



Checklist for a Physical Containment Level 2 (PC2) Laboratory Facility

(The Gene Technology Regulator's *Guidelines for Certification of Facilities/Physical Containment Requirements* applies)

Facility Name:.....

.....

Certification Number:.....

IBC Name:.....

IBC Number:.....

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

.....

.....

.....

.....

.....

.....

Date of check:.....

Time taken to complete this form:

Hours		Minutes	

Conditions for a PC2 Laboratory Facility

Please circle the appropriate answer for the following questions in relation to the current conditions within the specified PC2 Laboratory Facility.

If you answer 'No' or 'Not applicable' to any of the following questions you must provide an explanation in the 'Details' section allocated. If you require more space, please attach the information and indicate that you have added an attachment.

Note: If this inspection is carried out prior to certification of the facility please indicate your intentions for when the facility will be operating as a PC2 Laboratory Facility in the 'details' section provided.

Facilities

1. Is the facility labelled with the following adhesive signs as supplied by the OGTR:

(a) A Physical Containment Level 2 (PC2) sign on the outside of facility access door(s)?

Yes / No

DETAILS:

(b) A biohazard symbol on the outside of facility access door(s)?

Yes / No

DETAILS:

(c) A PC2 Facility Practice sign prominently displayed inside the facility?

Yes / No

DETAILS:

Note: If you have answered 'No' for any of the above questions, please state below the number and type of signs you require?

2. Is the facility a fully enclosable space contained within walls, doors, windows, floors and ceilings? (For example, two rooms with a corridor between them cannot be certified as a facility unless the corridor itself is an enclosed space with restricted access.)

Yes / No

DETAILS:

3. Are all walls, floors, ceilings and benches smooth, impermeable to water, cleanable, and resistant to the cleaning agents and/or disinfectants used in the facility?

Yes / No

DETAILS:

4. Is all facility furniture, including seating, washable?

Yes / No

DETAILS:

5. Is a wash basin, fitted with a basin mixer of the hands-free operation type, provided for hand washing within the facility?

Yes / No

DETAILS:

6. Is the water supplied to the laboratory provided with back flow prevention?

Yes / No

DETAILS:

7. Are eye wash facilities (either a plumbed eye wash facility or single-use packs of sterile eye irrigation fluids) provided within the facility?

Yes / No

DETAILS:

8. Are eye wash facilities used and maintained in accordance with the manufacturer's instructions?

Yes / No

DETAILS:

9. Does the facility contain a pressure steam steriliser (autoclave) or have an autoclave that is accessible to facility users? (If the autoclave is not located in the facility, it is preferable that it be located within the same building as the facility.)

Yes / No

DETAILS:

10. Is there designated storage or hanging provisions for protective clothing available within the facility?

Yes / No

DETAILS:

11. Is there a supply of disinfectants for decontamination purposes available in the facility?
Yes / No

DETAILS:

12. Are the above-mentioned disinfectants clearly labelled with the contents and, where necessary, the expiry date?
Yes / No

DETAILS:

13. Are the open spaces between and under benches, cabinets and equipment accessible for cleaning?
Yes / No

DETAILS:

Personal Protective Clothing and Equipment

14. Is protective clothing, to protect the front part of the body, worn by all persons performing procedures in the facility?
Yes / No

DETAILS:

15. Do all persons performing procedures in the facility wear closed footwear?
Yes / No

DETAILS:

16. Are gloves worn for work undertaken in a biological safety cabinet?
Yes / No/ Not applicable

DETAILS:

17. Is protective clothing always removed after completing laboratory procedures and before leaving the facility? (This requirement does not apply if entering another containment facility, certified to PC2 by the Regulator, that is directly connected to the facility.)
Yes / No / Not applicable

DETAILS:

Containment Equipment

18. Does the facility contain a biological safety cabinet, or other equipment specifically approved in writing by the Regulator that is designed to contain aerosols? (Only applicable if procedures that generate aerosols containing GMOs are to be performed in the facility.)
Yes / No / Not applicable

If the answer is "no", but a biological safety cabinet in another certified facility is used, please outline details of the location of that biological safety cabinet (ie. room and facility certification number).

DETAILS:

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19. Is the installation, use and decontamination of the biological safety cabinet in accordance with the requirements of AS/NZS 2647: "*Biological safety cabinets - Installation and use*"?
Yes / No / Not applicable

DETAILS:

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20. Is the biological safety cabinet tested at least every 12 months by a NATA accredited organisation and is the cabinet labelled to show its test status?
Yes / No / Not applicable

DETAILS:

Work Practices

21. Are all requirements for a PC2 laboratory facility specified in the Certification Instrument issued by the Regulator complied with at all times, even if the work being performed in the facility involves organisms that are not GMOs? (If this inspection is carried out prior to certification of the facility, do you intend to comply with the above mentioned requirements? Please provide an explanation in 'details' section below.)
Yes / No

DETAILS:

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22. Is access to the facility restricted to authorised persons and/or authorised classes of persons?
Yes / No

DETAILS:

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23. Are windows closed while laboratory procedures are in progress? (Not applicable to the windows that are fitted with intact flyscreens.)
Yes / No / Not applicable
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DETAILS:

24. Are all facility doors closed when laboratory procedures are in progress?

Yes / No

DETAILS:

25. Are all facility personnel trained in the requirements of the OGTR PC2 Laboratory Facility Guidelines?

Yes / No

DETAILS:

26. Are only trained personnel permitted to clean contaminated equipment or surfaces, or handle hazardous material?

Yes / No

DETAILS:

27. Do all facility personnel indicate to the certification holder that they fully understand their training in OGTR requirements by signing a record of their training after completion and is a record of those trained kept and available if requested?

Yes / No

DETAILS:

28. Are all procedures that generate aerosols containing GMOs performed in a biological safety cabinet, or other equipment designed to contain aerosols specifically approved in writing by the Regulator?

Yes / No / Not applicable

DETAILS:

29. Are procedures in place to report any unintentional release of GMOs from the facility to the Regulator as soon as practicable?

Yes / No

DETAILS:

30. Are all work benches, surfaces and equipment where procedures have taken place decontaminated immediately after any spills and when laboratory procedures using GMOs are completed?

Yes / No

DETAILS:

31. Are all work surfaces and equipment, in relevant areas of the facility, decontaminated before maintenance is carried out?

Yes / No

DETAILS:

32. (a) Are all GMOs, organisms infected with GMOs, equipment or protective clothing contaminated with GMOs, and liquid and solid wastes containing GMOs, decontaminated by steam sterilisation (autoclaving), chemical treatment, incineration or any other method approved in writing by the Regulator?

Yes / No

DETAILS:

(b) Is the chemical disinfectant treatment mentioned above in accordance with Appendix E of Australian/New Zealand Standard 2243.3:2002 *Safety in laboratories – Part 3: Microbiological aspects and containment facilities*?

Yes / No / Not applicable

DETAILS:

(c) Is incineration performed in a high temperature, high efficiency, EPA-approved incineration facility?

Yes / No / Not applicable

DETAILS:

33. Where a pressure steam steriliser (autoclave) is used for decontamination:

(a) Are provisions made to allow for the penetration of steam into the container during autoclaving?

Yes / No / Not applicable

DETAILS:

(b) Is the coldest part of the load exposed to a minimum temperature of 121°C for at least 15 minutes?

Yes / No / Not applicable

DETAILS:

(c) Are measures taken to ensure that loads that have been processed can be differentiated from loads that have not? (For example, autoclave tape).

Yes / No / Not applicable

DETAILS:

(d) Is the temperature of each cycle monitored by use of one of the following means: a thermocouple and recorder; a maximum thermometer; a chemical indicator; spore strips; or readings from the autoclave panel?

Yes / No / Not applicable

DETAILS:

(e) Is the effectiveness of decontamination by the pressure steam steriliser (autoclave) used by the facility tested at least every month?

Yes / No / Not applicable

DETAILS:

(f) Is a notice posted on, or adjacent to, the autoclave indicating the result of the above-mentioned test and the date of the test?

Yes / No/ Not applicable

DETAILS:

34. Are GMOs, and waste potentially contaminated with GMOs, that are being transported out of the facility transported in accordance with the "*Guidelines for the Transport of GMOs*"?

Yes / No

DETAILS:

35. Are animals and plants not used in work being performed in the facility decontaminated by steam sterilisation (autoclaving), incineration or any other method approved in writing by the Regulator prior to removal from the facility?

Yes / No

DETAILS:

36. Are GMOs or organisms infected with GMOs stored outside the facility in a storage unit (freezer, fridge, controlled temperature room or other controlled temperature container)?

Yes / No

DETAILS:

If yes:

(a) Is the storage unit locked when not in use or is access restricted to the room or area where the storage unit is located?

Yes / No

DETAILS:

(b) Does it have a biohazard symbol posted on it?

Yes / No

DETAILS:

(c) Are the GMOs or organisms infected with GMOs being stored outside the facility double-contained?

Yes / No

DETAILS:

(d) Is the primary container sealed and unbreakable?

Yes / No

DETAILS:

(e) Is the primary container stored in an unbreakable secondary container and clearly labelled?

Yes / No

DETAILS:

(f) Is the transport of material between the facility and the storage unit in accordance with the "*Guidelines for the Transport of GMOs*"?

Yes / No

DETAILS:

(g) Are gloves worn while transferring primary containers between the storage unit and the secondary container used for transport?

Yes / No

DETAILS:

(h) Are procedures in place to report spills during storage outside the facility or transfer to the storage unit to the Regulator as soon as practicable?

Yes / No

DETAILS:

(i) Are procedures in place to decontaminate spilt material and the area?

Yes / No

DETAILS:

37. Are all cultures clearly identified?

Yes / No / Not applicable

DETAILS:

38. Are all cultures of fungi and other spore-dispersing organisms sealed during storage?

Yes / No / Not applicable

DETAILS:

39. Is eating, drinking, smoking, shaving and applying cosmetics are prohibited in the facility?

Yes / No

DETAILS:

40. Is food or drink intended for human consumption prohibited from being brought into or stored in the facility?

Yes / No

DETAILS:

41. Is long hair tied back or covered with a hair net at all times to avoid contamination?

Yes / No / Not applicable

DETAILS:

42. Is mouth pipetting prohibited in the facility?

Yes / No

DETAILS:

43. Are reading/writing material and computers essential to procedures performed within the facility the only such items used on work benches where procedures are performed?

Yes / No

DETAILS:

44. Is reading and writing material prohibited from being used inside a biological safety cabinet?

Yes / No / Not applicable

DETAILS:

45. Where possible does the facility provide and use dedicated reading/writing areas?

Yes / No

DETAILS:

46. Do persons who have been performing procedures in the facility wash or decontaminate their hands immediately before leaving the facility or before using any dedicated facility reading/writing areas?

Yes / No

DETAILS:

47. Is the facility and equipment in the facility maintained so that the facility meets the
"Guidelines for Certification of Facilities/ Physical Containment Requirements"?

Yes / No

DETAILS:

48. Are strategies in place to ensure that the facility is free of pests and is a record of the
program and dates of specific activities kept and available if requested?

Yes / No

DETAILS:
