



Australian Government

Department of Health and Aged Care

Office of the Gene Technology Regulator

Annual Inspection Checklist for PC2 Laboratories

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 Laboratory 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 Laboratory 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.

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				
	Any significant structural changes that may affect containment				
Surfaces	Smooth, impermeable to water, cleanable and resistant to damage by cleaning agents used in the facility (includes furnishings, benches, walls, floors etc.)				
Decontamination of hands	Hands free washbasin fitted OR				
	Other means of decontamination of hands (eg: dispensers containing decontaminant solution)				
Open spaces under benches and equipment	Accessible for decontamination				

		Yes	No	N/A	Notes
Eyewash	Equipment provided and maintained				
Aerosol containment	Dealings involving Risk Group 2 PC2 GMOs produce aerosols				
	BSC or other equipment specifically approved in writing present				
	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 – maintained and tested annually (if testable)				
	Changes to or new connections made to the water supply (If yes - new Risk Assessment required)				
	If RA requires backflow protection, is it installed and functioning properly 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 failed to carry 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	Pest control strategy in place				
Obligations of the certification holder in respect to the users of the facility					
		Yes	No	N/A	Notes
Authorised persons	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 Laboratory Version 3.2 – issued 1 March 2013</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 Laboratory Version 3.2 – issued 1 March 2013</i>)				