Guidelines for Certification of PC2 Facilities / Physical Containment 2 Requirements

Version 2.2 – 7 August 2003

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Copies of the *Gene Technology Act 200*0 and associated legislation is available via the OGTR website at **www.ogtr.gov.au/pubform/legislation.htm**

IMPORTANT NOTE

These Guidelines will be updated from time to time in a staged revision of the June 2001 Guidelines and to improve functionality where necessary. Users should ensure that they have access to the most recent version by checking on the OGTR website for the most recent issue date (on title page). The table in Section 2, Part 2 lists all of the Guidelines that are in force and their issue date. All revisions will be announced on the OGTR website and all accredited organisations will be advised of the revisions in writing.

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GLOSSARY OF TERMS AND ACRONYMS USED40

accredited organisation	an organisation accredited under Division 3 of Part 7 of the Act. For more information see the *Guidelines for the Accreditation of Organisation*s
the Act	the Commonwealth *Gene Technology Act 2000*
AS/NZS 2243.3:2002	Australian/New Zealand Standard 2243.3:2002 *Safety in laboratories – Part 3: Microbiological aspects and containment facilities*
certification	certification by the Regulator of a facility to a particular containment level under the Act
closed footwear	footwear that completely covers the foot, including the heel
dealings or deal with	has the same meaning as in the Act "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; and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (g)
environment	has the same meaning as in the Act "environment" includes: (a) ecosystems and their constituent parts; (b) natural and physical resources; and (c) the qualities and characteristics of locations, places and areas
EPA-approved	for the purposes of these Guidelines "EPA-approved" means approved by the relevant government authority in the jurisdiction in which an activity is occurring

facility	has the same meaning as in the Act "facility" includes, but is not limited to, the following: (a) a building or part of a building; (b) a laboratory; (c) an aviary; (d) a glasshouse; (e) an insectary; (f) an animal house; (g) an aquarium or tank
GM	genetically modified
GMO	genetically modified organism
housing (of plants or animals)	for the purposes of these Guidelines this means the sheltering, lodging or growing of animals or plants for the majority of their life during the work of the GMO dealing
IBC	Institutional Biosafety Committee
inspection report	a report on a facility's compliance with the containment requirements in these Guidelines
NATA	National Association of Testing Authorities
OGTR	Office of the Gene Technology Regulator
PC1	Physical Containment Level 1(the lowest containment level)
PC2	Physical Containment Level 2
PC3	Physical Containment Level 3
PC4	Physical Containment Level 4 (the highest containment level)
planthouse	glasshouse, greenhouse or any facility specifically designed to grow plants (other than a laboratory), either free-standing or part of a building
procedures	for the purposes of these Guidelines, the meaning of "procedures" shall include any activity involving work with organisms
the Record	the record of GMO and GM Product Dealings, as mentioned in section 138 of the Act
the Regulations	the Commonwealth *Gene Technology Regulations 2001*
the Regulator	the Gene Technology Regulator appointed under Section 118 of the Act

CHAPTER 1 – EXPLANATORY INFORMATION

ABOUT THESE GUIDELINES

Governing legislation

These Guidelines are issued in accordance with section 90 of the *Gene Technology Act 2000* (the Act) and set out the requirements for the certification of facilities to specified containment levels.

The Act and the accompanying *Gene Technology Regulations 2001* (the Regulations) form part of the national scheme for the regulation of gene technology and GMOs in Australia.

The objectives of the Act are to:

- Protect the health and safety of people (which includes facility workers and the general public); and
- Protect the environment.

The Act aims to fulfil these objectives by identifying risks posed by, or as a result of, gene technology and by managing those risks through regulating dealings with GMOs.

The Regulations complement the Act and provide additional information to assist the interpretation and operation of the provisions in the Act.

The Act establishes a statutory officer, the Regulator, who is responsible for deciding on applications for licences. The OGTR is responsible for administering the Act and the Regulations.

Purpose of Certification

Certain dealings with GMOs must be conducted within physical containment facilities. The purpose of certification is to satisfy the Regulator that the containment facility protects persons outside the facility from exposure to GMOs and prevents release of GMOs into the environment. The Regulator also imposes conditions of certification that require certain procedures to be followed to ensure the safety of people working inside containment facilities with GMOs.

Purpose of the Guidelines

These Guidelines detail technical and procedural requirements which are the criteria that must be met by a facility before it is certified, and which need to be met continually to maintain the certification. The certification instrument for a certified facility may contain additional conditions that need to be met.

A licence to conduct dealings with GMOs may require compliance with these Guidelines. Dealings that are notifiable low risk dealings (NLRD), as defined in the Regulations, are required to be conducted within facilities certified by the Regulator at PC2 or above unless written permission has been obtained from the Regulator. Similarly, aspects of dealings involving intentional release of a GMO into the environment (DIRs) may also be required to be conducted in certified facilities.

The Guidelines only include requirements that contribute to achieving the objectives of the Act. They do not provide a comprehensive coverage of biosafety, laboratory safety or broader occupational health and safety issues. For these purposes, certification holders should refer to all other relevant legislation applicable in the jurisdiction in which the facility is located and to the current version of Australian/New Zealand Standard 2243.3:2002 *Safety in laboratories – Part 3: Microbiological aspects and containment facilities* (AS/NZS 2243.3:2002).

The facility and the work being conducted in the facility must comply with the requirements of other applicable legislation in the jurisdiction in which the facility is located. Where there is a conflict between the requirements of these Guidelines and other legislative requirements, the matter should be discussed with the OGTR.

Revision of the Guidelines

The August 2003 version replaces all pages of the June 2001 version up to Chapter 7 Part 1 inclusive and the following sections of Chapter 7 Part 2:

- A (PC2 Laboratories);
- D (PC2 Plant House); and
- G (PC2 Animal Containment).

Further replacements to specific containment levels will be made during the course of the next year.

The table in Chapter 2, Part 2 of these Guidelines lists all the specific containment levels for which the Regulator has issued Guidelines and the version that is currently in force.

Users should ensure that they have access to the most recent version by checking on the OGTR website for the most recent issue date (on title page). All revisions will be announced on the OGTR website and all accredited organisations will be advised of the revisions in writing.

ABOUT CERTIFICATION

Certification of facilities

Facilities may be certified if the Regulator is satisfied that they meet the containment requirements set out in these Guidelines.

There are four levels of containment established by the Guidelines. These are in ascending order of the stringency of containment requirements, which reflect the level of risk:

- Physical Containment Level 1 (PC1)
- Physical Containment Level 2 (PC2)
- Physical Containment Level 3 (PC3)
- Physical Containment Level 4 (PC4)

The requirements for each facility type at different physical containment levels are set out in Chapter 2 part 2 of these Guidelines.

These containment levels are established specifically for the purposes of the national scheme for the regulation of gene technology and GMOs in Australia. They are intended to harmonise as closely as possible with the Physical Containment Levels described in AS/NZS 2243.3:2002.

Some requirements of AS/NZS 2243.3:2002 are not required by these Guidelines and some additional requirements have been included. These additional requirements are flagged for ease of identification.

Compliance with the requirements of these Guidelines does not constitute compliance with the requirements of AS/NZS 2243.3:2002. Likewise, compliance with the requirements of AS/NZS 2243.3:2002 does not circumvent the need to apply for certification by the Regulator and in itself would not be sufficient for the Regulator to make a decision on whether or not to approve an application.

Applying for certification

Applications should be made on behalf of an accredited organisation. Application forms for this purpose are available from the OGTR website *www.ogtr.gov.au*. Progressively, organisations will also be able to apply for certification on-line. For further information, please telephone the OGTR on 1800 181 030.

The Regulator requires that an inspection report be provided from a person with knowledge and experience in biocontainment. The applicant may choose to utilise the services of a member of the IBC or an independent expert.

Confidential commercial information

The Act provides that a person may apply to the Regulator for a declaration that specified information is confidential commercial information for the purposes of the Act.

The Act sets out those areas where the Regulator must satisfy himself/herself before declaring that certain information is confidential commercial information.

The applicant must satisfy the Regulator that the information specified in the application is:

(a) A trade secret;

(b) Any other information that has a commercial or other value that would be, or could reasonably be expected to be destroyed or diminished if the information were disclosed; or

(c) Other information that

  (i) concerns the lawful commercial or financial affairs of a person, organisation or undertaking; and

  (ii) if it were disclosed, could unreasonably affect the person, organisation or undertaking.

The Regulator may refuse to declare that the information is confidential commercial information if the Regulator is satisfied that the public interest in disclosure outweighs the prejudice that the disclosure would cause to any person.

For more detail regarding applications for treatment of information as confidential commercial information please refer to the OGTR *Handbook on the Regulation of Gene Technology in Australia.*

Details of facilities that have been certified are not included on the public Record of GMO and GM Product Dealings. Details of facilities would normally only be provided to a third party in response to an application under the Commonwealth *Freedom of Information Act 1982.*

Each piece of information (for which the organisation seeks protection) must be detailed in an application for a declaration and the criteria detailed in the Act must be met for each piece of information.

Assessment of applications for certification of facilities

Applications for certification of facilities are assessed by the OGTR and the Regulator. Regulation 14 of the *Gene Technology Regulations 2001* (the Regulations) provides that these applications are decided within 90 working days of receipt of the application, unless the period is extended because the Regulator has sought additional information from the applicant.

The Regulator usually requires inspection by the OGTR or an independent expert of facilities for which an application for certification to PC3 or PC4 containment is made. These inspections would be conducted prior to certification.

Notification of certification

If the application is successful, the Regulator issues a notice of certification that includes:

- The name of the certification holder;
- The name of the IBC advising on the facility;
- The name of the facility;
- The facility type and containment level;
- The conditions of the certification; and
- The period for which the facility is certified.

Variation of conditions of certification

The Act provides that the Regulator may at any time, by notice in writing given to the holder of the certification, vary the certification. The variation may mean imposing additional conditions or removing or varying conditions that were previously imposed by the Regulator.

The Regulator would generally vary a certification in one of two circumstances:

- if the holder of the certification applies to the Regulator for a variation of the certification; or
- if the Regulator decides that a variation is necessary.

Before the Regulator can unilaterally vary a certification, the Regulator must give written notice of the proposed variation to the holder of the certification. The notice may request relevant information from the holder of the certification and must invite a written submission from the holder of the certification within a designated timeframe. The Regulator must consider any written submissions made.

The requirement that the Regulator provide prior notice of the variation to the holder of the certification may be waived where the Regulator considers that the action is necessary to avoid an imminent risk of death, serious illness, serious injury or serious damage to the environment.

It is acknowledged that there may be circumstances where the full set of specific requirements laid out for each PC level/facility type may not be applicable. Where facility design or practices can be shown to provide the necessary containment or risk management for the dealings being conducted in that facility the requirements in question should be discussed with the OGTR. This applies to those preparing an application for certification of those wishing to vary their existing certification.

Suspension or cancellation of certification

Suspension or cancellation of certification can be at the instigation of the certification holder or Regulator.

While a facility is certified by the Regulator, all requirements for the facility specified in the certification instrument issued by the Regulator must be complied with at all times, even if the work being performed in the facility involves organisms that are not GMOs. Certification holders may wish to apply for suspension of the certification of the facility for a period if they wish to cease their GMO dealings in that facility while continuing other work.

The Act provides that the Regulator, by notice in writing, suspend or cancel the certification of a facility if the Regulator believes on reasonable grounds that a condition of the certification has been breached.

Before the Regulator can suspend or cancel a certification, he/she must give written notice of the proposed suspension or cancellation to the holder of the certification.

The notice may request relevant information from the holder of the certification and must invite a written submission from the holder of the certification, within a designated timeframe. The Regulator must consider any written submissions.

The requirement for the Regulator to provide prior notice of the suspension or cancellation may be waived where the Regulator considers that the action is necessary to avoid an imminent risk of death, serious illness, serious injury or serious damage to the environment.

Review of the Regulator's decision

Decisions by the Regulator to refuse an application for certification, to impose conditions or to vary, suspend or cancel certification of a facility are “reviewable decisions” under the Act. If the original decision was not made by the Regulator, the applicant may seek an internal review of the decision. An applicant may seek review of the Regulator’s decision by the Administrative Appeals Tribunal. The Regulator will include details of those review rights with notification of his/her decision.

Compliance with certification - conditions

Under section 86 of the Act, certification of a facility is subject to:

(a) Any conditions imposed by the Regulator at the time of certification;

(b) Any conditions imposed by the Regulator under section 87 after certification;

(c) Any conditions prescribed by the Regulations.

In the majority of cases the instrument of certification under section 84 of the Act will include or reference the following conditions:

- The general requirements listed in Part 1 of Chapter 2 of these Guidelines; and
- The specific requirements described in Part 2 of Chapter 2 of these Guidelines applicable to the particular containment level and facility type.

In all cases, it is the responsibility of the holder of the certification to ensure compliance with the conditions of certification.

The Regulator has authority under the Act to monitor compliance with the conditions of accreditation. Further information on monitoring and compliance can be obtained from the OGTR website.

Transitional period for changed requirements

It is recognised that where there are changes to the requirements for certification arising from the implementation of these facilities, there will be implications for owners, managers and users of facilities. Certification holders will be given time to make any necessary changes and should contact the OGTR to discuss their specific circumstances.

CHAPTER 2 – REQUIREMENTS OF CERTIFICATION

This Chapter is divided into two Parts:

General requirements (Part 1) outlines the requirements that must be complied with by the holder of any certification for a facility, irrespective of the type of facility and the containment level to which the facility is certified; and

Specific requirements (Part 2) outlines the specific requirements that must be complied with for facilities certified to varying containment levels.

PART 1: GENERAL REQUIREMENTS

The holder of the certification must:

- maintain control of GMO dealings in the facility through processes appropriate to the facility's containment level and type;
- prevent release of GMOs and organisms infected with GMOs from the facility unless specifically approved (in writing) by the Regulator;
- prevent the persistence of GMOs and organisms infected with GMOs within the facility other than those being stored or used in a dealing;
- comply, and ensure all people in the facility comply with, the Specific Conditions identified in Part 2 which apply to the facility, as specified in the Regulator's instrument of certification under section 84 of the Act; and
- ensure that the facility is inspected at least once per year. A copy of the inspection report must detail the extent of compliance with the Regulator's conditions of certification and must be provided to the Regulator if requested. Any non-compliance issues must be notified to the Regulator as soon as practicable.

PART 2: SPECIFIC REQUIREMENTS

The specific requirements for each of the different physical containment (PC) level and facility type combinations are outlined in the following sections:

PC Level	Facility Type	Issue Date	Section*
	Fish and other Aquatic Organisms	June 2001	L
	Large Scale Animal Houses	June 2001	O
	Large Scale Aquaria	June 2001	R
PC2	Laboratory Facility	August 2003	1
PC2	Large Scale Laboratory	June 2001	M
PC2	Plant Containment Facility	August 2003	2
PC2	Large Scale Plant Houses	June 2001	P
PC2	Animal Containment Facility	August 2003	3
PC2	Insectary	June 2001	I
PC2	Large Scale Insect Houses	June 2001	S
PC3	Laboratory	June 2001	B
PC3	Plant House	June 2001	E
PC3	Large Scale Plant Houses	June 2001	Q
PC3	Animal Containment	June 2001	H
PC3	Insectary	June 2001	J
PC4	Laboratory	June 2001	C
PC4	Large Scale Laboratory	June 2001	N
PC4	Plant House	June 2001	F
PC4	Insectary	June 2001	K

* June 2001 sections can be found in Chapter 7, Part 2 of the June 2001 version of Guidelines. August 2003 section numbers (shaded rows) are in Chapter 2, Part 2 of these Guidelines.

Other classifications may be added to the table as required. If the need to create a new classification is identified, please contact the OGTR.

NB: *The following revised PC2 Guidelines dated August 2003 will replace the June 2001 Guidelines for the Certification of Physical Containment Facilities on 1 August 2003. Where existing facilities require changes in order to comply with the August 2003 Guidelines, certification holders have until 30 June 2004 to put the changes into effect.*

1. REQUIREMENTS FOR A PHYSICAL CONTAINMENT LEVEL 2 (PC2) LABORATORY FACILITY

General

1 The work that can be conducted in a facility that is certified as a Physical Containment Level 2 (PC2) Laboratory Facility includes work with GMOs that present a low to moderate potential risk to people and/or the environment. It may include some work with plant tissue culture and some work with small animals, but must not include the housing of animals for lengthy periods or the growing of plants (except those in tissue culture or contained in a plant growth cabinet).

Facilities

2* The facility must be labelled with the following adhesive signs as supplied by the OGTR:

(a) a Physical Containment Level 2 (PC2) sign on the outside of facility access door(s);

(b) a biohazard symbol on the outside of facility access door(s); and

(c) a PC2 Facility Practice sign prominently displayed inside the facility.

3* The facility must be a fully enclosable space contained within walls, doors, windows, floors and ceilings.

4 Walls, floors, ceilings and benches must be smooth, impermeable to water, cleanable, and resistant to the cleaning agents and/or disinfectants used in the facility. Facility furniture, including seating, must be washable.

5 A wash basin must be provided for hand washing within the facility. By 30 June 2004 the wash basin must be fitted with a basin mixer of the hands-free operation type.

6 Water supplied to the laboratory must be provided with back flow prevention.

7 Eyewash facilities (either a plumbed eyewash facility or single-use packs of sterile eye irrigation fluids) must be provided within the facility. Eyewash facilities must be used and maintained in accordance with the manufacturer's instructions.

8 The facility must contain a pressure steam steriliser (autoclave) or have an autoclave that is accessible to facility users. If the autoclave is not located in the facility, it is preferable that it be located within the same building as the facility.

9 Designated storage or hanging provisions for protective clothing must be available within the facility.

10 A supply of disinfectants for decontamination purposes must be available in the facility. The disinfectants must be clearly labelled with the contents and, where necessary, the expiry date.

* OGTR requirement additional to AS/NZS 2243.3:2002

11 Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.

Personal protective clothing and equipment

12 Protective clothing to protect the front part of the body must be worn by all persons performing procedures in the facility.

13 Closed footwear must be worn.

14 Gloves must be worn for work undertaken in a biological safety cabinet.

15 Protective clothing must be removed after completing laboratory procedures and before leaving the facility. This requirement does not apply if entering another containment facility, certified to PC2 by the Regulator, that is directly connected to the facility.

Containment equipment

16 If procedures that generate aerosols containing GMOs are to be performed in the facility, the facility must contain a biological safety cabinet, or other equipment specifically approved in writing by the Regulator that is designed to contain aerosols.

17 Installation, use and decontamination of the biological safety cabinet must be in accordance with the requirements of AS/NZS 2647: "*Biological safety cabinets - Installation and use*".

18 The biological safety cabinet must be tested at least every 12 months by a NATA accredited organisation. The cabinet must be labelled to show its test status.

Work Practices

19* All requirements for a PC2 Laboratory Facility specified in the Certification Instrument issued by the Regulator must be complied with at all times, even if the work being performed in the facility involves organisms that are not GMOs.

20 Access to the facility must be restricted to authorised persons and/or authorised classes of persons.

21* Windows must remain closed while laboratory procedures are in progress unless they are fitted with intact flyscreens. Facility doors must be closed when laboratory procedures are in progress.

22 All facility personnel must be trained in the requirements of the OGTR PC2 Laboratory Facility Guidelines. Only trained personnel are to clean contaminated equipment and surfaces, or handle hazardous material.

23* Facility personnel must indicate to the certification holder that they fully understand their training in the OGTR requirements by signing a record of their training after completion. A record of those trained must be kept and made available if requested.

24 Any procedures that generate aerosols containing GMOs must be performed in a biological safety cabinet or other equipment designed to contain aerosols specifically approved in writing by the Regulator.

25 Any unintentional release of GMOs from the facility must be reported to the Regulator as soon as practicable.

26 Work benches, surfaces and equipment where laboratory procedures have taken place must be decontaminated immediately after any spills and when laboratory procedures using GMOs are completed.

27 All work surfaces and equipment, in relevant areas of the facility, must be decontaminated before maintenance is carried out.

28 GMOs, organisms infected with GMOs, equipment or protective clothing contaminated with GMOs, and liquid and solid wastes containing GMOs, must be decontaminated by pressure steam sterilisation (autoclaving), chemical treatment, incineration or any other method approved in writing by the Regulator. Chemical disinfectant treatment must be in accordance with Appendix E of AS/NZS 2243.3:2002. Incineration must be in a high temperature, high efficiency, EPA-approved incineration facility. Protective clothing that has not been contaminated with GMOs may be washed using normal laundry methods.

29 Where a pressure steam steriliser (autoclave) is used for decontamination:

(a) Provision must be made to allow for the penetration of steam into the container during autoclaving.

(b) The coldest part of the load must be exposed to a minimum temperature of 121° C for at least 15 minutes.

(c) Measures must be taken to ensure that loads that have been processed can be differentiated from loads that have not (e.g. by use of autoclave tape).

(d) The temperature of each cycle must be monitored by use of one of the following means: a thermocouple and recorder; a maximum thermometer; a chemical indicator; spore strips; or readings from the autoclave panel.

(e) The effectiveness of decontamination by the pressure steam steriliser (autoclave) used by the facility must be tested monthly with biological indicators. A notice must be posted on, or adjacent to, the autoclave indicating the result and the date of the latest test.

30* All GMOs, and waste potentially contaminated with GMOs, being transported out of the facility must be transported in accordance with the "*Guidelines for the Transport of GMOs*".

31* Animals and plants not used in the work being performed in the facility must be regarded as waste on removal from the facility and decontaminated by pressure steam sterilisation (autoclaving), incineration or any other method approved in writing by the Regulator.

32* GMOs or organisms infected with GMOs may be stored outside the facility in a storage unit (freezer, fridge, controlled temperature room or other controlled temperature container). The storage unit must be locked when not in use, unless access is restricted to the room or area where the storage unit is located, and have a biohazard symbol posted on it.

33* GMOs or organisms infected with GMOs being stored outside the facility must be double-contained. The primary container must be sealed and unbreakable. The primary container must be stored in an unbreakable secondary container and clearly labelled. In the case of a small storage unit such as a fridge, freezer or liquid nitrogen container, the secondary container may be the storage unit.

34* Transport of material between the facility and the storage unit must be in accordance with the "*Guidelines for the Transport of GMOs*". Gloves must be worn while transferring primary containers between the storage unit and the secondary container used for transport. Any spills that occur during storage outside the facility or when transferring to the storage unit, must be reported to the Regulator as soon as practicable. The spilt material and the area must be decontaminated.

35 All cultures must be clearly identified.

36 All cultures of fungi and other spore-dispersing organisms must be sealed during storage.

37 Eating, drinking, smoking, shaving and applying cosmetics are prohibited in the facility. Food or drink intended for human consumption must not be brought into or stored in the facility.

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

39 Mouth pipetting is prohibited in the facility.

40 Only reading/writing material and computers essential to procedures performed within the facility are permitted on work benches where procedures are performed. Reading and writing material must not be used inside a biological safety cabinet. Where possible dedicated reading/writing areas should be provided and used.

41 Persons who have been performing procedures in the facility must wash or decontaminate their hands immediately before leaving the facility or before using any dedicated facility reading/writing areas.

42* The facility and equipment in the facility must be maintained so that the facility meets the containment requirements of these Guidelines.

43 Strategies must be in place to ensure that the facility is free of pests. A record of the program and dates of specific activities must be kept and made available if requested

2. REQUIREMENTS FOR A PHYSICAL CONTAINMENT LEVEL 2 (PC2) PLANT CONTAINMENT FACILITY

General

1 The work that can be conducted in a facility that is certified as a Physical Containment Level 2 (PC2) Plant Containment Facility includes work with GM plants, and/or plants infected with GMOs, that present a low to moderate potential risk to people and/or the environment.

Facilities

2* The facility must be labelled with the following adhesive signs as supplied by the OGTR:

(a) a Physical Containment Level 2 (PC2) sign on the outside of the facility door(s) or the anteroom door(s);

(b) a biohazard symbol on the outside of facility access door(s) or the anteroom door(s); and

(c) a PC2 Facility Practice sign prominently displayed inside the facility.

3* The facility must be a fully enclosable, fixed structure with walls, a roof and a floor. Planthouses must have lockable doors and must be designed to prevent the entry of surface run-off water. The ground surrounding the facility must be kept free of plants (e.g. by paving the area or laying down gravel and using a herbicide regime).

4 The transparent sections of a planthouse must be made of glass, polycarbonate sheeting, or other similar durable material. It is not permitted to use flimsy materials, such as shade cloth or thin film plastic sheeting, or a combination of flimsy materials, as the only outer cladding of transparent sections. Transparent sections must be impact resistant or protected from impact.

5 The facility must have an anteroom. Entry to the facility must be through the anteroom, unless entry is through another containment facility certified by the Regulator to PC2. Emergency exits must not be used except in emergencies. The anteroom must be fitted with a system to kill arthropods (e.g. sticky pest strip, automatic insecticide aerosol dispenser or high voltage electrical insect trap).

6* The insides of the walls and roof, and the benches must be impermeable to water and resistant to the cleaning agents and/or disinfectants used in the facility. Facility furniture, including seating, must be washable.

7 The floors of the facility must be made of concrete or some alternative durable, impervious material.

* OGTR requirement additional to AS/NZS 2243.3:2002

8 Any openings in the walls, ceiling or roof must be screened with fine mesh screens having apertures of 0.56 mm and a wire diameter of 0.28 mm. The mesh must be of a material mechanically strong enough to withstand the airflow load, remain undamaged with regular cleaning, resist corrosion and resist attack by insects.

9 If the facility has drainage exits, they must be fitted with wire mesh to prevent entry of rodents and insects. Where the work of the facility involves GM micro-organisms the drains must be also be fitted with disinfectant traps or the run off must be contained (prevented from entering the drains) and treated as waste.

10 A wash basin must be provided, either in the anteroom or inside the facility. Where the entry to the Plant Containment Facility is through another containment facility certified by the Regulator to PC2, the wash basin may be located in the adjoining certified PC2 facility.

11* Designated storage or hanging provisions for protective clothing must be available within the facility or the anteroom.

12* A supply of disinfectants for decontamination purposes must be available in the facility if the work of the facility involves GM micro-organisms. The disinfectants must be clearly labelled with the contents and, where necessary, the expiry date.

13* Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.

Personal protective clothing and equipment

14* Protective clothing (e.g.. laboratory coats or overalls) must be worn by all persons performing procedures in the facility.

15* Protective clothing must be removed before leaving the facility. This may be in the anteroom. This requirement does not apply if entering another containment facility, certified by the Regulator to PC2, that is directly connected to the facility.

Work practices

16* All requirements for a PC2 Plant Containment Facility specified in the Certification Instrument issued by the Regulator must be complied with at all times, even if the work being performed in the facility involves organisms that are not GMOs.

17 Access to the facility must be restricted to authorised persons and/or authorised classes of persons.

18 All facility personnel must be trained in the requirements of the OGTR PC2 Plant Containment Facility Guidelines. Only trained personnel are to clean contaminated equipment and surfaces, or handle waste that contains GM micro-organisms or material capable of regenerating GMOs.

19* Facility personnel must indicate to the certification holder that they fully understand their training in the OGTR requirements by signing a record of their training after completion. A record of those trained must be kept and made available if requested.

20* Any unintentional release of GMOs from the facility must be reported to the Regulator as soon as practicable.

21* Work benches, surfaces and equipment, where procedures involving GM micro-organisms have taken place, must be decontaminated immediately after any spills, and when procedures using GM micro-organisms are completed. Work benches, surfaces and equipment that have collected material capable of regenerating GMOs must be cleaned regularly.

22* All surfaces and equipment, in relevant areas of the facility, that may contain GM micro-organisms or material capable of regenerating GMOs, must be decontaminated before maintenance is carried out.

23* Plants infected with GMOs, and material potentially contaminated with GM micro-organisms or containing reproductive material of GM plants (including soil and other growth media, waste resulting from a GMO dealing, and equipment), must be rendered biologically inactive by one of the following methods before disposal:

(a) pressure steam sterilisation (autoclaving);

(b) super heated (non-pressurised) steam; or

(c) any other method approved in writing by the Regulator,

unless being disposed of via incineration.

Incineration must be in a high temperature, high efficiency, EPA-approved incineration facility.

24* GM plants, micro-organisms and any reproductive material of GM plants that would survive treatment by non-pressurised super heated steam as per paragraph 23 , must be killed by one of the following methods before disposal:

(a) pressure steam sterilisation (autoclaving); or

(b) any other method approved in writing by the Regulator,

unless being disposed of via incineration.

Incineration must be in a high temperature, high efficiency EPA-approved incineration facility.

25 Where a pressure steam steriliser (autoclave) is used for decontamination:

(a) Provision must be made to allow for the penetration of steam into the container during autoclaving.

(b) The coldest part of the load must be exposed to a minimum temperature of 121 C for at least 15 minutes.

(c) Measures must be taken to ensure that loads that have been processed can be differentiated from loads that have not (e.g. autoclave tape).

(d) The temperature of each cycle must be monitored by use of one of the following means: a thermocouple and recorder; a maximum thermometer; a chemical indicator; spore strips; or readings from the autoclave panel.

(e) The effectiveness of decontamination by the pressure steam steriliser (autoclave) used by the facility must be tested monthly with biological indicators. A notice must be posted on, or adjacent to, the autoclave indicating the result and the date of the latest test.

26* Where superheated, non-pressurised, steam is used for decontamination

(a) Provision must be made to allow for the penetration of steam into the load.

(b) The coldest part of the load must be exposed to a minimum temperature of 98° C for at least 2 hours, or a minimum temperature and time approved in writing by the Regulator.

(c) Measures must be taken to ensure that loads that have been processed can be differentiated from loads that have not.

(d) Thermocouples must be used to record temperatures.

(e) Thermocouples must be calibrated to ensure that they indicate the correct temperature. The intervals between calibrations should be sufficiently frequent to provide confidence that routine cycles of the steam steriliser achieve the desired temperature. Records of such calibrations must be kept for inspection for at least 12 months.

27* All GMOs, and waste potentially contaminated with GMOs, being transported out of the facility must be transported in accordance with the "*Guidelines for the Transport of GMOs*".

28* Animals and plants not used in the work being performed in the facility must be regarded as waste on removal from the facility and decontaminated in accordance with paragraph 23.

29* Viable plant material must not be removed from the facility unless:

(a) it is to be transported to a containment facility certified by the Regulator to equivalent or higher containment level; or

(b) it is to be transported to another location for disposal or treatment prior to disposal; or

(c) it is to be transported to another site for a release subject to a licence for a Dealing Involving the Intentional Release of a GMO into the environment (DIR); or

(d) written permission has been given by the Regulator for an exemption to this requirement in respect of non-GM plants kept in growth cabinets, that have been clearly labelled, in facilities where no GM micro-organisms have been used and where there has been no possibility of cross-contamination or cross-fertilisation.

Viable plant material, except where exempted in (d) must be transported in accordance with the "*Guidelines for the Transport of GMOs*".

30* GMOs or organisms infected with GMOs may be stored outside the facility in a storage unit (freezer, fridge, controlled temperature room or other controlled temperature container). The storage unit must be locked when not in use, unless access is restricted to the room or area where the storage unit is located, and have a biohazard symbol posted on it.

31* GMOs or organisms infected with GMOs being stored outside the facility must be double-contained. The primary container must be sealed and unbreakable. The primary container must be stored in an unbreakable secondary container and clearly labelled. In the case of a small storage unit such as a fridge, freezer or liquid nitrogen container, the secondary container may be the storage unit.

32* Transport of material between the facility and the storage unit must be in accordance with the "*Guidelines for the Transport of GMOs*". Gloves must be worn while transferring primary containers between the storage unit and the secondary container used for transport. Any spills that occur during storage outside the facility or when transferring to the storage unit must be reported to the Regulator as soon as practicable. The spilt material and the area must be decontaminated.

33* Eating, drinking, smoking, shaving and applying cosmetics are prohibited in the facility. Food or drink intended for human consumption must not be brought into or stored in the facility.

34 Hands must be washed with soap and water before leaving the facility.

35* The facility and equipment in the facility must be maintained so that the facility meets the containment requirements of these Guidelines.

36 Regular inspections of the facility, including plants, soils and other growth media, for the presence of invertebrate pests and for any unwanted micro-organisms, must be undertaken.

37 When unwanted infestations are identified treatment of the facility is required to eradicate the infestation. A record of unwanted organisms detected, treatments to remove them and the dates of the treatments, must be kept and made available if requested.

3. REQUIREMENTS FOR A PHYSICAL CONTAINMENT LEVEL 2 (PC2) ANIMAL CONTAINMENT FACILITY

General

1 The work that can be conducted in a facility that is certified as a Physical Containment Level 2 (PC2) Animal Containment Facility includes work with GM animals, and/or animals containing GMOs, that present a low to moderate potential risk to people and/or the environment.

Facilities

2* The facility must be labelled with the following adhesive signs as supplied by the OGTR:

(a) a Physical Containment Level 2 (PC2) sign on the outside of the facility door or the anteroom door;

(b) a biohazard symbol on the outside of facility access door or the anteroom door; and

(c) a PC2 Facility Practice sign prominently displayed inside the facility.

3* The facility must be a fully enclosable space contained within walls, doors, windows, floors and ceilings.

4 The facility must have an anteroom. Entry to the facility must be through the anteroom. Emergency exits must not be used except in emergencies. Facility doors and doorways must be designed to prevent the escape of the animals contained within the facility.

5 Walls, floors, ceilings and benches must be smooth, impermeable to water, cleanable, and resistant to the cleaning agents and/or disinfectants used in the facility. Facility furniture, including seating, must be washable.

6 Any openings in the walls, ceiling or roof, such as air vents, must be screened with rodent proof mesh. Where a dealing being conducted in the facility involves animals infected with an agent capable of being transmitted by arthropods, then strategies must be in place to prevent the arthropods from entering or leaving the facility.

7* If the facility has drainage exits, they must be fitted with barriers (e.g. floor wastes or mesh) to prevent rodents or any other animal from entering the facility via the drains and to prevent the escape of animals from the facility. Where a dealing being conducted in the facility involves animals infected with an agent capable of being transmitted by arthropods, the drains must also be screened or designed to prevent arthropods from entering or leaving the facility via the drains (e.g. by use of "s" bends so the drain is permanently filled with water).

8* The joints between structural components of the facility must be sealed.

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* OGTR requirement additional to AS/NZS 2243.3:2002

9 A wash basin must be provided for hand washing within the facility. By 30 June 2004 the wash basin must be fitted with a basin mixer of the hands-free operation type.

10 Eyewash facilities (either a plumbed eyewash facility or single-use packs of sterile eye irrigation fluids) must be provided within the facility. Eyewash facilities must be used and maintained in accordance with the manufacturer's instructions.

11 The facility must contain a pressure steam steriliser (autoclave) or have an autoclave that is accessible to facility users. If the autoclave is not located in the facility, it is preferable that it be located within the same building as the facility.

12 Designated storage or hanging provisions for protective clothing must be available within the facility or the anteroom.

13 A supply of disinfectants for decontamination purposes must be available in the facility. The disinfectants must be clearly labelled with the contents and, where necessary, the expiry date.

14 Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.

Personal protective clothing and equipment

15 Protective clothing to protect the front part of the body must be worn by all persons performing procedures in the facility.

16 Closed footwear must be worn.

17 Protective clothing must be removed before leaving the facility. This may occur in the anteroom.

Containment equipment

18 If procedures that generate aerosols containing GMOs are to be performed in the facility, the facility must contain a biological safety cabinet, or other equipment specifically approved in writing by the Regulator that is designed to contain aerosols.

19 Installation, use and decontamination of the biological safety cabinet must be in accordance with the requirements of AS/NZS 2647: "*Biological safety cabinets - Installation and use*".

20 The biological safety cabinet must be tested at least every 12 months by a NATA accredited organisation. The cabinet must be labelled to show its test status.

Work practices

21* All requirements for a PC2 Animal Containment Facility specified in the Certification Instrument issued by the Regulator must be complied with at all times, even if the work being performed in the facility involves organisms that are not GMOs.

22 Access to the facility must be restricted to authorised persons and/or authorised classes of persons.

23 Facility doors must be closed while work is being undertaken in the facility and must remain locked when the animals are not under supervision.

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

25 All facility personnel must be trained in the requirements of the OGTR PC2 Animal Containment Facility Guidelines. Only trained personnel are to clean contaminated equipment and surfaces, or handle hazardous material.

26* Facility personnel must indicate to the certification holder that they fully understand their training in the OGTR requirements by signing a record of their training after completion. A record of those trained must be kept and made available if requested.

27 Any procedures that generate aerosols containing GMOs must be performed in a biological safety cabinet or other equipment designed to contain aerosols specifically approved in writing by the Regulator. Bedding material and waste from infected animal cages or pens must be handled in a manner that minimises the creation of aerosols.

28* Any unintentional release of GMOs from the facility must be reported to the Regulator as soon as practicable.

29 Work benches, surfaces and equipment where procedures have taken place must be decontaminated immediately after any spills containing viable GMOs and when procedures using GMOs are completed.

30 All work surfaces and equipment, in relevant areas of the facility, must be decontaminated before maintenance is carried out.

31 Equipment or protective clothing, pens, cages, bedding or wastes contaminated with GM micro-organisms must be decontaminated by pressure steam sterilisation (autoclaving), chemical treatment, incineration or any other method approved in writing by the Regulator. Chemical disinfectant treatment must be in accord with Appendix E of AS/NZS 2243.3:2002. Incineration must be in a high temperature, high efficiency, EPA-approved incineration facility. Protective clothing that has not been contaminated with GM micro-organisms may be washed using normal laundry methods.

32 Carcasses of animals infected with GM micro-organisms or GM animals infected with infectious agents must be decontaminated by pressure steam sterilisation (autoclaving), incineration or any other method approved in writing by the Regulator.

33 Where a pressure steam steriliser (autoclave) is used for decontamination:

(a) Provision must be made to allow for the penetration of steam into the container during autoclaving.

(b) The coldest part of the load must be exposed to a minimum temperature of 121 C for at least 15 minutes.

(c) Measures must be taken to ensure that loads that have been processed can be differentiated from loads that have not (e.g. autoclave tape).

(d) The temperature of each cycle must be monitored by use of one of the following means: a thermocouple and recorder; a maximum thermometer; a chemical indicator; spore strips; or readings from the autoclave panel.

(e) The effectiveness of decontamination by the pressure steam steriliser (autoclave) used by the facility must be tested monthly with biological indicators. A notice must be posted on, or adjacent to, the autoclave indicating the result and the date of the latest test.

34* All GMOs, and waste potentially contaminated with GMOs, being transported out of the facility must be transported in accordance with the "*Guidelines for the Transport of GMOs*".

35* Animals and plants not used in the work being performed in the facility, that are potentially infected with infectious agents, must be regarded as waste on removal from the facility and decontaminated by pressure steam sterilisation (autoclaving), incineration, or any other method approved in writing by the Regulator.

36 Viable animals must not be removed from the facility unless they are to be transported to a containment facility certified by the Regulator to equivalent or higher containment level. Animals must be transported in accordance with the "*Guidelines for the Transport of GMOs*".

37* All animal cages or containers must be labelled to enable identification of the animals being contained and to indicate the number of animals in the containers.

38 Large animals must be clearly marked so they can be readily identified (e.g. with a tattoo, permanent tag, microchip or permanent brand).

39 Eating, drinking, smoking, shaving and applying cosmetics are prohibited in the facility. Food or drink intended for human consumption must not be brought into or stored in the facility.

40* Long hair must be tied back or covered with a hair net, to avoid contamination, when the work of the facility involves animals inoculated with infectious agents.

41* Cuts and abrasions on the skin of facility personnel must be covered while working in the facility.

42 Only reading/writing material and computers essential to procedures performed within the facility are permitted on work benches where procedures are performed. Reading and writing material must not be used inside a biological safety cabinet. Where possible, dedicated reading/writing areas should be provided and used.

43 Persons who have been performing procedures in the facility must wash or decontaminate their hands immediately before leaving the facility or before using any dedicated facility reading/writing areas.

44* The facility and equipment in the facility must be maintained so that the facility meets the containment requirements of these Guidelines.

45 Strategies must be in place to ensure that the facility is free of pests. A record of the program and dates of specific activities must be kept and made available if requested.

Authorisation Stamp

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