Australian Government

Department of Health and Aged Care

Office of the Gene Technology Regulator

Annual Inspection Checklist for a PC3 Invertebrate Facility

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 Invertebrate Facility Version 2.1 – 21 September 2011.*

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 13. 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 13.
- A completed copy of this proforma will be accepted by the OGTR as the annual inspection report for a certified facility under Condition 13, 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 Invertebrate Facility

About completing this proforma

- The conditions in this proforma are the usual conditions of certification as detailed in the Gene Technology Regulator's *Guidelines for Certification of a Physical Containment Level 3 Invertebrate Facility Version 2.1 – xx September 2011*.

- 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 11. The following work must not be conducted in this facility:

(a) dealings with any GMO that under the conditions of a licence requires containment at a higher level than PC3, or any GMO that is a risk group 4 organism as specified in AS/NZS 2243.3;
(b) unless otherwise authorised by the Regulator, dealings with any aquatic organism, except for the aquatic life stage of invertebrates that are necessary for dealings being conducted in the facility;
(c) the growing of any plants, beyond the minimum time that they are required for conducting the dealings with GMOs;
(d) the housing/keeping/rearing of terrestrial vertebrates, beyond the minimum time that they are required for conducting the dealings with GMOs;
(e) dealing with invertebrates smaller than the aperture size of the screens fitted on the facility openings as per requirement 14; or
(f) any other work prohibited by notification in writing by the Regulator.

Q. 11 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.

Section 2 – General conditions

Please answer all questions in this section.

Condition 12 (Intentionally left blank)

Condition 13 (Intentionally left blank)

Condition 14. Each access door to the facility must be labelled with the following 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 persons entering the facility are able to clearly see that they are entering a certified PC3 facility.

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.

Condition 15. 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. 15 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. 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 for decontamination purposes. 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. 16 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. 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. 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.

Section 3 – Facility construction and access conditions

Please answer all questions in this section.

Condition 18. The certification holder must ensure that the physical attributes of the facility and fittings are maintained so that the relevant 'Facility construction and access requirements' continue to be met.

Condition 18.1 (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. 18.1 Does the facility comply with condition 18.1?

☐ **Yes**

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

Condition 18.2 (Requirement 2). The facility must be maintained to enable gaseous decontamination of the whole facility to be achieved.

Q. 18.2 Does the facility comply with condition 18.2?

☐ **Yes**

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

Condition 18.3 (Requirement 3). All facility penetrations must be fitted with seals to limit air leakage.

Q. 18.3 Does the facility comply with condition 18.3?

☐ **Yes**

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

Condition 18.4 (Requirement 4). The facility boundaries (walls, windows, doors, floors, ceilings etc.) must be maintained to prevent the escape of the organisms being contained and to prevent the incursion of pests.

Q. 18.4 Does the facility comply with condition 18.4?

☐ **Yes**

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

Condition 18.5 (Requirement 5). Entry of authorised persons into the work area must be through an airlock and an anteroom.

Q. 18.5 Does the facility comply with condition 18.5?

☐ **Yes**

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

Condition 18.6 (Requirement 6). Airlock doors must be self-closing and each door must be fitted with seals to limit air leakage, and contain a viewing panel. The outer airlock door must have a mechanism in place to restrict access to the facility. Mechanisms (e.g. interlocking or an alarm system) must also be in place to ensure that only one airlock door can be opened at any time.

Q. 18.6 Does the facility comply with condition 18.6?

☐ **Yes**

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

Condition 18.7 (Requirement 7). The facility must contain an anteroom located between the airlock and work area. The anteroom doors must be self-closing.

Q. 18.7 Does the facility comply with condition 18.7?

☐ **Yes**

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

Condition 18.8 (Requirement 8). A mechanism must be in place in the anteroom to effectively prevent invertebrates from traversing the boundary of anteroom/airlock.

Q. 18.8 Does the facility comply with condition 18.8?

☐ **Yes**

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

Condition 18.9 (Requirement 9). A device for inspection and removal of invertebrates from persons exiting the facility must be provided in the anteroom.

Q. 18.9 Does the facility comply with condition 18.9?

☐ **Yes**

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

Condition 18.10 (Requirement 10). Provision must be made for viewing of work areas from outside the facility.

Q. 18.10 Does the facility comply with condition 18.10?

☐ **Yes**

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

Condition 18.11 (Requirement 11). All windows in the facility must be closed and sealed.

Q. 18.11 Does the facility comply with condition 18.11?

☐ **Yes**

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

Condition 18.12 (Requirement 12). The following surfaces in the facility must be smooth, impermeable to water, easily cleanable, and resistant to damage by the cleaning agents, decontamination agent and gaseous decontaminants that will be used in the facility:

(a) walls, floors, ceilings, doors, windows and benches; and
(b) furniture, including seating.

Q. 18.12 Does the facility comply with condition 18.12?

☐ **Yes**

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

Condition 18.13 (Requirement 13). 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. 18.13 Does the facility comply with condition 18.13?

☐ **Yes**

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

Condition 18.14 (Requirement 14). 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 sufficiently small as to prevent entry or exit of invertebrates or other animals.

Q. 18.14 Does the facility comply with condition 18.14?

☐ **Yes**

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

Condition 18.15 (Requirement 15). Where present, liquid drainage exits must be protected against entry or exit of invertebrates or other animals by the use of screens, liquid traps or an equivalent effective method. The apertures of the screen must be sufficiently small as to prevent entry or exit of invertebrates or other animals.

Q. 18.15.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q18.15.2**

☐ **No. Continue to condition 18.16**

Q. 18.15.2 Does the facility comply with condition 18.15?

☐ **Yes**

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

Condition 18.16 (Requirement 16). 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. 18.16 Does the facility comply with condition 18.16?

☐ **Yes**

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

Condition 18.17 (Requirement 17). Designated storage or hanging areas for personal protective clothing and equipment must be available within the anteroom and/or work area.

Q. 18.17 Does the facility comply with condition 18.17?

☐ **Yes**

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

Condition 19. Prior to any structural changes that will affect the containment of GMOs in the facility; the applicant must request a suspension of the certification, in writing, 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 which 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. 19.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q19.2**

☐ **No. Continue to condition 20**

Q. 19.2 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.

Section 4 –Containment equipment conditions

Please answer all questions in this section.

Condition 20. 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 20.1 (Requirement 18). The work area of the facility must contain a biological safety cabinet (BSC), or other aerosol containment equipment approved in writing by the Regulator, appropriate for the dealings which are to be undertaken in the facility.

Installation, use, decontamination and testing of Class I, Class II and Class III BSC must be in accordance with the requirements of AS 2252.1, AS 2252.2, AS 2252.3 and AS 2252.4.

Other aerosol containment equipment must also be installed in accordance with the requirements of the relevant AS/NZS, where available, and/or manufacturer's instructions. Such containment equipment must be tested, commissioned and results documented before use.

Q. 20.1 Does the facility comply with condition 20.1?

☐ **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 21. The certification holder must ensure that the physical attributes of the facility and fittings are maintained so that the relevant 'Laboratory services and equipment requirements' continue to be met.

Condition 21.1 (Requirement 19). 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 anteroom.

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 20). 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 and other equipment supplied with non-potable water, e.g. humidifiers;
(b) outlets within a class II BSC; and
(c) direct connection to an autoclave.

Backflow prevention must isolate the facility to the exclusion of all other areas.

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 21). Autoclave and backflow prevention devices in, or connected, to the facility must be installed in accordance with the requirements of the relevant AS/NZS and/or manufacturer's instructions where available. Such equipment/devices must be tested, commissioned and results documented before use.

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 22). The anteroom and work area of the facility must contain either a dedicated hand wash basin fitted with tap(s) of the hands-free operation type, or some other means of decontaminating hands at or near the exit of the anteroom and the work area. If the facility contains multiple work areas, each work area must contain a dedicated hand wash basin or some other means of decontaminating hands at or near the exit of that work area.

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 23). The work area of the facility must contain eyewash equipment (either plumbed eyewash equipment or single-use packs of sterile eye irrigation fluids).

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 24). 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. 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 25). Piped gas supplies to the facility must have reverse flow prevention on outlets located within a BSC or other approved aerosol containment equipment.

Q. 21.7.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q21.7.2**

☐ **No. Continue to condition 22**

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

Q. 22 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. All services or equipment added to the facility after certification is finalised must be tested, commissioned and found to meet the conditions of certification.

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.

Condition 24. All effluent from the work area must be decontaminated before being discharged.

Q. 24 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.

Section 6 –Ventilation conditions

Please answer all questions in this section.

Condition 25. 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 25.1 (Requirement 26). The facility must have a ventilation system that establishes a negative air pressure gradient in the facility and directional airflow into a 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.

Q. 25.1 Does the facility comply with condition 25.1?

☐ **Yes**

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

Condition 25.2 (Requirement 27). 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 of the PC3 containment barrier.

Q. 25.2 Does the facility comply with condition 25.2?

☐ **Yes**

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

Condition 25.3 (Requirement 28). 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 gaseous decontamination of the facility must be able to be purged to the atmosphere in such a manner that it is dispersed away from occupied buildings and air intakes.

Q. 25.3 Does the facility comply with condition 25.3?

☐ **Yes**

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

Condition 25.4 (Requirement 29). The exhaust filter must be a HEPA filter as specified in the definitions to this document, or another filter that meets all requirements of AS 4260 with a minimum performance of Grade 2. An exhaust pre-filter of the same or higher standard as the supply filter must be installed and mounted upstream of the HEPA filter.

Q. 25.4 Does the facility comply with condition 25.4?

☐ **Yes**

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

Condition 25.5 (Requirement 30). Each exhaust HEPA filter must be mounted in a gastight 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(s) must allow for access to and integrity testing of the HEPA filter.

Q. 25.5 Does the facility comply with condition 25.5?

☐ **Yes**

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

Condition 25.6 (Requirement 31). 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;

(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 0.2µm hydrophobic membrane type filter that is protected from physical impact; and

(d) where separate supply ducts are not fitted, HEPA filter gaseous decontamination would require decontamination of the facility as well.

Q. 25.6 Does the facility comply with condition 25.6?

☐ **Yes**

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

Condition 25.7 (Requirement 32). 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 it can be read immediately before entering the facility.

Q. 25.7 Does the facility comply with condition 25.7?

☐ **Yes**

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

Condition 25.8 (Requirement 33). The facility must be equipped with an alarm that will alert people both inside and outside the facility, and be activated when the pressure in the facility is more than 25 Pa above the set point.

Q. 25.8 Does the facility comply with condition 25.8?

☐ **Yes**

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

Condition 25.9 (Requirement 34). 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 event of central control system malfunction.

Q. 25.9 Does the facility comply with condition 25.9?

☐ **Yes**

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

Condition 25.10 (Requirement 35). Supply or replacement air to the facility must be filtered with 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. 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 the door.

Q. 25.10 Does the facility comply with condition 25.10?

☐ **Yes**

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

Condition 26. 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. 26.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q26.2**

☐ **No. Continue to condition 27**

Q. 26.2 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 27. Biological safety cabinets must be inspected and tested in accordance with the requirements of AS 2252.1 (class I), AS 2252.2 (class II) or AS 2252.3 (class III). This testing is required at least annually and additionally after relocation of a cabinet, or after HEPA filters are replaced. The inspection and testing of cabinets must be carried out by a qualified person.

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 have not been met and the defect has not been corrected, the cabinet 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 the annual tests for the last 3 years must be kept and made available to the Regulator if requested.

Q. 27 Can compliance with condition 27 be demonstrated?

☐ **Yes**

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

Condition 28. Other aerosol containment equipment installed in the facility (e.g. a plastic isolator with sleeve openings) must be inspected and tested at least annually. Where fitted testing must include HEPA filter integrity testing and the containment

equipment 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.

Q. 28 Can compliance with condition 28 be demonstrated?

☐ **Yes**

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

Condition 29. Testing and maintenance of facility ventilation systems must be carried out at least annually and 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, by a qualified person. 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.

Q. 29 Can compliance with condition 29 be demonstrated?

☐ **Yes**

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

Condition 30. If the facility contains a liquid effluent decontamination system, it must be tested and maintained annually by a competent person. Testing must include but may not be limited to:

(a) calibration of all instruments that control or monitor critical process parameters;
(b) confirmation that all parameters of the system are operating within the specified limits (e.g. temperature, time, pH, concentration of chemical);
(c) checking and maintenance of equipment to ensure effective operating condition; and
(d) checking of all safety and relief equipment.

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

Q. 30.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q30.2**

☐ **No. Continue to condition 31**

Q. 30.2 Can compliance with condition 30 be demonstrated?

☐ **Yes**

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

Condition 31. The physical parameters and efficacy of the autoclave, or other heat-based equipment used to decontaminate GMOs, must be validated monthly.

The physical parameters of the autoclave must be validated by the use of:

(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 must be validated by the use of:

(a) biological indicators such as spore strips; or
(b) bacterial enzyme indicators; or
(c) other methods approved in writing by the Regulator.

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

Q. 31 Can compliance with condition 31 be demonstrated?

☐ **Yes**

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

Condition 32. Any heat-based equipment used to decontaminate GMOs must be calibrated annually by a person competent to do so. The results of the annual calibration for the previous 3 years must be kept and made available to the Regulator, if requested. When an autoclave is used for decontamination, annual calibration of the thermometer, timers, thermocouple and safety valves must be performed.

Q. 32 Can compliance with condition 32 be demonstrated?

☐ **Yes**

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

Condition 33. If any 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. 33.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q33.2**

☐ **No. Continue to condition 34**

Q. 33.2 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. 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. 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.

Section 8 –Work practices

Please answer all questions in this section.

Condition 35. The outer door of the facility must be kept locked when the room is unoccupied by personnel.

Q. 35 Do the facility work practices comply with condition 35?

☐ **Yes**

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

Condition 36. Airlock doors must remain closed at all times, except when authorised persons are entering or exiting the facility.

Q. 36 Do the facility work practices comply with condition 36?

☐ **Yes**

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

Condition 37. Emergency exits must only be opened in the event of an emergency.

Q. 37 Do the facility work practices comply with condition 37?

☐ **Yes**

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

Condition 38. Persons must enter and exit the work area only through the airlock.

Q. 38 Do the facility work practices comply with condition 38?

☐ **Yes**

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

Condition 39. With the exception of transport (in accordance with Conditions 62 and 63), dealings with GMOs and/or invertebrates must only take place in the work area.

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. The following personal protective clothing and equipment (PPCE) must be worn by all authorised persons 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;
(c) eye protection;
(d) gloves, and
(e) waterproof dressings on all broken skin not covered by other PPCE.

Q. 40 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 41. Before entering the airlock from the anteroom, authorised persons must check to ensure they are not inadvertently carrying invertebrates on their persons.

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. Upon exit from the facility and prior to entering the airlock, personal protective clothing and equipment must be removed and disposed of, or stored in designated storage or hanging spaces in the work area and/or anteroom.

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. 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. 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. All life stages of invertebrates used in the facility must be contained in primary containers that are designed to prevent the escape of the invertebrates.

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. Any dealings involving GM micro-organisms that may generate aerosols must be performed in a BSC or in specialised aerosol containment equipment that has been approved in writing by the Regulator.

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. If centrifugation is undertaken, it must be carried out in sealed containers (tubes, buckets or rotors). Centrifugation containers must only be opened in a BSC or other aerosol containment equipment approved by the Regulator.

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. Procedures with invertebrates must only be undertaken by authorised persons who have been trained to do so.

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. Handling of the invertebrates containing GMOs, and any experimental procedures conducted on GM invertebrates, must be carried out in a way that minimises the possibility of escape of the invertebrates and exposure of people to the GMOs and invertebrates carrying the GMOs.

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. If invertebrates containing GMOs escape within the facility, trapping devices must be used to capture the invertebrate and either return to its container or cage or euthanase them.

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 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. Decontamination of the facility must take place:

(a) after a spill of GMOs, or escape of GM invertebrates or invertebrates containing GMOs, from primary containment that cannot be effectively decontaminated by another means;
(b) prior to maintenance work on equipment installed in the facility that cannot be decontaminated by another means;
(c) prior to suspension, surrender, expiry or cancellation of certification; and
(d) prior to re-certification of the facility at a lower containment level, if stipulated by the Regulator.

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. With the exception of transport of viable GMOs (in accordance with conditions 62 and 63) to another certified PC3 facility, all items, including equipment, personal protective clothing and waste, contaminated or potentially contaminated with GMOs, must be decontaminated prior to removal from the facility.

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

Q. 53.1 Is this condition relevant to the facility?

☐ **Yes. Answer Q53.2**

☐ **No. Continue to condition 54**

Q. 53.2 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 54. Prior to discharge of decontaminated liquid effluent, the parameters of the decontamination process (e.g. temperature, time, pH etc) must be verified to have met the validated requirements.

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

Q. 55 Do the facility work practices comply with condition 55?

☐ **Yes**

What decontamination method is used

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

Condition 56. 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 or decontaminated before discharge.

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. If a double-ended autoclave is installed across the barrier, it must have a mechanism in place such that it cannot be opened on the clean side without a complete decontamination cycle being undertaken.

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 other heat-based treatment must be performed using a combination of temperature and time that has been validated as 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 chemical decontamination agent treatment must be validated as effective in rendering the GMOs and/or invertebrates carrying GMOs non-viable.

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. (Intentionally left blank)

Condition 61. (Intentionally left blank)

Condition 62. GMOs and material containing GMOs or potentially containing GMOs must not be removed from the facility unless:

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

Q. 60 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. GMOs and material containing GMOs or potentially containing GMOs being transported out of the facility must be transported in accordance with any transport guidelines and other relevant guidelines issued by the Regulator, in force at the time.

Q. 61 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. GMOs must be stored within the work area of a PC3 facility.

GMOs must be stored in a sealed primary container, which has been surface decontaminated prior to enclosure within a sealed secondary container.

Q. 62 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.

Condition 65. Non-essential personal effects, including handbags, personal mobile phones, personal organisers and other non-essential electronic equipment, which will not remain within the work area, should not be taken into the airlock.

Q. 63 Do the facility work practices comply with condition 65?

☐ **Yes**

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

Section 9 –Facility management

Please answer all questions in this section.

Condition 66. A facility manager must be appointed by the certification holder. The facility manager, or his or her delegate(s), must be capable of demonstrating an understanding of the technical aspects of facility design, operation and maintenance.

Q. 64 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.

Condition 67. The certification holder must ensure that the facility manager or his or her delegate(s) is capable of undertaking the functions detailed in the Conditions of Certification.

Q. 65 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.

Section 10 –Facility manual

Please answer all questions in this section.

Condition 68. 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. 66 Does the facility manual comply with condition 68?

☐ **Yes**

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

Condition 69. The facility manual must be reviewed at least annually and updated as necessary.

Q. 67 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 – Training

Please answer all questions in this section.

Condition 70. Training, must include familiarisation with the elements of the facility manual (Condition 68).

Q. 68 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.

Condition 71. Training must include theoretical instruction, and where applicable, supervised practical experience and assessment of competence.

Q. 69 Does the facility comply with condition 71?

☐ **Yes**

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

Condition 72. Training of authorised persons and training records 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 or invertebrates are used in the facility.

Q. 70 Does the facility comply with condition 72?

☐ **Yes**

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

Condition 73. Training records must be updated at least annually and kept for a period of at least three years.

Q. 71 Does the facility comply with condition 73?

☐ **Yes**

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