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

Checklist for a Physical Containment Level 3 Laboratory

(Checklist against the requirements of the Gene Technology Regulator's *Guidelines for Certification of a Physical Containment Level 3 Laboratory, Version 3.1 – 28 May 2012*)

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	

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 Laboratory

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

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

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

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. 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.

Q. 6.1 Is this requirement relevant to the facility?

☐ **Yes. Answer 6.2**

☐ **No. Continue to Requirement 7**

Q. 6.2 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. 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.

Q. 7.1 Is this requirement relevant to the facility?

☐ **Yes. Answer 7.2**

☐ **No. Continue to Requirement 8**

Q. 7.2 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. 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

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. 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. 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. 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.

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

Q. 11 Does the facility comply with Requirement 11?

☐ **Yes**

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

Requirement 12. Provision must be made for viewing of work areas from outside the facility.

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. 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. 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.

Section 2 – Containment equipment requirements

Please answer all questions in this section.

Requirement 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.

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. 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.

Q. 15 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.

Section 3 – Laboratory Services and equipment requirements

Please answer all questions in this section.

Requirement 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.

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

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.

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

(a) laboratory sink outlets;
(b) outlets within a BSC or other aerosol containment equipment; and
(c) direct connections to an autoclave.

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

Q. 18 Does the facility comply with Requirement 18?

☐ **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 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.

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

Q. 20 Does the facility comply with Requirement 20?

☐ **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 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.

Q. 21.1 Is this requirement relevant to the facility?

☐ **Yes. Answer 21.2**

☐ **No. Continue to Requirement 22**

Q. 21.2 Does the facility comply with Requirement 21?

☐ **Yes**

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

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

Q. 22.1 Is this requirement relevant to the facility?

☐ **Yes. Answer 22.2**

☐ **No. Continue to Requirement 23**

Q. 22.2 Does the facility comply with Requirement 22?

☐ **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 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.

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. 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.

Q. 24 Does the facility comply with Requirement 24?

☐ **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 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.

Q. 25 Does the facility comply with Requirement 25?

☐ **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 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 discharges 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 it is dispersed away from occupied buildings and air intakes.

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. 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.

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 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.

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. 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.

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. 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..

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. 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.

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 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.

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.

Section 5 – Capacity to comply with certification conditions

Requirement 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.

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.

Section 6 – Documentation to be supplied with the application

Requirement 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.

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.