)** and gaseous **decontamination** of the **facility**;
    (i) co-ordination of immunisation of persons working within the **facility** where appropriate;
    (j) ensuring that emergency contact numbers are clearly visible from inside and outside the **facility**;
    (k) ensuring that access to external surfaces of the **facility** is restricted to authorised persons;
    (l) ensuring that a record of all organisms (**GM** and non-**GM**) used in the **facility** since the most recent gaseous **decontamination** is kept and is made available to **the Regulator** if requested.

32. A **facility** manual must be readily available to all authorised users of the **facility**. All procedures documented in the **facility** manual must be followed at all times by persons working in the **facility**. The manual must include:
    (a) the **facility** manager's contact details;
    (b) a list of persons authorised to enter the **facility**;
    (c) a copy of the certification instrument for the **facility**;
    (d) a copy of these *Guidelines for Certification of a PC4 Facility*;
    (e) a copy of the schematic of the **facility**;
    (f) a copy of all **licences** for work with **GMOs** and **NLRDs** integral to **licensed dealings** conducted in the **facility**;
    (g) a list of all organisms being **dealt** with in the **facility** and the risks associated with the use of these organisms, including animal handling where applicable;
    (h) documented procedures that must be followed by all persons entering and exiting the **facility**, including the use of personal protective clothing and equipment;
    (i) documented procedures for the use of positive pressure suits and biological safety cabinets, where applicable;
    (j) documented procedures for the use of normal and emergency communication systems;
    (k) documented procedures for the movement of all equipment into and out of the **facility**, including **decontamination** of that equipment;
    (l) documented procedures for **decontamination**;
    (m) documented procedures for waste and effluent disposal, including transport and **decontamination** procedures;
    (n) documented procedures for the transport of viable material inside the **facility**;
    (o) documented procedures for the transport of viable material outside the **facility** when approved in writing by **the Regulator**;
    (p) documented procedures for gaseous **decontamination** of the **facility** (this may include contact details of a company contracted to undertake the work);
    (q) a list of circumstances or events which must be notified to **the Regulator**;
    (r) documented emergency response plans, including procedures and specialised equipment required for responding to:
        (i) spills inside and outside the **facility**;
        (ii) accidental exposure to organisms used within the **facility**, including documented procedures for the management and treatment of persons suspected to be infected or contaminated with/exposed to Risk Group 4 organisms;
        (iii) alarms for fire or loss of pressure;
        (iv) loss, theft or unintentional release of **GMOs** from the **facility**;
        (v) failure of power or ventilation systems;
        (vi) fire and natural disasters;
        (vii) serious injury or medical emergencies to persons within the **facility**;
        (viii) security threats; and
        (ix) other life-threatening situations.

Animal control conditions

Where any of the **dealings** conducted in the **facility** involve animals, the **facility** must meet the following condition in addition to all other conditions listed:

33. The **facility** must have an effective insect and rodent control program in place.

Plant control conditions

Where any of the **dealings** conducted in the **facility** involve plants, the **facility** must meet the following condition in addition to all other conditions listed:

34. The **facility** must have an effective insect and rodent control program in place. Plants must be inspected at appropriate intervals for signs of infestation or unwanted disease infections. If the work permits, plants must be sprayed regularly with an appropriate pesticide.

Part C

Mandatory Behavioural Requirements

Physical Containment Level 4 Facility
Version 2.1 – effective 1 July 2007

Training

1. While the **facility** is in operation, all persons conducting **dealings** in the **facility** must be trained prior to entry in accordance with these Mandatory Behavioural Requirements.

2. While the **facility** is in operation, maintenance staff must be supervised by persons trained in accordance with these Mandatory Behavioural Requirements.

3. Where applicable, training must include theoretical instruction, supervised practical experience and assessment of competence in the **facility**.

4. Training must include familiarisation with the **facility** manual (see condition 32 of the Conditions for Certification at Part B of this document), as follows:
   (a) the persons to contact in case of emergency;
   (b) the conditions of the certification instrument for the **facility**;
   (c) the conditions and mandatory behavioural requirements set out in these *Guidelines for Certification of a PC4 Facility*;
   (d) the structure and operation of the **facility**;
   (e) the conditions of any **licences** for work with **GMOs** conducted in the **facility**;
   (f) familiarisation with the organisms being **dealt** with in the **facility** and the risks associated with the use of these organisms, including animal handling where applicable;
   (g) the procedures that must be followed by all persons entering and exiting the **facility**, including the use of personal protective clothing and equipment;
   (h) the procedures for the use of positive pressure suits and biological safety cabinets, where applicable;
   (i) the procedures for the use of normal and emergency communication systems;
   (j) the procedures for the movement of all equipment into and out of the **facility**, including **decontamination** of that equipment;
   (k) the procedures for **decontamination**;
   (l) the procedures for waste and effluent disposal, including transport procedures;
   (m) the procedures for the transport of viable material inside the **facility**
   (n) the procedures for the transport of viable material outside the **facility** when approved in writing by **the Regulator**;
   (o) the procedures and circumstances for gaseous **decontamination** of the **facility**;
   (p) the circumstances or events which must be notified to **the Regulator**;
   (q) the emergency response plans, including the procedures and use of specialised equipment required for responding to:

(i) spills inside and outside the **facility**;
(ii) accidental exposure to organisms used within the **facility**, including procedures for the management and treatment of persons suspected to be infected or contaminated with/exposed to Risk Group 4 organisms;
(iii) alarms for fire or loss of pressure;
(iv) loss, theft or unintentional release of **GMOs** from the **facility**;
(v) failure of power or ventilation systems;
(vi) fire and natural disasters;
(vii) serious injury or medical emergencies to persons within the **facility**;
(viii) security threats; and
(ix) other life-threatening situations.

5. Training of authorised persons involving the use of communication systems, responding to accidents and emergencies, and dealing with spills inside and outside the **facility** must be updated at least annually. Additionally, training in accordance with any of the mandatory behavioural requirements must be updated whenever the procedures are changed.

Entry and exit

6. The outer door of the **facility** must be kept locked at all times, except when persons are entering or exiting the **facility**.

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

   NOTE: It is recommended that proper directional airflow into the **facility** be verified prior to entry.

8. Persons entering or exiting the **facility** must indicate, either manually or electronically, the time of each exit and entry. Records of all entries and exits must be kept for 12 months and provided to **the Regulator** if requested.

9. Persons must enter and exit the **work area** only through the outer change room, shower **airlock** and inner change room.

10. Prior to entering the **facility**, persons must remove all street clothing in the outer change room. This clothing must be stored in the outer change room. The person must put on appropriate **facility** clothing, such as undergarments, pants, shirt or full body suit as applicable, shoes, and gloves, prior to entering the **work area** through the shower **airlock** and inner change room.

11. Before exiting the **facility**, persons must remove all **facility** clothing in the inner change room prior to showering in the shower **airlock**. In the event of an emergency, persons exiting the **facility** may omit showering. **Facility** clothing must be **decontaminated** before re-use or disposal.

Containment equipment

12. Any procedures with **GMOs**, including opening of any primary and secondary containers containing viable material, must be performed in a biological safety cabinet.

Decontamination

13. All **decontamination** procedures must be carried out by trained personnel.

14. **GMOs** must be rendered non-viable prior to disposal.

15. Wastes containing **GMOs** must be **decontaminated** prior to disposal.

16. Work benches, surfaces and equipment where procedures involving **GMOs** have taken place must be **decontaminated** when the **dealings** are completed.

17. Any equipment or non-viable material removed from the **facility** must be **decontaminated** prior to removal.

18. All liquid effluent, including that from the **work area**, shower and inner change room, must be **decontaminated** before being discharged.

19. Gaseous **decontamination** of the **facility** must take place:
    (a) in the event of a spill of viable organisms occurring outside of primary containment (eg. biological safety cabinet); or
    (b) prior to surrender or cancellation of certification; or
    (c) prior to re-certification of the **facility** at a lower containment level, if stipulated by **the Regulator**.

20. If provided, the dunk tank must be sealed during gaseous **decontamination** of the **facility**.

21. If provided, the gaseous **decontamination** chamber must be **decontaminated** after each exposure to the **work area**.

22. **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.

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

    NOTE: If an **autoclave** is used for **decontamination**:
    (a) loads must be packed and loaded to allow for the penetration of steam into the material being **decontaminated** in accordance with AS/NZS 2243.3:2002;
    (b) the coldest part of the load must be exposed to a minimum temperature of 121°C and 103 kPa for at least 15 minutes or at 134°C and 203 kPa for at least 3 minutes in accordance with AS/NZS 2243.3:2002;

(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.

24. Any chemical disinfectant treatment must be effective in rendering the **GMO** non-viable.

NOTE: AS/NZS 2243.3:2002 is a recommended source of information when selecting and using chemical disinfectant agents.

Spills

25. All accidents, spills and accidental exposures inside and outside the **facility** must be reported to **the Regulator** as soon as reasonably possible.

Removal and storage of GMOs

26. Viable material must not be transported from the **facility** unless written permission has been obtained from **the Regulator**.

27. **GMOs** that require **PC4** containment must not be stored outside of the **work area** of the **facility**.

Monitoring

28. When working in the **facility**, persons undertaking procedures with **GMOs** must be monitored by at least one other person.

NOTE: It is preferable that monitoring of persons is to be external to the **facility**, for example, by use of CCTV or a viewing panel.

Sharps

29. Needles and syringes or other sharp instruments must be restricted in the **facility** for use only when there is no alternative, such as for parenteral injection, phlebotomy, or aspiration of fluids from **facility** animals and diaphragm bottles. Non-disposable sharps must be placed in a hard-walled container for **decontamination**.

Personal effects

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

Suit area

Where a specially designed suit area is provided in the **facility**, persons entering the area must comply with the following mandatory behavioural requirements in addition to all other mandatory behavioural requirements listed:

31. Entry to the suit area must be through a chemical shower **airlock** fitted with gastight interlocked doors in addition to the outer change room, shower **airlock** and inner change room described in mandatory behavioural requirement 9.

32. The operation of the suit must be tested before entering the **work area**.

33. Upon exiting the **work area**, a chemical disinfectant shower must be taken in the chemical shower **airlock** to **decontaminate** the outer surface of the suit. The suit and clothing must be removed in the inner change room, and a full body shower must be taken in the shower **airlock** before leaving the **facility**.

Animal handling

Where any of the **dealings** conducted in the **facility** involve animals, persons must comply with the following mandatory behavioural requirements in addition to all other mandatory behavioural requirements listed:

34. Animals kept in pens must be restrained while housed in the **facility**.

35. Persons undertaking procedures with animals must be trained to do so in accordance with mandatory behavioural requirement 4(f).

36. Where **dealings** involve animals infected with **GM** Risk Group 4 human pathogens, measures must be taken to prevent exposure to those pathogens.

    NOTE: Measures may include the use of BSCs, sealed HEPA filtered cages, or where the room is the primary containment barrier, a one-piece positive pressure suit.

Non-compliance

37. Any non-compliance with the conditions and mandatory behavioural requirements set out in these *Guidelines for Certification of a PC4 Facility*, including any actual or suspected unintentional release of **GMOs** from the **facility**, must be reported to **the Regulator** as soon as reasonably possible.

Attachment 1

Standards referenced in this document

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

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

AS 1324.1:2001	Air filters for use in general ventilation and airconditioning Part 1: Application, performance and construction
AS 1324.2:1996	Air filters for use in general ventilation and airconditioning Part 2: Methods of test
AS 1807.6:2000	Cleanrooms, workstations, safety cabinets and pharmaceutical isolators - Methods of test Method 6: Determination of integrity of terminally mounted HEPA filter installations
AS 1807.7:2000	Cleanrooms, workstations, safety cabinets and pharmaceutical isolators - Methods of test Method 7: Determination of integrity of HEPA filter installations not terminally mounted
AS/NZS 2243.3:2002	Safety in laboratories Part 3: Microbiological aspects and containment facilities
AS 2845.3:1993	Water supply - Backflow prevention devices Part 3: Field testing and maintenance
AS/NZS 3500.1:2003	Plumbing and drainage Part 1: Water services
AS 4260:1997	High efficiency particulate air (HEPA) filters Classification, construction and performance