



Australian Government

Department of Health and Aged Care

Office of the Gene Technology Regulator

## Annual Inspection Checklist for PC2 Plant Facility

### Please Note

- The use of this checklist proforma is **not** mandatory, rather it is provided to assist in the annual inspection of certified facilities. While the proforma is **not** intended to be the **only** acceptable format, a completed copy of this proforma will be accepted by the OGTR as satisfying the annual inspection requirement of Condition 12 of Part B of the *Guidelines for Certification of a Physical Containment Level 2 Plant Facility Version 3.2 – 1 March 2013* (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 3.2 – 1 March 2013*.

- 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.

<b>Facility name:</b>						
<b>Inspected by:</b>			<b>Date:</b>			
			<b>OGTR Identifier number:</b>			
<b>Facility and fitting conditions</b>						
			<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Notes</b>
<b>Facility</b>	Is the facility site subject to flooding or storm surges as described in requirement 1 of Part A.					
	<b>If yes;</b> Are there strategies in place to minimise the risk of loss of containment during such events					
	<b>Structure</b>					
	Fully enclosed space bounded by walls, doors, windows, floors and ceilings					
	Any significant structural changes that may affect containment					
<b>Boundaries</b>	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					

		Yes	No	N/A	Notes
<b>Anteroom</b>	Facility has an anteroom and entry to the facility is via the anteroom				
	<b>If GMOs or GM products have the potential to be disseminated by invertebrates</b> – anteroom has strategies in place to prevent entry and exit of invertebrates				
<b>Surfaces</b>	Impermeable to GMOs or effective mechanisms in place to decontaminate them				
<b>Decontamination of hands</b>	Washbasin or other means of hand decontamination present				
<b>Drainage exits (Barriers)</b>	Fitted with barriers to prevent invertebrates, animals, GM plants or GM propagative plant material entering or escaping via the drains				
<b>Drainage exits (Effluent Control)</b>	Fitted with liquid traps that are permanently filled with appropriate decontaminant				
	Liquid entering drains contained and treated as waste				
<b>Open spaces under benches and equipment</b>	Accessible for decontamination				

**Dealings involving GM micro-organisms**

(these conditions must also be met if any of the dealings in the facility involve GM micro organisms)

		Yes	No	N/A	Notes
<b>Aerosol containment</b>	Dealings involving Risk Group 2 PC2 GMOs produce aerosols				
	BSC or other equipment specifically approved in writing present				
	<b>If BSC Class I or II used to contain the aerosols:</b>				
	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				
<b>Heat based decontamination equipment</b>	Validated monthly				
	Calibrated annually				
<b>Backflow prevention</b>	<b>If installed</b> – maintained and tested annually (if testable)				
	Changes to or new connections made to the water supply ( <b>If yes</b> - new Risk Assessment required)				
	If RA requires backflow protection, is it installed and functioning properly				

General Conditions					
		Yes	No	N/A	Notes
<b>Ownership of facility</b>	Certification holder owns or has authority to maintain facility and fittings				
	<b>If no</b> – has owner not carried out or refused to carry out required maintenance				
<b>Signs</b>	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)				
<b>Disinfectant</b>	Supply suitable for use against the GMOs dealt with in the facility available				
<b>Pests</b>	Pest control strategy in place.				
Obligations of the certification holder in respect to the users of the facility					
		Yes	No	N/A	Notes
<b>Authorised persons</b>	Facility access restricted to authorised persons (as described in Part B, conditions 1 to 9, of the <i>Guidelines for Certification of Physical Containment Facilities PC2 Plant Facility Version 3.2 – issued 1 March 2013</i> )				
Behavioural Requirements					
<b>Training</b>	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 3.2 – issued 1 March 2013</i> )				