



Annual Inspection Checklist for PC 2 Plant Facility

Please Note

- The use of this checklist proforma is **not** mandatory in order to satisfy the inspection requirement of Condition 4 of Part B of the *Guidelines for Certification of a Physical Containment Level 2 Plant Facility Version 3.1 - 1 July 2007* (the Guidelines). A completed copy of this proforma will be accepted by the OGTR as an annual inspection report for assessment of the facility's compliance for a certified facility under Condition 4, but the proforma is **not** intended to be the **only** acceptable format for the report. 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, as outlined in Part B of the Guidelines.
- **Please do not send this report to the OGTR unless specifically requested.**

About Completing this Proforma

This proforma is based on the usual conditions of certification as detailed in the Gene Technology Regulator's *Guidelines for Certification of a Physical Containment Level 2 Plant Facility Version 3.1 - 1 July 2007*.

- 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. A request for a variation may be necessary.

| | |
|-----------------------|--------------------------------|
| Facility name: | |
| Inspected by: | Date: |
| | OGTR Identifier number: |

| Facility and fitting conditions | | | | | |
|--|---|------------|-----------|------------|--------------|
| | | Yes | No | N/A | Notes |
| Facility | Fully enclosed space bounded by walls, doors, windows, floors and ceilings, including any transparent sections | | | | |
| Boundaries | Maintained to be rigid, durable and suitable for the environmental conditions they are exposed to, and able to withstand expected wear and tear | | | | |
| | Transparent sections are made of glass, polycarbonate sheeting or similar durable material | | | | |
| | Boundaries impact resistant or protected from impact | | | | |
| | Entry of surface run off water prevented | | | | |
| Anteroom | Facility has an anteroom and entry to the facility is via the anteroom | | | | |
| | arthropods | | | | |

| | | Yes | No | N/A | Notes |
|---|--|-----|----|-----|-------|
| Anteroom cont. | If dealings have the potential to be disseminated by arthropods – anteroom has strategies in place to prevent entry and exit of | | | | |
| Decontamination of hands | Washbasin or other means of hand decontamination present | | | | |
| Drainage exits | Fitted with barriers to prevent arthropods, animals or GM plants or GM propagative plant material entering or escaping via the drains | | | | |
| Facility alterations | Are there any significant structural changes that may affect containment? | | | | |
| Dealings involving GM micro-organisms (these conditions must also be met if any of the dealings in the facility involve GM micro organisms) | | | | | |
| Surfaces | Smooth, impermeable to water, cleanable and resistant to damage by cleaning agents used in the facility | | | | |
| Open spaces under benches and equipment | Accessible for decontamination | | | | |
| Drainage exits | Fitted with liquid traps that are permanently filled with appropriate decontaminant | | | | |
| | Liquid entering drains contained and treated as waste | | | | |

| | | Yes | No | N/A | Notes |
|---|---|-----|----|-----|-------|
| Aerosol containment | PC2 GM dealings produce aerosols | | | | |
| | Aerosols are contained in a BSC or other equipment specifically approved in writing | | | | |
| | If BSC Class I or II used to contain the aerosols: | | | | |
| | BSC inspected and tested at least once within last 12 months | | | | |
| | Certificate of test results and date of next test affixed to side of cabinet | | | | |
| Heat based decontamination equipment | Validated monthly | | | | |
| | Calibrated annually | | | | |
| Backflow prevention | If installed at time of certification – maintained and tested annually (if testable) | | | | |
| | Risks have been altered and/or been reviewed | | | | |
| | Backflow prevention is required to be installed due to new risks | | | | |

| General Conditions | | | | | |
|--|--|------------|-----------|------------|--------------|
| | | Yes | No | N/A | Notes |
| Ownership of facility | Certification holder owns or has authority to maintain facility and fittings | | | | |
| | If no – has owner not carried out or refused to carry out required maintenance | | | | |
| Signs | OGTR signage and biohazard signs affixed to access door/s (signs are on or near access door/s and able to be clearly seen by persons entering facility) | | | | |
| Disinfectant | Supply suitable for use against the GMOs dealt with in the facility available | | | | |
| Pests | Control strategy in place | | | | |
| Obligations of the certification holder in respect to the users of the facility | | | | | |
| Authorised persons | Facility access restricted to authorised persons (as described in Part B, conditions 8 to 16, of the <i>Guidelines for Certification of Physical Containment Facilities PC2 Plant Facility Version 3.1 – issued 1 July 2007</i>) | | | | |
| Behavioural Requirements | | | | | |
| Training | Persons conducting dealings with GMOs in the facility have been trained in the behavioural requirements (as listed in Part C of <i>Guidelines for Certification of Physical Containment Facilities PC2 Plant Facility Version 3.1 – issued 1 July 2007</i>) | | | | |