



Australian Government

Department of Health

Office of the Gene Technology Regulator

Application Checklist for a Physical Containment Level 2 Large Scale Facility

Checklist against the requirements of the Gene Technology Regulator's *Guidelines for Certification of a Physical Containment Level 2 Large Scale Facility* version 3.1 – issued 28 February 2018

Organisation Name

Facility Name

IBC Name

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

Date of Inspection

Time taken to complete this form:

Hours		Minutes	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Please read this page first

- If you require more space, please attach the information and indicate that you have added an attachment.
- If you have indicated below that the facility does not meet a certain requirement, please provide details of how this is intended to be managed.
- If you do not understand the intention or details of a requirement, please consult the Guidelines for Certification of a Physical Containment Level 2 Large Scale Facility version 3.1
- The order of this checklist is intended to generally reflect movement through the facility as you are conducting an inspection. The rows highlighted in blue are intended to show where the relevant records or results may need to be kept as part of compliance with the conditions of certification.
- **This report must be provided to the OGTR as part of the Application for Certification.**

Current and anticipated use of the facility

Describe the dealings anticipated to be undertaken in the facility, work flow, expected volumes and timelines. List any other relevant laboratory regulatory requirements/certification

Requirements for Certification of a Physical Containment Level 2 Large Scale Facility

Please tick the appropriate answer or provide the requested information for the following questions, which relate to the requirements for Certification of the specified Large Scale Facility.

Req. No.	Requirement		Complies? (Yes/No/NA)	Comments (if N/A to “Complies?” provide details)
R8	<p>Personal protective clothing</p> <p>Facility must include designated storage or hanging facilities for protective clothing – so contaminated clothing will not cross-contaminate other surfaces and items.</p>	Storage		Location
R1, R2	<p>Facility Structure</p> <p>Fully enclosable - bounded by walls, doors, windows, floors and ceilings - doors and windows lockable or otherwise able to be secured.</p> <p>Any openings in walls, ceiling or roof (e.g. air vents) filtered or screened with insect-proof mesh.</p>	Fully enclosed (R1)		
		Filtered/screened appropriately (R2)		
R3, R4	<p>Facility cleanability</p> <p>Surfaces are able to be decontaminated, i.e:</p> <ul style="list-style-type: none"> • smooth • impermeable to water • resistant to damage by cleaning agents • accessible for cleaning (esp. open spaces under benches etc) <p>Applies to surfaces where contamination can occur e.g. walls, floors, benches, ceilings, furniture</p> <p>Open spaces between and under benches etc. must be accessible for decontamination.</p>	Walls (R3)		
		Floors (R3)		
		Benches (R3)		
		Furniture, including seating (R3)		
		Ceilings/other (R3)		
		Accessible for cleaning (R4)		

Req. No.	Requirement		Complies? (Yes/No/NA)	Comments (if N/A to "Complies?" provide details)
R6, R7	<p>Hand and Eyewash</p> <p>Hand wash present and hands-free:</p> <ul style="list-style-type: none"> dedicated washbasin with potable water and hands-free operation, or hands-free dispensers of decontaminant solution, or other suitable means as long as hands-free <p>Eye wash present – plumbed or single-use packs</p> <p>Emergency drench showers present.</p>	Hand wash or alternative (R6)		How is it operated? Plumbed? Chemical disinfectant?
		Eye wash (R7)		Plumbed or portable? Location? Maintained?
		Drench shower (R7)		Location?
R9-R12	<p>Backflow Prevention</p> <p>Please provide details of where the backflow device is located.</p> <p>All potable water supplies protected in accordance with AS/NZS 3500.1</p> <p>Applies to any device or system that could contaminate a potable water supply. Device must be tested annually and, if does not pass test, any failures must be rectified and the device re-tested until compliance is achieved.</p> <p>Other reticulated services (gas/air/steam) linked to primary containment device capable of forming cross connection must undergo risk assessment to determine whether backflow prevention required. Risk assessment must be documented and kept.</p> <p>If determined backflow is required, backflow prevention must be implemented.</p>	Present (R9)		Device type, location
		Risk assessment (R10)		Determination?
		Records kept (C68)		Risk assessment, testing

Req. No.	Requirement		Complies? (Yes/No/NA)	Comments (if N/A to “Complies?” provide details)
R14, R15, R21	Closed systems for GMOs <ul style="list-style-type: none"> Facility must contain closed system Closed system designed to prevent the release of GMOs – including via ventilation. Cultures must be contained in closed systems Aerosols must be contained when taking samples from, adding materials to or transferring fluids between closed systems. Closed lines used for transfer. Records must be kept. Risk Assessment of need to wear respiratory protection. 	Present (R14)		Reactor type, volume, manufacturer
		Closed transfer lines (R14 Note)		For transfer of viable GMOs
		Designed to prevent release of GMOs (R15)		
		Risk assessment (R21)		Outcome
R16-R18	Single-use <ul style="list-style-type: none"> Able to be tested for leaks prior to loading with GMOs – i.e. filled with media to enable leak detection. Tubing/lines, fittings and filters visually inspected. Mechanisms to secure large bio-reactor bags (if present) Capable of being decontaminated without release of GMOs (including aerosols) <p>Note: an N/A response to this question could mean, for example, that no single use system present in facility.</p>	Leak detection (R16)		How?
		Mechanisms to secure large bio-reactor bags (R17)		Secure and easy removal for decon?
		Single use decontamination method (R18)		How? Autoclave? Chemical?
		Other equipment		Filtration? Centrifuge?

Req. No.	Requirement		Complies? (Yes/No/NA)	Comments (if N/A to “Complies?” provide details)
R19, R20	Reusable <ul style="list-style-type: none"> Capable of being decontaminated in situ Capable of being tested for integrity before each use and after relocation/maintenance <p>Note: an N/A response to this question could mean, for example, that no reusable system in facility.</p>	Reusable decontamination method (R19)		How? In situ?
		Reactor inspection/maintenance (R20)		Details
R24	Secondary Containment Equipment e.g. Bunding Must be of sufficient capacity to contain the volume of fluid held in the largest single container, or group of containers where interconnection could result in leakage from multiple containers plus the volume of any disinfectant that might be used with additional capacity to prevent any expected general fluid movement from breaching the secondary containment.	Bunding		Max volume
		Other		Details e.g. type, volume
R23	Containment Equipment (other) Other equipment used to process GMOs (Centrifuge, filtration system etc.) must be able to contain GMOs including aerosols.	Present		Details
		Aerosols contained		How? HEPA? 0.2 um?
R22	Biological Safety Cabinets Must be present if dealings (other than inoculating, culturing GMOs in and taking samples from closed systems) will produce aerosols containing RG 2 GM microorganisms. Must be installed in accordance with AS/NZS 2252.4 Note: an N/A response to this question could mean, for example, that a BSC is not being used in the facility.	Decontamination method		How? Autoclave? Chemical?
		Other equipment		Filtration? Centrifuge?

Req. No.	Requirement		Complies? (Yes/No/NA)	Comments (if N/A to “Complies?” provide details)
R13	Spills procedures There must be documented procedures and the means in place to decontaminate any spills in the work area of the facility, including large spills, involving GMOs.	Means in place		
		Documented procedure		
R5	Decontamination Must be mechanisms in place to ensure all liquid effluent can be decontaminated prior to discharge (can be met, for example, by having documented procedures to ensure viable liquid effluent is not discharged down sink)	Mechanisms in place		Details
R25	Liquid Waste Treatment System (LWTS) <ul style="list-style-type: none"> Fully enclosed pipes, tanks and other components Robust construction materials capable of being decontaminated for inspection/maintenance Likelihood of damage must be minimised (e.g. by protected location) Pipes capable of being inspected and labelled appropriately. Where not inspectable, must be double skinned or have leak detection mechanisms Vents to pipes, tanks etc. filtered to prevent release of GMOs Strategies in place to ensure seal integrity of LWTS and components (drain pipes, holding tanks and vent lines) Screening provided to limit solids leaving the work area via the LWTS Secondary containment provided (e.g. bunding) in room/s or area/s housing LWTS. Must be <ul style="list-style-type: none"> sufficient to contain the volume of liquid waste held in the largest single container, or group of containers where interconnection could result in leakage from multiple containers, plus the volume of any disinfectant that might be used and any expected general fluid movement; and smooth, impermeable to water, easily cleanable, and resistant to damage by the cleaning/ 	Fully enclosed (R25 a.)		Location? Authorised persons only?
		Materials (R25 b.)		Able to be inspected? Materials used?
		Likelihood of damage minimised (R25 c.)		How? By location?
		Pipes (R25 d.)		Labelled appropriately? Capable of inspection/double skinned/leak detection?
		Vents filtered (R25 e.)		0.2 µm? HEPA?
		Seal integrity (R25 f.)		Strategies?
		Screening for solids (R25 g.)		
		Bunding (R25 h.)		Max volume? Smooth, impermeable, able to decon?

Req. No.	Requirement		Complies? (Yes/No/NA)	Comments (if N/A to “Complies?” provide details)
	<p>decontamination agents to be used.</p> <ul style="list-style-type: none"> Documented contingency plan and means in place to respond to leakage of waste containing GMOs/failure of LWTS. Must include details of specialised equipment to be used for responses. Records must be kept <p>Note: an N/A response to this question could mean, for example, that no LWTS external to facility used to treat GMOs.</p>	Other secondary containment (R25 h.)		Max volume? Smooth, impermeable, able to decon?
		Contingency plan (R25 i.)		Specialised equipment?
		Records kept (C68)		Records of R25 i
R26	<p>Capacity to comply with Conditions</p> <p>The applicant must be able to demonstrate a capacity to comply with the conditions of certification that will generally be applied to a certified PC2 Large Scale Facility. These conditions are found in Part B of the Guidelines for Certification of a Physical Containment Level 2 Large Scale Facility version 3.1.</p>	Able to comply		

Documents to be provided with the certification application (R27)

The following is a list of documentation required to be supplied with an application for certification of a PC2 Large Scale Facility.

Requirement	Documentation to be supplied with the application	Included?	Comments
R27(a)	Floor plan A floor plan of the facility including locations of laboratory services, containment equipment and decontamination equipment		
R27(b)	Closed system Details of the closed system/s (e.g. type, number, maximum volume of each system)		
R27(c)	Secondary containment Details of the secondary containment mentioned (e.g. bunding or other; capacity)		
R27(d)	Backflow prevention device Location and results of commissioning and testing of backflow prevention devices installed on pipes supplying water to the facility		
R27(e)	Biological safety cabinets Results of testing and commissioning of Biological Safety Cabinets (if installed in the facility)		
R27(f)	Decontamination equipment Results of testing and commissioning of all decontamination equipment installed in the facility, including autoclaves		
R27(g)	Decontamination method Details of the proposed decontamination method for process waste contaminated with GMOs and evidence of its effectiveness		
R27(h)	Respiratory protection Details of any risk assessment of operator exposure to aerosols when working with closed systems, as mentioned in R21		
R27(i)	External liquid waste treatment system (LWTS) (if present) <ul style="list-style-type: none"> i) details of the LWTS (e.g. type, brand, volume etc.); ii) results of its testing and commissioning; iii) floor plan showing location of LWTS in relation to other locations (i.e. the facility, other restricted areas or areas accessible by the general public); iv) a schematic of pipes associated with the LWTS; v) details of the secondary containment for the LWTS (e.g. bunding or other, volume); and vi) the contingency plan mentioned in R25(i) for responding to spills and/or failure of the LWTS including pipes. 		