



Application for the Certification of a Physical Containment Facility

Applicant Organisation Name:

Accreditation Number*:

* If organisation is accredited by the Gene Technology Regulator

Is this application accompanied by an application for a declaration that certain information be treated as **Confidential Commercial Information (CCI)** ?

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
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Time taken to complete this form:

Hours		Minutes	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

General Instructions

Application for certification

This application is for the certification of a facility to a specified containment level in accordance with Guidelines for the Certification of Physical Containment Facilities issued under the *Gene Technology Act 2000* (Commonwealth) (the Act). The Gene Technology Regulator (the Regulator) may require you to provide additional information. If this is necessary, the Regulator or the Regulator's delegate will notify you in writing of the additional information required. If the spaces provided are not sufficient to set out the requested information, you should attach a separate sheet for additional information and clearly mark on the attachment which section, part and question the information relates to. You should also indicate against the item that there is additional information attached, noting the attachment title/number and the page number(s).

Accuracy of information

Please answer all questions unless otherwise indicated. Please check that the information provided in this application is true and accurate. The Act provides for penalties to a person who knowingly gives information to the Regulator that is false or misleading.

Confidentiality

If you wish to make an application for a declaration that specifies information is Confidential Commercial Information (CCI) for the purposes of the Act, you must also complete the CCI application form available at <www.ogtr.gov.au> and place it at the end of this application.

Privacy

Any personal information is safeguarded by the *Privacy Act 1988*. This prevents the submitted personal information from being used for purposes other than assessing the certification application, or other circumstances specified by the *Gene Technology Act 2000* (Commonwealth). In certain circumstances information supplied as part of a certification application may, according to their specific needs, be given to the following:

- an officer or employee of the Department of Health and Ageing;
- an officer or employee of a State government agency or organisation;
- Courts, Tribunals and/or other Commonwealth agencies where it is an obligation under law to provide it;
- law enforcement authorities; and
- the relevant Minister.

Authorisation

Please ensure that if you are completing this application on behalf of the organisation, you hold the proper authority to submit this application on behalf of the organisation.

For further information

Please contact the OGTR by:

Telephone: 1 800 181 030
E-mail: ogtr@health.gov.au

The *Handbook on the Regulation of Gene Technology in Australia - A User's Guide to the Gene Technology Act 2000*, related legislation and other information are available at <www.ogtr.gov.au>.

The completed application can be lodged in person or as follows:

Mail: Office of the Gene Technology Regulator
MDP 54 PO Box 100
WODEN ACT 2606
Fax: (02) 6271 4202 (the original to follow in the mail)

Please retain a copy of your completed application. If you have not received a certification acknowledgement with the application identifier within two weeks, please e-mail ogtr@health.gov.au or telephone 1 800 181 030.

Section 1:

Application Contact Details

Contact for this application

(Details of the person the OGTR can contact regarding this application)

Surname:	<input type="text"/>	Preferred first name:	<input type="text"/>
Personal title: (eg Ms/Mr/Dr)	<input type="text"/>	Job title:	<input type="text"/>
Phone number:	<input type="text"/>	Fax number:	<input type="text"/>
Mobile number:	<input type="text"/>	E-mail address:	<input type="text"/>
Street number and name:	<input type="text"/>		
Town/City:	<input type="text"/>	State:	<input type="text"/>
Postcode:	<input type="text"/>	Country:	<input type="text"/>
Postal address: (if different)	<input type="text"/>		

Applicant Organisation type

Status/type of Organisation

Please indicate below the legal entity type of the applicant organisation eg. university, public hospital, research body, body corporate under the *Corporations Act 2001*

Section 2:

Facility Details

Level and type of containment facility

Please choose one containment level and one facility type from either of the following lists.

PC1	<input type="checkbox"/>	(Laboratory/Plant/Animal) Facility	<input type="checkbox"/>
		Large Grazing Animal Facility	<input type="checkbox"/>
		Large Scale Facility	<input type="checkbox"/>

OR

PC2	<input type="checkbox"/>	Animal Facility	<input type="checkbox"/>
PC3	<input type="checkbox"/>	Aquatic Organism Facility	<input type="checkbox"/>
PC4	<input type="checkbox"/>	Arthropod Facility	<input type="checkbox"/>
		Constant Temperature Room	<input type="checkbox"/>
		Laboratory	<input type="checkbox"/>
		Large Scale Facility (PC2 only)	<input type="checkbox"/>
		Plant Facility	<input type="checkbox"/>

For further guidance please see the OGTR *Guide to Physical Containment Levels and Facility Types*, available on the OGTR website <www.ogtr.gov.au>

OGTR Certification

Is this facility currently certified by the Regulator under another certification number (eg. by another organisation)?

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Unknown	<input type="checkbox"/>
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If Yes, please indicate the OGTR Certification number and facility type and PC level:

Certification number:	<input type="text"/>
Facility type and PC level: (eg PC2 Laboratory)	<input type="text"/>

AQIS premises

Is this facility approved by AQIS as a Quarantine Approved Premises?

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
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If Yes, please indicate the AQIS approval number and Quarantine Containment level:

AQIS approval number:	<input type="text"/>
Quarantine Containment level: (eg QC2, QC3)	<input type="text"/>

Facility name and address details

Please be specific as the facility name will appear on the Certification instrument, along with the room number/s and organisation name.

Room number/s:	<input type="text"/>		
Facility name:	<input type="text"/>		
Floor/Level:	<input type="text"/>		
Building name:	<input type="text"/>		
Street number and name:	<input type="text"/>		
Town/City:	<input type="text"/>	State:	<input type="text"/>
Postcode:	<input type="text"/>		

Facility contact person

This is the person, such as the Facility Manager, that the OGTR can contact for further information about the facility, both during the evaluation of this application and during the period of certification.

Surname:	<input type="text"/>	Preferred first name:	<input type="text"/>
Personal title: (eg Ms/Mr/Dr)	<input type="text"/>	Position title:	<input type="text"/>
Phone number:	<input type="text"/>	Fax number:	<input type="text"/>
Mobile number:	<input type="text"/>	E-mail address:	<input type="text"/>
Building name: (if applicable)	<input type="text"/>		
Street number and name: (if different from org. address)	<input type="text"/>		
Town/City:	<input type="text"/>	State:	<input type="text"/>
Postcode:	<input type="text"/>	Country:	<input type="text"/>
Postal address: (if different from above)	<input type="text"/>		

Facility ownership

Does the applicant own the facility?

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
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If “No”, can the applicant comply with any conditions which require:

- (a) upkeep of the physical containment attributes of the facility?:
- (b) upkeep of fittings required by the conditions of certification?:
- (c) the capacity to exclude persons from the facility?:

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
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Facility equipment

Does the applicant own the equipment in the facility?

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
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If “No”, can the applicant comply with any conditions which require testing, upkeep and operation of the containment equipment?:

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
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Facility diagram

Please attach a floor-plan or sketch of the facility. A formal floor plan is preferred but a sketch map will suffice. At the minimum, the floor plan should show all doorways and doors in the facility, and the area surrounding the facility.

If certification of a whole building, or the majority of the building, is being sought, the entire floor plan will be required. If certification is sought for one or more rooms within a larger area, the plan or sketch must show the boundary of the facility (doors and walls) as well as any adjoining corridors and their doors. If there are any lifts or stairs in the facility or adjoining areas/corridors they must be indicated as they may have a significant bearing on the approval of the application.

When applying for certification of facilities that require anterooms (arthropod, animal and plant facilities, PC3/PC4 laboratories) the anteroom(s) must be clearly indicated. If an adjoining corridor or another certified or non-certified room is proposed to perform the function of an anteroom, the floor plan must show all doors, lifts, stairs, and any other relevant details that may compromise the functioning of the corridor or room as an anteroom.

Attachment _____

Section 3:

Organisation Inspection Declaration/Checklist

The facility must be inspected by a person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skill enabling that person to assess compliance with the Requirements for certification of a physical containment facility. The organisation may choose to use the services of an IBC member, a contractor or an independent expert, an employee or some one else.

Applications for certification of a PC1 or PC2 facility

After inspection is complete, the person with the authority to sign on behalf of the applicant organisation must confirm the following:

Has the facility been inspected by an appropriate person as outlined above ?

Yes

No

Does the facility meet all requirements contained in the relevant PC1 or PC2 guidelines ?

Yes

No

If “no” please advise:

- in what way does the facility fail to comply with the relevant guidelines; and
- what strategies you suggest to enable certification of the facility

Note: A copy of the inspection checklist may be requested by the OGTR

Applications for certification of a PC1/PC2 Large Scale Facility, or any PC3 or PC4 facility:

A report of the inspection must be provided to support the application for these facility types. The report must address the extent of compliance with the Requirements for certification for the specific facility type/PC level being applied for. The OGTR will arrange an independent inspection of the facility in addition to the organisation's inspection.

Note: The OGTR is willing to undertake joint inspections with the organisations inspectors and/or third party inspectors for AQIS. Please contact the OGTR well in advance of anticipated/proposed inspection dates to make arrangements for this to occur.

Inspection checklists are available on the OGTR website <www.ogtr.gov.au>.

Only a single checklist should be used even if the facility is inspected by more than one person.

Inspection Report/Checklist is at Attachment _____

Attachments:

Is there any other information that may assist the OGTR in making a decision about this application?

Section 4:

Declarations

Declaration of the organisation submitting this application

This declaration must be completed and signed by the CEO (or equivalent), or a person with the authority to sign on behalf of the organisation.

I DECLARE THAT:

- I am duly authorised to sign this declaration;
- the information supplied on this form and any other attachment is true and correct; and
- I am aware that the making of a false or misleading statement may be punishable by imprisonment or a fine under the *Gene Technology Act 2000* or corresponding state law.

Printed name:	<input type="text"/>	Signature:	<input type="text"/>
Job title:	<input type="text"/>	Date:	<input type="text"/>