



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

Explanatory Information

Guide to Physical Containment Levels and Facility Types

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GUIDE TO PHYSICAL CONTAINMENT LEVELS AND FACILITY TYPES

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DEFINITIONS

Unless defined otherwise in this document, words and phrases used in the requirements have the same meaning as in the *Gene Technology Act 2000* (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.

Where a word in the text is **bolded**, it indicates that the word has been defined (see below).

dealings or deal with	<p>In relation to a GMO, means the following:</p> <ul style="list-style-type: none">(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; <p>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).</p>
facility	<p>The whole of the space that is to be certified by the Regulator to a specific level of containment.</p>

INTRODUCTION

Section 84 of the Act allows Gene Technology Regulator (the Regulator) to certify facilities to a specified containment level if the facility meets the containment requirements specified in guidelines issued by the Regulator under section 90 of the Act.

This document describes the Physical Containment (PC) levels used by the Regulator in the certification of **facilities** under the Act and explains the categories of organisms and types of **dealings** intended to be contained in each **facility** type and PC level.

Applicants may use this section to guide their decision about which PC level and **facility** type to apply for. If you have any queries about the different categories, please contact the Office of the Gene Technology Regulator (OGTR) to discuss the options.

PART 1 – PC LEVELS

- 1.1 There are four levels of physical containment applied to **facilities** certified by the Regulator. These are arranged in order of ascending stringency of containment requirements, which reflect the level of risk involved in the **dealings** that can be undertaken at each level. The four levels are:
- Physical Containment Level 1 (PC 1)
 - Physical Containment Level 2 (PC 2)
 - Physical Containment Level 3 (PC 3)
 - Physical Containment Level 4 (PC 4)
- 1.2 These levels are intended to harmonise as closely as possible with the PC levels described in AS/NZS 2243.3¹.
- 1.3 The required PC level for the containment of a **dealing** is governed by the gene technology legislation as follows:
- Conditions of licences can specify the level of containment required for the conduct of the dealing. Typically such conditions will be found in a licence to conduct dealings not involving an intentional release into the environment. However licences permitting direction intentional release of a GMO may also contain conditions requiring containment of a GMO to a specific level of containment.
 - Notifiable Low Risk Dealings (NLRDs) mentioned in Part 1 of Schedule 3 of the regulations, as in force from 1 July 2007, must be undertaken in a **facility** certified by the Regulator to at least PC level 1.
 - NLRDs mentioned in Part 2 of Schedule 3 of the regulations, as in force from 1 July 2007, must be undertaken in a **facility** certified by the Regulator to at least PC level 2.
- 1.4 When determining the required PC level for a DNIR involving GM micro-organisms, or GM animals or plants containing pathogenic organisms, the Regulator may be guided by the PC levels described in AS/NZS 2243.3.
- 1.5 The tables of example organisms in AS/NZS 2243.3 are not exhaustive and so, if applicants have any queries about which PC level is likely to be appropriate for the GMOs being **dealt** with in the **facility**, they should contact the OGTR to discuss the matter.
- 1.6 A PC level determined by one of the above methods is the minimum PC level at which a **dealing** can be conducted. A **dealing** may be conducted in a **facility** that is certified to a higher PC level, provided the higher level **facility** type is appropriate for the organisms involved, is certified by the Regulator, and that the conditions of certification do not prevent the **dealing** being conducted there.
- 1.7 Table 1 summarises the **dealings** that can be conducted at the four PC levels.

¹ Australian/New Zealand Standard 2243.3 *Safety in laboratories Part 3: Microbiological aspects and containment facilities*.

Table 1 - Physical Containment Levels

PC level	Type of GMO dealings that can be conducted at PC level
1	NLRDs involving large grazing animals that do not contain GM micro-organisms
	NLRDs mentioned in Part 1 of Schedule 3 of the regulations, as in force from 1 July 2007, must be undertaken in a facility certified by the Regulator to at least PC 1.
	Some DNIRs – <i>only when permitted</i> by licence
2	NLRDs mentioned in Part 2 of Schedule 3 of the regulations, as in force from 1 July 2007, must be undertaken in a facility certified by the Regulator to at least PC 2.
	DNIRs – when specified by licence
3	NLRDs – <i>not recommended</i> – these dealings must be conducted under PC 3 conditions while the facility is certified by the Regulator
	DNIRs – when specified by licence
4	DNIRs – when specified by licence

PART 2 – FACILITY TYPES

- 2.1 For the purposes of an application for a licence to conduct a **dealing** with a GMO, or for the conduct of a NLRD, the following categories of PC level and **facility** type can be used as a guide to the appropriate certified facility.
- 2.2 There may be reasons to depart from these categories where the **dealings** in a **facility** are proposed to involve more than one category of organism. Applications for certification, or for variation to the conditions of certification, should include the reasons for needing to contain the different categories of organisms, along with supporting information about how the **facility** is designed to contain them and how any risks of escape will be managed.

PC 1 Facility

- 2.3 A **facility** certified as a PC 1 Facility is appropriate for the conduct of the **dealings** listed below, provided it meets the specific requirements described in the PC 1 Facility guidelines for the **dealing** type:
- GM micro-organisms (when there is less than 25 litres of culture of any one GMO);
 - GM animals (whether or not they contain micro-organisms);
 - non GM animals containing GM micro-organisms; and
 - non-GM plants that contain or host GMOs.
- 2.4 A PC 1 Facility is not appropriate for the following:
- **dealings** with any GMO that under the Act, or under the conditions of a licence, requires containment in any PC level higher than PC 1

PC 1 Large Grazing Animals Facility

- 2.5 Permission may be given by the Regulator to use **facilities** of this type in certain limited circumstances in connection with **dealings** involving large grazing animals, which may include animals such as sheep, cattle, goats, pigs and horses. A person proposing to conduct such **dealings** may apply to the Regulator to conduct the **dealings** in this **facility** type.
- 2.6 The Regulator will not authorize the use of this containment level where a proposed **dealing** involves large grazing animals which could potentially shed or transmit GMOs.

PC 1 Large Scale Facility

- 2.7 A **facility** certified as a PC 1 Large Scale Facility is appropriate for the conduct of **dealings** when there is greater than or equal to 25 litres of culture of any one GMO.
- 2.8 A PC 1 Large Scale Facility is not appropriate for the following:
- **dealings** with any GMO that under the Act, or under the conditions of a licence, requires containment in any PC level higher than PC 1;
 - the housing/keeping/rearing of any animals or aquatic organisms; or
 - the growing of any plants.

PC 2 Animal Facility

2.9 A **facility** certified as a PC 2 Animal Facility is appropriate for the conduct of the **dealings** listed below:

- the housing/keeping/rearing of GM animals (except arthropods and aquatic organisms - including amphibians); or
- the housing/keeping/rearing of animals (except arthropods and aquatic organisms - including amphibians) that contain GMOs.

2.10 A PC 2 Animal Facility is not appropriate for the following:

- **dealings** with any GMO that under the conditions of a licence requires containment in any PC level higher than PC 2;
- the housing/keeping/rearing of any arthropods, or aquatic organisms, for longer than the minimum time required to complete procedures on them;
- **dealings** with GMO cultures greater than 25 litres; or
- any other **dealings** notified in writing by the Regulator.

PC 2 Aquatic Organism Facility

2.11 A **facility** certified as a PC 2 Aquatic Organism Facility is appropriate for the conduct of the **dealings** listed below:

- the keeping or rearing of GM aquatic organisms (including amphibians); or
- the keeping or rearing of aquatic organisms (including amphibians) that contain GMOs.

2.12 A PC2 Aquatic Organism Facility is not appropriate for the following:

- **dealings** with GM non-aquatic micro-organisms, unless they are integral to the **dealings** being conducted in the **facility**;
- the housing/keeping/rearing of terrestrial animals or terrestrial arthropods; or
- the growing of any terrestrial plants.

PC 2 Arthropod Facility

2.13 A **facility** certified as a PC 2 Arthropod Organism Facility is appropriate for the conduct of the **dealings** listed below:

- the keeping or rearing of GM terrestrial arthropods; or
- the keeping or rearing of terrestrial arthropods that contain GMOs.

2.14 A PC 2 Arthropod Facility is not appropriate for the following:

- **dealings** with any GMO that under the Act, or under the conditions of a licence, requires containment in any PC level higher than PC 2;
- **dealings** with GM micro-organisms, unless they are integral to the **dealings** being conducted in the **facility**;
- the housing/keeping/rearing of animals (other than terrestrial arthropods) or aquatic organisms (including amphibians); or
- the growing of any plants, other than non-GM plants that are required as part of a **dealing** with GM arthropods.

PC 2 Constant Temperature Room

- 2.15 Constant Temperature Rooms are intended to store or grow GMOs, and/or allow a limited range of procedures to be performed on GMOs, in controlled temperature conditions.
- 2.16 The most common use of Constant Temperature Rooms is for growing plants, but cultures of micro-organisms may need to be stored in constant temperature rooms.
- 2.17 Certification would not generally be approved for housing/keeping/rearing of animals, arthropods or aquatic organisms (including amphibians) in constant temperature rooms. It would be expected that the appropriate **facility** type would be used to house them and the required temperature regime provided there.
- 2.18 Applicants are welcome to contact the OGTR to discuss their needs prior to making an application.

PC 2 Laboratory

- 2.19 A **facility** certified as a PC 2 Laboratory is appropriate for the conduct of the **dealings** listed below:
- **dealings** with GM micro-organisms;
 - **dealings** with GM plant tissue culture or GM plants contained in a plant growth cabinet;
 - performance of laboratory procedures involving small terrestrial animals and non-adult forms of terrestrial arthropods, if not otherwise prohibited by licence conditions; and
 - performance of laboratory procedures involving aquatic organisms (including amphibians), subject to additional conditions and if not otherwise prohibited by licence conditions.
- 2.20 A PC 2 Laboratory is not appropriate for the following:
- **dealings** with any GMO that under the conditions of a licence requires containment in any PC level higher than PC 2;
 - the housing/keeping/rearing of any animals, arthropods, or aquatic organisms for longer than the minimum time required to complete laboratory procedures on them;
 - the growing of any plants (except those in tissue culture, or contained in a plant growth cabinet or other containment device approved in writing by the Regulator); or
 - **dealings** with GMO cultures greater than 25 litres.

PC 2 Large Scale Facility

- 2.21 A **facility** certified as a PC 2 Large Scale Facility is appropriate for the conduct of **dealings** when there is greater than or equal to 25 litres of culture of any one GMO.
- 2.22 A PC 2 Large Scale Facility is not appropriate for the following:
- **dealings** with any GMO that under the Act, or under the conditions of a licence, requires containment in any PC level higher than PC 2;
 - the housing/keeping/rearing of any animals or aquatic organisms; or
 - the growing of any plants.

PC 2 Plant Facility

- 2.23 A **facility** certified as a PC 2 Plant Facility is appropriate for the conduct of the **dealings** listed below:
- the growing of GM terrestrial plants; or
 - the growing of terrestrial plants that contain GMOs.
- 2.24 A PC 2 Plant Facility is not appropriate for the following:
- **dealings** with any GMO that under the conditions of a licence requires containment in any PC level higher than PC 2;
 - **dealings** with any GM micro-organisms unless they are integral to the **dealing** being conducted in the **facility**;
 - the housing/keeping/rearing of any animals, arthropods, or aquatic organisms unless they are integral to the **dealing** being contained in the **facility**;
 - **dealings** with GMO cultures greater than 25 litres; or
 - any other **dealings** notified in writing by the Regulator.

PC 3 Animal Facility

- 2.25 A **facility** certified as a PC 3 Animal Facility is appropriate for the conduct of the **dealings** listed below:
- the housing/keeping/rearing of GM animals (except arthropods and aquatic organisms - including amphibians); or
 - the housing/keeping/rearing of animals (except arthropods and aquatic organisms - including amphibians) that contain GMOs.
- 2.26 A PC 3 Animal Facility is not appropriate for the following:
- **dealings** with any GMO that under the conditions of a licence requires containment in any PC level higher than PC 3;
 - the housing/keeping/rearing of any arthropods, or aquatic organisms, for longer than the minimum time required to complete procedures on them;
 - **dealings** with GMO cultures greater than 25 litres; or
 - any other **dealings** notified in writing by the Regulator.

PC 3 Arthropod Facility (Insectary)

2.27 A **facility** certified as a PC 3 Arthropod Facility is appropriate for the conduct of the **dealings** listed below:

- the keeping or rearing of GM terrestrial arthropods; or
- the keeping or rearing of terrestrial arthropods that contain GMOs.

2.28 A PC 3 Arthropod Facility is not appropriate for the following:

- **dealings** with any GMO that under the Act, or under the conditions of a licence, requires containment in any PC level higher than PC 3;
- **dealings** with GM micro-organisms unless they are being used in conjunction with the arthropods being contained in the **facility**;
- the housing/keeping/rearing of animals (other than terrestrial arthropods) or aquatic organisms; or
- the growing of any plants, other than non-GM plants that are required as part of a **dealing** with GM arthropods.

PC 3 Laboratory

2.29 A **facility** certified as a PC 3 Laboratory is appropriate for the conduct of the **dealings** listed below:

- **dealings** with GM micro-organisms;
- laboratory procedures involving small terrestrial animals and non-adult forms of terrestrial arthropods, if not otherwise prohibited by licence conditions; and
- laboratory procedures involving aquatic organisms (including amphibians), subject to additional conditions and if not otherwise prohibited by licence conditions.

2.30 A PC 3 Laboratory is not appropriate for the following:

- **dealings** with any GMO that under the conditions of a licence requires containment in any PC level higher than PC 3;
- the housing/keeping/rearing of any animals, arthropods, or aquatic organisms for longer than the minimum time required to complete laboratory procedures on them;
- the growing of any plants (except those in tissue culture, or contained in a plant growth cabinet or other containment device approved in writing by the Regulator); or
- **dealings** with GMO cultures greater than 25 litres.

PC 3 Plant Facility

2.31 A **facility** certified as a PC 3 Plant Facility is appropriate for the conduct of the **dealings** listed below:

- the growing of GM terrestrial plants; or
- the growing of terrestrial plants that contain GMOs.

2.32 A PC 3 Plant Facility is not appropriate for the following:

- **dealings** with any GMO that under the conditions of a licence requires containment in any PC level higher than PC 3;
- **dealings** with any GM micro-organisms unless they are integral to the **dealing** being contained in the **facility**;
- the housing/keeping/rearing of any animals, arthropods, or aquatic organisms unless they are integral to the **dealings** being contained in the **facility**;
- **dealings** with GMO cultures greater than 25 litres; or
- any other **dealings** notified in writing by the Regulator.

PC 4 Facility

2.33 A **facility** certified as a PC 4 Facility is appropriate for the conduct of **dealings** that require containment in a PC 4 Facility.