Working with Biosecurity Goods Procedure

Section 1 - Purpose and Scope

(1) The Australian Government regulates the import, export, and use of goods subject to biosecurity control in Australia under the Biosecurity Act 2015 (the Act). The Department of Agriculture, Fisheries and Forestry (DAFF) administers requirements of the Act and classifies materials based on the risk to the Australian environment.

(2) This Procedure outlines the requirements at The University of Queensland (UQ) for importing or working with biosecurity goods. This Procedure supports UQ's Biosafety Policy and outlines the requirements UQ workers must meet to comply with biosecurity regulations.

(3) This Procedure applies to all staff, students, visitors, volunteers, and contractors (UQ workers) importing or conducting work with biosecurity goods or working in areas where biosecurity goods are used at UQ.

(4) This Procedure should be read in conjunction with the UQ Biosafety Policy and procedures that apply for other types of biological material.

(5) Further information about the regulations surrounding import, export, or use of goods subject to biosecurity control is available from UQ's Biosafety Advisors or from DAFF.

Section 2 - Process and Key Controls

(6) UQ workers must comply with the following measures when importing or conducting work with goods subject to biosecurity control at UQ:

a. UQ workers must pass a 'fit and proper person requirements' test and complete all required training prior to any work with biosecurity goods at UQ.
b. Prior to the importation of goods, UQ workers must:
    i. check the Australian Government's BICON system (import conditions database for searching commodities and applying for import permits); and
    ii. ensure any required import permits or in vivo approvals are obtained.
c. Import permits may only be held at UQ by a senior researcher, a Chief Investigator, or the Head of Organisational Unit. Students, including higher degree by research students, must not hold import permits.
d. Work with goods subject to biosecurity control must be undertaken in an Approved Arrangement ('AA').

Section 3 - Key Requirements

Training and Competency

(7) All UQ workers planning to use biosecurity goods at UQ must be appropriately trained, deemed competent, and deemed a 'fit and proper person'.

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Training (Accreditation)

(8) Before working with biosecurity goods, UQ workers must complete the following:

a. Online biosecurity training module; and
b. On site induction hosted by the relevant Organisational Unit.

(9) Completion of this training provides UQ workers with accreditation to work at a UQ registered AA. Periodic updates of this training may be required as directed from UQ's Biosafety Advisors (e.g. any changes to operating requirements).

(10) UQ's accreditation does not permit UQ workers to use biosecurity goods outside of UQ (including Translational Research Institute facilities). UQ workers must undertake training provided by the relevant registering organisation to use biosecurity goods outside of a UQ registered AA.

Fit and Proper Person Requirements Test

(11) UQ workers must complete a 'fit and proper person requirements' test:

a. prior to applying for an Import Permit or in vivo approval; or
b. prior to using an Import Permit to import biosecurity goods, regardless of whether the goods are subject to biosecurity control (directed to an AA) or released from biosecurity control upon arrival in Australia;
c. prior to using biosecurity goods or working in AA at UQ; and
d. every five (5) years whilst using biosecurity goods or working in AAs at UQ.

(12) The test is administered and approved by the Approved Arrangement Manager or local Work Health and Safety Coordinator/Safety Manager. Completed tests are to be uploaded to the UQSafe Certification database by the person approving the application.

(13) The Health, Safety and Wellness Division oversees the 'fit and proper person requirements' test process, including revisions, record-keeping requirements and responding to further enquiries about applications from DAFF.

(14) UQ workers that become unable to maintain a positive 'fit and proper person' status must immediately notify their Approved Arrangement Manager and UQ's Biosafety Advisors and must not work with biosecurity goods until approval is granted by the Health, Safety and Wellness Division.

Importation of Goods

(15) Prior to organising the importation of goods, the following must be undertaken:

a. UQ workers must check the Australian Government's Biosecurity Imports Conditions system (BICON) to determine if:
    i. there are any restrictions or conditions on the goods that must be met; and
    ii. an import permit is required for the goods.
b. UQ workers must ensure that they have the necessary capabilities and capacity, i.e., infrastructure, equipment, to meet the conditions associated with the goods prior to arranging importation of the goods. If the Import Permit states that the goods must remain in an Approved Arrangement unless released by approved methods, the UQ worker must contact the relevant Approved Arrangement Manager to seek permission to use the AA on the Permit and to import the goods into the facility.

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Import Permits

(16) Certain goods will require a valid import permit from the Department of Agriculture, Fisheries and Forestry (DAFF) to be allowed into Australia. If goods requiring an import permit arrive without a valid permit, they will be exported (returned to the sender) or destroyed by DAFF at the expense of the importer.

(17) Compliance with import permit conditions and other directions prescribed by the Australian Government is mandatory and will be audited by DAFF. UQ workers must ensure that they understand and can comply with all relevant conditions in BICON or a draft import permit prior to submitting the final application. Goods must not be ordered or imported into Australia before an import permit is issued.

(18) Further information about the Australian Government's import permit requirements, including relevant fees and charges, is available from DAFF. UQ workers can also contact the Health, Safety and Wellness Division for advice about importing biosecurity goods.

In Vivo Approvals

(19) For in vivo work on animals, humans or plants not specified on the import permit conditions, UQ workers must apply for separate in vivo approval using the approved form and in consultation with the relevant Approved Arrangement Manager.

Approved Arrangements

(20) UQ has a voluntary arrangement with DAFF that permits it to autonomously manage biosecurity risks and/or perform the documentary assessment of goods in accordance with government requirements, with periodic compliance monitoring and auditing by DAFF.

(21) Goods that are to be held under biosecurity control on arrival in Australia will be directed to an AA site (facility) of suitable class, type, and level in the import permit.

(22) All work with biosecurity goods must occur within the specified AAs listed on the import permit. UQ has the following AA types and biocontainment levels on its campuses in St Lucia, Herston and Gatton:

a. BC5.1.1 (Microbiology), BC5.1.2 (Animal)
b. BC5.2.1 (Microbiology), BC5.2.2 (Animal), BC5.2.3 (Aquatic), BC5.2.4 (Plant) and BC5.2.5 (Invertebrate)
c. BC5.3 (Microbiological) and BC5.3 (Animal)

(23) The biocontainment level and type will determine what goods can be used within the facility and have requirements outlining what is expected of the users and managers of the facility. UQ workers must adhere to all requirements that relate to the AA in which they operate.

(24) The class, level and type of AA can be obtained from the relevant Approved Arrangement Manager or from UQ's Biosafety Advisors (biosafety@uq.edu.au).

Applying for an Approved Arrangement

(25) Applications for new AA must be submitted via UQ's Biosafety Advisors (biosafety@uq.edu.au). Costs associated with applications that require a third-party assessor (e.g., to inspect and produce a report on the facility) must be met by the Organisational Unit. UQ workers must first contact UQ's Biosafety Advisors when considering an application for a new AA.

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Section 4 - Roles, Responsibilities and Accountabilities

Chief Operating Officer

(26) The Chief Operating Officer (COO) is UQ's Biosecurity Industry Participant (as defined under the Act) and is responsible for ensuring that UQ's biosecurity activities are carried out in accordance with AA.

Heads of Organisational Units Authorised to Conduct Work

(27) Heads of Organisational Units are responsible for carrying out the requirements of the Act on behalf of the COO, for all work with biosecurity goods that occurs in facilities under their control. They are responsible for providing assurance to the COO (as UQ's Biosecurity Industry Participant) that the Organisational Unit's biosecurity activities are compliant with requirements prescribed in AAs and under the Act. They must work with Chief Investigators and Approved Arrangement Managers to ensure:

a. facilities are appropriate for the type of work are available and maintained in compliance with relevant legislative requirements (e.g. ensuring AA facilities are maintained to meet DAFF approval requirements, including funding and arrangements for maintenance, routine testing and servicing); and
b. any work with material subject to biosecurity control is conducted in compliance with any relevant legislative or UQ requirements (e.g. ensuring all persons working with the material meet the 'fit and proper person' criteria and have completed online biosafety and biosecurity training).

Approved Arrangement Managers

(28) Approved Arrangement Managers are responsible for providing assurance to the Head of Organisational Unit, that biosecurity activities undertaken within their facilities are compliant with requirements prescribed in AAs and under the Act. Approved Arrangement Managers are required to ensure:

a. biosecurity goods users are correctly trained and deemed to be 'fit and proper persons';
b. AA sites and structures are kept in good condition and in accordance with their type and biocontainment level;
c. records associated with the management of the AA are maintained and accurate, including the transfer or hand over of documents when research groups are disbanded or UQ workers leave UQ;
d. all import permits, directions and other approvals are held;
e. all local standard operating procedures associated with working with biosecurity goods are available to UQ workers and reviewed regularly to ensure they reflect current requirements; and
f. they monitor all aspects of the operation of an AA, including import permits, and report any actual or potential non-compliance concerns as soon as practicable to UQ's Biosafety Advisors in the Health, Safety and Wellness Division (biosafety@uq.edu.au).

Health, Safety and Wellness Division

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

a. providing UQ workers with education, advice and support regarding biosafety and biosecurity compliance obligations at UQ;
b. assessing whether Organisational Units and UQ workers can demonstrate compliance with this Procedure and that any compliance issues that are identified are rectified in a timely manner; and
c. reporting to the COO and UQ Senior Management on the status of the University's compliance with the

regulations described by the Act.

(30) UQ's Biosafety Advisors within the Health, Safety and Wellness Division are responsible for:

a. advising UQ workers about specific biosecurity matters affecting UQ, including workplace safety obligations and regulatory compliance;
b. reporting to or advising UQ's Institutional Biosafety Committee (IBC) on biosecurity matters as required; and
c. liaising with DAFF with respect to UQ's biosecurity compliance obligations (including hosting regulator site visits or inspections).

UQ Workers

(31) All UQ workers that work with biosecurity goods at UQ are required to comply with this Procedure, and ensure they are:

a. following the requirements for the facility being worked in (e.g. completing relevant training and fit and proper persons requirements test prior to commencing work, complying with import permit requirements, complying with any personal protective equipment requirements specified in the work area);
b. aware of any approvals or permits that are in place for the work they are conducting (e.g. aware of import permit and its conditions); and
c. meeting the record-keeping requirements of import permits, including the transfer or hand over of documents when research groups are disbanded or UQ workers leave UQ.

(32) UQ workers that work with biosecurity goods at locations external to UQ must comply with the local procedures and requirements of the external organisation.

(33) UQ workers must not permit unaccompanied visitors into AA facilities unless they have been approved by the relevant Approved Arrangement Manager.

Section 5 - Monitoring, Review and Assurance

Compliance

(34) Approved Arrangement Managers will monitor all aspects of the operation of an AA, including import permits, and report any actual or potential non-compliance concerns as soon as practicable to UQ's Biosafety Advisors in the Health, Safety and Wellness Division (biosafety@uq.edu.au).

(35) UQ's Biosafety Advisors will provide ongoing monitoring and review of UQ's biosecurity systems and controls on behalf of the IBC, including annual audits and inspections of AA facilities. UQ's Biosafety Advisors will review this Procedure as required to ensure it remains relevant and current.

Non-compliance

(36) UQ workers that do not comply with this Procedure will be subject to corrective actions from the IBC and/or the Health, Safety and Wellness Division, which may include suspension of work if conditions are not met. Appropriate action may also be instigated by the UQ worker's line management.

(37) UQ may be subject to corrective actions or notices issued by the Australian Government to suspend work that does not comply with regulatory requirements.

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Section 6 - Recording and Reporting

(38) Approved Arrangement Managers must ensure that the record-keeping requirements of import permits are met. Approved Arrangement Managers are also responsible for ensuring all certifications, records and documents as described in the relevant Approved Arrangement requirements and conditions of approval are kept and available at the time of inspection by Biosafety Advisors and auditing by DAFF.

(39) UQ workers are responsible for coordinating with Approved Arrangement Managers to ensure that the record-keeping requirements of import permits are met, including the transfer or hand over of documents when research groups are disbanded or UQ workers leave UQ.

(40) UQ Biosafety Advisors will report outcomes of regulator audits of AA facilities to the IBC on a quarterly basis. The IBC Chair will report any non-compliance with the Act to the University Senior Executive Team and relevant Senior Management.

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

Section 7 - Appendix

Definitions

Term	Definition
Approved Arrangement or AA	a facility registered by the Australian Government's Department of Agriculture, Fisheries and Forestry (DAFF) that is fit for purpose to allow work with biosecurity goods.
Biosecurity goods	a biological agent or material that is subject to legislative requirements under the Biosecurity Act 2015 (goods may include a biological agent such as microbes, organics reagents, animals, plants, soil, water, diagnostic kits).
Import Permit	legal documentation issued by the Australian Government prescribing the goods and associated conditions that must be met. Import permits include the following information: • description of what is permitted to be imported; • the class and/or specific Approved Arrangement; • methods of release (i.e. treatment of derivatives); • post entry/end use conditions; and • conditions of administration (record keeping). Import permits for some high-risk materials, or for goods not previously imported into Australia, may take several months to process. UQ workers should consider such timeframes when planning activities.
UQ workers	for the purposes of this Procedure includes: • UQ staff, including continuing, fixed-term and casual staff; • contractors, subcontractors and consultants; • students enrolled at UQ, including post graduate researchers, higher degree by research students and undergraduate students; • visiting academics and researchers; • visiting research students; and • volunteers engaged by UQ that may be required to handle biosecurity goods

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