Australian Government

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

Guidelines for Certification

of a

Physical Containment Level 3 Facility

Version 1.0 – Effective 1 December 2022

These Guidelines contain the requirements for the certification of a Physical Containment Level 3 (PC3) Facility and standard conditions that may be applied to the facility to contain GMOs. They are issued by the Gene Technology Regulator (the Regulator) pursuant to section 90 of the *Gene Technology Act 2000* (the Act) and corresponding State and Territory laws.

Requirements and conditions listed in these Guidelines are applicable for the certification of all PC3 facilities.

Requirements

The requirements that must be met for certification of a PC3 facility by the Regulator under section 84 of the Act are listed in Part A of these Guidelines and also in Annex 1A and Annex 2A, as applicable. The requirements apply to all applications for certification of PC3 Facilities received on or after the day on which these Guidelines take effect.

Conditions

Once a facility is certified, the certification instrument imposes conditions on the facility pursuant to section 86 of the Act. The standard conditions of certification are listed in Part B and in Annex 1B and Annex 2B, as applicable. Once issued, the conditions may be varied by the Regulator as necessary and appropriate.

Annexes

These Guidelines contain Annexes which include additional requirements for the certification of a PC3 facility and the conditions that are likely to be imposed on the facility or room where GMO dealings are conducted with animals (vertebrates) or invertebrates, including animals or invertebrates containing GM micro-organisms. Table 1 is a guide on the parts and annexes of the Guidelines that apply depending on the type of facility or room and dealings conducted in the facility.

Certified PC3 Facilities are not to be used for dealings involving GMOs that are classified as higher than Risk group 3 organisms or otherwise require a containment level higher than PC3.

These Guidelines should be read in conjunction with the *PC3 Certification Guidance document*.

For details on the process of certification see the *Explanatory Information on Guidelines for Certification of Physical Containment Facilities*.

Table 1. Applicable sections of the PC3 Guidelines based on types of work to be conducted in the facility

	Facility/Room type		
	Laboratory	**Animal**	**Invertebrate**
Part A – General requirements	✓	✓	✓
Part B – General conditions	✓	✓	✓
Annex 1A – Additional animal requirements		✓	
Annex 1B – Additional animal conditions		✓	
Annex 2A – Additional invertebrate requirements			✓
Annex 2B – Additional invertebrate conditions			✓

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Definitions and acronyms

Unless defined otherwise in these Guidelines, words and phrases used have the same meaning as in the Act and the Gene Technology Regulations 2001 (the Regulations).

Words in the singular include the plural, and words in the plural include the singular.

Where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning.

aerosol	Suspension in air of finely dispersed solids and/or liquids.
airlock	A room designed to reduce pressure fluctuations during entry and exit from the work area of a facility or from different work areas within the facility that are maintained at different air pressure.
animal	All land-based vertebrate animals.
annual maintenance shutdown	Pre-planned period to service and repair equipment and fittings in the facility.
anteroom	A room used during entry and exit of a room that has specific containment functions.
arrestance	A measure of the ability of an air filter to remove suspended particles from the air, expressed as a mass percentage.
AS	Australian Standard.
AS/NZS	Australian/New Zealand Standard.
authorised person	A person who has been granted permission by the certification holder, or their delegate (e.g. facility manager) to access the facility and who has not been excluded from the facility by the certification holder on the direction of the Regulator.
autoclave	Pressure steam steriliser.
BSC	Biological safety cabinet.
dealings or deal with	In relation to a GMO, means the following: (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO;

	(d) propagate the GMO; (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO; (h) transport the GMO; (i) dispose of the GMO; and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (i).
decontaminate or decontamination	A physical and/or chemical process which removes, kills or renders non-viable the GMOs used in the facility but does not necessarily result in sterility.
decontamination chamber	A room at the boundary of the facility designed for the fumigation of items prior to removal from the facility
disposal	The destruction, discarding or throwing away of decontaminated GMOs. *Note: A method of disposal may also be a method of decontamination e.g. Incineration*.
facility	The whole of the space that is to be certified including the work area(s), airlock and ducting for air intake/exhaust up to and including the HEPA filter housing, and where present, the inner change room, shower and anteroom.
GMO	Genetically modified organism.
High-Efficiency Particulate Air (HEPA) filter	An air filter corresponding to one of the following two types: (a) Type 1, Class A filters as specified in AS 1324.1 with separators and elastomeric compression seals or gel seals that do not support microbiological growth, which meet all requirements of AS 4260 with a minimum performance of Grade 2; or (b) Separator-less filters that meet all the requirements of AS 4260 with a minimum performance of Grade 2.

inner change room	A room within the facility used by authorised persons for putting on facility clothing and PPE on entry and for removing it on exit.
invertebrates	For the purposes of these Guidelines, invertebrates are all multi-cellular animal species without a vertebral column that are land-based as adults. This includes relevant species of annelids, flatworms, nematodes, molluscs and arthropods. Protozoans are not included.
IVC	Individually ventilated cage.
liquid waste treatment system (LWTS)	A system, including all associated piping and tanks, used to decontaminate liquid waste containing, or potentially containing, GMOs from the facility.
micro-organism	An organism too small to be viewed by the unaided eye, including bacteria, fungi, protozoans, viruses and some multicellular organisms. For the purposes of these Guidelines, this definition includes viral vectors and dormant life stages such as spores.
OGTR	Office of the Gene Technology Regulator.
outer change room	Room used by authorised persons to remove personal clothing prior to entry and to put on personal clothing after exit from an airlock.
PC3	Physical Containment Level 3.
PC3 GMO	A GMO required to be contained in a PC3 facility, in accordance with Regulation 13 and Schedule 3 Part 2.2 of the Regulations, or by a licence issued by the Regulator, or otherwise specified in writing by the Regulator.
PPE	Personal protective equipment (includes clothing and powered or unpowered reusable respirators).
primary container	A container immediately surrounding the GMO.
primary containment facility	A facility where the GMOs cannot be exclusively contained within a BSC, cage, growth cabinet or storage container. This is often the case when working with large animals inoculated with GM micro-organisms which are unable to be housed in a HEPA-ventilated cage, and are potentially secreting GM micro-organisms.

qualified person	A person approved by the certification holder and who has acquired through training, qualifications, accreditation or experience, or a combination of these, the knowledge and skills to complete the task assigned to them.
the Regulator	The Gene Technology Regulator or a delegate of the Gene Technology Regulator.
unbreakable	Able to withstand all reasonably expected conditions of transport and storage such as: the forces, shocks and impacts expected during handling; or changes of temperature, humidity or air pressure.
viable	Micro-organisms, cells and cell cultures: • able to survive or multiply including those dormant or requiring resuscitation e.g. when sub-lethally damaged by being frozen, dried, heated, or affected by chemicals, including decontamination agents. Other organisms, whole or part: • able to live and grow independently of its parent or source organism, or able to reproduce or contribute genetic material to reproduction (e.g. sperm, ova, pollen, seeds, vegetative propagules).
work area	Any area within the facility excluding the airlock, anteroom, shower and outer change rooms.

Part A - Requirements for Certification

Physical Containment Level 3 Facility

Version 1.0 – effective 1 December 2022

CONTAINMENT REQUIREMENTS THAT MUST BE MET IN ORDER FOR A PC3 FACILITY TO BE CERTIFIED BY THE REGULATOR.

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.

Note: Additional requirements may also be imposed on the facility by the Regulator depending upon the design, construction and proposed dealings to be conducted in the facility.

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 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.

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.

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.

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;

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.

Note: Any accidental or emergency discharge of untreated waste into the LWTS must be reported to the Regulator (Condition C71).

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.

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.

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.

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 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.

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.

Note: A fan and filter for the supply air may also be present.

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.

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.

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 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.

Part B - Conditions of Certification

Physical Containment Level 3 Facility

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Conditions are imposed on facilities by the Regulator at the time of certification pursuant to section 86 of the Act. The conditions in this section are those that can be expected, in most cases, to be included in the certification instrument as the conditions of certification for a PC3 facility. Individual certification conditions may differ from these standard conditions depending upon the design, construction and proposed GMO dealings to be conducted in the facility. Once issued, the conditions may be varied by the Regulator as necessary and appropriate.

Where a condition in this document conflicts with OGTR-issued licence conditions, the Regulations, or any applicable Guidelines issued under Section 27(d) of the Act, then licence conditions, the Regulations, or applicable Guidelines prevail.

C1. Except during the annual maintenance shutdown, the facility must comply with all the conditions of its certification instrument (standard conditions listed under Part B of this document), whether or not dealings with GMOs are being conducted in the facility.

Note: If the annual maintenance involves structural changes in the facility, condition C22 applies.

C2. In the event of an annual maintenance shutdown, certification holders must ensure:

a. The Regulator is notified at least 7 days prior to commencing the shutdown;

b. Prior to commencing the shutdown:

i. staff must be notified of the shutdown period;

ii. all dealings must cease, and GMOs destroyed or be appropriately stored according to condition C75; and

iii. the facility must be decontaminated, and the records of the decontamination documented.

c. At completion of the shutdown and prior to commencing dealings:

i. the facility must be inspected by a qualified person and found compliant with all conditions of its certification instrument, and records of the inspection retained for 3 years; and

ii. the Regulator must be notified in writing when the facility is once again compliant with all condition of its certification.

Note: Notification should be sent to OGTR.Applications@health.gov.au

Obligations of the certification holder

C3. The certification holder must appoint a facility manager empowered by senior management with the necessary authority and resources to ensure that the facility complies with the conditions of certification at all times.

C4. The certification holder must have the authority to admit persons to the facility and associated restricted areas, and to exclude persons from these areas or obtain such authority in writing from the owner of the premises before GMO dealings commence. If the certification holder no longer has the authority to admit or exclude persons from these areas, then the certification holder must notify the Regulator in writing, as soon as practicable.

C5. While dealings with GMOs are being conducted in the facility, the certification holder must ensure that access to the facility is restricted to authorised persons only.

C6. If the Regulator directs the certification holder to exclude a person or class of persons from entry to the facility, on the grounds that the person or class of persons has behaved, or is behaving, in a manner which:

a. contravenes the Work Practices detailed in conditions C39-84; or

b. has caused or may cause loss of containment of the GMOs being dealt with in the facility; or

c. has posed, or may pose any risk to the health and safety of people and the environment, from exposure to GMOs in the facility;

the certification holder must exclude that person, or class of persons, from the facility, unless and until otherwise directed by the Regulator.

C7. If the Regulator directs the certification holder to admit a person, or class of persons, to the facility subject to entry conditions the certification holder must only admit the persons under those entry conditions and must advise the persons of the certification conditions that apply to them.

C8. If the Regulator invites the certification holder to make a submission on whether a person or class of persons should:

a. be excluded from entry to the facility; or

b. be admitted to the facility subject to entry conditions;

the certification holder may make such a submission within the time stipulated by the Regulator.

C9. The Regulator or a person authorised by the Regulator must, at all reasonable times, be allowed to enter the facility, or access the LWTS room for the purposes of auditing or monitoring the relevant conditions.

C10. If the certification holder is not the owner of the facility and does not have the authority to maintain the facility, fittings and/or containment equipment and LWTS, the certification holder must not allow dealings in the facility until such authority is obtained in writing from the owner of the facility. If the certification holder does not have the capacity to prevent dealings from being conducted, the certification holder must notify the Regulator in writing, as soon as practicable.

Work not permitted in this facility

C11. The following must not be conducted in this facility:

a. dealings with any GMO that, under the gene technology legislation or conditions of a licence, require containment in a physical containment level higher than PC3;

b. dealing involving a micro-organism that satisfies the criteria in AS/NZS 2243.3 for classification as Risk Group 4;

c. the housing/keeping/growing of any plants, invertebrates and animals beyond the minimum time that they are required for conducting the dealings with GMOs, unless it is approved in writing by the Regulator or included in the conditions of the facility certification instrument; or

d. any other dealings with a GMO prohibited by notification in writing by the Regulator.

General conditions

C12. The certification holder must ensure that the physical attributes of the facility and fittings are maintained so that the requirements listed in Part A of this document, and all additional requirements imposed by the Regulator continue to be met, except where any exemption has been granted.

C13. The facility must not be used as a primary containment facility unless approval is granted in writing by the Regulator.

C14. The facility must be inspected at least once every 12 months by a qualified person, to assess the facility's compliance with the certification conditions (generally those listed in Part B and, if applicable, Annex 1B and/or Annex 2B, of this document).

C15. An inspection report that records the compliance with the certification conditions must be prepared. Inspection reports must be kept for 3 years and made available to the Regulator, on request.

If the certification holder becomes aware of non-conformity with certification conditions posing a risk of loss of containment, this must be reported to the Regulator as soon as practicable.

Note: An OGTR inspection of the facility may constitute an inspection for the purpose of this condition.

C16. Each facility entry must be labelled with the following signs on or next to the access door such that persons entering the facility are able to clearly see they are entering a certified PC3 facility:

a. a current PC3 facility sign, supplied by the OGTR;

b. a biohazard symbol; and

c. emergency contact numbers (e.g. 24 hour contacts for the facility manager and for alarm response).

C17. Emergency contact numbers (e.g. 24-hour contacts for the facility manager and for alarm response) must also be clearly displayed and visible within each work area of the facility.

C18. The airlock and the outer change room must not be used to conduct dealings with GMOs (other than transport).

C19. If present, the anteroom must not be used to conduct dealings with GMOs other than transport, and decontamination where an autoclave is located in the anteroom.

C20. A supply of disinfectants effective against the GMOs present in the facility must be available in all relevant work areas of the facility. All containers of disinfectants must be clearly labelled with the contents, concentration and, where appropriate, the expiry date. Decontamination agents must not be used after the expiry date.

C21. Effective pest prevention strategies must be documented and implemented. A record of pest prevention strategies and any pest control activities must be kept for 3 years and made available to the Regulator, on request.

Suspension conditions

C22. Prior to any structural changes to the facility that may affect the containment of GMOs, the certification holder must request and receive written permission from the Regulator for either:

a. a suspension of the certification; or

b. a variation to the certified area to allow dealings to continue in any part of the facility unaffected by the structural changes.

Before a suspension of certification can be lifted and prior to commencing dealings with GMOs:

c. the facility must be inspected by a qualified person and found compliant with all the conditions of its certification instrument, and records of inspection retained for 3 years; and

d. the certification holder must request and receive a notice in writing from the Regulator.

Note: Depending on the nature or extent of the structural changes to the facility, the OGTR may inspect the facility. This inspection constitutes an inspection for the purpose of this condition.

C23. Storage of GMOs in a suspended facility must be as described in condition C76.

Facility services and equipment conditions

C24. All services and equipment must be compliant and used and maintained in accordance with the relevant AS/NZS, if applicable, or the manufacturer's instructions, and the conditions and requirements imposed by the Regulator.

C25. All services and equipment must be decontaminated prior to testing or repair.

C26. All services or equipment, critical to the decontamination and containment of GMOs which are added to the facility after certification, must be tested, commissioned, and found to meet the conditions of certification prior to use with GMOs. All relevant documents must be kept for 3 years and made available to the Regulator, on request.

Ventilation conditions

C27. Any failure of the ventilation system (exhaust air fan or interlocked supply/exhaust system) that results in:

a. loss of the negative air pressure gradient; or

b. positive air pressure

must be reported to the Regulator as soon as practicable.

Testing conditions

BSCs, IVCs or other aerosol containment equipment

C28. All aerosol containment devices must be inspected and tested by a qualified person at least annually, after relocation, after mechanical or electrical maintenance, or after HEPA filters are replaced.

a. BSCs must be tested in accordance with the requirements of the relevant Australian standard.

b. IVCs, or other aerosol containment equipment approved in writing by the Regulator, must be tested in accordance with manufacturer's guidelines. HEPA filter integrity testing must be included.

Note: The use of inhalation exposure systems will require additional conditions. The certification holder should consult the PC3 guidance document.

C29. The equipment must pass tests for containment efficacy. A certificate summarising the test results and the date of the next test must be affixed to the equipment.

C30. Where testing has shown that the performance requirements for HEPA filter integrity or containment efficacy are not met and the defect has not been corrected, the defective equipment must be clearly labelled and must not be used for procedures involving GMOs until the defect has been corrected.

C31. Records of all tests must be kept for 3 years and made available to the Regulator, on request.

Heat-based decontamination systems

C32. The physical parameters of the autoclave used to decontaminate GMOs, must be validated at least quarterly. If the autoclave is not used frequently, the validation must occur immediately prior to or with the decontamination cycle. Efficacy must be validated by:

a. independent thermocouples or resistance thermometers, to ensure that the required temperature has been achieved for the required time; or

b. chemical indicators which use a combination of moisture, heat, and time and which progressively change colour with the time exposed at the specified temperature; or

c. other methods approved in writing by the Regulator.

Before commencing dealings with GMOs, the effective physical parameters (combination of temperature and time) must be determined against the load

types used within the facility.

The results of validation of the physical parameters of the autoclave must be kept for 12 months and made available to the Regulator, on request.

Note: The efficacy of any other heat-based system for decontamination of GMOs is to be tested as determined at the time of facility certification or renewal of facility certification.

C33. Equipment used for heat-based decontamination of GMOs, such as autoclaves and heat-based LWTS, must be tested and maintained by a qualified person at least annually or more frequently if recommended by the manufacturer. Testing and maintenance must include, but is not limited to:

a. calibration of temperature and pressure measuring probes;

b. testing and confirmation that all parameters of the system (temperature, time, pressure and flowrate) are operating within the specified limits;

c. testing of all safety and relief components, including the autoclave safety valves; and

d. maintenance of the equipment to ensure effective operating conditions.

C34. Maintenance reports for the previous 3 years must be kept and made available to the Regulator, on request. Any autoclave must be clearly labelled to show that it has been monitored for effectiveness, calibrated and maintained in the manner required by conditions C32 and C33 above. Any LWTS, or other equipment approved by the Regulator for the heat-based decontamination of GMOs must be clearly labelled to show that it has been calibrated and maintained in the manner required by condition C33 above

C35. Defective decontamination equipment must be clearly labelled and must not be used for decontaminating GMOs, waste or equipment associated with GMO dealings until the defect has been corrected.

Backflow prevention systems

C36. If backflow prevention devices are present, these devices must be tested at least every 12 months in accordance with the relevant Australian Standard, by a licensed plumber. Any failures must be rectified, and the device re-tested until compliance is achieved. A record of the annual test result for the previous 3 years must be kept and made available to the Regulator, on request. If a backflow prevention device is found to be defective, equipment attached to the reticulated service must be clearly labelled to show that the equipment must not be used until the defect has been corrected.

Ventilation system

C37. Testing and maintenance of the facility ventilation system must be carried out at least annually by a qualified person. This must include:

a. testing of the pressure differentials;

b. checking directional airflow;

c. verifying that the alarms operate to comply with R40;

d. testing of components of the ventilation system in a system failure scenario;

e. calibration of transducers fitted to the air-handling system and validation of air-handling performance (i.e. an over-pressure or under-pressure response);

f. calibration of pressure gauges;

g. the air handling control system;

h. if applicable, the building management system; and

i. integrity testing of all HEPA filters in accordance with the relevant Australian Standard. The HEPA filter must be decontaminated prior to testing.

C38. Records of the tests in Condition C37 items (a) to (i), and of any maintenance conducted, must be kept for 3 years and made available to the Regulator, on request.

C39. If the ventilation system malfunctions, dealings involving GMOs must cease until the failure is rectified and re-testing shows that compliance with the above conditions has been achieved. Storage of GMOs in the facility is permitted if failure occurs, provided containment of the GMOs is not compromised.

Work practices

Personal effects

C40. Food or drink intended for human consumption must not be brought into or stored in the facility. Eating and drinking are prohibited in the facility.

C41. Personal items, including bags, mobile phones and portable electronic devices, must not be taken into the facility.

C42. Essential personal items such as prescription glasses worn in the facility must be decontaminated before exiting the facility if they are known, or suspected to be, contaminated with GMOs.

Entry and exit

C43. The outer door of the facility must be kept locked when the room is unoccupied by personnel.

C44. Airlock doors must remain closed, except when authorised persons are entering or exiting the facility.

C45. Under normal operation, persons must enter and exit the facility through the airlock.

C46. Where present, dedicated emergency exits must only be opened in the event of an emergency.

Personal Protective Equipment (PPE)

C47. The following PPE must be worn by all authorised persons in the work area(s):

a. protective clothing to protect the front of the body (e.g. long-sleeved, back-fastening, tight-wristed protective clothing);

b. closed footwear;

c. gloves;

d. eye protection; and

e. waterproof dressings on all broken skin.

C48. Long hair must be tied back or covered with a hair net to avoid contamination.

C49. When exiting a work area where higher risk dealings are conducted and/or prior to entering the airlock or anteroom,

a. PPE must be removed and disposed of, hung in designated spaces or stored for decontamination. Used laboratory gowns that are intended to be re-used must be hung in a manner such that one gown does not overhang another gown; and

b. all persons must wash or decontaminate their hands.

Note: Examples of higher risk dealings include the use of respiratory viruses and dealings more likely to generate aerosols such as the use of an inhalation exposure system for the infection of animals in a specific room within the facility.

C50. Gloves and over-sleeves worn while using the BSC must be removed on completion of the dealing and prior to leaving the BSC.

C51. When conducting dealings likely to result in exposure to the GMO, all persons must wash or decontaminate their hands immediately after the work is completed.

Aerosol containment

C52. Dealings that may generate aerosols containing GMOs must be conducted in a BSC or other aerosol containment equipment approved in writing by the Regulator.

C53. Use and decontamination of a BSC must be in accordance with the requirements of the relevant Australian Standard. Use and decontamination of other similar aerosol containment equipment must be in accordance with the manufacturer's instructions, the requirements of the relevant AS/NZS, if applicable, and directions from the Regulator.

C54. Suspensions of GMOs must be centrifuged in sealed containers (tubes, buckets or rotors). Centrifugation containers must only be opened in a BSC or other aerosol containment equipment approved in writing by the Regulator.

Use of sharps

C55. Sharps must not be used in dealings with GMOs unless no alternatives are available. An assessment of the need to use sharps and the procedures for safe handling must be documented in the facility manual (condition C82).

Note: 'Sharps' includes any object (in its intact or broken form) able to pierce human skin.

Decontamination

C56. All decontamination procedures (including decontamination of spills) must be carried out by personnel trained in accordance with condition C70.

C57. Work benches, surfaces and equipment where procedures involving GMOs have taken place must be decontaminated after each procedure and/or at the end of each working day.

C58. Work surfaces and equipment where maintenance is to be carried out must be decontaminated prior to maintenance taking place.

C59. GMOs and organisms infected with GMOs must be rendered non-viable before removal from the facility.

C60. All items must be decontaminated prior to removal from the facility including:

a. filters potentially contaminated with GMOs e.g. used in a BSC, autoclave, LWTS or aerosol containment device;

b. liquid and solid waste potentially containing GMOs;

c. dedicated laboratory equipment, including all reading and writing material, computers, communication devices including dedicated laboratory phones, and other items such as radios or other audio equipment;

d. equipment used by external contractors, such as tools; and

e. any items that have been potentially in contact with GMOs including exhaust air ductwork.

An exemption for the transport of viable GMOs in accordance with condition C74 is permitted.

C61. PPE contaminated with GMOs must be removed as soon as practicable and decontaminated prior to reuse or disposal.

C62. Decontamination must be carried out in a manner that prevents the release of GMOs, including via aerosols.

C63. Decontamination may be achieved by any of the following methods:

a. heat treatment such as pressure steam sterilisation (autoclaving);

b. chemical treatment;

c. gas treatment; or

d. any other method approved in writing by the Regulator.

C64. If an autoclave is used for decontamination:

a. loads must be packed such that steam can contact all material being decontaminated;

b. the coldest part of the load must be exposed to a minimum temperature of 121°C for at least 15 minutes, or 134°C for at least 3 minutes;

c. measures must be taken to ensure that loads that have been decontaminated can be differentiated from loads that have not (e.g. by use of autoclave indicator tape); and

d. all displaced or evacuated air, steam and liquid must be filtered (e.g. with 0.2 µm filter or equivalent) or decontaminated before discharge.

C65. If a double-ended autoclave is installed across the facility barrier, the autoclave must have a mechanism in place to prevent it being opened on the clean side before the completion of a successful decontamination cycle.

C66. Where GMOs are decontaminated using heat-based treatment (e.g. in an autoclave), the combination of parameters (e.g. pressure, temperature, time) that is used, must have been validated as effective against the organism being decontaminated or suitable surrogate.

C67. Where GMOs are decontaminated using chemical treatment, the concentration and exposure time must be effective against the GMOs being decontaminated.

C68. Where GMOs are decontaminated using gaseous treatment, the gaseous agent must be effective in rendering the GMOs non-viable. Whether decontaminating the entire facility, part of the facility or selected equipment, successful gaseous decontamination must be validated by use of appropriate indicators (e.g. spore strip tests) placed throughout the space to be decontaminated. Records of the tests must be kept for 3 years and made available to the Regulator, on request.

Note: Gaseous decontamination is only considered effective if confirmed by all indicators employed. The type, number and location of indicators must be appropriate for the nature of the gaseous decontamination agent used and the space being decontaminated.

C69. Gaseous decontamination of the facility must take place:

a. after a spill, or escape of animals or invertebrates infected with viable GMOs outside primary containment (e.g. BSC or IVC), that cannot be decontaminated by another means;

b. prior to surrender, expiry or cancellation of certification;

c. prior to re-certification of the facility at a lower containment level;

d. prior to suspension or shutdown of the facility where the facility cannot be decontaminated by another means; and

e. prior to maintenance work on facility equipment that cannot be decontaminated by another means.

Spills

C70. If a spill occurs in the facility outside of a BSC or other approved aerosol containment device, a spill procedure (see condition C82) must be implemented to decontaminate the spill as soon as practicable. Significant incidents must be reported to the Regulator as soon as practicable.

Note: The spill procedure must also be used for accidents that release aerosols such as dropping of an agar plate.

Note: If a spill occurs outside the certified facility, procedures in the Regulator's Guidelines for the Transport, Storage and Disposal of GMOs in force at the time must be implemented including reporting the incident to the Regulator as soon as practicable.

C71. Accidental or emergency discharge of untreated waste into the LWTS must be reported to the Regulator as soon as practicable.

Record keeping

C72. A documented system of accounting of the GMOs used in the facility must be in place. The documentation must be made available to the Regulator, on request.

C73. Containers of GMOs must be clearly identifiable and labelled to indicate that they contain GMOs. Any unlabelled material must be treated as a GMO and handled in accordance with the conditions of the facility certification instrument.

Transport and storage of GMOs

C74. Viable PC3 GMOs and/or material containing or potentially containing such GMOs must not be removed from the facility unless transport is in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*, as in force from time to time; and:

a. they are to be transported to another PC3 or a PC4 facility; or

b. they are to be transported for the purpose of export; or

c. written permission has been given by the Regulator.

C75. Non-GMOs must not be removed from the facility while a dealing with a GMO is being conducted in a facility unless:

a. non-GMOs are free of contamination with GMOs; and

b. all primary containers and transport containers are surface decontaminated prior to removal from the facility.

Procedures to achieve the above must be documented and made available to the Regulator, on request.

If other organisms, material or equipment is contaminated or suspected of being contaminated with GMOs, they must be handled and disposed of in accordance with the conditions of the facility certification instrument, as if dealing with a GMO.

C76. PC3 GMOs must be stored within the work area(s) of a PC3 facility unless a written exemption is obtained from the Regulator. GMOs must be stored in a sealed, unbreakable primary container, which has been surface decontaminated prior to being enclosed within a sealed (except when samples are stored in liquid

nitrogen), unbreakable secondary container. The secondary container can then be placed in a fridge, freezer or vessel (the tertiary container).

Note: GMOs used in the facility not requiring PC3 containment may be transported and stored outside of the facility in accordance with the Regulator's Guidelines for the Transport, Storage and Disposal of GMOs provided they are not contaminated with PC3 GMOs.

Training

C77. Authorised persons not conducting dealings with GMOs must be trained in the sections of the facility manual that are relevant to the activities they are undertaking in the facility.

C78. Prior to commencing dealings with GMOs, authorised persons must complete training that includes:

a. all information contained in the facility manual (condition C82); and

b. where applicable, supervised practical experience and assessment of competence.

C79. Authorised persons conducting dealings with GMOs must undertake re-training as required to maintain proficiency appropriate to the dealings being conducted in the facility. Training material, procedures and the facility manual must be updated, and relevant persons re-trained, whenever there are:

a. changes to licence or certification conditions imposed by the Regulator related to the facility;

b. changes to any applicable Guidelines issued by the Regulator (e.g. *Guidelines for the Transport, Storage and Disposal of GMOs*);

c. changes to procedures or equipment used in the facility;

d. new risks associated with GMOs dealt with in the facility; or

e. new GMOs and/or new host organisms dealt with in the facility.

C80. Where multiple GM or non-GM organisms are used in a facility, authorised persons intending to undertake dealings with GMOs or work on non-GMOs, must not undertake any such work unless:

a. documented procedures are implemented to ensure that no contamination occurs between organisms in the facility; and

b. persons are trained in these procedures.

C81. Acknowledged and dated training records for all authorised persons must be kept by the certification holder for a period of at least 3 years and made available to the Regulator, on request.

Facility manual

C82. A facility manual (either paper or electronic) must be readily available to all authorised persons within the facility. The facility manual must document the following:

a. the facility manager's contact details;

b. the persons to contact in case of emergency;

c. copies of conditions imposed under the Gene Technology Legislation that must be followed or a link to the relevant documents (only if the manual is provided electronically), including:

   i. conditions of certification of the facility;
   ii. conditions imposed by licences for dealings with GMOs;
   iii. conditions imposed by other relevant guidelines issued by the Regulator, such as those concerning transport, storage or disposal of GMOs;

d. details of any other authorisations granted to deal with GMOs in the facility (e.g. Notifiable Low Risk Dealings-NLRDs);

e. the structure and operation (including design limits) of the facility;

f. details of all GM and non-GM organisms being handled in the facility, the risks associated with these organisms, and the management strategies for these risks, if applicable;

g. procedures for the handling of any animals and invertebrates held within the facility, if applicable;

h. procedures that must be followed by all persons entering and exiting the facility, including the use of PPE and the order in which the PPE is removed;

i. procedures for the operation and use of the BSC (if applicable) and any other Regulator-approved aerosol containment equipment;

j. circumstances in which sharps need to be used and the procedures for the use of sharps (condition C55);

k. procedures for the movement of all equipment out of the facility, including decontamination of that equipment;

l. procedure for the use of a decontamination chamber (if present) including how the decontamination process is validated;

m. procedures for decontamination of GMOs, including operation of the autoclave and effective use for different load types;

n. procedures and circumstances for gaseous decontamination of the facility;

o. procedures for disposal of waste and effluent, including procedures for their transport;

p. procedures for the transport of GMOs within the facility, including for storage of GMOs;

q. procedures for the transport of GMOs outside the facility (e.g. transport to another PC3 facility) as outlined in the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs,* or in other written permission issued by the Regulator;

r. circumstances or events which must be notified or reported to the Regulator; and

s. contingency plans, including the procedures and use of specialised equipment required for responding to:

    i. spills of GMOs in the facility (both inside and outside BSCs) and spills while transporting GMOs outside the facility;
    ii. accidental exposure to GMOs dealt within the facility, as outlined in condition C85;
    iii. escape of animals or invertebrates containing GMOs within or outside the facility, if applicable;
    iv. alarms for fire or loss of pressure;
    v. loss, theft or unintentional release of GMOs from the facility;
    vi. failure of power or ventilation systems;
    vii. failure of autoclaves and other decontamination systems;
    viii. failure of BSCs and other aerosol containment equipment;
    ix. natural disasters and fire;
    x. medical emergencies or serious injury to persons within the facility; and
    xi. security threats.

C83. A list of persons authorised to enter the facility must be maintained and made available to the Regulator, on request.

C84. The facility manual must be updated as per condition C79 and be reviewed at least annually.

Health monitoring

C85. Where dealings are being conducted with GM human pathogens, or potential human pathogens, a documented plan must be in place to:

a. report accidents and exposures to GMOs dealt with in the facility to the facility manager; and

b. respond to potential exposure to GMOs associated with the dealings undertaken in the facility.

Any accidents and exposure to GMOs or illnesses associated with these events must be reported to the Regulator as soon as practicable.

Annex 1A
Additional Requirements of Certification (Animal)

Physical Containment Level 3 Facility

Version 1.0 – effective 1 December 2022

TO BE CERTIFIED BY THE REGULATOR, ADDITIONAL CONTAINMENT REQUIREMENTS MUST BE MET FOR A PC3 FACILITY IN WHICH DEALINGS WITH ANIMALS ARE TO BE UNDERTAKEN.

This Annex outlines additional requirements for certification of a PC3 facility where dealings with animals, including animals containing GM micro-organisms, are to be undertaken. These requirements are intended for PC3 facilities where animals are housed within primary containment devices that contain both the animal and any micro-organisms they may be infected with. Additional requirements may apply where the facility is used for primary containment.

Each requirement must be met unless the Regulator grants an exemption from meeting a particular requirement.

Containment equipment

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.

Note: This container should only be opened inside another primary containment device such as a BSC.

Annex 1B
Additional Conditions of Certification (Animal)

Physical Containment Level 3 Facility

Version 1.0 – effective 1 December 2022

TO REMAIN CERTIFIED BY THE REGULATOR, ADDITIONAL CONTAINMENT CONDITIONS MUST BE MET FOR A PC3 FACILITY IN WHICH DEALINGS WITH ANIMALS ARE TO BE UNDERTAKEN.

This Annex outlines additional conditions that can be expected, in most cases, to be included in the certification instrument for certification of a PC3 facility where dealings with animals, including animals containing GM micro-organisms, are to be undertaken. Individual certification conditions may differ from these standard conditions depending upon the design, construction and proposed GMO dealings to be conducted in the facility. Once issued, the conditions may be varied by the Regulator as necessary and appropriate. Additional conditions may apply where the facility is used for primary containment.

Facility access conditions

Ani-C1. Appropriate signage indicating the nature of the animals present in the facility and any special entry requirements must be posted on the outer entry door of the facility and work area/room containing the animals.

Animal handling

Ani-C2. Procedures with animals must only be undertaken by trained, authorised persons.

Ani-C3. Handling of, or experimental procedures on, GM animals or animals containing GMOs must be conducted in a way that minimises the possibility of the animals escaping and exposure of people to the GMOs.

Ani-C4. When not being handled, all animals must be contained within cages/enclosures designed to prevent the escape of all life stages of the animal.

Ani-C5. Animals infected with aerosol-transmissible GMOs must be housed in sealed cages/enclosures fitted with exhaust HEPA filters, either as IVCs or ventilated enclosures that are HEPA-filtered. IVCs must be run in containment mode and not in isolation mode.

Safety mechanisms must be in place that prevent the primary aerosol containment equipment and exhaust air paths from becoming positively pressured relative to the surrounding area in the event of failure of the exhaust fan. The equipment must also be alarmed to indicate when operational malfunctions occur.

Ani-C6. If an animal generates aerosols that may contain GMOs, dealings involving that animal must be performed in a BSC, or in specialised aerosol containment equipment approved in writing by the Regulator.

Ani-C7. All animals or cages/containers, racks or rooms containing animals must be labelled to indicate that the animals are a GMO and/or contain GMOs, as applicable.

Ani-C8. Cages or containers must be labelled to enable identification of animals being contained and to indicate the number of animals in the containers. Where practicable, animals (e.g. mice) must be clearly marked so they can be readily identified.

Ani-C9. All animals in the facility must be accounted for in a documented system. The records must be kept by the certification holder for a period of at least 12 months and made available to the Regulator, on request

Ani-C10. If an animal escapes, every effort must be made to capture and return the animal to its container or cage, or euthanised. If the animal escapes from the facility or the animal is not captured, the incident must be reported to the Regulator as soon as practicable.

Decontamination

Ani-C11. Animal carcasses must be decontaminated before being removed from the facility. If carcasses cannot be decontaminated immediately, they may be stored in appropriate storage equipment located in the facility.

Ani-C12. Equipment, cages, bedding and animal waste must be decontaminated before being removed from the facility.

Annex 2A
Additional Requirements of Certification (Invertebrate)

Physical Containment Level 3 Facility

Version 1.0 – effective 1 December 2022

TO BE CERTIFIED BY THE REGULATOR, ADDITIONAL CONTAINMENT REQUIREMENTS MUST BE MET FOR A PC3 FACILITY IN WHICH DEALINGS WITH INVERTEBRATES ARE TO BE UNDERTAKEN.

This Annex outlines additional requirements for certification of a PC3 facility where dealings with invertebrates, including GM invertebrates or invertebrates containing GM micro-organisms, are to be undertaken. Each requirement must be met unless the Regulator grants an exemption from meeting a particular requirement. Additional requirements may apply where the facility is used for primary containment.

Facility construction and access

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.

Note: Examples of such means are an appropriately sized and positioned mirror and vacuum aspiration device.

Annex 2B
Additional Conditions of Certification (Invertebrate)

Physical Containment Level 3 Facility

Version 1.0 – effective 1 December 2022

TO REMAIN CERTIFIED BY THE REGULATOR, ADDITIONAL CONTAINMENT CONDITIONS MUST BE MET FOR A PC3 FACILITY IN WHICH DEALINGS WITH INVERTEBRATES ARE TO BE UNDERTAKEN.

This Annex outlines additional conditions that can be expected, in most cases, to be included in the certification instrument for certification of a PC3 facility where dealings with invertebrates, including invertebrates containing GM micro-organisms, are to be undertaken. Individual certification conditions may differ from these standard conditions depending upon the design, construction and proposed GMO dealings to be conducted in the facility. Once issued, the conditions may be varied by the Regulator as necessary and appropriate. Additional conditions may apply where the facility is used for primary containment.

Facility access conditions

Inv-C1. Appropriate signage indicating the type of the invertebrates present in the facility and any special entry requirements must be posted on the outer entry door of the facility and any work area/room containing the invertebrates.

Inv-C2. Prior to exiting the anteroom, all persons must check they are not inadvertently carrying invertebrates on their person.

Invertebrate handling

Inv-C3. Procedures with invertebrates must only be undertaken by trained, authorised persons.

Inv-C4. Handling of, or experimental procedures on, GM invertebrates or invertebrates containing GMOs, must be conducted in a way that minimises the possibility of invertebrates escaping and exposure of people to the GMOs.

Inv-C5. When not being handled, all invertebrates must be contained within cages/enclosures designed to prevent the escape of all life stages of the invertebrates.

Inv-C6. Cages or containers must be labelled to enable identification of invertebrates being contained as being GMOs or containing GMOs, as applicable.

Inv-C7. A record of the invertebrates, GM or containing GMO, used in the facility must be kept by the certification holder for a period of at least 12 months and made available to the Regulator, on request.

Inv-C8. If any invertebrate escapes, every effort must be taken/made to capture and return the invertebrate to its container or cage, or euthanised. If any invertebrate escapes from the facility or the invertebrate is not captured, the incident must be reported to the Regulator as soon as practicable

Inv-C9. To monitor for the presence of escaped invertebrates, the room housing invertebrates must be fitted with at least one invertebrate trap suitable for capturing invertebrates being contained in the facility.

Inv-C10. Any dealings with invertebrates involving GM micro-organisms and potentially generating aerosols must be performed in a BSC, or in specialised aerosol containment equipment approved in writing by the Regulator.

Decontamination

Inv-C11. Invertebrates must be euthanised before being removed from the facility.

Inv-C12. Cages/containers used to house GM invertebrates or invertebrates containing GM micro-organisms must be decontaminated before removal from the facility.

Standards referred to in this document

'AS/NZS' followed by a number or other identification is a reference to the Australian New Zealand Standard so numbered or identified. Refer to the most recent issue of the Standards.

AS/NZS 2243.3	Safety in laboratories Part 3: Microbiological safety and containment
AS 4260	High efficiency particulate air (HEPA) filters Classification, construction and performance

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