



Application Checklist for a Physical Containment Level 3 Invertebrate Facility

(Checklist against the requirements of the Gene Technology Regulator's *Guidelines for Certification of a Physical Containment Level 3 Invertebrate Facility, Version 2.1 – 21 September 2011*)

Organisation Name

Facility Name

IBC Name

Is this checklist provided as part of an application for:

Certification of a new facility?

Variation to an existing Certification?

For variations please provide the OGTR Certification Number

Name(s) and signature(s) of person(s) inspecting the facility (please print name clearly)

Date of Inspection

Time taken to complete this form:

Hours		Minutes	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Please read this page first

Important Notes

- If you require more space, please attach the information and indicate that you have added an attachment.
- If in answer to any of the questions below you have indicated there is work pending completion or procedures yet to be implemented, please provide the expected completion date. Please be aware that the OGTR will require confirmation when work has been completed and it is unlikely the facility will be certified until this confirmation has been received.

Requirements for a Physical Containment Level 3 Invertebrate Facility

Please tick the appropriate answer or provide the requested information for the following questions, which relate to the conditions applying to the specified Invertebrate Facility.

Section 1 – Facility construction and access requirements

Please answer all questions in this section.

Requirement 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.

Q. 1 Does the facility comply with requirement 1?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 2. The facility must be constructed to enable gaseous decontamination of the whole facility to be achieved.

Q. 2 Does the facility comply with requirement 2?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

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

Q. 3 Does the facility comply with requirement 3?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 4. The facility boundaries (walls, doors, floors, windows, ceilings etc.) must be constructed and maintained to prevent the escape of the organisms being contained and to prevent the incursion of pests.

Q. 4 Does the facility comply with requirement 4?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

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

Q. 5 Does the facility comply with requirement 5?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

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

Q. 6 Does the facility comply with requirement 6?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

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

Q. 7 Does the facility comply with requirement 7?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

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

Q. 8 Does the facility comply with requirement 8?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

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

Q. 9 Does the facility comply with requirement 9?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 10. Provision must be made for viewing of work areas from outside the facility.

Q. 10 Does the facility comply with requirement 10?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

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

Q. 11 Does the facility comply with requirement 11?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

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

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

Q. 12 Does the facility comply with requirement 12?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 13. Benches, cupboards, and other fittings and services must be installed to enable decontamination, including gaseous decontamination, of all spaces in the facility. Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.

Q. 13 Does the facility comply with requirement 13?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 14. Any openings in the walls or ceiling, such as ventilation inlets and outlets, must be screened. The screens must be fixed and sealed against their mounting. The apertures of the screen must be sufficiently small as to prevent entry or exit of invertebrates or other animals.

Q. 14 Does the facility comply with requirement 14

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 15. Where present, liquid drainage exits must be protected against entry or exit of invertebrates or other animals by the use of screens, liquid traps or an equivalent effective method. The apertures of the screen must be sufficiently small as to prevent entry or exit of invertebrates or other animals.

Q. 15.1 Is this condition relevant to the facility?

Yes. Answer Q15.2

No. Continue to condition 16

Q. 15.2 Does the facility comply with requirement 15

Yes

No – please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 16. The facility must have two alternative, independent communication systems for contact between persons inside and outside the facility. Two-way communication must be able to be conducted on at least one system.

Q. 16 does the facility comply with requirement 16

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

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

Q. 17 Does the facility comply with requirement 17

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Section 2 – Containment equipment requirements

Please answer all questions in this section.

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

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

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

Q. 18 Does the facility comply with requirement 18?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Section 3 – Laboratory Services and equipment requirements

Please answer all questions in this section.

Requirement 19. The facility must contain an autoclave that is suitable for the load size and type of material to be decontaminated. The autoclave must not be located in the airlock or anteroom.

Q. 19 Does the facility comply with requirement 19?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to

rectify the situation OR reasons why an exemption may be justified.

Requirement 20. The following water supplied to the facility must be protected against backflow by registered testable devices that have a high hazard rating for protection against both back-pressure and back-siphonage in accordance with the requirements of AS/NZS 3500.1:

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

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

Q. 20 Does the facility comply with requirement 20?

Yes – Please provide the location(s) of the backflow prevention device(s)

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

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

Q. 21 Does the facility comply with requirement 21?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 22. The anteroom and work area of the facility must contain either a dedicated hand wash basin fitted with tap(s) of the hands-free operation type, or some other means of decontaminating hands at or near the exit of the anteroom and the work area. If the facility contains multiple work areas, each work area must contain a dedicated hand wash basin or some other means of decontaminating hands at or near the exit of that work area.

Q. 22 Does the facility comply with requirement 22?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 23. The work area of the facility must contain eyewash equipment (either plumbed eyewash equipment or single-use packs of sterile eye irrigation fluids).

Q. 23 Does the facility comply with requirement 23?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

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

Q. 24.1 Is this requirement relevant to the facility?

Yes. Answer 24.2

No. Continue to requirement 25

Q. 24.2 Does the facility comply with requirement 24?

Yes

No - reason(s) for non-compliance and details of any actions being taken to rectify the situation.

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

Q. 25.1 Is this requirement relevant to the facility?

Yes. Answer 25.2

No. Continue to requirement 26

Q. 25.2 Does the facility comply with requirement 25?

Yes

No - reason(s) for non-compliance and details of any actions being taken to rectify the situation.

Section 4 – Ventilation requirements

Please answer all questions in this section.

Requirement 26. The facility must have a ventilation system that establishes a negative air pressure gradient in the facility and directional airflow into a work area. All exhaust air from the facility must be filtered. Where facilities have a supply air system, the supply and exhaust air systems must be interlocked to prevent positive pressurisation of the facility in the event of failure of the exhaust system.

Q. 26 Does the facility comply with requirement 26?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 27. The work area must be maintained at an air pressure of at least 50 Pa below the pressure of adjacent areas outside the facility when both airlock doors are closed. When either door is open, the work area pressure must remain at least 25 Pa below that of the adjacent areas outside of the PC3 containment barrier.

Q. 27 Does the facility comply with requirement 27?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 28. The pressure differential must be achieved by means of an independent room exhaust fan located downstream of a HEPA filter and discharging to the outside atmosphere. All exhaust air and decontaminating gases used during gaseous decontamination of the facility must be able to be purged to the atmosphere in such a manner that it is dispersed away from occupied buildings and air intakes.

Q. 28 Does the facility comply with requirement 28?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 29. The exhaust filter must be a HEPA filter as specified in the definitions to this document, or another filter that meets all requirements of AS 4260 with a minimum performance of Grade 2. An exhaust pre-filter of the same or higher standard as the supply filter must be installed and mounted upstream of the HEPA filter.

Q. 29 Does the facility comply with requirement 29?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 30. Each exhaust HEPA filter must be mounted in a gastight housing, with sealed access doors, and the ductwork between the facility and the HEPA filter housing must also be gas-tight. The design and location of the filter housing(s) must allow for access to and integrity testing of the HEPA filter.

Q. 30 Does the facility comply with requirement 30?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 31. HEPA filter housings must incorporate the following features:

- (a) a gas-tight isolating valve on the air outlet duct (and air inlet duct, if present). If gaseous decontamination of the filter is to be performed separately from decontamination of the facility, isolating valves on the air inlet duct and upstream and downstream valved ports are also required;
- (b) secure filter element clamping and mounting tracks;
- (c) if the housing contains upstream and downstream valved pressure tapings to permit monitoring and display of the filter air flow pressure drop, the tapping on the facility side of the HEPA filter must be fitted with a 0.2µm hydrophobic membrane type filter that is protected from physical impact; and

- (d) where separate supply ducts are not fitted, HEPA filter gaseous decontamination would require decontamination of the facility as well.

Q. 31 Does the facility comply with requirement 31?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 32. The work area must be equipped to measure and display the pressure difference between the facility and areas adjacent to the facility. The display must be located so it can be read immediately before entering the facility.

Q. 32 Does the facility comply with requirement 32?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 33. The facility must be equipped with an alarm that will alert people both inside and outside the facility, and be activated when the pressure in the facility is more than 25 Pa above the set point.

Q. 33 Does the facility comply with requirement 33?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 34. The facility must have an emergency stop button for the ventilation system, which is easily accessible in case of an emergency. The emergency stop button must operate independently of the main ventilation control and main facility pressure control system such that emergency isolation of the ventilation can be implemented in event of central control system malfunction.

Q. 34 Does the facility comply with requirement 34?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Requirement 35. Supply or replacement air to the facility must be filtered with Type 1 Class A or Class B filters complying with AS 1324.1 and having a minimum arrestance efficiency of 90% when tested in accordance with AS 1324.2 with Test Dust No. 4. Where replacement air is drawn from adjacent areas, adjustable dampers must be provided in the transfer aperture to assist in setting up the reduced room pressure. This aperture and filter must not be mounted in the door.

Q. 35 Does the facility comply with requirement 35?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Section 5 – Documentation to be supplied with the application

Requirement 36. The following documentation must be submitted with the application for certification of the PC3 Invertebrate Facility:

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

Q. 36 Have the documents outlined in requirement 36 been provided with the application?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.

Section 6 – Capacity to comply with certification conditions

Requirement 37. The applicant must be able to demonstrate a capacity to comply with the conditions of certification that will generally be applied to a certified PC3 Invertebrate Facility.

Q. 37 Does the facility comply with requirement 37?

Yes

No - please explain the reasons for non-compliance and details of EITHER any actions being taken to rectify the situation OR reasons why an exemption may be justified.