Working in a PC3 Facility Procedure

Section 1 - Purpose and Scope

(1) This Procedure outlines requirements at The University of Queensland (UQ) for conducting work within a UQ facility classified as Physical Containment level 3 (PC3).

(2) This Procedure applies to all staff, students, visitors, volunteers, and contractors (UQ workers) working in or intending to work in a PC3 facility at the St Lucia, Gatton and Herston campuses and associated working areas (including Greenslopes and the Translational Research Institute).

(3) This Procedure supports the University's Biosafety Policy and outlines the requirements of UQ workers to ensure regulatory compliance, safety, and protection of the environment. It should be read in conjunction with the UQ Biosafety Policy and procedures that apply for other types of activities involving genetically modified organisms (GMOs) or high-risk biological material, including:

a. Working with Biosecurity Goods Procedure.
b. Low Risk Genetically Modified Dealings Procedure.
c. Working with Hazardous Biological Material Procedure.

Context

(4) The Australian Government regulates GMOs under the Gene Technology Act 2000 (the Act). The Office of the Gene Technology Regulator (OGTR) administers requirements of the Act, including facility certification requirements, and classifies materials based on risk to the health and safety of people and the environment.

(5) This Procedure is based on requirements of the OGTR and "AS/NZS 2243.3 2022 – Safety in Laboratories - Microbiological safety and containment" (the Standard).

Section 2 - Process and Key Controls

(6) The following measures apply to working in a PC3 facility at UQ:

a. Work conducted at UQ with any infectious microorganism meeting the AS2243.3 risk group 3 (RG3) classification must be contained in a PC3 facility unless assessed by the UQ Institutional Biosafety Committee (IBC) as requiring a different level of containment.
b. The University's IBC is responsible for ensuring that its biosafety containment facilities are certified to meet the requirements of the Standard and the OGTR.
c. Work in a PC3 facility may only be undertaken by UQ workers that have:
    i. obtained all relevant approvals and permits as required under the Act (to work with GMOs) or by UQ IBC (for high-risk biological material) and have completed the application process for working in a PC3 facility;
    ii. completed the health surveillance and risk assessment process in consultation with UQ's Occupational Health Nurse Advisor and/or Occupational Physician, and Biosafety Advisor;

iii. completed required training detailed in clauses 15-16 below;
iv. read and understood the facility manual associated with the PC3 facility in which the work is being undertaken; and
v. been authorised by the UQ IBC representative to work within the specific PC3 facility.

Section 3 - Key Requirements

Containment of Infectious Microorganisms

(7) The World Health Organisation has categorised all infectious microorganisms into four main categories and advises that each country consider these categories and the risks present in their country's environment. In Australia, the recommended risk category definitions are detailed in the Standard and any infectious microorganism meeting the criteria in the Standard as RG3 must be contained in a PC3 facility.

(8) UQ requires that any infectious microorganism meeting the criteria in the Standard as RG3 or classified by the Canadian Public Health Agency (specified in their Pathogen safety data sheets), the US Centers for Disease Control and Prevention or the World Health Organisation as RG3, must be contained in a PC3 facility unless assessed by the UQ IBC as requiring a different level of containment.

(9) In relation to new and emerging diseases or infectious agents where a risk category has not been assigned, UQ workers must consult the UQ's IBC for assessment and risk categorisation. The IBC may also advise that certain Risk Group 2 (RG2) infectious microorganisms be contained in a PC3 facility (this is considered during the application process – see clause 17).

Certified Containment Facilities

(10) UQ's IBC is responsible for ensuring that UQ's containment facilities are certified to meet the requirements of the Standard and the OGTR. UQ workers must not conduct any work with RG3 infectious microorganisms or GMOs outside of an appropriately certified containment facility.

(11) PC3 facilities must not be used for containment of Level 3 Biosecurity goods unless additionally certified by the Australian Government Department of Agriculture, Fisheries, and Forestry (DAFF). Refer to the Working with Biosecurity Goods Procedure for further information.

Working in a PC3 Facility

(12) UQ workers must not commence work with any RG3 infectious microorganism or GMO without the relevant IBC approvals or permissions as required under:

a. Low Risk Genetically Modified Dealings Procedure; and
b. Working with Hazardous Biological Material Procedure.

(13) UQ workers proposing to work in a PC3 facility must have the endorsement of their supervisor and the Chief Investigator or manager of the PC3 facility before applying for authorisation from the IBC.

(14) Authorisation from the IBC requires the following:

Training

(15) UQ workers intending to work in a PC3 facility must complete the following training prior to beginning any work in a PC3 facility:

a. Online Biosafety Training (required for all biological facilities);
b. Online PC3 Theory Training; and
c. PC3 Facility Specific Practical Training (conducted by the Project Supervisor and Facility Manager).

(16) Further information about training requirements is available from the Health, Safety and Wellness Division training and induction website.

Application Forms

(17) UQ workers must complete and return the following forms:

a. Health Surveillance Form (available on request from the UQ Occupational Health Nurse Advisor);
b. Risk assessment/theory part 2 assessment form (available on request from the IBC secretary after online PC theory training is completed in Workday);
c. Training Checklist (issued by IBC secretary upon completion of theory training requirements); and
d. Declaration Form (issued by IBC secretary upon completion of theory training requirements).

Health Surveillance

(18) All persons working in PC3 facilities shall be informed of and understand the risk of occupational exposure to microorganisms to which they may not be immune. Immunisation or disease screening may be required prior to commencing work with some pathogen. Refer to the Vaccinations and Immunisation Procedure and Vaccinations and Immunisation Guideline.

(19) Health monitoring of exposure is overseen at UQ by the UQ IBC, UQ's Occupational Health Nurse Advisor (email: ohna@uq.edu.au) and Occupational Physician.

(20) Health surveillance information must be updated and provided annually to the IBC secretary/Occupational Health Nurse Advisor while the UQ worker continues to work in the PC3 facility.

PC3 Facility Manual

(21) Each PC3 facility must have a dedicated facility manual containing standard operating procedures, emergency procedures and information regarding the infectious microorganisms that are contained within that facility. The OGTR requires this manual to be reviewed annually.

Access Conditions

(22) Access to PC3 facilities is restricted to authorised UQ workers that have met the requirements prescribed in clauses 12-25 of this Procedure and obtained authorisation from UQ IBC.

(23) Unauthorised UQ workers (including contractors, cleaners, and security staff) must not enter a PC3 facility. UQ workers with authorisation to access a PC3 facility must not provide access to others that do not have authorisation.

(24) Scheduled services and maintenance activities must be conducted during the annual shut down period of the facility, after the facility has been decontaminated by a method approved by the Regulator. During this time, research work is suspended, and relevant contractors are provided restricted access to complete service and maintenance requirements.

(25) A request for access to any PC3 facility outside of the conditions set in this Procedure must be made directly to the IBC secretary (email: biosafety@uq.edu.au) for consideration.

Section 4 - Roles, Responsibilities and Accountabilities

Institutional Biosafety Committee (IBC)

(26) The UQ IBC will undertake duties in accordance with its Terms of Reference and provide UQ workers with education, information and support to enable them to understand their biosafety compliance obligations at UQ.

Health, Safety and Wellness Division

(27) The Health, Safety and Wellness Division is responsible for:

a. providing UQ workers with education, advice and support regarding OGTR requirements and gene technology regulatory compliance obligations at UQ; and
b. assessing whether Organisational Units and UQ workers are able to demonstrate compliance with this Procedure and that any compliance issues identified are rectified in a timely manner.

(28) Biosafety Advisors within the Health, Safety and Wellness Division are responsible for:

a. advising UQ workers about specific gene technology, biosafety and biosecurity matters affecting UQ, including workplace safety obligations and regulatory compliance;
b. reporting to or advising the University's IBC on gene technology, biosafety and biosecurity matters as required;
c. liaising with the OGTR with respect to UQ's gene technology and containment facility compliance obligations (including hosting regulator site visits or inspections); and
d. supporting the UQ IBC to fulfil its functions, as per the IBC Terms of Reference.

Heads of Organisational Units

(29) Heads of Organisational Units that undertake dealings with Risk Group 3 GMOs or that house PC3 facilities must work with Chief Investigators to ensure containment facilities are compliant with OGTR requirements, including:

a. facilities appropriate for the type of work are available and maintained in compliance with relevant legislative requirements (e.g. PC3 certified facilities maintained to OGTR certification requirements, including funding and arrangements for maintenance, routine testing and servicing, and appointment of Facility Manager);
b. confirmation of support for PC3 level research work is only granted where a facility appropriate for the type of work can be made available; and
c. any work with material classified as Risk Group 3 is conducted in compliance with any relevant legislative or UQ requirements, associated facility certification requirements or IBC approvals (e.g. GM work has appropriate approvals in place before commencing, all UQ workers have completed appropriate training requirements prior to commencing work).

PC3 Facility Managers

(30) PC3 Facility Managers are responsible for providing assurance to the Head of their Organisational Unit (of the Head of Organisational Unit housing the PC3 facility), that activities undertaken within their facilities are compliant with the associated facility manual and any associated approvals or facility requirements. PC3 Facility Managers are required to ensure:

a. PC3 users are correctly trained prior to entering the facility or commencing work.
b. PC3 facilities are kept in good condition and in accordance with their certification requirements.

c. Records associated with the management of the facility are maintained and accurate.
d. A facility manual is available for the facility detailing entry and exit procedures, and local standard operating procedures associated with the work being undertaken in the facility.
e. Ensuring the facility manual is updated whenever practices in the facility change and annually as per the OGTR certification requirement.
f. Ensuring any incidents within the facility are reported to the Biosafety Advisors as soon as reasonably practical.

Chief Investigators

(31) Chief Investigators are responsible for the ongoing monitoring, management, and oversight of PC3 containment facilities and must ensure:

a. Planned or continuing work with dealings is conducted in the appropriate facilities and that the facilities are tested, serviced and maintained to comply with OGTR requirements.
b. The correct authorisations and licences are in place and maintained.
c. Records are maintained in accordance with the facility certification or licence requirements.
d. UQ workers that handle, store or use RG3 infectious microorganisms or GMOs:
    i. are trained in accordance with OGTR requirements; and
    ii. comply with all conditions of approval from the IBC and/or for the use of the containment facility, including supervision of any classes of person not authorised by the IBC to work unsupervised within a PC3 facility.

UQ Workers

(32) All UQ workers that are working, in or intending to work, in a PC3 facility at UQ must comply with this Procedure, understand, and comply with any additional requirements and conditions specified by the OGTR and ensure they:

a. follow the requirements for the facility being worked in (i.e. complete relevant training, comply with PPE and vaccine preventable disease (VPD) requirements (e.g. immunisations) and refer to the facility's manual);
b. complete required health monitoring as needed and update health information to the Occupational Health Nurse Advisor;
c. are aware of any approvals or permits that are in place for the work they are conducting;
d. keep records and information involving dealings and license/permit activities;
e. keep records of material in storage;
f. inform the Facility Manager, Chief Investigator or the UQ IBC secretary of any non-compliance as soon as possible; and
g. inform the Facility Manager if they develop symptoms or are diagnosed with an illness potentially caused by the microorganism they are working with.

(33) UQ workers handling RG3 material or working in PC3 facilities at locations external to UQ must comply with the local procedures and requirements of the external organisation.

Section 5 - Monitoring, Review and Assurance

Compliance

(34) UQ Biosafety Advisors will provide ongoing monitoring and review of UQ's biosafety systems and controls on behalf of the IBC, including annual audits and inspections of PC3 containment facilities to monitor compliance. UQ Biosafety Advisors will review this Procedure as required to ensure it remains current and accurately reflects

regulatory requirements.

Non-compliance

(35) UQ workers and Chief Investigators that do not comply with this Procedure will be subject to corrective actions from the IBC and/or the Health, Safety and Wellness Division, and the suspension of work if conditions are not met. Non-compliance with this Procedure may be considered research misconduct under the University's Managing Complaints about the Conduct of Research Procedure and/or the Staff Code of Conduct Policy.

(36) UQ may be subject to corrective actions or notices issued by the OGTR (or the Department of Agriculture, Fisheries and Forestry for work with biosecurity goods) to suspend work that does not comply with regulatory requirements.

Section 6 - Recording and Reporting

(37) Chief Investigators must ensure that the record-keeping requirements of certified facilities are met. UQ Biosafety Advisors will report outcomes of audits of certified facilities to the IBC on a quarterly basis and the IBC will report any non-compliances or potential breaches to the University Senior Executive Team and relevant senior management.

(38) The UQ IBC reports annually to the OGTR and Department of Agriculture on non-compliances or other requests from the regulators.

(39) The Director, Health Safety and Wellness is responsible for reporting any matters required by the Act to the OGTR.

Section 7 - Appendix

Definitions, Terms, Acronyms

Term	Definition
Chief Investigator	For the purposes of this Procedure, includes supervisors, managers and academic Principal Advisors that are conducting research at UQ and hold an academic or research appointment.
Dealing	In relation to a GMO, the Act defines 'dealing' as: • conduct experiments with the GMO • make, develop, produce or manufacture the GMO • breed the GMO • propagate the GMO • use the GMO in the course of manufacture of a thing that is not the GMO • grow, raise or culture the GMO • import the GMO • transport the GMO • dispose of the GMO • possess, supply or use the GMO for the purposes of, or in the course of, any of the above.
GM/GMO	Genetically Modified/Genetically Modified Organism
IBC	UQ's Institutional Biosafety Committee
OGTR	Office of the Gene Technology Regulator (Australian Government)

Term	Definition
UQ workers	For the purposes of this Procedure includes: • staff - continuing, fixed-term, research (contingent funded) and casual staff • contractors, subcontractors and consultants • visiting academics and researchers • affiliates - academic title holders, visiting academics, emeritus professors, adjunct and honorary title-holders, industry fellows and conjoint appointments • higher degree by research students • volunteers and students undertaking work experience and that may be required to handle OGTR regulated material.

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