



Australian Government

Department of Health and Ageing
Office of the Gene Technology Regulator

Application Checklist for a Physical Containment Facility Level 2 Laboratory

Checklist against the requirements under Part A of the Gene Technology Regulator's
Guidelines for Certification of a Physical Containment Level 2 Laboratory Version 3.1 - 1 July 2007

Please Note

- The use of this checklist proforma is **not** mandatory in order to conduct an inspection of certified facilities for compliance with the requirements of certification under Part A of *Guidelines for Certification of a Physical Containment Level 2 Laboratory Version 3.1 - 1 July 2007*. Rather, it is provided to assist those who find it convenient to use for the above mentioned inspection.
- This proforma is based on the requirements 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* (the Guidelines). **Applicants must refer to these guidelines for full details of the requirements before confirming compliance on the application form.**
- If in answer to any of the questions below it is indicated that the facility does not meet the requirements of certification under Part A of the Guidelines or may not be able to meet the expected conditions of certification, as listed in Part B of the Guidelines, then this information should be reported under section 3 of the *Application for the Certification of a Physical Containment Facility* along with any suggested strategies to enable certification of the facility.
- **Please do not send this report to the OGTR unless specifically requested.**

Organisation name:	
Facility name:	
Inspected by:	
	Date:

Facility and fitting requirements				
		Yes	No	Notes/Details
Facility	Fully enclosed space bounded by walls, doors, windows, floors and ceilings			
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			
Decontamination of hands	Hands free washbasin fitted OR			
	Other means of decontamination of hands			
Eyewash	Equipment provided (either a plumbed eyewash or single use packs of sterile eye irrigation fluids)			

		Yes	No	Notes/Details
Aerosol containment	PC2 GM dealings proposed will produce aerosols			
	If yes - BSC installed (Class I or Class II BSC must be installed in accordance with the requirements of AS/NZS 2647:2000) OR			
	Other equipment to contain aerosols to be used (will require written permission from the Regulator)			
Backflow prevention	Device or system that may cause contamination of a potable water supply with GMOs requiring PC 2 containment connected directly or indirectly to any part of a water service			
	If yes - Backflow risk assessment has been carried out			
	Backflow prevention necessary and prevention measures implemented in accordance with the requirements of section 4 of AS/NZS 3500.1:2003			
Capacity to comply with certification conditions				
Capacity to comply	Demonstrated capacity to comply with the conditions of certification that will generally be applied to a certified PC2 Laboratory (these conditions are set out under Part B of <i>Guidelines for Certification of Physical Containment Facilities PC2 Laboratory Version 3.1 – issued 1 July 2007</i>)			