



**Australian Government**

**Department of Health and Ageing**

**Office of the Gene Technology Regulator**

## **Annual Inspection Checklist for PC2 Laboratories**

### **Please Note**

- The use of this checklist proforma is **not** mandatory in order to satisfy the annual inspection requirement of Condition 4 of part B the *Guidelines for Certification of a Physical Containment Level 2 Laboratory 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 Laboratory 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.

<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>	Fully enclosed space bounded by walls, doors, windows, floors and ceilings				
	Are there any significant structural changes that may affect containment?				
<b>Surfaces</b>	Smooth, impermeable to water, cleanable and resistant to damage by any cleaning agents used				
<b>Open spaces under benches and equipment</b>	Accessible for decontamination				
<b>Decontamination of hands</b>	Hands free washbasin fitted <b>OR</b>				
	Other means of decontamination of hands (eg: dispensers containing decontaminant solution)				

		Yes	No	N/A	Notes
<b>Eyewash</b>	Equipment provided and maintained				
<b>Aerosol containment</b>	PC2 GM dealings produce aerosols				
	Aerosols are contained in a BSC or other equipment specifically approved in writing				
	<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 at time of certification</b> – maintained and tested annually (if testable)				
	Risks have altered and/or been reviewed				
	Backflow prevention required to be installed due to new risks				

<b>General conditions</b>					
		<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Notes</b>
<b>Ownership of facility</b>	Certification holder owns or has authority to maintain facility and fittings				
	<b>If no</b> – has owner failed to carry 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>	Control strategy in place				
<b>Obligations of the certification holder in respect to the users of the facility</b>					
<b>Authorised persons</b>	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 Laboratory Version 3.1 – issued 1 July 2007</i> )				
<b>Behavioural Requirements</b>					
<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 Laboratory Version 3.1 – issued 1 July 2007</i> )				