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

Annual Inspection Checklist for a PC3 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 3.1 - 28 May 2012.

Organisation Name	
IBC 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 16. 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 16.
- A completed copy of this proforma will be accepted by the OGTR as the annual inspection report for a certified facility under Condition 16, 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 3 Laboratory Version 3.1 – 28 May 2012*.

- 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 – Obligations of the certification holder

Please answer all questions in this section.

Condition 1. The certification holder must have the authority to admit persons to the facility and exclude persons from the facility.

Q. 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. A facility manager must be appointed by the certification holder.

Q. 2 Does the facility comply with Condition 2?

☐ **Yes**

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

Condition 3. Any delegate of the facility manager must be appointed by the certification holder.

Q. 3 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 certification holder must ensure that the facility manager or their delegate has an understanding of the technical aspects of facility design, operation and maintenance.

Q. 4 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. The certification holder must ensure that the facility manager, or their delegate(s), undertake the following functions:

(a) ensure that access to voids around the perimeter of the facility (if applicable) and the ventilation system of the facility is restricted to authorised persons;
(b) develop and maintain documented policies and documented procedures for the safe operation of the facility (e.g. entry and exit procedures, work practices, decontamination procedures and emergency plans);
(c) facilitate training to all persons as per the Training Conditions (Conditions 67 and 68);
(d) provide information to all authorised persons on changes to facility operating policies and procedures;
(e) develop, document, and undertake an annual review of a facility manual, as stipulated in Conditions 65 and 66;
(f) develop, document, implement and validate decontamination procedures effective for all organisms and equipment used in the facility;

(g) ensure that successful decontamination of the facility, equipment or work area is carried out when required;
(h) retain documentation relating to gaseous decontamination and to the maintenance and testing of the facility equipment and services, including the air handling system, primary aerosol containment equipment (e.g. BSC) and autoclave(s);
(i) co-ordinate immunisation of persons working within the facility, where appropriate;
(j) ensure that current emergency contact numbers are clearly visible from inside and outside the facility (e.g. 24-hour contacts for medical emergency and for alarm response);
(k) ensure that a record of all organisms (GM and non-GM) used in the facility since the most recent gaseous decontamination is kept and is made available to the Regulator if requested; and
(l) coordinate all work in the facility where multiple projects or work on different organisms is taking place in the facility.

Q. 5 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.

Conditions 6 – 13 (Intentionally left blank)

Section 2 – Work not permitted in this facility

Please answer all questions in this section.

Condition 14. The following work must not be conducted in this facility:

(a) dealings with any GMO that, under the conditions of a licence, requires containment in any physical containment level higher than PC3;
(b) dealings with any GMO that is a Risk Group 4 organism as specified in AS/NZS 2243.3
(c) the housing/keeping/rearing of any animals, including invertebrates and aquatic organisms, beyond the minimum time that they are required for conducting the dealings with GMOs;
(d) the growing of any plants beyond the minimum time that they are required for conducting the dealings with GMOs; or
(e) any other work prohibited by notification in writing by the Regulator.

Q. 14 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.

Section 2 – General conditions

Please answer all questions in this section.

Condition 15 (Intentionally left blank)

Condition 16 (Intentionally left blank)

Condition 17. Each access door to the facility must be labelled with the following adhesive signs:

(a) a current PC3 sign, supplied by the OGTR;
(b) a biohazard symbol; and
(c) emergency contact numbers (e.g. 24-hour contacts for medical emergency and for alarm response).

The signs identified in (a) to (c) must be placed so that they can be clearly seen by all persons entering the facility.

Q. 17 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. Emergency contact numbers (e.g. 24-hour contacts for medical emergency and for alarm response) must also be visible within the work area of the facility.

Q. 18 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. A supply of decontamination agents effective against the GMOs being dealt with in the facility must be available in the work area of the facility. All containers of decontamination agents must be labelled with the contents, concentration and, where appropriate, the expiry date. Decontamination agents must not be used after the expiry date.

Q. 19 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 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.

Section 3 – Facility construction and access conditions

Please answer all questions in this section.

Condition 21. The certification holder must ensure that the physical attributes of the facility and fittings are maintained so that the 'Facility construction and access requirements' listed in Part A of this document continue to be met.

Condition 21.1 (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. 21.1 Does the facility comply with Condition 21.1?

☐ **Yes**

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

Condition 21.2 (Requirement 2). The facility must be maintained to enable gaseous decontamination of the whole facility.

Q. 21.2 Does the facility comply with Condition 21.2?

☐ **Yes**

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

Condition 21.3 (Requirement 3). All facility penetrations must be fitted with seals to minimise air leakage.

Q. 21.3 Does the facility comply with Condition 21.3?

☐ **Yes**

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

Condition 21.4 (Requirement 4). All windows in the facility must be closed and sealed.

Q. 21.4 Does the facility comply with Condition 21.4?

☐ **Yes**

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

Condition 21.5 (Requirement 5). The facility boundaries (walls, windows, doors, floors, ceilings etc.) must be maintained to prevent the incursion of pests.

Q. 21.5 Does the facility comply with Condition 21.5?

☐ **Yes**

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

Condition 21.6 (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. 21.6.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q21.6.2**

☐ **No. Continue to Condition 21.7**

Q. 21.6.2 Does the facility comply with Condition 21.6?

☐ **Yes**

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

Condition 21.7 (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. 21.7.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q21.7.2**

☐ **No. Continue to Condition 21.8**

Q. 21.7.2 Does the facility comply with Condition 21.7?

☐ **Yes**

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

Condition 21.8 (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. 21.8 Does the facility comply with Condition 21.8?

☐ **Yes**

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

Condition 21.9 (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. 21.9 Does the facility comply with Condition 21.9?

☐ **Yes**

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

Condition 21.10 (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. 21.10 Does the facility comply with Condition 21.10?

☐ **Yes**

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

Condition 21.11 (Requirement 11). Designated storage or hanging areas for PPE must be available within each work area.

Q. 21.11 Does the facility comply with Condition 21.11?

☐ **Yes**

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

Condition 21.12 (Requirement 12). Provision must be made for viewing of work areas from outside the facility.

Q. 21.12 Does the facility comply with Condition 21.12?

☐ **Yes**

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

Condition 21.13 (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. 21.13 Does the facility comply with Condition 21.13?

☐ **Yes**

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

Condition 22. Prior to any structural changes that will affect the containment of GMOs in the facility, the applicant must request, in writing, a suspension of the certification from the Regulator. Before a suspension of the certification can be lifted, the facility must be inspected by a person qualified to assess the facility's compliance with the conditions listed under:

(a) General conditions;
(b) Facility construction and access conditions;
(c) Containment equipment conditions;
(d) Laboratory services and equipment conditions;
(e) Ventilation conditions; and
(f) Testing conditions;

to ensure that the facility meets the conditions of certification. An inspection report that records the extent of compliance with these conditions must be made and

provided to the Regulator with the request to lift the suspension. Dealings with GMOs may not commence until the Regulator has lifted the suspension by notice in writing.

Q. 22.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q22.2**

☐ **No. Continue to Condition 23**

Q. 22.2 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 airlock must not be used to conduct dealings (other than transport) with GMOs.

The airlock must not contain laboratory equipment or used PPE. Storage of small supplies of clean PPE is permissible. The airlock must not be used for long term storage of laboratory supplies.

Q. 23 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 4 –Containment equipment conditions

Please answer all questions in this section.

Condition 24. The certification holder must ensure that the physical attributes of the facility and fittings are maintained so that the relevant 'Containment equipment requirements' continue to be met.

Condition 24.1 (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. 24.1 Does the facility comply with Condition 24.1?

☐ **Yes**

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

Condition 24.2 (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. 24.2 Does the facility comply with Condition 24.2?

☐ **Yes**

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

☐ **Yes**

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

Condition 25. Use and decontamination of Class I and Class II BSC must be in accordance with the requirements of AS 2252.4. Use and decontamination of other aerosol containment equipment must be in accordance with the manufacturer's instructions and the requirements of the relevant AS/NZS, where applicable.

Q. 25 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.

Section 5 – Laboratory services and equipment conditions

Please answer all questions in this section.

Condition 26. The certification holder must ensure that the physical attributes of the facility and fittings are maintained so that the 'Laboratory services and equipment requirements' listed in Part A of this document continue to be met.

Condition 26.1 (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. 26.1 Does the facility comply with Condition 26.1?

☐ **Yes**

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

Condition 26.2 (Requirement 17). All autoclaves and other decontamination equipment must be tested and commissioned and the results documented before use.

Q. 26.2 Does the facility comply with Condition 26.2?

☐ **Yes**

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

Condition 26.3 (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. 26.3 Does the facility comply with Condition 26.3?

☐ **Yes**

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

Condition 26.4 (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. 26.4 Does the facility comply with Condition 26.4?

☐ **Yes**

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

Condition 26.5 (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. 26.5 Does the facility comply with Condition 26.5?

☐ **Yes**

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

Condition 26.6 (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. 26.6.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q26.6.2**

☐ **No. Continue to Condition 26.7**

Q. 26.6.2 Does the facility comply with Condition 26.6?

☐ **Yes**

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

Condition 26.7 (Requirement 22). Piped gas supplies to the facility must have reverse flow prevention on outlets located within the BSC.

Q. 26.7.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q26.7.2**

☐ **No. Continue to Condition 27**

Q. 26.7.2 Does the facility comply with Condition 26.7?

☐ **Yes**

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

Condition 27. All services and equipment must be used and maintained in accordance with the relevant AS/NZS or the manufacturer's instructions.

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. All services or equipment added to the facility after certification must be tested, commissioned and found to meet the conditions of certification prior to use with GMOs.

Q. 28.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q28.2**

☐ **No. Continue to Condition 29**

Q. 28.2 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.

Section 6 –Ventilation conditions

Please answer all questions in this section.

Condition 29. The certification holder must ensure that the physical attributes of the facility and fittings are maintained so that the relevant 'Ventilation requirements' continue to be met.

Condition 29.1 (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. 29.1 Does the facility comply with Condition 29.1?

☐ **Yes**

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

Condition 29.2 (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. 29.2 Does the facility comply with Condition 29.2?

☐ **Yes**

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

Condition 29.3 (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. 29.3 Does the facility comply with Condition 29.3?

☐ **Yes**

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

Condition 29.4 (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. 29.4 Does the facility comply with Condition 29.4?

☐ **Yes**

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

Condition 29.5 (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. 29.5 Does the facility comply with Condition 29.5?

☐ **Yes**

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

Condition 29.6 (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. 29.6 Does the facility comply with Condition 29.6?

☐ **Yes**

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

Condition 29.7 (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. 29.7 Does the facility comply with Condition 29.7?

☐ **Yes**

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

Condition 29.8 (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. 29.8 Does the facility comply with Condition 29.8?

☐ **Yes**

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

Condition 29.9 (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. 29.9 Does the facility comply with Condition 29.9?

☐ **Yes**

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

Condition 29.10 (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. 29.10 Does the facility comply with Condition 29.10?

☐ **Yes**

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

Condition 30. While the facility is operational, any failure of the ventilation 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 reasonably possible.

Q. 30.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q30.2**

☐ **No. Continue to Condition 31**

Q. 30.2 Has the failure of the ventilation system been reported to the Regulator?

☐ **Yes**

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

Section 7 – Testing conditions

Please answer all questions in this section.

Condition 31. Biological safety cabinets must be inspected and tested in accordance with the requirements of AS 2252.1 (class I) or AS 2252.2 (class II). This testing is required at least annually and additionally after relocation of a cabinet, after mechanical or electrical maintenance and after HEPA filters are replaced. The inspection and testing of cabinets must be carried out by a qualified person. The cabinet must be decontaminated prior to testing.

The cabinet(s) must pass tests for containment efficiency and a certificate, summarising the test results and the date of the next test, must be affixed to the cabinet.

Where testing has shown that the performance requirements for inward air velocity or HEPA filter integrity (Class I), or air barrier containment or exhaust HEPA filter integrity (Class II) are not met and the defect has not been corrected, the cabinet must be clearly marked to show that it is defective and must not be used for procedures involving GMOs until the defect has been corrected.

Records of all tests must be kept for 3 years, and made available to the Regulator if requested.

Q. 31 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. Other aerosol containment equipment installed in the facility must be inspected and tested by a qualified person at least annually and additionally after relocation of the equipment, after mechanical or electrical maintenance and after HEPA filters are replaced. Testing must include HEPA filter integrity and containment efficiency testing and a certificate summarising the test results and the date of the next test must be affixed to the equipment.

Where testing has shown that the performance requirements for HEPA filter integrity or containment efficiency are not met and the defect has not been corrected, the equipment must be clearly marked to show that it is unsafe and must not be used for procedures involving GMOs until the defect has been corrected.

Records of all tests must be kept for 3 years and made available to the Regulator if requested.

Q. 32.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q32.2**

☐ **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. Testing and maintenance of facility ventilation systems must be carried out at least annually by a qualified person. This must include:

(a) testing of the pressure differentials;
(b) integrity testing of all HEPA filters in accordance with AS 1807.6 or AS 1807.7, as applicable. The HEPA filter must be decontaminated prior to testing;
(c) checking directional airflow;
(d) verifying that the alarms operate when the air pressure in the facility is raised;
(e) calibration of transducers fitted to the air-handling system and validation of air-handling performance (i.e. an over-pressure or under-pressure response);
(f) calibration of pressure gauges;
(g) the air handling control system; and
(h) if applicable, the building management system.

Records of the tests in items (a) to (h), and of any maintenance conducted, must be kept for 3 years and made available to the Regulator if requested.

If any failures occur, dealings involving GMOs in the facility must cease until the failures are rectified and re-testing has shown that compliance with these Conditions has been achieved. Storage of GMOs in the facility is permitted when failures occur provided containment of the GMOs is not compromised.

Q. 33 Can compliance with Condition 33 be demonstrated?

☐ **Yes**

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

Condition 34. The physical parameters of the autoclave, or other heat-based equipment used to decontaminate GMOs, must be validated either at least monthly (if it is in frequent use) or before or with each decontamination cycle (if it is in intermittent use) with:

(a) thermocouples or resistance thermometers, to ensure that the required temperature has been achieved; or

(b) chemical indicators which use a combination of moisture, heat and time and which progressively change colour with the time exposed at the specified temperature; or
(c) other methods approved in writing by the Regulator.

The efficacy of the autoclave, or other heat-based equipment used for decontamination, must be validated either at least monthly (if it is in frequent use) or before or with each decontamination cycle (if it is in intermittent use) with:

(i) biological indicators such as spore strips; or
(ii) bacterial enzyme indicators; or
(iii) other methods approved in writing by the Regulator.

Indicators that determine the efficacy of the autoclave must be placed in locations that are least likely to encounter the physical conditions required for effective decontamination (e.g. at the centre of the load or coldest part of the autoclave).

Q. 34 Can compliance with Condition 34 be demonstrated?

☐ **Yes**

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

Condition 35. The results of testing of physical parameters and efficacy of the autoclave or other heat-based decontamination equipment (as specified in Condition 34) must be kept for 12 months and made available to the Regulator if requested.

Q. 35 Can compliance with Condition 35 be demonstrated?

☐ **Yes**

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

Condition 36. Any equipment (heat, chemical or other) used to decontaminate GMOs must be tested and maintained annually by a person qualified or trained to do so. The results of the annual maintenance for the previous 3 years must be kept and made available to the Regulator, if requested. Annual maintenance must include, but may not be limited to:

(a) calibration of all instruments that control or monitor critical process parameters. For autoclaves this includes calibration of thermometers, timers, and thermocouples;
(b) confirmation that all parameters of the system are operating within the specified limits (e.g. temperature, time, pH, concentration of chemical);
(c) testing and maintenance of equipment to ensure effective operating conditions; and
(d) testing of all safety and relief equipment, including the autoclave safety valves

Q. 36 Can compliance with Condition 36 be demonstrated?

☐ **Yes**

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

Condition 37. If any autoclave or other decontamination equipment is found to be defective and the defect has not been corrected, the equipment must be clearly marked to show that it is defective and must not be used for decontaminating GMOs, waste or equipment associated with dealings with GMOs until the defect has been corrected.

Q. 37.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q37.2**

☐ **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 testable water supply backflow prevention devices must pass an annual test, conducted in accordance with AS 2845.3 by a licensed plumber accredited to test backflow prevention devices. A record of the annual test for the last 3 years must be kept and made available to the Regulator if requested.

Q. 38 Can compliance with Condition 38 be demonstrated?

☐ **Yes**

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

Section 8 –Work practices

Please answer all questions in this section.

Condition 39. The outer door of the facility must be kept locked when the room is unoccupied by personnel.

Q. 39 Do the facility work practices comply with Condition 39?

☐ **Yes**

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

Condition 40. Airlock doors must remain closed at all times, except when authorised persons are entering or exiting the facility.

Q. 40 Do the facility work practices comply with Condition 40?

☐ **Yes**

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

Condition 41. Under normal operation of the facility, persons must enter and exit the work area through the airlock.

Q. 41 Do the facility work practices comply with Condition 41?

☐ **Yes**

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

Condition 42. Where present, dedicated emergency exits must only be opened in the event of an emergency.

Q. 42 Do the facility work practices comply with Condition 42?

☐ **Yes**

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

Condition 43. With the exception of transport, dealings with GMOs must only take place in the work area(s).

Q. 43 Do the facility work practices comply with Condition 43?

☐ **Yes**

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

Condition 44. The following PPE must be worn by all authorised persons in the work area(s):

(a) protective clothing to protect the front part of the body (e.g. long-sleeved, back-fastening, tight-wristed protective clothing);
(b) closed footwear;
(c) gloves;
(d) eye protection; and
(e) waterproof dressings on all broken skin.

Q. 44 Do the facility work practices comply with Condition 44?

☐ **Yes**

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

Condition 45. When exiting the work area and prior to entering the airlock, PPE must be removed and disposed of, or stored in designated storage or hanging spaces. If a facility contains multiple work areas in which different GMOs are being dealt with, gloves and gowns worn at the BSC must be removed before exiting each work area.

Q. 45 Do the facility work practices comply with Condition 45?

☐ **Yes**

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

Condition 46. When exiting the work area and immediately prior to entering the airlock all persons must wash or decontaminate their hands. If a facility contains multiple work areas, all persons must wash or decontaminate their hands immediately before exiting each work area.

Q. 46 Do the facility work practices comply with Condition 46?

☐ **Yes**

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

Condition 47. Any dealings that may generate aerosols containing GMOs must be conducted in a BSC or other aerosol containment equipment approved in writing by the Regulator.

Q. 47 Do the facility work practices comply with Condition 47?

☐ **Yes**

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

Condition 48. Any centrifugation of GMOs must be carried out in sealed containers (tubes, buckets or rotors). Centrifuge containers must only be opened in a BSC or other aerosol containment equipment approved in writing by the Regulator.

Q. 48 Do the facility work practices comply with Condition 48?

☐ **Yes**

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

Condition 49. Sharps must not be used in direct connection with GMOs unless no alternatives are available. An assessment of the need to use sharps and the procedures for safe handling must be documented in the facility manual (Condition 65(i)).

Q. 49 Do the facility work practices comply with Condition 49?

☐ **Yes**

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

Condition 50. Work benches, surfaces and equipment where procedures involving viable GMOs have taken place must be decontaminated immediately after each procedure and/or at the end of each working day.

Q. 50 Do the facility work practices comply with Condition 50?

☐ **Yes**

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

Condition 51. Gaseous decontamination of the facility must take place:

(a) after a spill of viable GMOs outside primary containment (e.g. BSC) and that cannot be decontaminated by another means;
(b) prior to suspension, surrender, expiry or cancellation of certification;
(c) prior to re-certification of the facility at a lower containment level, if stipulated by the Regulator; and
(d) prior to maintenance work on equipment in the facility that cannot be decontaminated by another means.

Q. 51 Do the facility work practices comply with Condition 51?

☐ **Yes**

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

Condition 52. All contaminated liquid effluent must be decontaminated by heat or chemical treatment before being discharged to sewer.

Q. 52 Do the facility work practices 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 items, including equipment, PPE and waste, must be decontaminated prior to removal from the facility. An exception is permitted for the transport of GMOs to another certified PC3 facility, or for export, in accordance with Condition 61.

This includes all reading and writing material, computers, communication devices including phones, and other items such as radios or other audio equipment.

Q. 53 Do the facility work practices comply with Condition 53?

☐ **Yes**

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

Condition 54. Decontamination can be effected by autoclaving or other heat treatment, by chemical or gas treatment, or by any other method approved in writing by the Regulator

Q. 54 Do the facility work practices comply with Condition 54?

☐ **Yes**

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

Condition 55. If an autoclave is used for decontamination:

(a) loads must be packed and loaded to allow for the penetration of steam into the material being decontaminated;
(b) the coldest part of the load must be exposed to a minimum temperature of 121°C and 103 kPa for at least 15 minutes or at 134°C and 203 kPa for at least 3 minutes;
(c) measures must be taken to ensure that loads that have been processed can be differentiated from loads that have not (e.g. by use of autoclave tape); and
(d) all displaced or evacuated air, steam and liquid must be filtered (e.g. 0.22µm) or decontaminated before discharge.

Q. 55.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q55.2**

☐ **No. Continue to Condition 56**

Q. 55.2 Do the facility work practices comply with Condition 55?

☐ **Yes**

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

Condition 56. If a double-ended autoclave is installed across the facility barrier, it must have a mechanism in place such that it cannot be opened on the clean side without completion of a successful decontamination cycle.

Q. 56.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q56.2**

☐ **No. Continue to Condition 57**

Q. 56.2 Do the facility work practices comply with Condition 56?

☐ **Yes**

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

Condition 57. Any other heat-based treatment used for decontamination must be performed using a combination of pressure, temperature and time that has previously been validated as effective in rendering the GMOs non-viable.

Q. 57.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q57.2**

☐ **No. Continue to Condition 58**

Q. 57.2 Do the facility work practices comply with Condition 57?

☐ **Yes**

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

Condition 58. Any chemical decontamination agent must have been validated, prior to use, as being effective in rendering the GMOs non-viable.

Q. 58 Do the facility work practices comply with Condition 58?

☐ **Yes**

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

Condition 59. Any gaseous decontamination agent must be validated as effective in rendering the GMOs non-viable. When gaseous decontamination of the facility, part of the facility or selected laboratory equipment is conducted, validation of successful

decontamination must be achieved by use of appropriate indicators (e.g. spore strip tests) placed throughout the space to be decontaminated. Records of the tests must be kept for 3 years and made available to the Regulator if requested.

Gaseous decontamination is only considered effective if confirmed by all indicators employed. The type, number and location of indicators must be appropriate for the nature of the gaseous decontamination agent used and the space being decontaminated.

Q. 59 Do the facility work practices comply with Condition 59?

☐ **Yes**

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

Condition 60. If any spill occurs in the facility, the spills procedure (see Condition 65(r)(i)) must be implemented to decontaminate the spill as soon as reasonably possible.

Q. 60 Do the facility work practices comply with Condition 60?

☐ **Yes**

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

Condition 61. Viable PC3 GMOs and/or material containing or potentially containing such GMOs must not be removed from the facility unless:

(a) they are to be transported to another containment facility certified by the Regulator to at least PC3; or
(b) they are to be transported for the purpose of export; or
(c) written permission has been given by the Regulator..

Q. 61 Do the facility work practices comply with Condition 61?

☐ **Yes**

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

Condition 62. Transport of the GMOs must be in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*.

Q. 62 Do the facility work practices comply with Condition 62?

☐ **Yes**

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

Condition 63. PC3 GMOs must be stored within the work area of a PC3 facility. GMOs must be stored in a sealed, unbreakable primary container, which has been surface decontaminated prior to enclosure within a sealed, unbreakable secondary container. The secondary container can then be placed in a fridge or freezer (the tertiary container).

Q. 63 Do the facility work practices comply with Condition 63?

☐ **Yes**

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

Condition 64. Non-essential personal effects, including handbags, mobile phones, portable music devices, and other non-essential electronic equipment must not be taken into the facility.

Q. 64 Do the facility work practices comply with Condition 64?

☐ **Yes**

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

Section 10 –Facility manual

Please answer all questions in this section.

Condition 65. A facility manual (either paper or electronic) must be readily available to all authorised users from within the facility. The contents of the manual are detailed in the Conditions for Certification.

Q. 65 Does the facility manual comply with Condition 65?

☐ **Yes**

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

Condition 66. The facility manual must be reviewed at least annually and updated as necessary by the facility manager or their delegate(s).

Q. 66 Does the facility comply with Condition 66?

☐ **Yes**

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

Section 11 – Training

Please answer all questions in this section.

Condition 67. All authorised persons as defined by Condition 7(b) must undertake training that includes:

(a) all information contained in the facility manual (Condition 65);
(b) theoretical instruction; and
(c) where applicable, supervised practical experience and assessment of competence;

prior to commencing dealings with GMOs.

Q. 67 Does the facility comply with Condition 67?

☐ **Yes**

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

Condition 68. All authorised persons as defined by Condition 7(b) must undertake re-training at least annually. Re-training must assess ongoing ability to comply with the requirements specified in Condition 67. Training material and procedures must be updated whenever:

(a) licence conditions or certification conditions related to the facility change;
(b) any applicable guidelines issued by the Regulator change (e.g. *Guidelines for the Transport, Storage and Disposal of GMOs*) *;*
(c) there are new risks associated with GMOs dealt with in the facility;

(d) procedures or equipment used in the facility changes; or
(e) new GMOs are used in the facility.

Q. 68 Does the facility comply with Condition 68?

☐ **Yes**

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

Condition 69. Training records of all authorised persons described in Conditions 7(b) must be kept by the certification holder for a period of at least 3 years and made available to the Regulator if requested.

Q. 69 Does the facility comply with Condition 69?

☐ **Yes**

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

Section 11 – Health Monitoring

Condition 70. Where a zoonotic agent or human pathogen is in use, a documented system must be in place to:

(a) report accidents and exposures to micro-organisms;
(b) monitor employee absenteeism; and
(c) provide medical surveillance of illnesses that are potentially associated with the dealings conducted in the facility.

The Regulator must be informed of any accidents and exposures to GMOs or illnesses associated with these events as soon as reasonably possible

Q. 70 Does the facility comply with Condition 70?

☐ **Yes**

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