



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

Annual Inspection Checklist for a PC 1 Large Scale Facility

Checklist for annual inspection against the usual Conditions of Certification of the Gene Technology Regulator's Guidelines for Certification of a Physical Containment Level 1 Large Scale Facility version 2.1 – 1 September 2006

Organisation Name

Facility Name

OGTR Certification
Number

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

Date of Inspection

Please Note

- The use of this checklist proforma is **not** mandatory in order to satisfy the annual inspection reporting component of Condition 21. Rather, it is provided to assist those who find it convenient to use in the annual inspection of certified facilities for compliance with the conditions of certification under Condition 21.
- A completed copy of this proforma will be accepted by the OGTR as the annual inspection report for a certified facility under Condition 21, but the proforma is **not** intended to be the **only** acceptable format for the report.
- Please use the 'Application Checklist' against the requirements for certification (as opposed to this 'Annual Inspection Checklist') when applying for a new certification, or when seeking a variation to the requirements for certification of a facility (e.g. lifting the suspension of a certification after modifications to the facility.)
- **Please do not send this report to the OGTR unless specifically requested.**

Conditions of Certification for a Physical Containment Level 1 Large Scale Facility

About completing this proforma

- The conditions in this proforma are the usual conditions of certification as detailed in the Gene Technology Regulator's *Guidelines for Certification of a Physical Containment Level 2 Aquatic Organism Facility Version 2.1 - 1 September 2006*.
- Where an exemption or variation to one or more conditions of certification has been approved by the Regulator (or delegate) then inspection must be made against the conditions as approved on the instrument of certification for the facility.
- In such cases you can make a note in the space provided and report on compliance against the variation to the usual condition that is detailed on the proforma.
- If answering '**No**' to a condition for which there is no exemption or variation, please make a comment about the reason for the non-compliance and any actions being taken to rectify the situation.

Section 1 – Work not permitted in this facility

Please answer all questions in this section.

Condition 1. The following work must not be conducted in this facility:

- (a) work with any GMO that under the Act, or under the conditions of a licence, requires containment in any physical containment level higher than PC1;
- (b) the housing/keeping/rearing of any animals or aquatic organisms; or
- (c) the growing of any plants.

Q. 1.1 Does the facility comply with condition 1?

Yes

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

Condition 2. (Intentionally left blank.)

Section 2 – Facility conditions

Please answer all questions in this section.

Condition 3. The facility must be labelled with the following adhesive signs:

- (a) a PC1 sign, as supplied by the OGTR; and
- (b) a biohazard symbol.

Q. 3.1 Does the facility comply with condition 3?

Yes

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

Condition 4. The facility must be maintained as a fully enclosable space contained within walls, doors, windows, floors and ceilings. Doors and windows must be maintained so they are lockable.

Any changes to the physical structure of a facility must not affect compliance with these conditions of certification.

Q. 4.1 Does the facility comply with condition 4?

Yes

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

Condition 5. Any openings in the walls, ceiling or roof, such as air vents, must be screened with insect proof mesh.

Q. 5.1 Is this condition relevant to the facility?

Yes. Answer 5.2

No. Continue to condition 6

Q. 5.2 Does the facility comply with condition 5?

Yes

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

Condition 6. 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. 6.1 Does the facility comply with condition 6?

Yes

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

Condition 7. Open spaces between and under benches, cabinets and equipment must be accessible for cleaning at all times.

Q. 7.1 Does the facility comply with condition 7?

Yes

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

Condition 8. 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. 8.1 Does the facility comply with condition 8?

Yes

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

Condition 9. Eyewash facilities (either a plumbed eyewash facility or single-use packs of sterile eye irrigation fluids) must be provided within the facility at all times. If plumbed facilities are installed, they must be used and maintained in accordance with the manufacturer's instructions.

Q. 9.1 Does the facility comply with condition 9?

Yes

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

Condition 10. Where any device or system that may cause contamination of a potable water supply is connected directly or indirectly to any part of a water service, backflow prevention must be enabled via a registered testable device that has an appropriate hazard rating for protection against both back-pressure and back-siphonage in accordance with the requirements of AS/NZS 3500.1.

Q. 10.1 Is this condition relevant to the facility?

Yes. Answer 10.2

No. Continue to condition 11

Q. 10.2 Does the facility comply with condition 10?

Yes

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

Condition 11. If the facility is fitted with any testable water supply backflow prevention devices (in accordance with AS/NZS 3500.1), these devices must pass a test every 12 months. These tests must be conducted in accordance with AS 2845.3 by a licensed plumber accredited to test backflow prevention devices.

Q. 11.1 Is this condition relevant to the facility?

- Yes. Answer 11.2
- No. Continue to condition 12

Q. 11.2 Does the facility comply with condition 11?

Yes

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

Condition 12. Designated storage or hanging provisions for protective clothing must be available within the facility at all times.

Q. 12.1 Does the facility comply with condition 12?

Yes

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

Condition 13. A supply of disinfectants effective against the GMOs used in the facility must be available in the facility for decontamination purposes. Containers of disinfectants must be clearly labelled with the contents and, where relevant, the expiry date.

Q. 13.1 Does the facility comply with condition 13?

Yes

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

Section 3 – Containment equipment conditions

Please answer all questions in this section.

Condition 14. Where any biological safety cabinets are installed and used for procedures with GMOs, they must be inspected and tested in accordance with the Conditions for Certification.

Q. 14.1 Is this condition relevant to the facility?

Yes. Answer 14.2

No. Continue to condition 15

Q. 14.2 Does the facility comply with condition 14?

Yes

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

Condition 15. All cultures of GMOs, with the exception of inocula and samples taken during production, must be contained within a primary container or closed vessel.

Any closed system must be maintained so that it is capable of being decontaminated *in situ*.

Q. 15.1 Does the facility comply with condition 15?

Yes

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

Condition 16. Secondary containment, such as bunding, must be maintained in the facility to retain any leakage from the closed system. It must be of sufficient capacity to retain:

- (a) the maximum volume of fluid in the primary container or 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. 16.1 Does the facility comply with condition 16?

Yes

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

Section 4 – Facility management

Please answer all questions in this section.

Condition 17. Access to the facility must be restricted to authorised persons and/or authorised classes of persons.

Q. 17.1 Does the facility comply with condition 17?

Yes

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

Condition 18. The facility must have procedures and the means in place to clean up any spills in the facility, including large spills, involving GMOs.

Q. 18.1 Does the facility comply with condition 18?

Yes

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

Condition 19. All facility personnel must be trained in the use of equipment present in the facility and also in the procedures to be used in the facility. Records of this training must be kept.

Q. 19.1 Does the facility comply with condition 19?

Yes

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

Condition 20. The facility must be kept free of pests. A record of any pest prevention strategies or pest control activities must be kept and made available to the Regulator if requested, along with the dates and details of any pest control and/or eradication activities.

Q. 20.1 Does the facility comply with condition 20?

Yes

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

Condition 21. The facility must be inspected at least once every 12 months. The inspection report must detail the extent of compliance with the conditions of certification and a copy of the most recent inspection report must be provided to the Regulator if requested.

Q. 21.1 Does the facility comply with condition 21?

Yes

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

Section 5 – Personal protective clothing and equipment

Please answer all questions in this section.

Condition 22. The following personal protective clothing must be worn by personnel performing procedures in the facility:

- (a) laboratory coat or gown, or equivalent, to protect the arms and front part of the body from spills or any other source of contamination.

Q. 22.1 Does the facility comply with condition 22?

Yes

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

Condition 23. Laboratory coats, gowns or equivalent and equipment must be removed before leaving the facility and stored in designated storage or hanging provisions or disposed of.

Q. 23.1 Does the facility comply with condition 23?

Yes

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

Section 6 – Work practices

Please answer all questions in this section.

Condition 24. Facility doors must remain closed when laboratory procedures are in progress and must be locked when the facility is unattended.

Q. 24.1 Does the facility comply with condition 24?

Yes

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

Condition 25. Windows must remain closed while procedures are in progress.

Q. 25.1 Does the facility comply with condition 25?

Yes

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

Condition 26. Work benches, surfaces and equipment where procedures involving GMOs have taken place must be decontaminated when the procedures are completed.

Q. 26.1 Does the facility comply with condition 26?

Yes

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

Condition 27. All work surfaces and equipment where maintenance is to be carried out must be decontaminated prior to maintenance taking place.

Q. 27.1 Does the facility comply with condition 27?

Yes

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

Condition 28. If a spill of GMOs occurs in the facility, a spills procedure (as required in Condition 18) must be implemented to decontaminate the spill.

Q. 28.1 Does the facility comply with condition 28?

Yes

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

Condition 29. Decontamination of contaminated items or material must be performed in accordance with the Conditions of Certification.

Q. 29.1 Does the facility comply with condition 29?

Yes

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

Condition 30. Decontamination must be effected in accordance with the Conditions of Certification.

Q. 30.1 Does the facility comply with condition 30?

Yes

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

Condition 31. Where use of a pressure steam steriliser (autoclave) is required for sterilisation purposes, it must be used in accordance with the Conditions for Certification.

Q. 31.1 Is this condition relevant to the facility?

- Yes. Answer 31.2
- No. Continue to condition 32

Q. 31.1 Does the facility comply with condition 31?

Yes

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

Condition 32. Organisms that are not GMOs must not be removed from the facility while a dealing with a GMO is occurring in a facility unless:

- (a) procedures are implemented to ensure that dealings with GMOs do not mix with or contaminate work with any other organisms that are not part of the dealing;
- (b) the above procedures are documented; and
- (c) all primary containers and transport containers are decontaminated prior to removal from the facility.

If mixing or cross-contamination of any other work by GMOs occurs, or is suspected to have occurred, then the other work must be handled and disposed of in accordance with the conditions of certification, as if it were dealing with a GMO.

Q. 32.1 Is this condition relevant to the facility?

- Yes. Answer 32.2
- No. Continue to condition 33

Q. 32.2 Does the facility comply with condition 32?

Yes

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

Condition 33. Volumes greater than 25 litres of culture containing GMOs must not be removed from the facility.

Volumes less than or equal to 25 litres of culture containing GMOs must not be removed from the facility unless:

- (a) they are to be transported to a containment facility that at least meets the Regulator's requirements for PC1 level containment;
- (b) they are to be transported to another location for storage;
- (c) they are to be transported for disposal or decontamination prior to disposal; or
- (d) written permission has been given by the Regulator for transport to another destination.

Q. 33.1 Is this condition relevant to the facility?

- Yes. Answer 33.2**
- No. Continue to condition 34**

Q. 33.2 Does the facility comply with condition 33?

- Yes**

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

Condition 34. All GMOs, and waste contaminated with GMOs, being transported out of the facility must be transported in accordance with any transport guidelines and other relevant guidelines, as in force from time to time, issued by the Regulator.

Q. 34.1 Does the facility comply with condition 34?

- Yes**

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

Condition 35. Volumes less than or equal to 25 litres of cultures containing GMOs may be stored outside the facility in a storage unit (freezer, fridge, controlled temperature room or other controlled temperature container). A biohazard symbol must be posted on the storage unit and it must be locked when not in use, unless access is restricted to the room or area where the storage unit is located.

Q. 35.1 Is this condition relevant to the facility?

- Yes. Answer 35.2
- No. Continue to condition 36

Q. 35.2 Does the facility comply with condition 35?

- Yes

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

Condition 36. GMOs or organisms infected with GMOs being stored outside the certified facility must be double-contained. The primary container must be sealed and leak proof. The primary container must be clearly labelled so it can be identified and must be stored in an unbreakable secondary container. In the case of a small storage unit such as a fridge, freezer or liquid nitrogen container, the secondary container may be the storage unit.

Q. 36.1 Is this condition relevant to the facility?

- Yes. Answer 36.2
- No. Continue to condition 37

Q. 36.2 Does the facility comply with condition 36?

- Yes

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

Condition 37. Transport of GMOs between the certified facility and the storage unit must be in accordance with any transport guidelines and other relevant guidelines, as in force from time to time, issued by the Regulator. Any spills of GMOs that occur outside the certified facility must be reported to the Regulator as soon as practicable. The spilt material and any contaminated surfaces must be decontaminated.

Q. 37.1 Is this condition relevant to the facility?

Yes. Answer 37.2

No. Continue to condition 38

Q. 37.2 Does the facility comply with condition 37?

Yes

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

Condition 38. All cultures of viable material must be clearly identified and labelled.

Q. 38.1 Does the facility comply with condition 38?

Yes

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

Condition 39. Any unintentional release or suspected unintentional release of GMOs from the facility must be reported to the Regulator as soon as practicable.

Q. 39.1 Does the facility intend to comply with condition 39 when applicable?

Yes

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

Condition 40. Persons who have been performing procedures in the work area must remove gloves and/or decontaminate their hands before leaving the work area. This can be achieved by washing, or use of appropriate chemical decontaminant.

Q. 40.1 Does the facility comply with condition 40?

Yes

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