Australian Government

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

Application Checklist for a new Physical Containment Level 3 Facility

(Checklist for the inspection of a new facility 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 - 1 December 2022)*

Organisation Name	
Facility Name	

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

Date of Inspection	

Important Notes

- If you require more space, please attach the information and indicate that you have added an attachment.
- If in answer to any of the questions below you have indicated there is work pending completion or procedures yet to be implemented, please provide the expected completion date. Please be aware that the OGTR will require confirmation when work has been completed and it is unlikely the facility will be certified until this confirmation has been received.

Please answer all questions.

Requirement		Comply?	If not, provide reasons why and alternative approach(es)
R1	A facility must meet each of the requirements for certification of a PC3 facility, unless the certification holder receives a written exemption from meeting a particular requirement from the Regulator.		
Facility construction and access			
R2	The facility must be a fully enclosable space, bounded by walls, doors, windows, floors and ceilings that permit the facility to operate under negative air pressure and to undergo gaseous decontamination.		
R3	The facility must be constructed so that upon commissioning it achieves an air leakage rate of no more than 120 L/min, at a differential pressure of 200 Pa.		
R4	The facility windows must be closed, sealed and made of impact resistant materials.		
R5	Facility penetrations must be sealed to minimise air leakage.		
R6	The facility must not contain any lifts that open into the certified space.		
R7	The facility must have an airlock for use when entering/exiting. The airlock doors must be self-closing and sealable. The outer airlock door must have a mechanism in place to restrict access to the facility. Both doors must not be able to be opened simultaneously, even in the event of power failure. Manual override is authorised in the event of an emergency.		
R8	If the facility boundary includes devices such as pass-through boxes or barrier autoclave, then the device doors must not be able to be opened simultaneously, even in the event of	If present	

Requirement		Comply?	If not, provide reasons why and alternative approach(es)
	power failure. The outer door must have a mechanism in place to only be opened upon effective decontamination of contents.		
R9	If the facility boundary includes a decontamination chamber, the doors must be gas tight and must not be able to be opened simultaneously, even in the event of power failure. The outer decontamination chamber door must have a mechanism in place to restrict access to the facility and only be opened upon effective decontamination of contents.	If present	
R10	The facility boundaries (walls, windows, doors, floors, ceilings) must be constructed to prevent the escape of the organisms being contained and the incursion of pests and vectors.		
R11	Openings in the walls, ceiling or roof must be filtered or screened to prevent the entry or exit of animals and invertebrates. The filters or screens must be fixed and sealed against their mounting. The filter or screen must be of a material that is mechanically strong enough to withstand the airflow load, to prevent entry or exit of animals and invertebrates, to remain undamaged with regular cleaning, and to resist corrosion. Liquid drainage exits must be protected against entry or exit of animals and invertebrates by using screens, liquid traps or another effective method. Where a screen is used, the apertures of the screen must be small enough to prevent entry or exit of invertebrates or animals.		
R12	If the facility has a sink or floor drainage exit, mechanisms must be in place to ensure all liquid effluent can be decontaminated prior to discharge.	If fitted	
R13	Surfaces in the facility must be smooth, impermeable to water, easily cleanable, and resistant to damage by the cleaning agents and decontaminants that will be used in the facility.		
R14	Fixtures, fittings, equipment and services must be installed to enable all spaces in the facility to be decontaminated. Open spaces between and under fixtures, fittings and equipment must be accessible for decontamination.		
R15	Where the facility is comprised of multiple work areas where both GM and non-GM dealings are conducted, all areas where dealings with GMOs are being conducted must be clearly identifiable.	If relevant	

Requirement		Comply?	If not, provide reasons why and alternative approach(es)
R16	The facility must have adequate designated storage or hanging areas for storing PPE intended for re-use to prevent cross-contamination of the PPE.		
R17	The facility must have two alternative, independent communication systems for contact between persons inside and outside the facility.		
R18	Access to ventilation equipment that services the facility must be restricted to authorised persons.		
R19	Parts of ventilation systems that may be contaminated with GMOs, such as ducts, and access panels must be clearly identifiable to minimise risk of accidental exposure to GMOs.		
Facility services and equipment			
Biological safety cabinet (BSC)			
R20	The facility must contain at least one BSC that is appropriate for the dealings which are to be conducted in the facility. All aerosol containment equipment must be powered by an uninterruptible power supply.		
R21	BSCs or other similar aerosol containment equipment must be installed, commissioned, tested for compliance with the relevant Australian Standard and testing results documented before use.		
Autoclave			
R22	The facility must contain an autoclave, or other decontamination equipment approved in writing by the Regulator, that is suitable for the size and type of material to be decontaminated. Newly constructed facilities must be fitted with a barrier autoclave. The autoclave must not be located in the airlock.		
R23	Before use, autoclaves must be installed, commissioned and tested for compliance with the relevant Australian Standard and testing results documented before use.		
Liquid Waste Treatment System (LWTS)			
R24	If the facility contingency plan involves a LWTS, the following requirements must be met: a. access to the LWTS room, or area/s housing the system must be restricted to authorised persons;	If present	

Requirement		Comply?	If not, provide reasons why and alternative approach(es)
	b. the LWTS must be a fully enclosed system comprising of tanks, pipes and other associated components; c. the LWTS must be constructed from materials that are robust, suitable for the waste being treated, and able to be decontaminated for inspection and maintenance; d. pipes must be clearly identifiable and all components of the LWTS should be able to be maintained and inspected for prevention and detection of leaks. In areas where pipes are not able to be inspected, pipes must be double skinned or have a mechanism in place for detection of leaks; e. vents to pipes, tanks etc. must be filtered to prevent release of GMOs (e.g. fitted with 0.2 µm membrane or HEPA filters); and f. prior to commencing dealings with GMOs, the LWTS must be validated to ensure that it can achieve the parameters required to inactivate the most resistant organism used in the facility. This validation must be documented.		
Backflow prevention			
R25	Any device or system, that may cause contamination of water supply, and is connected directly or indirectly to any part of a water service, must be protected against backflow. This can be achieved by fitting registered testable backflow prevention devices that have high hazard rating for protection against both back-pressure and back siphonage (refer to relevant Australian Standard). If a registered testable backflow prevention device is not installed on a particular water supply service, a risk assessment must be conducted to determine whether backflow prevention is required.	If relevant	
R26	If the risk assessment determines that backflow prevention is necessary, and a registered testable backflow device is not subsequently installed, a risk management plan must be produced and implemented.	If relevant	
R27	The risk assessment, and if applicable, the risk management plan must be documented and provided to the Regulator. Any change impacting the outcome of this risk assessment must trigger a review of the requirement for a backflow prevention device and the reviewed risk assessment must be provided to the Regulator as soon as practicable.	If relevant	
R28	Where a vacuum system is used, 0.2 µm hydrophobic membrane filters and liquid disinfectant traps must be installed at the point of use. In the case of a central reticulated	If present	

Requirement		Comply?	If not, provide reasons why and alternative approach(es)
	vacuum system, the filter and trap must be on the facility side of the vacuum line. In the case of a portable vacuum pump, the filter and trap must be located before the pump.		
R29	Piped gas supplied to the facility must have reverse flow prevention on outlets located within the BSC or must be fitted with a filter with pore size of less than or equal to 0.2 µm.	If present	
Hand and eye decontamination equipment			
R30	Each work area of the facility must contain a means of decontaminating hands at or near the exit of the work area. All means of decontaminating hands must be able to be operated in a hands-free manner.		
R31	The facility must contain either plumbed eyewash equipment or single-use packs of sterile eye irrigation fluids.		
Ventilation system			
R32	The facility must have a ventilation system that establishes negative air pressure in the facility and a directional airflow into the work area(s). The system must be comprised of: a. at least one HEPA filter through which all exhaust air is filtered; b. a pre-filter located upstream of the exhaust HEPA filter of, at least, Type 1 Class A or Class B filters with a performance rating of G4 (average arrestance) or F9 (average efficiency) as described in the relevant Australian Standard, or an equivalent filter approved in writing by the Regulator; c. an exhaust fan located downstream of the exhaust HEPA filter; and d. gas-tight air ducts between the facility and the HEPA filter housing.		
R33	Each exhaust HEPA filter must be mounted in a gas-tight housing with sealed access doors, and a gas-tight isolating valve on the air outlet duct. The design and location of the filter housing must allow for: a. easy access to the HEPA filter; b. secure and damage-free handling of the HEPA filter; c. in situ gaseous decontamination of the HEPA filter housing; and d. maintenance, replacement and integrity testing of the HEPA filter.		

Requirement		Comply?	If not, provide reasons why and alternative approach(es)
R34	If gaseous decontamination of the HEPA filter is to be performed separately from decontamination of the facility, gas-tight isolating valves must be present on the air inlet duct, upstream and downstream of the valved ports.		
R35	After installation, the HEPA filter must be tested for compliance by a qualified person in accordance with the relevant Australian Standards and the results documented.		
R36	The supply and exhaust air systems must be interlocked to prevent positive pressurisation of the facility in the event that the supply or the exhaust fan(s) malfunction.		
R37	If the HEPA housing contains upstream and downstream pressure tappings to permit monitoring and display of the filter air flow pressure drop, the tapping on the facility side of the HEPA filter must be fitted with a 0.2 µm hydrophobic membrane filter or equivalent. Tappings, tubing, sensors and instruments must be protected from physical impact.	If present	
R38	The facility must be equipped to measure the air pressures in the airlock, anteroom if applicable, and the work area(s). The air pressures must be displayed at the entrance to the facility. In the case where facilities maintain different air pressures in different work areas, the pressure in a work area must be displayed either at the entrance to the work area(s) or the entrance to the facility.		
R39	The air pressure setpoint in all work areas must be at least 50 Pa below the pressure outside the facility. During normal operation of the facility, the pressure in the work areas must be maintained at the setpoint pressure.		
R40	When either airlock door is open, the air pressure in all work areas must remain at least 25 Pa below the pressure outside the facility.		
R41	The facility must be equipped with an alarm that will alert relevant persons both inside and outside the facility if the ventilation system malfunctions. The alarm must be activated when the pressure in the work area(s) or airlock deviates from the set point by 15 Pa for more than 2 minutes.		
R42	The facility must have mechanical means (e.g. emergency stop button to shut down the ventilation system) or procedures in place to manage failure or malfunction of the ventilation control system. The mechanical means must operate independently of the main		

	Requirement	Comply?	If not, provide reasons why and alternative approach(es)
	ventilation control and main facility pressure control system such that emergency isolation of the ventilation can be implemented in the event of central control system malfunction. The management procedures must be documented and provided to the Regulator, on request.		
Capacity to comply with certification conditions			
R43	The applicant must be able to demonstrate a capacity to comply with the conditions of certification that will generally be applied to a certified PC3 facility. These conditions are found in Part B and, if applicable, Annex 1B and/or Annex 2B, of this document.		
Annex 1A – Additional requirements of certification (Animal) if relevant			
Ani-R1	Primary containment devices appropriate for the animals being housed must be present in the facility.		
Ani-R2	Containers used for euthanising animals containing GM micro-organisms requiring PC3 containment that are capable of being shed must: a. be sealed during operation; and b. have the gas inlet fitted with a 0.2 µm hydrophobic membrane filter.		
Annex 2A – Additional requirements of certification (Invertebrate) if relevant			
Inv-R1	The facility must contain an anteroom for entry to the room(s) housing invertebrates. The anteroom doors must be self-closing.		
Inv-R2	The anteroom must be fitted with: a. mechanisms to effectively prevent invertebrates from traversing the boundary of the anteroom/airlock; and b. the capability to be maintained in a darkened or illuminated state, depending on which state discourages the contained invertebrates from escaping.		
Inv-R3	The anteroom must be provided with means to inspect and remove invertebrates on persons exiting the facility.		