Overview of Biological Containment Facilities

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What is a containment facility?

A containment facility is an area that is designed to contain and prevent the escape of the specific type of biohazard that it is designed to contain. This is achieved through the use of specific physical security, building structures, engineering controls, equipment and behavioural practices.

There are many different types of containment facilities that are designed to contain different types of genetically modified organisms (e.g., large animals, small animals, insects, plants, or microorganisms), biosecurity risks (various types of imported biological samples or organisms) and microorganisms.

The type of containment facility required, and its design and operational requirements is dependent on what is being contained and the risks presented by the work being undertaken.

When do I need to use a containment facility?

Work with genetically modified organisms must be undertaken in a containment facility certified by the Office of the Gene Technology Regulator (OGTR) where specified in the Gene Technology Act and Regulations, a licence from the OGTR, or in an associated IBC approval.

Imported goods subject to biosecurity control must be handled exclusively in a biosecurity Approved Arrangement where specified on an import permit issued by the Department of Agriculture, Fisheries

and Forestry (DAFF). Some soil, plant or animal materials from interstate may also need to be handled in specialist containment facilities.

All work with microorganisms and with samples known to contain risk group 2 (or higher) microorganisms is required to be undertaken in a microbiological containment facility. Work with , primary cells and processing of human and animal tissues and bodily fluids for research is also recommended to be undertaken in at least a PC2 microbiological containment facility.

Containment facility types

The type of containment facility that you need to use for your work is dependent on the type of organism being contained, the level of risk posed by the work or the organism, and the legislative requirements relating to the work you are doing. Each facility type will have unique requirements and can have multiple types of certifications applied. Where there is more than one type of certification for the facility, all conditions from all relevant standards and guidelines apply in unison.

Understanding which combinations of facility type, containment level and facility certification is required is not always straightforward. Please consult with the Research Compliance Officers for support and advice in identifying and interpreting the requirements.

Facility certification types

There are three main certification types for containment facilities in Australia:

1) Physical containment (PC) facilities certified by the Office of the Gene Technology Regulator (OGTR) are required for work involving gene technology and genetically modified organisms. Requirements for certification of facilities by the OGTR are specified in the Guidelines for Certification of Physical Containment Facilities.

2) Approved Arrangements certified by the Department of Agriculture, Fisheries and Forestry (DAFF) are required for handling goods subject to biosecurity control. These are commonly referred to as biosecurity containment (BC) facilities. Requirements for certification of biosecurity facilities are described in the class specific conditions for operating approved arrangements – Class 5 facilities are the most commonly used for research.

3) Microbiological physical containment facilities assessed by and registered with the Institutional Biosafety Committee are required for work involving microorganisms and samples containing microorganisms (e.g., primary cells, human and animal bodily fluids and tissues in a non-clinical setting).

   The requirements that apply to microbiological containment facilities are described in Australian/New Zealand Standard 2243.3: Safety in Laboratories: Microbiological Safety and Containment. These can be accessed via the University library's subscription to Australian Standards Online – access to the standard is available here: https://librarysearch.adelaide.edu.au/permalink/61ADELAIDE_INST/rinku3/alma9928573832201811

In addition, there are some more specialised accreditations or registrations that may be required in limited cases:

4) CA12 accredited laboratories, accredited by Primary Industries and Regions SA (PIRSA) to receive grapevine, soil and plant diagnostic materials.
5) A facility registered with PIRSA for handling notifiable animal disease agents.
6) A facility registered with the Department of Health for handling tier 1 or tier 2 Security Sensitive Biological Agents (SSBAs). These facilities must comply with the requirements set out under the SSBA Standards.

Containment facility levels

There are four levels of containment facilities used for research – physical containment (PC) levels 1 to 4 for GMO and microbiological work, and biosecurity containment (BC) levels 1 to 4 for work with goods subject to biosecurity control.

The classification is based on the structural integrity of the facility, engineering controls, what equipment is used and the behavioural requirements that apply to users of the space. An overview of the types of work that can be conducted at each level is provided in the table on the following page.

The University currently does not own or operate any containment level 3 or 4 facilities.

Overview of the type of work that can be performed in different containment facility levels.

	PC/BC Level	Type of work that can be conducted at that PC/BC level
Lowest risk work	**OGTR PC1**	Notifiable Low Risk Dealings described in Schedule 3, Part 1 of the Gene Technology Regulations.
		Some DNIRs – only when permitted by licence.
	Micro PC1	Work with risk group 1 microorganisms.
	BC1	Handling of goods subject to biosecurity control that are required to be held in a Class 5.1 Biosecurity Approved Arrangement.
Low to medium risk work	**OGTR PC2**	Notifiable Low Risk Dealings described in Schedule 3, Part 2, 2.1 of the Gene Technology Regulations.
		DNIRs – when permitted by licence.
	Micro PC2	Work with risk group 2 microorganisms & samples containing these. Work with primary cells, human and animal bodily fluids and tissues.
	BC2	Handling of goods subject to biosecurity control that are required to be held in a Class 5.2 Biosecurity Approved Arrangement.
Medium to high-risk work	**OGTR PC3**	Notifiable Low Risk Dealings described in Schedule 3, Part 2, 2.2 of the Gene Technology Regulations.
		Other NLRDs – permitted but not recommended – all dealings (including NLRDs) must be conducted according to PC3 conditions.
		DNIRs – when permitted by licence.
	Micro PC3	Work with risk group 3 microorganisms & samples containing these.
	BC3	Handling of goods subject to biosecurity control that are required to be held in a Class 5.3 Biosecurity Approved Arrangement.
Highest risk work	**OGTR PC4**	DNIRs – when permitted by licence.
	Micro PC4	Work with risk group 4 microorganisms & samples containing these.
	BC4	Handling of goods subject to biosecurity control that are required to be held in a Class 5.4 Biosecurity Approved Arrangement.

Containment facility classes

There are many different types of containment facilities that are designed to contain different types of organisms. The most common examples that may be required for research activities at the University are:

- Animal facility – a facility designed for the housing/keeping/rearing of animals (excluding invertebrates, aquatic organisms, or amphibians) that need to be held at the corresponding containment level. This could include housing/keeping/rearing of animals containing a GMO or microorganism requiring containment at that level.

- Aquatic facility – a facility designed for the keeping or rearing of aquatic animals, including amphibians, that need to be held at the corresponding containment level. This could include keeping/rearing of aquatic animals containing a GMO or microorganism requiring containment at that level.

- Constant temperature room – a facility designed to store or grow GMOs that always remain under primary containment (i.e., within an enclosed container) whilst in the room. Only applicable for OGTR certified facilities and only to be used for exempt, PC1 or PC2 GMOs.

- Invertebrate facility – a facility designed for the keeping or rearing of terrestrial invertebrates that need to be held at the corresponding containment level. This could include keeping/rearing of invertebrates containing a GMO or microorganism requiring containment at that level.

- Laboratory – a facility designed for in vitro work or for performance of short-term, supervised laboratory procedures involving animals, invertebrates, or aquatic organisms suitable to be undertaken at the corresponding containment level, and if not otherwise prohibited by licence conditions.

- Large grazing animal facility – a facility designed to contain PC2 GMO large grazing animals, which may include sheep, cattle, goats, pigs, and horses that will not shed or transmit GMOs. The OGTR will only permit use of facilities of this type under limited circumstances.

- Microbiological biosecurity facility – A facility designed for work with microorganisms subject to biosecurity control, or to samples that may contain such microorganisms.

- Plant facility- A facility designed for the growing of GM terrestrial plants that need to be held at the corresponding containment level. This could include growing plants containing a GMO or microorganism requiring containment at that level.

Matrix of containment levels available for different facility and certification types.

Facility type	**Certification Type**	**Containment Level**			
		1	**2**	**3**	**4**
Animal facility	OGTR		✓	✓	
	DAFF	✓	✓	✓	✓
	Micro	✓	✓	✓	✓
Aquatic facility	OGTR		✓		
	DAFF	✓	✓		
	Micro	✓	✓	✓	
Constant temperature room	OGTR		✓		
	DAFF	N/A			

	Micro	N/A			
Facility	OGTR	✓		✓	✓
	DAFF	N/A – covered by other types			
	Micro	N/A – covered by other types			
Invertebrate facility	OGTR		✓	✓	
	DAFF	✓	✓		
	Micro	✓	✓	✓	✓
Laboratory	OGTR		✓	✓	
	DAFF	See 'microbiological facility'			
	Micro	✓	✓	✓	✓
Large grazing animal facility	OGTR		✓		
	DAFF	N/A			
	Micro	N/A			
Large scale facility	OGTR		✓		
	DAFF	N/A			
	Micro	N/A			
Microbiological facility	OGTR	See 'laboratory' type			
	DAFF	✓	✓	✓	✓
	Micro	See 'laboratory' type			
Plant facility	OGTR		✓		
	DAFF	✓	✓	✓	
	Micro	✓	✓	✓	✓

Containment facility requirements

Each different certification type, facility level and facility type has different requirements, which are specified in the individual guidelines or standards that relevant to that facility type.

- Requirements for certification of facilities by the OGTR are specified in the Guidelines for Certification of Physical Containment Facilities.
- Requirements for certification of biosecurity facilities are described in the class specific conditions for operating approved arrangements – Class 5 facilities are the most commonly used for research.
- Requirements for microbiological containment facilities are described in AS/NZS 2243.3. These can be accessed via the University library's subscription to Australian Standards Online – access to the standard is available here: https://librarysearch.adelaide.edu.au/permalink/61ADELAIDE_INST/rinku3/alma9928573832201811

It is possible for a single facility to have three different certification types (i.e., OGTR, biosecurity and microbiological), and the level of containment and type of facility required for your work may differ between the different standards and guidelines. This is why it is important to discuss your facility requirements with the Research Compliance Officers before commencing any planning for certification.

Certification of containment facilities

Process for getting a containment facility certified

1. To being the certification process, contact the Research Compliance Officers to determine what type of facility you will need, and what requirements will apply.

2. Once the appropriate requirements have been identified, the facility will need to be set up to meet those conditions.
    - The Research Compliance Officer will undertake an initial inspection to provide advise on what actions may be required.
    - For BC2 facilities, it is also advisable to engage the DAFF-approved Third-Party Assessor (TPA) to undertake an initial inspection and set out their expectations for certification.
    - In some cases, the changes required may be minor (e.g., installing some hand sanitiser or gown hooks, preparing documentation and procedures) whilst in other cases refurbishment may be required before the facility is able to be certified. This will depend on the existing condition of the facility and the type of facility that you need.
    - The Research Compliance Officers can inspect throughout the process for larger refurbishments or new builds to ensure that conditions are being met.

Plan well ahead as this process can take time depending on the level of changes required.

3. Once all requirements are met in the facility, the Research Compliance Officer will undertake a final inspection. For BC2 (or higher) biosecurity facilities, a DAFF-approved TPA must also be engaged to undertake inspection.

4. Provided that the final inspection is passed, the Research Compliance Officers will prepare and submit applications for certification to the OGTR and/or DAFF. You may be asked to provide some information required during this application process. Microbiological facilities will be confirmed on the day of final inspection provided that the facility meets relevant requirements.
    - OGTR are permitted to take up to 90 business days to assess an application for a new certification facility. Typically, the process takes up to 1 month, but be prepared to wait for longer.
    - DAFF certifications take several months before they are approved.

5. For OGTR facilities, once the facility is certified you will be provided with a certification instrument and sign. You will be expected to commence inductions and start complying with all relevant conditions from the first date of certification. The facility will be audited at least once annually by the IBC, and ad-hoc by the OGTR.

6. For DAFF facilities, you will be issued a notice of probationary approval. Final certification is dependent on passing probation audits during the first six- to twelve-months of operation. During this time and thereafter, the facility must remain compliant with all conditions relevant to that class of facility. The facility will be inspected and audited by a Research Compliance Officer annually and by a DAFF-auditor generally once every 12-18 months.

Maintaining certification of a containment facility

To retain certification of a containment facility, the facility must continue to meet the requirements set forth in the relevant guidelines and/or standards for the entire period of certification.

Facility managers, facility users and principal investigators all have an obligation to ensure that they operate according to the behavioural requirements of the facility, and that any damage to the facility is reported for repair.

The Research Compliance Officers will undertake inspections and audits of the facility to assess compliance with the requirements. If any issues affecting containment are identified, corrective actions notice will be issued identifying required rectifications with a cut-off date. The Research Compliance Officers will work with you to find solutions for issues in facilities, but if required actions are not completed, the University may, in many cases, be required to revoke the certification of your facility.

Building works in containment facilities

If you have any building works or building repairs occur in your facilities during the time the facility is certified, please contact the Research Compliance Officers as soon as you know what is happening. Depending on the nature of the works, we may need to temporarily suspend the facility, or submit a notification to the Regulator.

- For BC2 facilities, no works can be undertaken without permission from DAFF.

- For OGTR-certified facilities, some minor works are permitted whilst the facility is certified but a notification must be submitted to the OGTR before the works proceed– see further information here.
- Other works in OGTR-certified facilities will require temporary suspension of certification before the works can proceed.
- For microbiological containment facilities, facility users and managers are required to decontaminate areas where maintenance workers will be accessing before the works can proceed.

In all cases, work requiring containment must not be undertaken whilst maintenance or building contractors are present in the facility.