Australian Government
Department of Health
Office of the Gene Technology Regulator

Guidelines for Certification

of a

Physical Containment Level 2 Large Scale Facility

Version 3.1 – issued 28 February 2018

These guidelines contain the requirements and conditions for certification of a Physical Containment Level 2 (PC2) Large Scale Facility issued pursuant to section 90 of the *Gene Technology Act 2000* (the Act).

Certified PC2 Large Scale Facilities are to be used for dealings producing more than 25 litres of GMO culture in any one vessel.

The Office of the Gene Technology Regulator (OGTR) will inspect PC2 Large Scale facilities prior to any decision on an application for certification.

Once a facility is certified, the certification instrument imposes conditions on the facility pursuant to section 86 of the Act. The conditions of certification (Part B), detail the usual conditions that will apply to a PC2 Large Scale Facility. Individual certification conditions may differ from these in some respects but generally an applicant can expect that their conditions will closely follow those published here. Once issued, the conditions may be varied by the Gene Technology Regulator as necessary and appropriate.

When planning a new facility, applying for certification of an existing facility or varying an existing certification, the risks of GMOs escaping in an emergency event must be assessed. Emergency events include, but are not limited to flooding, coastal storm surges or land slippage. If the risk assessment determines that there is a greater than negligible risk from the emergency event, then the applicant should develop a risk management plan to assist them in minimising the risks from the emergency event.

The risk management plan may include, for example, removal or destruction of GMOs and decontamination of equipment and surfaces or other measures well before the event impacts the facility. Consideration should be given to the resources needed to implement the risk management plan, and their availability, during such events.

A list of the Australian/New Zealand Standards that are referenced throughout this document is also attached.

A separate document - *Explanatory Information on Guidelines for Certification of Physical Containment Facilities* - contains details about the process of certification. This document can be downloaded from the OGTR website.

Contents

Definitions

Unless defined otherwise in these guidelines words and phrases used in the guidelines 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
autoclave	Pressure steam steriliser.
bunding	An embankment or barrier to contain potential spillage. For example the provision of a low wall around potential spillage areas.
closed system	A system for growth, processing and/or storage of large scale cultures of GMOs consisting of an enclosed vessel or vessels and transfer lines. This may include systems comprised either partly, or fully, of single-use components. This does not include systems used only for waste treatment.
competent person	A person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skill enabling that person to perform a specified task.
dealing 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).
decontamination	A physical or chemical process that removes, kills or renders non-viable the GMOs used in the facility but does not necessarily result in sterility.
disposal	The destruction, discarding or throwing away of decontaminated GMOs. Note: A method of disposal may also be a method of decontamination i.e. Incineration.
facility	The whole of the space that is to be certified by the Regulator to a specific level of containment including any external liquid waste treatment system (LWTS) directly connected to the facility and all associated components (piping, tanks etc.)
large scale	More than 25 litres of GM culture in any one vessel.
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.
risk group 2 microorganism	An organism that satisfies the criteria in AS/NZS 2243.3 for classification as a Risk Group 2 microorganism.
work area	Any area inside the facility that is not defined as the LWTS.

Part A

Requirements for Certification

Physical Containment Level 2 Large Scale Facility

Version 3.1 – issued 28 February 2018

These are the requirements for the certification of a PC2 Large Scale Facility issued under section 90 of the *Gene Technology Act 2000* (the Act) and, as applicable, corresponding State law. These requirements apply to applications for certification of PC2 Large Scale Facilities received on or after the day on which these guidelines take effect.

To be granted certification, a facility must meet each of the requirements for certification of a PC2 Large Scale Facility, unless the facility receives a written exemption from meeting a particular requirement from the Regulator or a delegate of the Regulator. Additional conditions may also be imposed on the facility by the Regulator or delegate of the Regulator.

Facility and fittings requirements

R1. The work area of the facility must be a fully enclosable space bounded by walls, doors, windows, floors and ceilings. The facility doors and windows must be lockable or otherwise able to be secured.

Note: The walls, doors, windows, floors and ceilings form the physical containment barrier of the facility where dealings with GMOs will be conducted. This barrier protects all spaces outside the facility, including internal spaces of buildings in which a certified facility is located, and the environment.

R2. Any openings in the walls, ceiling or roof must be filtered or screened to prevent the entry or exit of animals, including invertebrates. The filter or screen must be of a material mechanically strong enough to withstand any airflow load, remain undamaged with regular cleaning, and resist corrosion and penetration by animals, including invertebrates.

R3. The following surfaces in the facility must be smooth, impermeable to water, easily cleanable, and resistant to damage by the cleaning agents and/or decontamination agents that will be used in the facility:

a. walls, floors, doors, windows and benches;

b. furniture, including seating; and

c. any other surfaces, where contamination is likely to occur or where decontamination is required.

R4. Open spaces between and under benches, cabinets and equipment in the facility must be accessible for decontamination.

Note: The requirement for access to open spaces is to allow for easier decontamination of spills and prevent any persistence of GMOs.

R5. If the facility has a sink or floor drainage exits, there must be mechanisms in place to ensure all liquid effluent can be decontaminated prior to discharge.

Note: This requirement could be met, for example, by having documented procedures that ensure that viable liquid effluent is not discharged down the sink, or by directing all effluent to a LWTS.

R6. The facility must contain either a dedicated wash-basin or some other means of decontaminating hands, such as dispensers filled with decontaminant solutions. All means of decontaminating hands must be able to be operated in a hands-free manner.

R7. An emergency drench shower and eyewash equipment (either plumbed eyewash equipment or single-use packs of sterile eye irrigation fluids) must be provided within the facility.

Note: AS/NZS 2982 provides information on eyewash equipment. The Regulator does not require the placement of more than one piece of eyewash equipment in the facility. Consideration should be given to the provision of appropriate forms of eye protection.

R8. Designated storage or hanging provisions for reusable personal protective clothing must be available in the facility.

R9. Where any device or system that may cause contamination of a potable water supply is connected directly or indirectly to any part of a water service, backflow prevention must be provided by a registered testable device that has a high hazard rating for protection against both back-pressure and back-siphonage in accordance with the requirements of AS/NZS 3500.1.

Note: This includes any water supplied to the facility, e.g. sinks, basins and supply to autoclave.

R10. Where any other reticulated service (e.g. air, gas or steam) linked to a large scale primary containment device (eg. closed system, LWTS), is capable of forming a cross-connection that may result in a release of a GMO outside the certified facility, a risk assessment must be conducted to determine whether backflow prevention is required.

Note: Generally, a filter with pore size of less than or equal to 0.2 µm is appropriate for air and gas. Appropriate filter or mechanisms which can prevent backflow in steam lines should be considered.

R11. If it is determined that backflow prevention is required, backflow prevention measures appropriate for the risks posed by the GMO must be implemented.

R12. The risk assessment mentioned in requirement R10 must be documented, along with its conclusions and any backflow prevention measures implemented as a result of the assessment. This documentation must be kept and made available to the Regulator, if requested.

Note: Condition C68 requires records of this assessment to be maintained

Facility management requirements

R13. 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.

Containment equipment requirements

R14. The facility must contain a closed system/s for containment of large scale cultures of GMOs during growth and processing. This may include systems comprised, either partly or fully, of single-use components.

Note: Closed vessels and lines used only for internal waste treatment are not considered part of the closed system.

R15. Closed systems (including those containing reusable or single-use components) must be designed to prevent release of GMOs into the facility.

Note: This would include release via any ventilation of the closed system. A filter with pore size of less than or equal to 0.2 µm is generally appropriate for containing aerosols in ventilation lines for bacterial or cell culture fermentation.

R16. Where any proposed large scale dealings in the facility will involve single-use components (i.e. single-use bioreactor bags, tubing, filters etc.), components must be capable of being tested for leaks, prior to being loaded with GMOs.

Note: Prior to inoculating with GMOs, single-use systems should be filled with media to enable any leaks to be detected. This will allow integrity testing of single-use bioreactor bags, and any attached lines that are open, to be tested for leaks under operating pressure. All other tubing/lines, fittings and filters should be visually inspected prior to being loaded with GMOs.

R17. Mechanisms must be in place to allow large single-use bioreactor bags to be appropriately secured while in use and easily removed for decontamination after being used for dealings with GMOs.

R18. Single-use components must be capable of being decontaminated, without any release of GMOs, including via aerosols, after being used for dealings with GMOs and before disposal.

R19. Reusable closed systems must be capable of being decontaminated without release of GMOs, including via aerosols, after being used for dealings with GMOs.

R20. Reusable closed systems must be capable of being tested for integrity.

Note: Integrity testing for reusable systems could be achieved by, for example, pressure testing the system to ensure it is able to contain the GMO culture while in operation. Other methods of testing the integrity of a reusable system are also appropriate.

R21. Prior to working with closed systems, a risk assessment of operator exposure to aerosols containing GMOs must be undertaken to determine whether there is a need to wear respiratory protection. This document must be kept and made available to the Regulator, if requested.

Note: While the likelihood of aerosol release from closed systems is expected to be extremely low, there may be a higher likelihood at specific times such as when taking samples or opening valves. Where the consequences of exposure could be high, a risk assessment is considered necessary

Guidance on considerations for respiratory protection can be found in AS/NZS 1715.

Condition C68 requires records of this assessment to be maintained.

R22. Where dealings in the facility, other than those within a LWTS or closed system, will produce aerosols containing Risk Group 2 GM microorganisms, the facility must contain a Class I or Class II biological safety cabinet, installed in accordance with the requirements of AS/NZS 2252.4, or other equipment specifically approved in writing by the Regulator that is designed to contain aerosols.

R23. Other equipment used to process GMOs (e.g. centrifuges, filtration systems) must be able to contain the GMOs, including any aerosols containing GMOs that may be generated during the process.

R24. Secondary containment, such as bunding, must be provided to retain any leakage from the closed system. It must be of sufficient capacity to contain:

a. the volume of fluid held in the largest single container, or group of containers where interconnection could result in leakage from multiple containers; plus

b. the volume of any disinfectant that might be used

with additional capacity to prevent any expected general fluid movement from breaching the secondary containment.

Liquid waste treatment system (LWTS) requirements

R25. If the facility has a LWTS located partially or fully outside of the work area of the facility, the following requirements must be met:

a. the LWTS must be a fully enclosed system comprising of tanks, pipes and other associated components;

b. construction materials of the LWTS and associated components, must be robust, suitable for the waste being treated, and must be capable of being decontaminated for inspection and maintenance;

c. the likelihood of physical damage to components (such as pipes and collection tanks) must be minimised. For example, they could be located in an area where they are protected from potential sources of damage;

d. pipes should be capable of being inspected throughout and must be labelled appropriately. In areas where pipes are not able to be inspected, such as where they traverse walls or floors, pipes must be double skinned or have a mechanism in place for detection of leaks;

e. any vents to pipes, tanks etc. must be filtered to prevent release of GMOs (eg. fitted with 0.2 µm membrane or HEPA filters);

f. strategies must be in place to ensure the seal integrity of liquid waste treatment and untreated holding components, such as drain pipes, holding tanks and vent lines;

g. screening must be provided to limit solids leaving the work area via the LWTS;

h. secondary containment, such as bunding, must be provided in the room/s or area/s housing the LWTS to retain any leakage from the system. It must be:

(i) of sufficient capacity 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, with additional capacity to prevent any expected general fluid movement from breaching the secondary containment; and

(ii) smooth, impermeable to water, easily cleanable, and resistant to damage by the cleaning agents and/or decontamination agents that will be used in case of leakage of the LWTS.

i. there must be a documented contingency plan and the means in place to respond to any leakage of waste containing GMOs and/or a failure of the LWTS. This plan must include details of any specialised equipment that will be used for such responses.

Note: Failure of the LWTS could include:

a. sensor/valve failures;

b. loss of power;

c. loss of critical utilities;

d. inability to receive effluent; or

e. loss of heating/cooling processes.

Capacity to comply with certification conditions

R26. 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 this document.

Documentation to be supplied with the application

R27. The following documentation must be submitted with the application for certification of PC2 Large Scale Facility:

a. a floor plan of the facility including locations of laboratory services, containment equipment and decontamination equipment;

b. details of the closed system/s (e.g. type, number, maximum volume of each system);

c. details of the secondary containment mentioned in requirement R24 (e.g. the volume of liquid able to be contained by bunding);

d. location and results of testing and commissioning of backflow prevention devices installed on pipes supplying water to the facility;

e. results of testing and commissioning of Biological Safety Cabinets (if installed in the facility);

f. results of testing and commissioning of all decontamination equipment installed in the facility, including autoclaves;

g. details of the proposed decontamination method for process waste contaminated with GMOs and evidence of its effectiveness;

h. details of any risk assessment of operator exposure to aerosols when working with closed systems, as mentioned in R21;

i. if the facility has an external LWTS that is to be used for decontamination of GMOs:

   (i) details of the LWTS (e.g. type, brand, volume etc.);

   (ii) results of its testing and commissioning;

   (iii) a floor plan showing the location of the external liquid waste treatment system and its vicinity 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 mentioned in requirement R25(h) (e.g. the volume of bunding provided for the LWTS); and

   (vi) the contingency plan mentioned in requirement R25(i) that details the procedures for responding to spills and/or failure of the LWTS including pipes associated with the system.

Part B

Conditions of Certification

Physical Containment Level 2 Large Scale Facility

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Conditions are imposed on facilities by the Regulator at the time of certification pursuant to section 86 of the *Gene Technology Act 2000* (the Act) and, as applicable, corresponding State law. The condition clauses in this section are the ones that can be expected, in most cases, to be included in the certification instrument as the conditions of certification for a Physical Containment Level 2 (PC2) Large Scale Facility.

Where a specific condition in this document conflicts with a condition of a licence, the Gene Technology Regulations 2001 (the Regulations), or any applicable guidelines issued under Section 27(d) of the Act, then the condition of a licence, the Regulations, or applicable guidelines prevails.

All the conditions listed under the headings of 'Facility and fittings conditions', 'Containment equipment conditions', 'Facility management' and 'Testing conditions' must be complied with at all times whether or not the facility is being used for a dealing with a GMO.

Note: If facility is no longer able to meet these conditions, the certification holder must notify the Regulator in writing. This notification may include an application for a variation to the conditions and must also include an alternative, effective strategy to manage any risks associated with dealings with GMOs in the facility.

Work not permitted in this facility

C1. The following work must not be conducted in this facility:

a. work with any GMO that under the Act, or under the conditions of a licence, requires containment in any physical containment level higher than PC2;

b. the housing/keeping/rearing of any animals, invertebrates or aquatic organisms; or

c. the growing of any plants.

Facility and fittings conditions

C2. The certification holder must ensure that the physical attributes of the facility and fittings are maintained so that the 'Facility and fittings requirements' listed in Part A of this document, with any exemptions and/or additional requirements imposed by the Regulator or their delegate, continue to be met.

C3. Each entry point to the facility must be labelled with the following signs on or next to each access door such that persons entering the facility are able to clearly see they are entering a certified PC2 facility:

a. a PC2 Large Scale facility sign as supplied by the OGTR, and

b. a biohazard symbol.

Note: Signs may be stuck onto removable fixtures, such as backing boards or plastic frames, which must be secured to the door or wall and must not be transferred to any other location. Signs do not need to be displayed on or next to the outside of emergency exits (which are not to be used to enter the facility).

C4. A supply of disinfectants effective against the GMOs used in the facility must be available in the facility for decontamination purposes. Containers of disinfectants must be clearly labelled with the contents and, where relevant, the expiry date.

Facility management conditions

C5. The certification holder must ensure that the 'Facility management requirements' listed in Part A of this document continue to be met, with any exemptions and/or additional conditions or requirements imposed by the Regulator or their delegate.

C6. While any dealings with GMOs are being conducted in the facility, the certification holder must ensure that access to the facility, including to the LWTS, is restricted to authorised persons. For the purposes of this condition, an authorised person is:

a. a person who:

i. has been trained in accordance with conditions C31 and C32;

ii. has provided the signed training record mentioned in condition C31, to the certification holder; and

iii. has not been excluded from the facility by the certification holder on the direction of the Regulator; or

b. is a person, or class of persons, who does not intend to undertake dealings with GMOs and has the permission of the certification holder, the facility manager, or other representative of the certification holder, to enter the facility.

C7. While the facility is in operation, any person covered by condition C6.b who enters the facility or accesses the LWTS must be supervised by a person mentioned in condition C6.a.

C8. If the Regulator directs the certification holder to exclude a person, or class of persons, from entry to the facility, or from accessing the LWTS, on the grounds that the person, or class of persons:

a. has behaved, or is behaving, in a manner which has caused, or which may cause, GMOs to escape from the facility; or

b. has behaved, or is behaving, in a manner which has exposed, or exposes, other persons in the facility to a GMO in circumstances where the exposure causes, or is capable of causing, a threat to the health and safety of those other persons;

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

C9. If the Regulator directs the certification holder to admit a person, or class of persons, to the facility subject to additional conditions the certification holder must only admit the person, or class of persons, subject to those conditions.

C10. For the purposes of condition C9, before admitting a person, or class of persons, subject to conditions, the certification holder must notify the person(s) of any conditions that apply to them.

C11. If the Regulator invites the certification holder to make a submission on whether or not a person, or class of person, should:

a. be excluded from entry to the facility or from accessing the LWTS; or

b. be admitted to the facility or have access to the LWTS subject to conditions;

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

C12. If the certification holder is not the owner of the facility and does not have the authority to admit and exclude persons from the premises, 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 occurring, the certification holder must notify the Regulator of this in writing as soon as practicable.

C13. The Regulator or a person authorised by the Regulator must, at all reasonable times, be allowed to enter the facility or access the LWTS for the purposes of auditing or monitoring the conditions applying to the facility and any dealings being conducted in it.

C14. Effective pest prevention strategies must be documented and implemented.

Note: Condition C68 requires records of pest control strategies and activities to be maintained.

C15. The facility, including the LWTS, must be inspected at least once every 12 months by a person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skills to assess the facility's compliance with the conditions of certification. An inspection record which details the extent of compliance with those conditions must be made.

Note: Condition C68 requires records of inspections to be maintained.

A checklist that may be used for annual inspections of PC2 Large Scale Facilities is available on the OGTR website but its use is not mandatory. Annual inspection records should not be sent to the Regulator unless requested. An OGTR inspection of the facility constitutes an inspection for the purpose of this condition.

Containment equipment conditions

C16. The certification holder must ensure that the physical attributes of the facility and fittings are maintained so that the 'Containment equipment requirements' listed in Part A of this document, with any exemptions and/or additional conditions or requirements imposed by the Regulator or their delegate, continue to be met.

Liquid waste treatment system (LWTS) conditions

C17. The certification holder must ensure that the physical attributes of the facility and fittings are maintained so that the 'Liquid waste treatment system (LWTS) requirements' listed in Part A of this document, with any exemptions and/or additional conditions or requirements imposed by the Regulator or their delegate, continue to be met.

Suspension Conditions

C18. Prior to any structural changes that will affect the containment of GMOs in the facility, the applicant must either:

(a) request a suspension of the certification, in writing, from the Regulator; or

(b) request a variation to the area of certification in writing, from the Regulator, to allow dealings to continue in a part of the facility unaffected by the structural changes.

Note: For example, it may be possible to apply for a variation to temporarily partition the facility to provide containment for GMOs at one end while the other end is being modified. Once the work is complete another variation would need to be applied for, to re-instate any area removed from the certification.

C19. Before a suspension of the certification can be lifted, the facility, including the LWTS, must be inspected by a person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skills to assess the facility's compliance with the conditions of certification.

C20. Dealings with GMOs that require a certified facility must not recommence in a facility that has its certification suspended until the Regulator has lifted the suspension by notice in writing. Storage of GMOs in a suspended facility must be in accordance with the requirements listed in the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as in force from time to time.

Note: Before a suspension can be lifted, an inspection by the OGTR may be required. A variation to the conditions of certification may also be required, which would be determined on a case-by-case basis.

Testing conditions

C21. Inspection and testing of the integrity of any reusable closed system must be undertaken by a qualified person before each use and after relocation or any maintenance of the equipment.

Note: Integrity testing for reusable systems could be achieved by, for example, pressure testing the system to ensure it is able to contain the GMO culture while in operation. Other methods of integrity testing of a reusable system may also be appropriate.

Condition C68 requires records of integrity testing to be maintained.

C22. Where testing of a reusable closed system has shown that containment cannot be achieved and the defect has not been corrected, the equipment must be clearly labelled to show that it is unsafe and must not be used for dealings involving GMOs until the defect has been corrected.

C23. Inspection and testing of the integrity of any single-use components must be performed, *in situ*, prior to being loaded with GMOs, as per requirement R16.

Note: Condition C68 requires records of integrity testing to be maintained.

C24. Where testing of a single-use component has shown that containment cannot be achieved, the component must not be used for dealings involving GMOs.

C25. Any autoclave or other heat-based equipment (not including the LWTS), in the facility, used for the purposes of decontaminating GMOs must be:

a. monitored:

i. monthly for effectiveness (if used frequently); or

ii. before or with each decontamination cycle (if used intermittently); and

b. calibrated annually;

in accordance with Decontamination Methods specified in the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as in force from time to time.

Note: Condition C68 requires records of this monitoring and calibration of decontamination equipment to be maintained.

C26. The LWTS (if present), including any pipes associated with the system, must be:

a. monitored monthly for effectiveness; and

b. inspected annually by a competent person;

and any maintenance or calibration required to ensure effectiveness of the system and containment of GMOs must be carried out as soon as reasonably practicable.

Note: Condition C68 requires records of inspection, monitoring, maintenance and calibration of decontamination equipment to be maintained.

C27. Where any Class I or Class II biological safety cabinet is installed and used for dealings involving GMOs, it must be inspected and tested in accordance with the performance requirements of AS 2252.1 and AS 2252.2. This testing is required at least every 12 months and additionally after relocation of a cabinet, after mechanical or electrical maintenance and after high efficiency particulate air (HEPA) filters are replaced. The certificate summarising the test results and the date of the next test, must be affixed to the cabinet.

Note: Condition C68 requires records of inspection and testing to be maintained.

C28. Where testing has shown that the following performance requirements of a biological safety cabinet are not met and the defect has not been corrected, the cabinet must be clearly labelled to show that it is defective and must not be used for dealings that produce aerosols containing GMOs:

a. for Class I, inward air velocity or HEPA filter integrity; or

b. for Class II, air barrier containment or exhaust HEPA filter integrity.

C29. If the facility is fitted with any testable backflow prevention devices (in accordance with AS/NZS 3500.1), these devices must be tested at least every 12 months. These tests must be conducted in accordance with AS 2845.3 by a licensed plumber accredited to test backflow prevention devices. Any failures must be rectified and the device re-tested until compliance is achieved.

Note: Condition C68 requires records of testing to be maintained.

C30. If a backflow prevention device is found to be defective and the defect has not been corrected, any equipment attached to the water or other reticulated service, must be clearly labelled to show that it must not be used when attached to the service until the defect has been corrected.

Training conditions

C31. Any persons intending to undertake dealings in the facility must be trained in the Conditions of Certification (Part B of this document), with any exemptions and/or additional conditions or requirements imposed by the Regulator or their delegate, and in the use of equipment present in the facility, and must sign and date a record of this training.

Note: A person is considered an Authorised person for the purpose of condition C6 once they have been trained, signed the training record and provided the record to the certification holder.

Condition C68 requires records of training to be maintained.

C32. Required training, as mentioned in condition C31 must include, where applicable:

a. transport, storage and disposal of the GMOs being dealt with in the facility;

b. identification of risks associated with the GMOs being dealt with in the facility;

c. spills and decontamination procedures;

d. emergency procedures;

e. personal protective equipment;

f. reporting requirements;

g. certification requirements;

h. conditions of any GMO licence under which dealings are being conducted in the facility; and

i. the structure and operation of the facility relevant to each person's role.

Work practices

The conditions listed under the heading of 'Work Practices' must be complied with by all persons in the facility whenever a dealing with a GMO is being conducted in the facility.

Note: A GMO dealing includes possession, supply, use, transport, disposal and storage of a GMO for the purposes of a dealing.

Entry and exit

C33. Facility doors must remain closed when dealings involving GMOs are in progress and must be locked when the facility is unattended.

C34. Windows must remain closed.

C35. Persons who have been performing dealings with GMOs in the facility must remove gloves and decontaminate their hands before leaving the facility. This can be achieved by washing, or use of appropriate chemical decontaminant.

Personal protective equipment

C36. Personnel performing dealings involving GMOs in the facility must wear personal protective equipment, including at least the following:

a. protective clothing to afford protection to the arms and front part of the body;

Note: A rear-fastening gown is preferable.

b. disposable gloves, when dealing with GM viral vectors or GMOs which satisfy the criteria for classification as Risk Group 2 microorganisms; and

c. respiratory protection (if deemed necessary by the assessment mentioned in requirement R21).

C37. Personal protective equipment must be removed before leaving the facility and stored in designated storage or hanging provisions or disposed of.

Containment Equipment

C38. Dealings in the facility, other than those within a LWTS or closed system, that produce aerosols containing Risk Group 2 GM microorganisms must be performed in a biological safety cabinet or other equipment specifically approved in writing by the Regulator that is designed to contain aerosols.

Note: Procedures such as centrifuging and vortexing that use sealed tubes need not be carried out in a biological safety cabinet provided that the tubes are only opened in a biological safety cabinet.

C39. Installation and use of Class I or Class II biological safety cabinets must be in accordance with the requirements of AS/NZS 2252.4.

C40. The collection of GMOs from a closed system, the addition of materials to a closed system, or the transfer of fluids from one closed system to another must be conducted in a manner that prevents the release of GMOs, including via aerosols.

Decontamination

C41. Details of any proposed decontamination method for process waste, including evidence of its effectiveness, must be provided to the Regulator prior to use.

C42. All decontamination procedures, including by way of the LWTS, must be carried out in a manner that prevents the release of GMOs, including via aerosols.

C43. For closed systems (including continuous flow centrifuges), except for single use components, decontamination must occur via an *in situ* method such as steam or chemical decontamination.

C44. All decontamination procedures (including decontamination of spills) must be carried out by trained personnel.

C45. Work benches, surfaces and equipment (including single-use components of closed systems) where dealings involving GMOs have taken place must be decontaminated when the dealings are complete.

C46. All work surfaces and equipment where maintenance is to be carried out must be decontaminated prior to maintenance taking place.

Note: This is to minimise cross contamination with any other work and to minimise any persistence of GMOs inside the facility.

C47. All liquid and solid wastes potentially containing GMOs must be decontaminated prior to disposal or discharge.

Note: For example, process waste from floor drains could be collected in a holding tank and treated with chemical disinfectant or heat.

C48. Any filters potentially contaminated with GMOs, e.g. used in conjunction with a closed system, autoclave, LWTS or aerosol containment device, must be decontaminated prior to disposal.

C49. GMOs and organisms infected with GMOs must be rendered non-viable prior to disposal.

C50. Equipment must be decontaminated prior to removal from the facility.

Note: Any items or materials not contaminated with GMOs (such as packaging waste etc.) can be removed from the facility without being decontaminated provided procedures are in place to ensure they are not contaminated.

C51. Personal protective equipment contaminated with GMOs must be taken off as soon as practicable and decontaminated prior to reuse or disposal.

C52. Decontamination of GMOs, including material or equipment contaminated with GMOs, may be effected by any of the following methods:

a. pressure steam sterilisation (autoclaving) or other heat treatment;

b. chemical treatment; or

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

C53. Where chemical treatment is used for decontamination, the treatment must be effective against the particular type of GMOs being decontaminated.

Note: AS/NZS 2243.3 is a recommended source of information on the selection and use of chemical disinfectant agents. However, properties of the GMOs should be taken into account.

Condition C68 requires evidence of effectiveness of decontamination methods for process waste to be maintained.

C54. Where an autoclave or other heat treatment (including the LWTS, if present) is required for decontamination, a combination of temperature and time that has been validated as effective for the decontamination of the particular type of GMOs must be used.

Note: Details on methods for validating effectiveness of autoclaves are specified in the Regulator's Guidelines for the Transport, Storage and Disposal of GMOs, as in force from time to time.

Condition C68 requires records of monitoring and calibration and evidence of effectiveness of heat based equipment to be maintained.

C55. Where an autoclave or other heat treatment (excluding the LWTS, if present) is required for decontamination, measures must be taken to ensure that loads that have been processed can be differentiated from loads that have not.

C56. Any autoclave, or other heat-based equipment to be used for the decontamination of GMOs (including the LWTS, if present), must be clearly labelled to show that it has been monitored for effectiveness, calibrated and otherwise maintained in the manner required by C25 (or C26 for a LWTS) and according to the Decontamination Methods contained in the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as in force from time to time.

Note: Compliance with the above condition may be achieved by placing a notice on the equipment, containing dates and results of calibration and monitoring.

Any autoclave in the facility that is not intended to be used for the decontamination of GMOs should be clearly labelled to indicate this fact, such that it will not be mistakenly used for this purpose.

C57. If any decontamination equipment is found to be defective and the defect has not been corrected, the equipment must be clearly labelled to show that it is defective and must not be used for decontaminating GMOs, waste or equipment associated with dealings with GMOs until the defect has been corrected. Defective decontamination equipment must be decontaminated prior to maintenance or repair.

C58. Decontamination of Class I or Class II biological safety cabinets must be in accordance with the requirements of AS/NZS 2252.4.

Spills

C59. If a spill of GMOs occurs inside the facility, a spills procedure (as required by requirement R13) must be implemented to decontaminate the spill.

C60. If a spill occurs outside the certified facility procedures contained in the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* must be implemented and the incident must be reported to the Regulator within the timeframe specified in condition C67.

C61. If a failure of the external LWTS results in a spill outside of the work area, the contingency plan mentioned in requirement R25i must be implemented.

Note: Condition C67 requires incidents to be reported to the Regulator in a specified time-frame.

Labelling

C62. All containers of GMOs must be clearly labelled so as to indicate that they contain GMOs. Any unlabelled potentially viable material must be treated as a GMO and handled in accordance with these requirements.

Note: Labelling enables the separation of GM work from non-GM work and enhances the control of GMOs within the facility.

Removal and storage

C63. Volumes of culture greater than 25 litres that contain GMOs must not be removed from the facility unless written permission has been given by the Regulator for transport to another location.

Note: Large volumes of liquid waste may be decontaminated via a LWTS that is part of the facility.

C64. Volumes of culture that are less than or equal to 25 litres and contain GMOs which do not meet the requirements for an exempt dealing, must not be removed from the facility unless:

a. 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

b. they are to be transported to a containment facility that, at a minimum, meets the Regulator's requirements for PC2 level containment; or

c. they are to be transported to another location for storage; or

d. they are to be transported for decontamination, or for disposal if the method of disposal is also the method of decontamination; or

e. written permission has been given by the Regulator for transport to another destination.

C65. Volumes of culture that are less than or equal to 25 litres that contain GMOs that do not meet the requirements of an exempt dealing may be stored outside the facility in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*, as in force at the time.

C66. Organisms that are not GMOs must not be removed from the facility while a dealing with a GMO is occurring in a facility unless:

a. procedures to ensure that work with the non-GMOs are not contaminated with GMOs have been documented;

b. the above procedures have been implemented; and

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

If mixing or cross-contamination of any other work by GMOs occurs, or is suspected to have occurred, then the other organisms, material or equipment must be handled and *disposed of in accordance with the conditions of certification, as if dealing with a GMO.*

Note: Means of preventing cross-contamination of other work by GMO dealings could include physical separation of the work, or separation by working at different times and ensuring any contaminated surfaces are decontaminated prior to commencing different work.

Reporting

C67. The following incidents must be reported to the Regulator as soon as reasonably practicable:

a. critical defect in the closed system while the facility is in operation;

Note: This refers to any defect in the closed system that has the potential to affect containment of GMOs.

b. release of GMOs from the facility or spill outside the facility including as a result of failure of the LWTS;

c. major release of GMOs from primary containment (e.g. large spill in the facility);

d. potential exposure of a person/s to GMOs that are Risk Group 2 human pathogens.

Note: For the purpose of this condition, as soon as reasonably practicable means a report should be provided to the OGTR (ogtr.m&c@health.gov.au) within one to two business days of an incident, via the Incident Reporting Form available on the OGTR website. Notification without delay will allow the OGTR to conduct a risk assessment on the incident and attend the location if required.

In case of an emergency (e.g. if it is known or suspected that GMOs have escaped containment) please contact the OGTR via free call on 1800 181 030 (24 hours).

Record Keeping

C68. The following records, which relate to actions required by other conditions, must be made and kept for five years from the date of creation, unless otherwise specific below, and made available to the Regulator if requested:

a. Training records and signed statements of authorised persons;

b. Records of pest prevention strategies and pest control activities;

c. Annual inspection of the facility;

d. Records of integrity testing of closed systems, including both reusable and single use systems;

e. Results of monitoring and calibration (monthly and annual) of any autoclave or other heat based equipment (including the LWTS if present) used in the facility for the purposes of decontaminating GMOs;

f. Evidence of effectiveness of decontamination methods used for process waste;

g. Results of testing of any Class I or Class II biological safety cabinet installed in the facility and used for dealings with GMOs;

h. Results of testing of any testable backflow prevention devices (in accordance with AS/NZS 3500.1);

i. Results of maintenance of the LWTS (if present);

j. Documentation of any risk assessment conducted for backflow prevention must be kept for as long as relevant;

k. Documentation of any risk assessment of operator exposure to aerosols when working with closed systems must be kept for as long as relevant.

Note: For the purposes of this condition, "as long as relevant" means until another risk assessment is conducted, or the facility is no longer certified.

Standards referenced in this document

'AS' followed by a number or other identification is a reference to the Australian Standard so numbered or identified, as in force or existing from time to time.

'AS/NZS' followed by a number or other identification is a reference to the Australian New Zealand Standard so numbered or identified, as in force or existing from time to time.

AS/NZS 2243.3	Safety in laboratories Part 3: Microbiological aspects and containment facilities
AS/NZS 2252.1	Biological safety cabinets - Biological safety cabinets (Class I) for personnel and environment protection
AS/NZS 2252.2	Controlled environments - Biological safety cabinets Class II - Design
AS/NZS 2252.4	Biological safety cabinets Classes I and II Installation and use
AS 2845.3	Water supply - Backflow prevention devices Part 3: Field testing and maintenance
AS/NZS 2982.1	Laboratory design and construction Part 1: General requirements
AS/NZS 3500.1	Plumbing and drainage Part 1: Water services
AS/NZS 1715	Selection, use and maintenance of respiratory protective equipment