

Containment Facility Internal Certification Procedure (MPF1151)

GOVERNING POLICY

This procedure is made under the [Containment Facility Internal Certification Policy](#).

SCOPE

This procedure applies to all areas of the University where hazardous infectious agents or biological material (including diagnostic samples), that might reasonably be expected to contain these agents, is stored, used, handled, transported or disposed.

PROCEDURE

1. Internal certification requirements

- 1.1. The Gene Technology and Biosafety Committee will determine the [requirements for internal certification](#). These will be published on the Office for Research Ethics and Integrity website.
- 1.2. The Gene Technology and Biosafety Committee may make changes to the requirements in response to changes in external microbiological safety and containment requirements or risk assessments that indicate a change in management practice is warranted.

2. Inspection for certification by the Gene Technology and Biosafety Committee

- 2.1. Work groups wishing to have a facility internally certified must notify, and have the consent of, the relevant head of department or their delegate.
- 2.2. The Biosecurity and Biosafety Officer or the Gene Technology and Biosafety Officer must conduct a preliminary inspection of the facility to be certified.
- 2.3. The inspecting officer will report any non-compliance with the relevant requirements (refer to section 1.1) identified during the inspection to the relevant department for remedy.
- 2.4. Once any non-compliances identified during the preliminary inspection are rectified, the Biosecurity and Biosafety Officer or Gene Technology and Biosafety Officer will conduct a formal inspection of the facility to be certified.

3. Gene Technology and Biosafety Committee certification process

- 3.1. The work group or department must provide information about the facility to be certified, as described in the [Internal Certification of a Facility Application Form](#) available on the [Office for Research Ethics and Integrity website](#).

The information must include:

- a brief description of the work conducted in the facility
- a description of access control and security arrangements
- other information as decided by the Gene Technology and Biosafety Committee.

- 3.2. Standard operating procedures (SOPs) and training records against these SOPs will not need to be submitted with the application but must be available on request.

3.3. The Gene Technology and Biosafety Committee will certify a facility if the requirements for certification are met and are appropriate for the level of risk presented by the agents used and procedures conducted in the facility.

3.4. Once certified, the Gene Technology and Biosafety Committee will provide the work group or department with a letter that outlines the certification requirements and signage for the door that indicates the level of containment that the facility provides and the date that the internal certification for the facility expires.

4. Timing of inspections

4.1. All internally certified containment facilities will be inspected on an annual basis by a person who is both qualified to assess compliance with the relevant requirements, and authorised to do so by the Gene Technology and Biosafety Committee.

4.2. The Biosecurity and Biosafety Officer or Gene Technology and Biosafety Officer will provide the work group or department with an inspection report based on the authorised assessor's findings. The inspection report will outline non-compliances, including:

- the priority of each non-compliance
- the corrective action that must be taken to address each non-compliance
- the time frame (clearance date) required for remedying each non-compliance.

4.3. The Office for Research Ethics and Integrity will publish an annual inspection schedule on its [website](#).

4.4. To retain certification, the facility must meet all of the relevant requirements of certification by the specified clearance dates.

4.5. The Biosecurity and Biosafety Officer or Gene Technology and Biosafety Officer may inspect a certified facility at any time.

5. Non-compliance

5.1. Non-compliances may relate to the structural or physical attributes of an internally certified facility, to the work practices and / or the behaviour of personnel.

5.2. Failure to rectify non-compliances by the clearance dates set by the Biosecurity and Biosafety Officer or Gene Technology and Biosafety Officer may result in the certification of the facility being suspended or revoked.

5.3. An authorised assessor will inspect facilities in which non-compliances have been observed shortly after the clearance dates for remedy of those non-compliances and prior to the next scheduled annual inspection in order to confirm that suitable actions have been taken.

5.4. The Biosecurity and Biosafety Officer or Gene Technology and Biosafety Officer may suspend or revoke a certification, or close a facility, if:

- repeated or serious non-compliances are observed, or
- non-compliances are not remedied by the clearance date.

5.5. If a decision is made to suspend or revoke a certification, the Biosecurity and Biosafety Officer or Gene Technology and Biosafety Officer must notify the relevant head of department, the Gene Technology and Biosafety Committee and the Deputy Vice-Chancellor (Research).

5.6. The Biosecurity and Biosafety Officer or Gene Technology and Biosafety Officer will only reinstate a certification that has been suspended or revoked when the relevant work group or department can demonstrate compliance with all of the necessary requirements.

6. Varying an internal certification

6.1. Changes to the type of agents used, work conducted or space utilised in a certified facility may necessitate changes to the requirements that a facility must meet in order to afford the appropriate level of containment and ensure the safety of personnel working in those facilities.

6.2. The Biosecurity and Biosafety Officer or Gene Technology and Biosafety Officer may vary an existing certification provided that the necessary risk assessment has been performed by the work group.

7. Suspending an internal certification

7.1. The Biosecurity and Biosafety Officer or Gene Technology and Biosafety Officer may suspend a certification as a result of non-compliance or to allow maintenance or renovation to be performed.

7.2. Work with hazardous infectious agents or potentially hazardous biological material is not permitted in a facility for which the certification has been suspended.

7.3. The Biosecurity and Biosafety Officer or Gene Technology and Biosafety Officer may lift a suspension at the request of the responsible head of department or their delegate. The officer must inspect the facility to confirm that the certification requirements are being met.

8. Surrendering an internal certification

8.1. A department may surrender an internal certification if the facility is no longer used for work with hazardous infectious agents or potentially hazardous biological material.

8.2. The department must notify the Biosecurity and Biosafety Officer or Gene Technology and Biosafety Officer of the surrender and confirm that the facility has been appropriately decontaminated and agents securely stored or disposed of.

8.3. The relevant work group or department must remove all signage upon surrender so that it is clear the facility can no longer be used for work with hazardous infectious agents or biological material reasonably likely to contain these agents.

RELATED DOCUMENTS

- Australian/New Zealand Standards, 2243.3: Safety in Laboratories Part 3: Microbiological safety and containment (available through [University Library](#))
- [Infectious Agent Project Approval Policy](#)
- [Infectious Agent Project Approval Procedure](#)
- [Infectious Agent Reporting Policy](#)
- [Infectious Agent Reporting Procedure](#)
- [Internal Certification of a Facility Application Form](#)
- [Requirements for Internal Certification](#)

DEFINITIONS

Term	Definition
biological material	Any material such as tissue (including organs and bone), cell lines or body fluids sourced from a living organism. Samples (for example, unscreened human blood or blood products) are included in this definition.
hazardous infectious agent	A bacterium, fungus, virus or other agent able to cause disease in an otherwise healthy host (for example, human, animal or plant).
infectious agent	An infectious agent is a bacterium, fungus, virus or other agent that is able to invade and replicate in a host organism (for example, human, animal or plant) and which may or may not cause a disease.
work group	A work group for the purposes of this policy is a person or people who share physical space and may be exposed to hazardous infectious agents that are being used in that physical space. Examples of work groups include all members of a laboratory, those working in clinical settings, diagnostic and reference laboratories, and pathology laboratories.

RESPONSIBLE OFFICER

The Director, Office for Research Ethics and Integrity is responsible for the development, compliance monitoring and review of this procedure and any associated guidelines.

IMPLEMENTATION OFFICER

The Biosecurity and Biosafety Officer, Office for Research Ethics and Integrity is responsible for the promulgation and implementation of this procedure in accordance with the scope outlined above. Enquiries about interpretation of this procedure should be directed to the implementation officer.

REVIEW

This procedure is to be reviewed by 30 November 2015.

VERSION HISTORY

Version	Approved By	Approval Date	Effective Date	Sections Modified
1	Senior Vice-Principal	1 Aug 2013	1 Aug 2013	N/A