Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

Guidelines for Certification

of a

Physical Containment Level 2

Animal Facility

Version 3.2– Effective 1 March 2013

The guidelines (Part A) contain the requirements for certification of a Physical Containment Level 2 (PC2) Animal Facility issued pursuant to section 90 of the *Gene Technology Act 2000* (the Act).

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 Animal Facility. Individual certification conditions may differ from these in some respect 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, proposing to apply for certification of an existing facility or varying an existing certification, an assessment of the risks of GMOs escaping in an emergency event should be undertaken. 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 of 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 <www.ogtr.gov.au>.

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Part A

Requirements for Certification

Physical Containment Level 2 Animal Facility

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CONTAINMENT REQUIREMENTS THAT MUST BE MET IN ORDER FOR A PHYSICAL CONTAINMENT LEVEL 2 (PC2) ANIMAL FACILITY TO BE CERTIFIED BY THE GENE TECHNOLOGY REGULATOR (THE REGULATOR).

Section 90 of the *Gene Technology Act 2000*

These are the requirements for the certification of a PC2 Animal Facility issued under section 90 of the *Gene Technology Act 2000* (the Act) and, as applicable, corresponding State legislation. These requirements apply to applications for certification of PC2 Animal 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 Animal 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.

Definitions and acronyms

Unless defined otherwise in this document, words and phrases used in this document 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.

anteroom An area or room between a pair of doors through which access is gained to the work area inside a facility.

The anteroom must not be used for performing any dealings other than transport of GMOs.

autoclave Pressure steam steriliser.

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 which removes, kills or renders non-viable the GMOs used. In the case of micro-organisms this may not necessarily result in sterility.

environment	Includes: (a) ecosystems and their constituent parts; (b) natural and physical resources; and (c) the qualities and characteristics of locations, places and areas.
facility	The whole of the space that is to be certified by the Regulator to a specific level of containment.
GM	Genetically modified.
GMO	Genetically modified organism.
micro-organism	An organism too small to be viewed by the unaided eye, including bacteria, fungi, viruses and some multicellular organisms. For the purposes of these guidelines, this definition includes replication defective viral vectors.
OGTR	Office of the Gene Technology Regulator.
PC2	Physical Containment Level 2.
personal protective equipment	Any devices or equipment, including clothing, designed to be worn or held by a person on its own, or part of a system, to protect against exposure to GMOs.
pest	An unwanted organism that could cause cross-contamination within the facility or compromise containment of the GMO.
primary container	The container directly surrounding the GMO.
risk group 2 organism	An organism that satisfies the criteria in AS/NZS 2243.3 for classification as Risk Group 2

sealed	Able to contain all GMOs or the reproductive material of GM plants or GM aquatic organisms (including pollen or gametes) being transported or stored, and able to remain closed during all reasonably expected conditions of transport and storage.
secondary container	The container immediately surrounding the primary container.
the Regulator	The Gene Technology Regulator.
viable	Micro-organisms, cells and cell cultures: • able to survive or multiply even though resuscitation procedures may be required, 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 inside a facility that is not performing the function of an anteroom. Dealings with GMOs other than transport, storage and disposal may only take place in the work area and any dealings with GMOs in the work area are subject to the conditions on the certification instrument.

Facility and fittings requirements

1. The facility to be certified 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.

2. The facility must have an anteroom.

   NOTE: If no dedicated anteroom is present, then an adjacent room, either uncertified or certified may act as an anteroom subject to approval by the Regulator. The Regulator may attach conditions to the room acting as the anteroom to the Animal Facility.

3. The facility boundaries (walls, doors, floors, ceilings etc.) must be designed to prevent the escape of the animals being contained.

4. If the facility has drainage exits, including hand basins, they must be fitted with barriers (e.g. screens, water traps). This barrier must be of a suitable size so to prevent the movement either in or out of the facility of animals via the drains.

   NOTE: Hand basins can utilise a water trap. If GM micro-organisms are present, then the barriers must be of a suitable type and size to prevent the movement of invertebrates across the facility boundary.

5. Any openings in the walls, ceiling or roof must be filtered or screened at the facility boundary 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.

   NOTE: If GMOs with the potential to be disseminated are present, then the filters or screens must be of a suitable type and size to prevent the movement of invertebrates across the facility boundary.

6. 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 to prevent any persistence of GMOs on the floor.

Dealings involving GM micro-organisms

If any of the dealings proposed to be conducted in the facility will involve GM micro-organisms, the facility must meet the following requirements in addition to all other requirements listed:

7. 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.

8. The facility must contain either a dedicated wash-basin fitted with taps of the hands-free operation type or some other means of decontaminating hands.

   NOTE: Decontamination of hands is considered an important means of preventing unintentional release of GM micro-organisms and protecting the health of facility personnel. If wash-basins are to be used, the provision of hand-operated taps is not acceptable, as they can be a source of contamination.

   Alternatives to wash-basins, such as dispensers filled with decontaminant solutions, are considered suitable.

9. If any proposed dealings in the facility are with GMOs that are Risk Group 2 organisms, then eyewash equipment (either plumbed eyewash equipment or single-use packs of sterile eye irrigation fluids) must be provided within the facility.

   NOTE: The Regulator does not require the placement of more than one piece of eyewash equipment in the facility.

   Consideration should be given to the wearing of appropriate forms of eye protection.

10. If any proposed dealings in the facility with GM micro-organisms will produce aerosols containing Risk Group 2 GM micro-organisms, then the facility must contain a biological safety cabinet or other equipment specifically approved in writing by the Regulator that is designed to contain aerosols.

    Where a Class I or Class II biological safety cabinet is installed, it must be installed in accordance with the requirements of AS 2252.4.

11. Where the facility complies with AS/NZS 2243.3, in relation to backflow prevention requirements for water supplied to the facility, no backflow prevention assessment is required.

12. Where the facility does not comply with AS/NZS 2243.3, an assessment must be undertaken to determine whether backflow prevention on the water supplied to the facility is necessary.

NOTE: Consideration should be given in the assessment to the potential hazards of the GMOs that are proposed to be dealt with in the facility; the presence of cross-connections, devices or systems that may cause contamination of a water supply connected directly or indirectly to any part of a water service; and the likelihood of a backflow event.

If it is determined that backflow prevention is necessary then backflow prevention measures, appropriate for the risks posed by the GMOs proposed to be dealt with in the facility, must be implemented.

Documentation which demonstrates the backflow prevention assessment, and any backflow prevention measures implemented, must be kept and made available to the Regulator if requested.

NOTE: AS/NZS 3500.1 specifies the requirements and methods for the prevention of contamination of potable water within the water service and the water main, and provides for the selection and installation of backflow prevention devices.

13. Designated storage or hanging provisions for personal protective equipment must be available in the facility.

Capacity to comply with certification conditions

14. 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 Animal Facility. These conditions are found in Part B of this document.

Information required with application forms

15. In addition to identifying the rooms to be certified, the floor plans for the facility submitted with the application must clearly identify rooms or spaces that are lifts, toilets, bathrooms, kitchens, lunch rooms and offices with carpets.

NOTE: The Regulator would not usually certify the above rooms or spaces as part of the certified facility.

Part B

Conditions of Certification

Physical Containment Level 2 Animal 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 legislation. 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) Animal 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.

Definitions and acronyms

The definitions and acronyms found in Part A of this document also apply to Parts B and C.

Obligations of the certification holder in respect of users of the facility

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

2. For the purposes of condition 1, an authorised person is a person who:

   (a) intends to undertake dealings and has been trained in accordance with the Behavioural Requirements listed at Part C of this document;

   (b) has signed, dated and provided to the certification holder a record of the training referred to in paragraph 2(a) above; and

(c) has not been excluded from the facility by the certification holder on the direction of the Regulator; or

(d) is an individual, or class of person, who does not intend to undertake dealings and has the permission of the certification holder, the facility manager or other representative of the certification holder to enter the facility.

3. If the Regulator requests the certification holder to provide a signed and dated record of the training provided to a particular authorised person, or class of person, the signed and dated record of that training must be available to the Regulator within a time period stipulated by the Regulator.

NOTE: These records may be in an electronic format.

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

(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;

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

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

6. For the purposes of condition 5, before admitting a person, or class of person, subject to conditions, the certification holder must notify the person(s) of any conditions that apply to them.

7. 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

(b) be admitted to the facility subject to conditions;

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

8. 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.

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

Work not permitted in this facility type

10. Unless otherwise agreed to in writing by the Regulator, the following work must not be conducted in this facility:

    (a) dealings with any GMO that under the conditions of a licence or legislation requires containment in any physical containment level higher than PC2;

    (b) the housing/keeping/rearing of any invertebrates, or aquatic organisms, for longer than the minimum time required to complete procedures on them;

    (c) the growing of any plants, unless integral to the dealings;

    (d) dealings producing more than 25 litres of liquid culture of GMOs in each vessel; or

    (e) any other work prohibited in writing by the Regulator.

General conditions

11. If the certification holder is not the owner of the facility, fittings and/or containment equipment and does not have the authority to maintain the facility, fittings and/or containment equipment, the certification holder must notify the Regulator in writing if the owner of the facility, fittings and/or containment equipment is incapable of carrying out, or refuses to carry out, or otherwise does not carry out, any maintenance required in order for the certification holder to continue to comply with the conditions of certification.

12. The facility 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 enabling that person to assess the facility's compliance with the conditions listed under the 'General conditions' and 'Facility and fittings conditions'. An inspection report which records the extent of compliance with those conditions must be made. A copy of the last three years' inspection reports must be kept and made available to the Regulator if requested.

NOTE: A checklist which may be used for annual inspections of PC2 Animal Facilities is available on the OGTR web site <www.ogtr.gov.au> but its use is not mandatory. Annual inspection reports should not be sent to the Regulator unless requested.

13. Each access door to the facility must be labelled with the following signs:

    (a) a current PC2 sign, as supplied by the OGTR; and

    (b) a biohazard symbol, if any dealings being undertaken in the facility involve GM micro-organisms, including viral vectors, where the parent organism satisfies the criteria for classification as a Risk Group 2 organism under AS/NZS 2243.3.

    The signs must be placed on or next to each access door (except for emergency exits) to the facility so that persons entering the facility are able to clearly see they are entering a certified PC2 facility.

    Signs may be attached 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.

14. A strategy to control pests must be implemented and maintained in the facility. Where GMOs in the facility have the potential to be disseminated via animals, including invertebrates, there must be strategies in place to prevent the entry or exit of animals including invertebrates via the anteroom.

Facility and fittings conditions

15. 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 continue to be met.

16. 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 be required to re-instate the area removed from certification.

17. Before a suspension of the certification can be lifted, the facility must be inspected by a person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skills enabling that person to assess the facility's compliance with the conditions listed under 'General conditions' and 'Facility and fittings conditions' to ensure that the facility meets the conditions of certification. Dealings with GMOs must not recommence in a facility which 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.

Dealings involving GM micro-organisms

Where any of the dealings conducted in the facility involve GM micro-organisms, the facility must meet the following conditions in addition to all other conditions listed:

18. The certification holder must ensure that the physical attributes of the facility and fittings are maintained so that the requirements stipulated under the heading 'Dealings involving GM micro-organisms' in Part A of this document continue to be met.

19. Where any Class I or Class II biological safety cabinet is installed and used for procedures with GMOs, it must be inspected and tested in accordance with the performance requirements of Section 5.2 *Critical for cabinet function* of AS 2252.1 and Section 5.2 *Critical performance tests for cabinet function* of AS 2252.2, respectively. 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 inspection and testing of cabinets must be carried out by a qualified person.

20. The certificate summarising the test results and the date of the next test, must be affixed to the cabinet.

21. Where testing has shown that the performance requirements for inward air velocity or HEPA filter integrity (Class I) or air barrier containment or exhaust HEPA filter integrity (Class II) are not met and the defect has not been corrected, the cabinet must be clearly marked to show that it is defective and must not be used for procedures that produce aerosols containing GM micro-organisms.

22. Where the certification holder is the owner or the entity with control of any autoclave or any other heat-based equipment used in decontaminating GMOs, that autoclave or other heat-based equipment must be:

    (a) monitored monthly, for effectiveness, and

    (b) calibrated annually,

    and the results of the monitoring and calibration must be documented, 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: Details on periodical monitoring and annual calibration of decontamination equipment are specified in the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as in force from time to time.

23. Where the certification holder is the owner, or the entity with control of, any autoclave or other heat-based equipment to be used for the decontamination of GMOs, the certification holder must ensure that a person intending to use that autoclave or other heat-based equipment is able to ascertain whether that autoclave or heat-based equipment has been monitored for effectiveness, calibrated and otherwise maintained in the manner required by 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 autoclave or other heat-based equipment, containing dates and results of calibration and monitoring. Details on periodical monitoring and annual calibration of decontamination equipment are specified in the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as in force from time to time.

24. If any decontamination equipment is found to be defective and the defect has not been corrected, the equipment must be clearly marked 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.

25. A supply of decontamination agents effective against any GM micro-organisms being dealt with in the facility must be available in the facility for decontamination purposes. All containers of decontamination agents, including any solutions for decontaminating hands, must be labelled with the contents and the expiry date (if applicable). Decontamination agents must not be used after the expiry date.

26. Any backflow prevention measures in place either at the time of certification or installed at a later time must be maintained until a change in the measures is indicated by a review of the backflow prevention assessment.

27. Where the facility does not comply with AS/NZS 2243.3 in relation to backflow prevention requirements for water supplied to the facility, and no backflow prevention assessment has been conducted previously, an assessment must be undertaken to determine whether backflow prevention on the water supplied to the facility is necessary considering the GMOs that are being dealt with in the facility.

28. Where there is an existing assessment on the need for backflow prevention, it must be reviewed when:

    (a) any new cross-connection, device or system that may cause contamination of a water supply is connected directly or indirectly to any part of the water service to the facility; or

    (b) connections were made prior to certification and were assessed as not requiring backflow prevention measures, but a new GMO is to be dealt with in the facility that presents different risks from the GMOs assessed at the time of certification.

29. If it is determined by review, that backflow prevention is necessary, then backflow prevention measures, appropriate for the risks posed by the GMOs proposed to be dealt with in the facility, must be implemented.

    NOTE: AS/NZS 3500.1 specifies the requirements and methods for the prevention of contamination of potable water within the water service and the water main, and provides for the selection and installation of backflow prevention devices.

30. The current backflow prevention risk assessment and, if required, details of the backflow prevention measures implemented, must be kept and made available to the Regulator if requested.

31. If the water supplied to the facility is fitted with any testable water supply backflow prevention devices, these devices must pass a test 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. Documentation of the last three years' test results must be kept and made available to the Regulator if requested.

32. If the backflow prevention device is found to be defective and the defect has not been corrected, any equipment attached to the water supply must be clearly marked to show that it must not be used when attached to the water supply system until the defect has been corrected.

Part C

Behavioural Requirements

Physical Containment Level 2 Animal Facility

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1. Persons undertaking dealings in the facility with GMOs requiring PC2 containment must comply with these Behavioural Requirements.

Non-GMOs, exempt dealings and PC1 dealings in the facility

2. Persons undertaking work in the facility on non-GMOs, exempt dealings or dealings which may be undertaken in a PC1 facility must comply with these Behavioural Requirements unless:

   (a) procedures are implemented to ensure that non-GMOs, exempt dealings or dealings which may be undertaken in a PC1 facility, are not cross-contaminated with GMO dealings requiring containment in a PC2 facility;

   (b) the above procedures are documented; and

   (c) the primary and any secondary container used to transport any organism out of the facility must be free of contamination with GMOs prior to being transported out of the facility.

   Dealings which may be undertaken in a PC1 facility, and where subclauses (a) to (c) above are met, may be conducted in accordance with the Behavioural Requirements in this document or the *Guidelines for Certification of a Physical Containment Level 1 Facility*.

   NOTE: Means of preventing cross-contamination could include physical separation of the work, or separation by working at different times and ensuring any contaminated surfaces are decontaminated prior to working with a different organism.

Doors & windows

3. Entry to and exit from the facility must be through the anteroom.

4. Dedicated "Emergency Only" exits must not be used to enter nor exit the facility except in an emergency.

5. Except during the entry and exit of personnel, supplies and/or equipment, doors of the facility must be closed while procedures with GMOs are being conducted. Entrance doors into the facility must remain locked, or the facility must be otherwise secured, when facility personnel are not in attendance.

6. Windows must be closed and locked or otherwise secured while GM animals or animals containing GMOs are in the facility.

Handling of animals

7. Handling of the GM animals or animals containing GMOs, and any experimental procedures conducted on the animals, must be carried out in a way that minimises the chance of escape of the animals and exposure of people to GMOs.

8. When not being handled, the GM animals or animals containing GMOs must be kept in containers or cages designed to prevent the escape of the animals being contained.

    NOTE: The facility physical boundaries of the facility alone are not sufficient for containment.

Decontamination

9. Decontamination must be undertaken in accordance with Section 3.1 of the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as in force from time to time unless otherwise approved in writing by the Regulator.

10. All decontamination procedures conducted inside the facility must be carried out by trained personnel.

11. GM animals, animals containing GMOs or any waste containing GMOs must be decontaminated prior to disposal if the method of disposal is not also the method of decontamination.

    NOTE: Where appropriate, visual inspection of the container(s) may be used to confirm whether decontamination is necessary (e.g. in the case of macroscopic GMOs which are visible to the naked eye)

12. Equipment, pens, cages or bedding contaminated with or suspected to be contaminated with GMOs must be decontaminated before being removed from the facility, except if they are being transported for the purposes of decontamination in accordance with the

Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs,* as in force from time to time, and other relevant guidelines issued by the Regulator.

Escape/Spills of GMOs

13. If a GM animal or animal containing GMOs escapes within the facility, the animal must be captured and returned to its container or cage, or euthanised.

14. Documented procedures must be in place to decontaminate any spills involving GM sperm, GM ova, GM embryos, GM micro-organisms or animal tissue containing GM micro-organisms inside the facility. The procedures must be made available to the Regulator if requested.

15. If a spill of GM sperm, GM ova, GM embryos, GM micro-organisms or animal tissue containing GMOs occurs inside the facility, the spills procedures must be implemented to decontaminate the spill as soon as reasonably practicable.

16. In the event of the escape, unintentional release, spill, leak or loss of GMOs outside of the facility:

    (a) efforts must be implemented as soon as reasonably practicable to locate and/or retrieve the GMOs and return the GMOs to containment or render them non-viable; and

    (b) the incident must be reported to the Regulator as soon as practicable.

Labelling

17. All animals or cages/containers of animals must be labelled so as to indicate that they are GMOs or contain GMOs. Cages or containers must be labelled to enable identification of the animals being contained and to indicate the number of animals in the containers. Large animals must be clearly marked so they can be readily identified (e.g. with a tattoo, permanent tag, microchip or permanent brand).

18. A documented system of accounting for the number of animals in the facility must be used. The documentation must be made available to the Regulator if requested.

Removal and storage of GMOs

19. Transport and storage of all GMOs, animals containing GM micro-organisms, GM sperm, GM ova, GM embryos or animal tissue containing GMOs outside of the facility must be conducted in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs,* as in force from time to time and other relevant guidelines issued by the Regulator.

20. All cultures of GMOs being stored inside the facility must be sealed during storage to prevent dissemination of the GMOs.

    NOTE: The type of container necessary to prevent the GMOs from escaping will vary depending on the type of organisms being stored.

Anteroom

21. Dealings with GMOs, other than transport, must not be undertaken in the anteroom.

Dealings involving GM micro-organisms

If any of the dealings proposed to be conducted in the facility will involve GM micro-organisms, the behavioural training must encompass the following requirements in addition to all other requirements listed:

Containment equipment

22. If any proposed dealings in the facility with GM micro-organisms will produce aerosols containing Risk Group 2 GM micro-organisms, then they 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 with GM micro-organisms such as centrifuging and vortexing in sealed tubes are not required to be performed in a biological safety cabinet, provided that the tubes are only opened in a biological safety cabinet.

23. Where any Class I or Class II biological safety cabinet is installed and used for procedures with GM micro-organisms, it must be used and decontaminated in accordance with the requirements of AS 2252.4.

Personal protective equipment

24. The following personal protective equipment must be worn by personnel undertaking dealings with GM micro-organisms in the facility:

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

        NOTE: A rear-fastening gown is preferable.

    (b) disposable gloves, when dealing with GM viral vectors or GM micro-organisms which fit into the classification of Risk Group 2 organisms, as described in AS/NZS 2243.3.

NOTE: Consideration should be given to the wearing of appropriate forms of eye protection.

25. If the work in the facility involves GM micro-organisms, or there is contact with GMOs that could persist on the clothing or equipment, then personal protective equipment must be removed before leaving the facility and disposed of or stored in designated storage or hanging provisions.

26. Personal protective equipment, with the exception of gloves, may be worn if moving directly to another containment facility, certified to at least PC2 by the Regulator, that is directly connected to the facility or is connected by a corridor, stairs or other space that is not a public thoroughfare and in which there is negligible risk of the release of the GMOs or of cross-contamination should other personnel be encountered or contacted in the corridor.

Decontamination

The general conditions relating to decontamination also apply to GM micro-organisms (see paragraphs 9, 10, 11 & 12).

27. Work benches and surfaces where procedures involving GM micro-organisms have taken place must be decontaminated when the dealings are completed. Equipment directly used in procedures involving GM micro-organisms must be decontaminated when the dealings are completed.

28. Carcasses of animals containing GM micro-organisms must be decontaminated prior to disposal if the method of disposal is not also the method of decontamination.

29. Personal protective equipment contaminated with or suspected to be contaminated with GM micro-organisms must be taken off as soon as practicable and decontaminated prior to reuse or disposal. Protective clothing that has not been contaminated with GM micro-organisms may be washed using normal laundry methods. Gloves must be disposed of after use and prior to exiting the facility.

30. Persons who have been performing procedures with GMOs in the facility must decontaminate their hands before leaving the facility.

NOTE: This may include the use of soap and water, if appropriate. If wash basins are to be used, the use of hand-operated taps is not acceptable, as they are a ready source of contamination. Soap and other decontamination agents should be dispensed from hands-free dispensers.

Labelling

31. All containers of GM micro-organisms must be clearly labelled. Any unlabelled 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.

Attachment 1

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/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 2252.1	Biological safety cabinets Part 1: Biological safety cabinets (Class I) for personnel and environment protection
AS 2252.2	Controlled environments Part 2: Biological safety cabinets Class II - Design
AS 2252.4	Controlled environments Part 4Biological safety cabinets Classes I and II - Installation and use (BS 5726:2005, MOD)
AS 2845.3	Water supply - Backflow prevention devices Part 3: Field testing and maintenance of testable devices
AS/NZS 3500.1	Plumbing and drainage - Part 1: Water services