



Australian Government

Department of Health and Aged Care
Office of the Gene Technology Regulator

Annual Inspection Checklist for a PC3 Facility

Checklist for annual inspection against the usual Conditions of Certification as detailed in the Gene Technology Regulator's *Guidelines for Certification of a Physical Containment Level 3 Facility Version 1.0 - 01 December 2022*

Name(s) and signature(s) of person(s) inspecting the facility (please print name clearly)

Date of Inspection

Please Note

- 1 The use of this checklist proforma is **not** mandatory in order to satisfy the annual inspection reporting component of Condition 15. 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 under Condition 15.
- 2 A completed copy of this proforma will be accepted by the OGTR as the annual inspection report for a certified facility under Condition 15, but the proforma is **not** intended to be the **only** acceptable format for the report.
- 3 Please use the 'Application Checklist' against the requirements for certification (as opposed to this 'Annual Inspection Checklist') when applying for a new certification, or when seeking a variation to the requirements for certification of a facility (e.g. lifting the suspension of a certification after modifications to the facility.)
- 4 Please do not send this report to the OGTR unless specifically requested.

1 Facility details

Organisation	
Facility details	Cert-xxx PC3 Facility <input type="checkbox"/> Animal room(s) <input type="checkbox"/> Invertebrates room(s)
GMOs in the facility	
Relevant non-GMOs present	
Licences associated with facility	
NLRD(s) associated with facility	

2 Facility management

2.1 Facility manual

Person who is responsible for training of staff: _____

Date of last review: _____

Information required in the facility manual:

Required information	Addressed
Facility manager's contact details	<input type="checkbox"/>
Emergency contacts details	<input type="checkbox"/>
Copy of certification instruments and conditions of certification	<input type="checkbox"/>
Copy of licences/NLRDs	<input type="checkbox"/>
Copy of <i>Guidelines for the Transport, Storage and Disposal of GMOs & Certification of a PC3 facility</i>	<input type="checkbox"/>
Structure & operation of facility (including design limits)	<input type="checkbox"/>
Details of all GM and non-GM organisms used in the facility, associated risks, and risk management strategies	<input type="checkbox"/>

Procedures to be included in the facility manual:

Procedures	Addressed
Procedures for handling animals and invertebrates held within the facility, if applicable, including the procedure to be implemented in the event an animal/invertebrate escape within or outside the facility and to account of all animal/invertebrate held within the facility	<input type="checkbox"/>

Entry & exit procedures, PPE requirements and protocols for use / removal	<input type="checkbox"/>
Procedures for use and operation of BSC / other aerosol containment equipment, including the removal of gloves and over-sleeves on completion of the dealing and prior to leaving the BSC	<input type="checkbox"/>
Procedures for the use of sharps, if applicable, including circumstances in which sharps to be used	<input type="checkbox"/>
Procedures for movement of equipment out of facility, including its decontamination	<input type="checkbox"/>
Procedures and validation for use of decontamination chamber if present	<input type="checkbox"/>
Procedures for decontamination of GM organisms, including use of the autoclave	<input type="checkbox"/>
Procedures and triggers for the gaseous decontamination	<input type="checkbox"/>
Procedures for disposal of waste and effluent, including their transport	<input type="checkbox"/>
Procedures for transporting viable GMOs inside the facility, including transport of GMOs for storage	<input type="checkbox"/>
Procedures for the transport of viable material outside the facility (e.g. to another PC3 facility)	<input type="checkbox"/>
Circumstances or events which must be reported to the Regulator	<input type="checkbox"/>
Contingency plans for:	
Spills of GMOs inside and outside the facility	<input type="checkbox"/>
Accidental exposure/medical emergencies to the GMOs	<input type="checkbox"/>
Escape of animals or invertebrates containing GMOs within or outside the facility, if applicable	<input type="checkbox"/>
Alarms for fire or loss of pressure	<input type="checkbox"/>
Release of GMOs from the facility (e.g., loss, theft or unintentional release)	<input type="checkbox"/>
Failure of power or ventilation systems	<input type="checkbox"/>
Failure of autoclaves and other decontamination systems	<input type="checkbox"/>
Failure of BSCs and other aerosol containment equipment	<input type="checkbox"/>
Natural disasters and fire	<input type="checkbox"/>
Medical emergencies to persons	<input type="checkbox"/>
Security threats	<input type="checkbox"/>

2.2 Record keeping

Required to keep for *at least 3 years of records

** at least 12 months of records

Conditions	Item	Frequency	Completed	Comments
C14, C15, C22	Inspection of facility	Annually*	<input type="checkbox"/>	
C21	Pest prevention strategy	Ongoing*	<input type="checkbox"/>	
C26 C28 C31	BSC	Annually*	<input type="checkbox"/>	
C26 C28 C31	IVCs & change stations	Annually*	<input type="checkbox"/>	
C26 C33 C34	Autoclave (maintain)	Annually*	<input type="checkbox"/>	
C32	Autoclave (validate)	Quarterly**	<input type="checkbox"/>	
C26 C33 C34	LWTS	Annually*	<input type="checkbox"/>	
C36	Backflow prevention device	Annually*	<input type="checkbox"/>	
C37 C38	Ventilation	Annually*	<input type="checkbox"/>	
C68	Gaseous decontamination	As required per C69	<input type="checkbox"/>	
C72	List of all GM organisms in the facility	As required per C72	<input type="checkbox"/>	
C77-81	Training/ Update training records	As required per C77-81*	<input type="checkbox"/>	
C83	List of persons authorised to enter the facility	As required per C83	<input type="checkbox"/>	
C84	Facility manual review	Annually*	<input type="checkbox"/>	

2.3 Other

	Section	Requirement	Comments
C2	Annual shutdown	Facility inspected after annual shutdown, if applicable <input type="checkbox"/>	
C11	Work not including	Dealings above PC3 containment <input type="checkbox"/> Housing of plants and aquatic animals beyond minimum time <input type="checkbox"/>	
C77 to C80	Training	Authorised persons re-trained on last updated procedures? Training records updated <input type="checkbox"/> Training of people who are authorised but not undertaking dealings <input type="checkbox"/> e.g. tradie	
C85	Health monitoring	Procedures developed to: record accidents and potential exposure to GM human pathogens <input type="checkbox"/> respond to exposure to GM human pathogens <input type="checkbox"/>	
C4 C5	Authorised entry	Authority to exclude people from the facility <input type="checkbox"/> Entry is restricted to authorised people <input type="checkbox"/>	
C21	Pest Program	Program is proactive <input type="checkbox"/> reactive <input type="checkbox"/> Frequency	

3 Work practices

	Section	Requirement	Comments
C47 C48	PPE worn	lab coat <input type="checkbox"/> closed footwear <input type="checkbox"/> eye protection <input type="checkbox"/> gloves <input type="checkbox"/> skin abrasions covered <input type="checkbox"/> Long hair tied/covered <input type="checkbox"/> Optional Mask <input type="checkbox"/> respirator <input type="checkbox"/> face shield <input type="checkbox"/> PAPR <input type="checkbox"/> booties <input type="checkbox"/> double gloves <input type="checkbox"/>	
R16	PPE storage	Dedicated hanging/storage for PPE <input type="checkbox"/> Reusable PPE are stored in a manner preventing cross contamination <input type="checkbox"/>	
C40 C41 C42	Personal effects	Food or drink not brought into/stored in the facility <input type="checkbox"/> Personal items not taken into the facility <input type="checkbox"/> Essential items decontaminated prior to exit <input type="checkbox"/>	
C74	Transport of GMOs	Viable GMOs removed from the facility <input type="checkbox"/> If yes, purpose of transport is: <ul style="list-style-type: none"> • Transport to other PC3 or PC4 facility <input type="checkbox"/> • Export <input type="checkbox"/> • Written permission from the Regulator <input type="checkbox"/> Transport conducted in accordance with the <i>Guidelines for the Transport, Storage and Disposal of GMOs</i> <input type="checkbox"/>	
C52 C54	Aerosol containment	Aerosol generating dealings with GMOs in BSC <input type="checkbox"/> Centrifugation of GMOs in sealed containers <input type="checkbox"/>	
C55	Sharps	Not used in direct connection with GMOs unless no alternatives are available <input type="checkbox"/>	
C23 C76	Storage of GMOs	within work area only <input type="checkbox"/> Triple contained <input type="checkbox"/>	Exemptions? Alternate site inspected?

4 Inspection of the physical facility

4.1 General facility

	Section	Requirement	Comments
R2 R3	Facility Boundary	Facility sealable for gaseous decontamination <input type="checkbox"/> Windows, if present, closed and sealed <input type="checkbox"/>	
C22	Structural changes	Any since last inspection <input type="checkbox"/>	
C13	Containment	Facility not used as a primary containment facility <input type="checkbox"/>	
R6	Lifts	No lifts present <input type="checkbox"/>	
R8	Pass through boxes /barrier autoclave	Type: Doors unable to be opened simultaneously <input type="checkbox"/> Autoclave outer door opens only after successful decontamination <input type="checkbox"/>	
R10 R11	Openings fitted with screens	Openings in walls, ceiling, or roof are screened <input type="checkbox"/> Screens are: fixed and sealed against mounting <input type="checkbox"/> made of appropriate material <input type="checkbox"/> Small enough to prevent movement of invertebrates or animal <input type="checkbox"/>	
R5	Penetrations	Sealed <input type="checkbox"/>	
R17	Communication equipment	Primary equipment <input type="checkbox"/> Alternative independent back-up system <input type="checkbox"/>	
R31	Eyewash	Plumbed <input type="checkbox"/> Single use <input type="checkbox"/>	
R13 R14	Surfaces Fixtures/fittings	Surfaces are: smooth, impervious to water and easily cleanable <input type="checkbox"/> resistant to cleaning agent and decontaminants <input type="checkbox"/> Open spaces between and under fixtures, fittings and equipment accessible for decontamination <input type="checkbox"/>	
R9	Decontamination Chamber	Present <input type="checkbox"/> Doors unable to be opened simultaneously <input type="checkbox"/>	

4.2 Entry, airlock, anteroom

	Section	Requirement	Comments
R38	Inward airflow	Air pressure at the entrance of the facility or each work area <input type="checkbox"/>	
R39 R40		During the normal operation, work area at least 50 Pa below the pressure outside the facility <input type="checkbox"/> and When either airlock door is opened, air pressure in all work area remains at least 25 Pa below the pressure outside the facility <input type="checkbox"/>	
C16	Signage on door	OGTR sign <input type="checkbox"/> Biohazard sign <input type="checkbox"/> Emergency contact numbers <input type="checkbox"/>	
C43 C44	Facility access	Outer facility door lockable when unoccupied <input type="checkbox"/>	
C45 C46		Entry and exit through airlock <input type="checkbox"/> Emergency exits only used in an emergency if present <input type="checkbox"/>	
R7	Airlock doors	Self-closing <input type="checkbox"/> Sealed <input type="checkbox"/> Outer door has mechanism to restrict entry <input type="checkbox"/> Doors unable to be opened simultaneously <input type="checkbox"/>	
C18	Airlock	No GMO dealings other than transport <input type="checkbox"/> No used PPE <input type="checkbox"/> No handwash basins <input type="checkbox"/> No equipment <input type="checkbox"/>	
C19	Anteroom	No GMO dealings other than transport (or autoclaving) <input type="checkbox"/> No used PPE <input type="checkbox"/> No handwash basins <input type="checkbox"/> No equipment <input type="checkbox"/>	

4.3 Work area

	Section	Requirement	Comments
C17	Emergency contacts	Visible in each work area <input type="checkbox"/>	
R30	Hand decontamination	Present at or near the exit of work area <input type="checkbox"/> Hands-free operation <input type="checkbox"/>	
R15	GM dealing in multi room facility	Areas where GMO dealings are conducted are clearly identified <input type="checkbox"/>	
C73	GMO labelling	Containers labelled to indicate they contains GMOs <input type="checkbox"/>	

4.4 Aerosol containment

	Section	Requirement	Comments
R20	BSC	Number & type	
		Powered by uninterruptable power supply <input type="checkbox"/>	
R21 C28 C29 C30 C52		Decontaminated before servicing <input type="checkbox"/> Tested annually and after relocation <input type="checkbox"/> HEPA filter integrity testing <input type="checkbox"/> Result and date of the next test affixed to BSCs <input type="checkbox"/> If defective, labelled appropriately <input type="checkbox"/>	
		Used for all GMO dealings producing aerosols <input type="checkbox"/>	Any exceptions?
C28b C29 C30	IVCs and other aerosol containment devices approved in writing by the Regulator	Device type: Decontaminated before servicing <input type="checkbox"/> Tested annually <input type="checkbox"/> HEPA filter integrity testing <input type="checkbox"/> Result and date of the next test affixed to equipment <input type="checkbox"/> If defective, labelled appropriately <input type="checkbox"/>	

4.5 Decontamination

	Section	Requirement	Comments
R12	Liquid effluent	Decontaminated prior to discharge from sink/floor drainage exit <input type="checkbox"/>	
C59	GMOs/organisms infected with GMOs	Rendered non-viable before removal <input type="checkbox"/>	
C60	Items removed from facility	Decontaminated prior to removal <input type="checkbox"/>	
C57	Work surfaces	immediately after use <input type="checkbox"/> at end of day <input type="checkbox"/>	
C49 C61	PPE	Removed when exiting work area <input type="checkbox"/> Removed prior to entering the airlock <input type="checkbox"/> Decontaminated before reuse or disposal <input type="checkbox"/>	
C25 C58	Equipment	Equipment decontaminated before maintenance <input type="checkbox"/>	
C63	Other methods	UV / Irradiation <input type="checkbox"/> Approved in writing by the Regulator <input type="checkbox"/>	
C70	Spills	Spills kit present <input type="checkbox"/>	

Chemical decontamination

	Section	Requirement	Comments
C20 C67	Chemical decontaminants	Available supply of disinfectants <input type="checkbox"/> Concentration and exposure time effective against the GMOs being decontaminated <input type="checkbox"/> Users aware of the minimum exposure time required for effective decontamination <input type="checkbox"/> Labelled (contents, concentration, expiry date) <input type="checkbox"/>	Present in all work areas

Gaseous decontamination

	Section	Requirement	Comments
C68	Gaseous decontamination	Chemical used for gaseous decontamination:	
		Has the chemical been validated as effective against the GMOs <input type="checkbox"/>	
		Use of appropriate indicators for the validation of the decontamination <input type="checkbox"/>	

Heat decontamination

	Section	Requirement	Comments
R22	Autoclave	present <input type="checkbox"/> Not in airlock <input type="checkbox"/>	
C65		Type: barrier <input type="checkbox"/> free-standing <input type="checkbox"/> Doors unable to be opened simultaneously <input type="checkbox"/>	
C32		Physical parameters validated at least quarterly <input type="checkbox"/> Via: Independent thermocouples <input type="checkbox"/> or Chemical indicators which use a combination of moisture, heat, and time <input type="checkbox"/> or Other <input type="checkbox"/>	
C66		Combination of parameters (pressure, temperature, time) validated as effective against the organism being decontaminated or suitable surrogate <input type="checkbox"/>	
C33		Annual testing and maintenance completed <input type="checkbox"/> , including: Calibration of temperature and pressure measuring probes <input type="checkbox"/> Testing and confirmation that all parameters of the system (temperature, time, pressure and flowrate) are operating within the specified limits <input type="checkbox"/> Testing of all safety and relief components, including the autoclave safety valves <input type="checkbox"/> and Maintenance of the equipment to ensure effective operating conditions <input type="checkbox"/>	
C34 C35		Result and date of the next test affixed to equipment <input type="checkbox"/> If defective, labelled appropriately <input type="checkbox"/>	
C64		Loads packed such that steam can be contact all material <input type="checkbox"/>	
		Measures to differentiate loads pre and post decontamination	autoclave tape <input type="checkbox"/>
		Air, steam & liquid is filtered / decontaminated prior to discharge <input type="checkbox"/>	

	Section	Requirement	Comments
R24 C33 C34 C60 C71	LWTS	Present <input type="checkbox"/> Fully enclosed system <input type="checkbox"/> Pipes clearly identifiable <input type="checkbox"/> Leak detection present <input type="checkbox"/> or double skin <input type="checkbox"/> Vents to pipes, tanks filtered <input type="checkbox"/> Restricted access to LWTS room <input type="checkbox"/> Validated to ensure that it can achieve the parameters required to inactivate the most resistant organism used in the facility <input type="checkbox"/>	
		Annual testing and maintenance completed <input type="checkbox"/> , including: Calibration of temperature and pressure measuring probes <input type="checkbox"/> Testing and confirmation that all parameters of the system (temperature, time, pressure and flowrate) are operating within the specified limits <input type="checkbox"/> Testing of all safety and relief components, including the autoclave safety valves <input type="checkbox"/> and Maintenance of the equipment to ensure effective operating conditions <input type="checkbox"/>	

4.6 Ventilation system

	Section	Requirement	Comments
R18 R19	Room access	Access to ventilation equipment restricted <input type="checkbox"/> Ducts, and access panels clearly identifiable <input type="checkbox"/>	
R32 R36	Exhaust and supply system	The facility fitted with a ventilation system establishing negative air pressure in the facility and a directional airflow into the work area(s) <input type="checkbox"/> Exhaust & supply system interlocked <input type="checkbox"/>	
		Exhaust fitted with: At least one HEPA filter through which all exhaust air is filtered <input type="checkbox"/> Pre filter upstream <input type="checkbox"/> Exhaust fan downstream of the exhaust HEPA <input type="checkbox"/> Gas-tight air ducts between the facility and the HEPA filter housing <input type="checkbox"/>	
R33 R34	Exhaust housing	HEPA mounted in gas-tight housing with sealed access doors <input type="checkbox"/>	

	Section	Requirement	Comments
R37		<p>Design and location of the filter housing allow for:</p> <p>Easy access <input type="checkbox"/></p> <p>Secure and damage free handling of the HEPA <input type="checkbox"/></p> <p>In situ gaseous decontamination <input type="checkbox"/></p> <p>Maintenance, replacement and integrity testing of the HEPA filter <input type="checkbox"/></p> <p>If gaseous decon performed on HEPA filters, Gas tight isolating valve present on:</p> <p>Air inlet duct <input type="checkbox"/></p> <p>Upstream port <input type="checkbox"/> and</p> <p>Downstream port</p> <p><i>If pressure across HEPA filter measured, 0.2µm hydrophobic membrane filter present on facility side of HEPA</i> <input type="checkbox"/></p>	
C27 R41 R42	Ventilation system malfunction and alarm	<p>Facility equipped with an audible alarm <input type="checkbox"/></p> <p>Alarm activated when pressure in the work area(s) or airlock deviates from the set point by 15 Pa for more than 2 minutes <input type="checkbox"/></p> <p>In the event of failure or malfunction of the ventilation system:</p> <p>Use emergency stop button <input type="checkbox"/> have procedures <input type="checkbox"/></p> <p>Notification to OGTR <input type="checkbox"/></p>	
R35 C25 C37	Testing of the Ventilation system	<p>Decontamination of the HEPA housing prior to testing or repair <input type="checkbox"/></p> <p>Annual testing and maintenance of the facility ventilation system including:</p> <p>Testing of the pressure differentials <input type="checkbox"/></p> <p>Checking directional airflow <input type="checkbox"/></p> <p>Testing of the alarm <input type="checkbox"/></p> <p>Testing of components of the ventilation system in a system failure scenario <input type="checkbox"/></p> <p>Calibration of transducers fitted to the air-handling system and validation of air-handling performance <input type="checkbox"/></p> <p>Calibration of pressure gauges <input type="checkbox"/></p> <p>The air handling control system <input type="checkbox"/></p> <p>If applicable, the building management system <input type="checkbox"/> and</p> <p>Integrity testing of all HEPA <input type="checkbox"/></p>	

4.7 Backflow prevention devices

	Section	Requirement	Comments
R25 R26 R27 C36	Backflow prevention	Water supply, connected directly or indirectly to any part of a water service, protected against backflow <input type="checkbox"/> If no backflow prevention devices, documentation on risk assessment/risk management plan available <input type="checkbox"/> If defective, labelled appropriately <input type="checkbox"/>	
R28	Vacuum system	Present <input type="checkbox"/> if so, fitted with: 0.2 µm hydrophobic membrane filters <u>and</u> liquid disinfectant traps <input type="checkbox"/> If central vacuum system, filter and trap on the facility side of the vacuum line <input type="checkbox"/> If portable pump, filter and trap located before the pump <input type="checkbox"/>	
R29	Piped gas	Present in a BSC <input type="checkbox"/> if so, Reverse flow prevention on outlets in BSC <input type="checkbox"/> or fitted with ≤0.2µm hydrophobic membrane filter <input type="checkbox"/>	

4.8 Animal work area

	Section	Requirement	Comments
Ani-C1 Ani-C9	Signs	Sign on outer door with special entry conditions/ animals present <input type="checkbox"/> Documented system to account for all animals <input type="checkbox"/>	
Ani-C6	Dealings generating aerosols	Conducted in BSC <input type="checkbox"/> or in aerosol containment equipment approved in writing by the Regulator (e.g., Inhalation exposure system) <input type="checkbox"/>	
Ani-R1 Ani-C4 Ani-C5 Ani-C7 Ani-C8	Cages/enclosure	Cages/enclosures devices appropriate for the animals being housed present (all life stages) <input type="checkbox"/> Animal infected with aerosol transmissible GMOs housed in sealed cages/enclosures fitted with exhaust HEPA filters (IVCs or ventilated enclosure HEPA filtered) <input type="checkbox"/> Cage is labelled to indicate it contains a GMO <input type="checkbox"/> and the number of animals within the cage/enclosure <input type="checkbox"/>	
A-R2	Containers used for Euthanising	Container used for euthanising animal containing GM micro-organisms requiring PC3 containment and capable of being shed are: sealed <input type="checkbox"/> and fitted with a gas inlet filtered with a 0.2 µm hydrophobic membrane <input type="checkbox"/>	

	Section	Requirement	Comments
Ani-C11 Ani-C12	Decontamination	Animal carcasses decontaminated prior to removal from the facility <input type="checkbox"/> Equipment, cages, bedding and animal waste decontaminated prior to removal from the facility <input type="checkbox"/>	

4.9 Invertebrate work area

	Section	Requirement	Comments
Inv-C1 Inv-C7	Signs	Sign on outer door with special entry conditions/ invertebrates present <input type="checkbox"/> Documented system to account for all invertebrates <input type="checkbox"/>	
Inv-R1 Inv-R2 Inv-R3	Anteroom	Anteroom present for entry to the room(s) housing invertebrates <input type="checkbox"/> Anteroom doors self-closing doors <input type="checkbox"/> No dealings conducted within the anteroom <input type="checkbox"/> Mechanism to prevent invertebrates from traversing anteroom/airlock boundary <input type="checkbox"/> and capable to be maintained in darkened/ lit state <input type="checkbox"/> Means present to inspect and remove invertebrates on persons exiting the anteroom <input type="checkbox"/>	
Inv-C5 Inv-C6	Cages/enclosure	Cages/enclosures devices appropriate for the animals being housed present (all life stages) <input type="checkbox"/> Cage is labelled to indicate it contains a GMO <input type="checkbox"/> and the number of animals within the cage/enclosure <input type="checkbox"/>	
Inv-C10	Aerosols	Dealings with aerosol transmissible GMOs dealings conducted in BSC <input type="checkbox"/>	
Inv-C11 Inv-C12	Decontamination	Invertebrates euthanised prior to removal from the facility <input type="checkbox"/> Cage/containers decontaminated prior to removal from the facility <input type="checkbox"/>	
Inv-C9	Invertebrate trap	Room fitted with a suitable invertebrate trap <input type="checkbox"/>	