



Australian Government

Department of Health and Aged Care

Office of the Gene Technology Regulator

Annual Inspection Checklist for PC2 Constant Temperature Room

Please Note

- The use of this checklist proforma is **not** mandatory in order to satisfy the annual inspection requirement of Condition 12 of part B the *Guidelines for Certification of a Physical Containment Level 2 Constant Temperature Room Version 2.1 - Effective 9 August 2011* (the Guidelines).
A completed copy of this proforma will be accepted by the OGTR as an annual inspection report under Condition 12, 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 Constant Temperature Room Version 2.1 - Effective 9 August 2011*.

- 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 may need to be submitted to the Regulator to vary the certification.

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

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 1,2,8 and 9, of the <i>Guidelines for Certification of Physical Containment Facilities PC2 Constant Temperature Room Version 2.1 - Effective 9 August 2011</i>)				
General conditions					
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	Control strategy in place				

Facility and fitting conditions

		Yes	No	N/A	Notes
Facility	Fully enclosed space bounded by walls, doors, windows, floors and ceilings				
	Facility doors and windows are lockable or otherwise secured				
	Are there any significant structural changes that may affect containment?				
Surfaces	Smooth, impermeable to water, cleanable and resistant to damage by any cleaning agents used				
Open spaces under benches and equipment	Accessible for decontamination				
Decontamination of hands	Hands free washbasin fitted OR				
	Other means of decontamination of hands (eg: dispensers containing decontaminant solution)				
Heat based decontamination equipment	Effectiveness monitored monthly				
	Calibrated annually				

Behavioural Requirements

		Yes	No	N/A	Notes
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 Constant Temperature Room Version 2.1 – Effective 9 August 2011</i>)				