



Checklist for a Physical Containment Level 2 Large Scale Facility

(Checklist against the requirements of the Gene Technology Regulator's *Guidelines for Certification of a Physical Containment Level 2 Large Scale Facility*)

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 2 Large Scale Facility

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

Section 1 – Facility requirements

Please answer all questions in this section.

Requirement 2. The **facility** to be certified must be a fully enclosable space bounded by walls, doors, windows, floors and ceilings, to prevent the release of any genetically modified organisms ('GMOs').

Q. 2.1 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. Any openings in the walls, ceiling or roof, such as air vents, must be screened with insect proof mesh.

Q. 3.1 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 following surfaces in the **facility** must be smooth, impermeable to water, cleanable, and resistant to damage by the cleaning agents and/or disinfectants that will be used in the **facility**:

- (a) walls, floors, and benches; and
- (b) ceilings, and any other surfaces, where contamination can occur or where **decontamination** is required.

Facility furniture, including seating, must be able to be **decontaminated**.

Q. 4.1 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. If the **facility** has floor drainage exits, all effluent from these drains must be **decontaminated** by heat treatment or chemical treatment before being discharged. If the **facility** has a sink, then all liquid effluent must be **decontaminated** prior to discharge down the sink.

Q. 5.1 Is this requirement relevant to your Large Scale Facility?

Yes. Answer 5.2

No. Continue to Requirement 6

Q. 5.2 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. Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.

Q. 6.1 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 either a wash basin fitted with hands-free tap(s) and supplied with potable water, or some other means of **decontaminating** hands.

Q. 7.1 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. Emergency drench showers and eyewash equipment (either plumbed eyewash equipment or single-use packs of sterile eye irrigation fluids) must be provided within the **facility**.

Q. 8.1 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. Potable 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 Australian Standard/New Zealand Standard ('AS/NZS') 3500.1.

Q. 9.1 Does the facility comply with requirement 9?

Yes – Please provide details of where the backflow prevention device is located

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. Designated storage or hanging provisions for protective clothing must be available within the **facility**.

Q. 10.1 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.

Section 2 – Containment equipment requirements

Please answer all questions in this section.

Requirement 11. All cultures of GMOs, with the exception of inocula and samples taken during production, must be contained within a closed system (ie, closed vessel used for propagation, growth and storage, and closed lines used for transfer).

Any closed system must be capable of being **decontaminated** *in situ*.

Gaseous exhaust products removed from any closed system must be filtered to prevent release of **aerosols** containing GMOs.

Q. 11.1 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. Where **procedures** in the **facility** (other than the process of inoculating, culturing GMOs within, and taking samples from, closed systems) will produce **aerosols** containing GMOs then the **facility** must contain a biological safety cabinet, or other equipment specifically approved in writing by the Gene Technology Regulator ('the Regulator') that is designed to contain **aerosols**.

Where any Class I or Class II biological safety cabinets is installed it must be installed in accordance with the requirements of AS/NZS 2647.

Q. 12.1 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. Other equipment used to process GMOs, (eg centrifuges, filtration systems), must be designed to contain the organisms.

Q. 13.1 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. Secondary containment, such as **bunding**, must be provided to retain any leakage from the closed system. It must be of sufficient capacity to retain:

- (a) the maximum volume of fluid in the closed system; and
- (b) the volume of any disinfectant that might be used,

with additional capacity to prevent any expected general fluid movement from breaching the secondary containment.

Q. 14.1 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.

Section 3 – Capacity to comply with certification conditions

Please answer all questions in this section.

Requirement 15. The **facility** must be able to demonstrate that it is capable of complying with the conditions of certification that will be applied to a certified PC2 Large Scale Facility, as attached to the 'Requirements for Certification' in the *Guidelines for Certification of Physical Containment Facilities, PC2 Large Scale Version 2.1*.

Q. 15.1 Will the facility be capable of complying with the conditions of certification that will be applied to a certified PC2 Large Scale Facility?

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.