



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

Annual Inspection Checklist for a PC 3 Laboratory

Checklist for annual inspection against the usual Conditions of Certification as detailed in the Gene Technology Regulator's *Guidelines for Certification of a Physical Containment Level 3 Laboratory*
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 39. 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 39.
- A completed copy of this proforma will be accepted by the OGTR as the annual inspection report for a certified facility under Condition 39, 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 3 Laboratory

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 PC3; or
- (b) the containment of animals and plants for longer than the minimum time necessary to complete laboratory procedures.

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 Physical Containment Level 3 (PC3) sign, as supplied by the Office of the Gene Technology Regulator (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 bounded by walls, doors, windows, floors and ceilings and must allow the operation of the facility under negative pressure.

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. Entry to the work area must be through an airlock. Airlock doors must remain closed when not in normal use (eg. persons entering or exiting the facility). Airlock doors must be self-closing, fitted with seals and must contain at least one glass viewing panel. The outer door must be lockable. Physical mechanisms (eg. interlocking or alarm system) must be in place to ensure that only one door can be opened at any time.

Q. 5.1 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. Windows in the facility must be closed and sealed.

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. All walls, floors, ceilings, benches and furniture surfaces must be smooth, impermeable to water, cleanable and resistant to damage by the cleaning agents, disinfectants and fumigants used in the facility.

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. 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.

Any heat treatment must be performed using a combination of temperature and time that has been validated as effective against the organisms being rendered non-viable.

Q. 8.1 Is this condition relevant to the facility?

Yes. Answer 8.2

No. Continue to condition 9

Q. 8.2 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. The facility must be constructed to enable fumigation of the whole facility to take place. Benches, cupboards and services must be constructed to enable decontamination, including fumigation, of all spaces in the facility. Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.

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. A communication system and a backup system must be provided inside the facility.

Q. 10.1 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. The facility must contain an autoclave.

Q. 11.1 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. The work area of the facility must contain either a dedicated hand wash basin fitted with hands-free tap(s) and supplied with potable water, or some other means of decontaminating hands. If the facility contains multiple laboratories, each laboratory must contain a dedicated hand wash basin or some other means of decontaminating hands at or near the exit of each laboratory.

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. Eyewash equipment (either plumbed eyewash equipment or single-use packs of sterile eye irrigation fluids) must be provided within the facility. Eyewash equipment must be used and maintained in accordance with the manufacturer's instructions.

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.

Condition 14. 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 AS/NZS 3500.1. Backflow prevention must isolate the certified PC3 facility or a group of certified PC3 facilities to the exclusion of all other areas.

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 testable backflow devices must pass a test every 12 months, conducted in accordance with AS 2845.3, by a licensed plumber accredited to test backflow prevention devices. Documentation of the most recent test results must be kept.

Q. 15.1 Is this condition relevant to the facility?

Yes. Answer 15.2

No. Continue to condition 16

Q. 15.2 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. Where a central reticulated vacuum system or portable vacuum pumps are used, 0.2 µm hydrophobic membrane-type filters, and liquid disinfectant traps must be installed at the point of use.

Q. 16.1 Is this condition relevant to the facility?

Yes. Answer 16.2

No. Continue to condition 17

Q. 16.2 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.

Condition 17. Designated storage or hanging provisions for personal protective clothing and equipment must be available within the facility, adjacent to the work area access door. Storage for personal effects, coats, etc must be provided outside the facility.

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. A supply of disinfectants effective against the organisms 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 necessary, the expiry date.

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.

Section 3 –Ventilation conditions

Please answer all questions in this section.

Condition 19. A ventilation system that establishes a negative air pressure gradient in the facility must be provided. Where facilities have supply air systems, the supply and exhaust airflow must be interlocked to prevent positive pressurisation of the facility in the event of failure of the exhaust fan. Directional airflow must be established in the facility to move air from the least to the most contaminated areas in the facility.

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. Any failure of the air handling system (exhaust air fan or interlocked supply/exhaust 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 practicable.

Q. 20.1 Does the facility intend comply with condition 20 when applicable?

Yes

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

Condition 21. 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 is open, the work area pressure must remain at least 25 Pa below that of the adjacent areas outside the facility.

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.

Condition 22. The facility must be equipped to measure and display the pressure difference between the facility and adjacent areas. The display must be able to be read before entering the facility.

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. The facility must be equipped with an alarm that is audible inside and outside the facility and activated when the pressure in the laboratory is more than 25 Pa above the set point.

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.

Condition 24. 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 fumigation of the facility, must be purged to the atmosphere in such a manner that it is dispersed away from occupied buildings and air intakes.

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. Supply or replacement air to the room must be filtered using 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.

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. An exhaust pre-filter of the same or higher standard as the air intake filter must be installed. The exhaust filter must be a HEPA filter as specified in Clause 1.3.15 of AS/NZS 2243.3:2002, or another filter that meets all requirements of AS 4260 with a minimum performance of Grade 2.

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

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. Filter housings must incorporate all the features detailed in the Conditions for Certification.

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. Annual testing of the facility's ventilation system must be carried out as detailed in the Conditions for 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.

Section 4 –Containment equipment conditions

Please answer all questions in this section.

Condition 30. The facility must contain a biological safety cabinet. Installation, use and decontamination of Class I and Class II biological safety cabinets must be in accordance with the requirements of AS/NZS 2647.

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. Biological safety cabinets must be inspected and tested in accordance with the Conditions for Certification.

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.

Section 5 –Facility management

Please answer all questions in this section.

Condition 32. A facility manager must be appointed. The facility manager must understand 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.

Q. 32.1 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. The facility manager must be responsible for establishing and maintaining policies and procedures for the safe operation of the facility.

The responsibilities of the facility manager are detailed in the Conditions for Certification.

Q. 33.1 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. Access to the facility must be restricted to trained people authorised by the Institutional Biosafety Committee (IBC) and then only after they have been advised of any hazards and meet all specific requirements such as immunisation.

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. A facility manual must be readily available to all authorised users of the PC3 facility. The contents of the manual are detailed in the Conditions for Certification.

Q. 35.1 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. Training must include theoretical instruction, supervised practical experience and assessment of competence in the facility. Details of the training are detailed in the Conditions for Certification.

Q. 36.1 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. Training of staff must be updated at least annually. Trained persons must indicate to the certification holder that they fully understand their training by signing a record of their training or re-training after completion. The trainer must also sign the record to indicate that the trained person is competent to work in the facility. The training records must be kept.

Q. 37.1 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. The facility must be kept free of pests. A record of any pest control activities must be kept and made available to the Regulator when requested, along with the dates and details of any pest control and/or eradication activities.

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. The facility must be inspected at least once every 12 months by a person approved by the certification holder. 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. Any non-compliance issues must be notified to the Regulator as soon as practicable.

Q. 39.1 Does the facility comply with condition 39?

Yes

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

Section 6 –Personal protective clothing and equipment

Please answer all questions in this section.

Condition 40. The following personal protective clothing and equipment must be worn by all personnel entering the work area:

- (a) protective clothing to protect the front part of the body (e.g. long-sleeved, back-fastening, tight-wristed protective clothing);
- (b) closed footwear; and
- (c) gloves.

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.

Condition 41. Personal protective clothing and equipment must be removed and stored in designated storage or hanging provisions before leaving the work area and before entering the airlock. If a facility contains multiple laboratories, personal protective clothing and equipment should be removed before exiting each laboratory.

Q. 41.1 Does the facility comply with condition 41?

Yes

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

Section 7 –Work practices

Please answer all questions in this section.

Condition 42. Access to the facility must be restricted by a lockable door which must be locked when no-one is present in the facility.

Q. 42.1 Does the facility comply with condition 42?

Yes

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

Condition 43. Any procedures that involve the use of pathogenic organisms requiring PC3 containment must be performed in a biological safety cabinet.

Q. 43.1 Is this condition relevant to the facility?

Yes. Answer 43.2

No. Continue to condition 44

Q. 43.2 Does the facility comply with condition 43?

Yes

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

Condition 44. If centrifugation is undertaken, it must be carried out in sealed containers (tubes, buckets or rotors). Centrifuge containers that may contain pathogenic organisms must be capable of being detached from the centrifuge and opened in a biological safety cabinet.

Q. 44.1 Is this condition relevant to the facility?

Yes. Answer 44.2

No. Continue to condition 45

Q. 44.2 Does the facility comply with condition 44?

Yes

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

Condition 45. Work benches, surfaces and equipment, including centrifuge containers, where procedures involving viable organisms have taken place must be decontaminated with an appropriate decontaminant when the procedures are completed.

Q. 45.1 Does the facility comply with condition 45?

Yes

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

Condition 46. If any spill occurs in the facility, a spills procedure (as required in Condition 35) must be implemented to decontaminate the spill.

Q. 46.1 Does the facility intend comply with condition 46 when applicable?

Yes

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

Condition 47. Fumigation 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), that cannot be effectively decontaminated by another means;
- (b) prior to surrender or cancellation of certification; and
- (c) prior to re-certification of the facility at a lower containment level, if stipulated by the Regulator.

Q. 47.1 Does the facility comply with condition 47?

Yes

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

Condition 48. All work surfaces and equipment where maintenance is to be carried out must be decontaminated prior to maintenance taking place.

Q. 48.1 Does the facility comply with condition 48?

Yes

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

Condition 49. All waste material other than effluent from floor drains must be decontaminated by autoclaving prior to removal from the facility.

Q. 49.1 Does the facility comply with condition 49?

Yes

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

Condition 50. Equipment (eg. fire extinguishers) or protective clothing must be decontaminated by autoclaving or chemical treatment prior to removal from the facility. The chemical decontamination treatment must take place within the facility.

Q. 50.1 Does the facility comply with condition 50?

Yes

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

Condition 51. Where an autoclave is used for decontamination it must be used and calibrated as detailed in the Conditions for Certification.

Q. 51.1 Is this condition relevant to the facility?

Yes. Answer 51.2

No. Continue to condition 52

Q. 51.2 Does the facility comply with condition 51?

Yes

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

Condition 52. Viable material must not be removed from the facility unless:

- (a) it is to be transported for the purpose of work to another containment facility certified by the Regulator to at least PC3; or
- (b) written permission has been given by the Regulator.

Any viable waste material must be decontaminated before being removed from the facility.

Q. 52.1 Is this condition relevant to the facility?

Yes. Answer 52.2

No. Continue to condition 53

Q. 52.2 Does the facility comply with condition 52?

Yes

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

Condition 53. All viable materials 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. The surface of the secondary container must be chemically decontaminated prior to removal from the facility.

Q. 53.1 Is this condition relevant to the facility?

Yes. Answer 53.2

No. Continue to condition 54

Q. 53.2 Does the facility comply with condition 53?

Yes

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

Condition 54. All cultures must be sealed during storage to prevent dissemination of the organism.

Q. 54.1 Is this condition relevant to the facility?

Yes. Answer 54.2

No. Continue to condition 55

Q. 54.2 Does the facility comply with condition 54?

Yes

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

Condition 55. Any unintentional release or suspected unintentional release of GMOs from the facility, or unintended exposure to GMOs, must be reported to the Regulator as soon as practicable.

Q. 55.1 Does the facility intend to comply with condition 55 when applicable?

Yes

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

Condition 56. Non-essential personal effects, including handbags, personal mobile phones, personal organisers and other non-essential electronic equipment, which will not remain within the facility, must not be taken into the facility. The above does not include other personal effects that will be covered by personal protective equipment at all times.

Q. 56.1 Does the facility comply with condition 56?

Yes

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

Condition 57. Reading and writing material must not be used inside a biological safety cabinet and must be decontaminated before removal from the facility.

Q. 57.1 Does the facility comply with condition 57?

Yes

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

Condition 58. All persons must remove gloves and wash or decontaminate their hands immediately before leaving the work area.

Q. 58.1 Does the facility comply with condition 58?

Yes

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