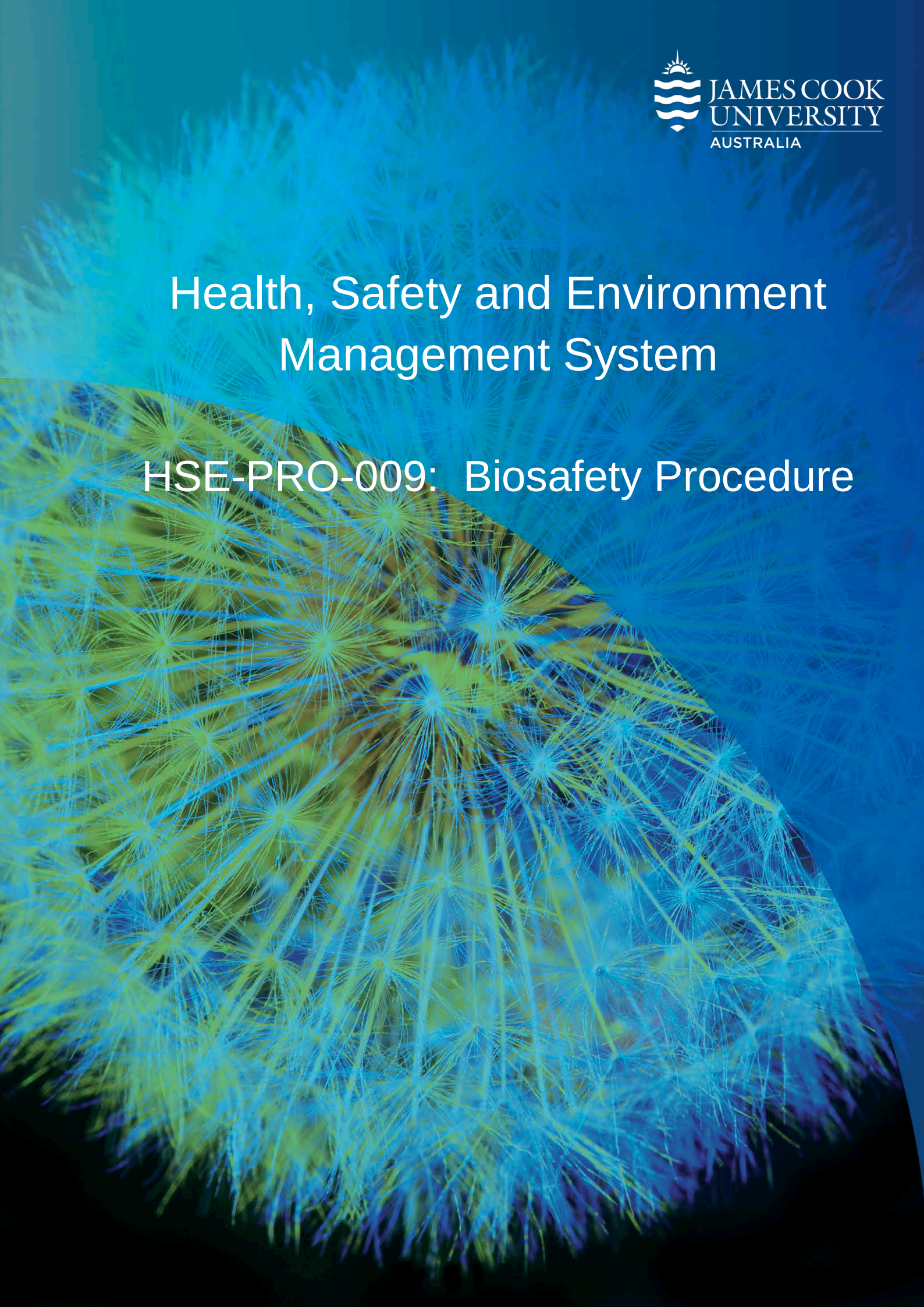
JAMES COOK UNIVERSITY
AUSTRALIA

Health, Safety and Environment Management System

HSE-PRO-009: Biosafety Procedure



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1 Intent

To document and communicate legal and other requirements for work with Biological Material.

Statutory requirements for biological safety in Queensland are regulated by the:

- *Gene Technology Act (Qld), 2001*
- *Gene Technology Regulation, (Qld), 2002*
- *Biosecurity Act (Qld), 2015*

2 Scope

This Procedure applies to all JCU workers, students, adjuncts, volunteers and visitors conducting work with biological material.

Controlled Entities are required to demonstrate compliance with relevant biosafety legislation and standards.

Biological activities that are covered by this Procedure include:

- Teaching and research with Genetically Modified Organisms (GMO)
- Teaching and research with materials derived from human sources
- Teaching and research with materials derived from animal sources
- Research and teaching with microorganisms
- Live animals
- Toxins from both live animals and synthesised toxins/biologicals.

This procedure also covers imported biological material which is regulated by Biosecurity Australia (formerly AQIS).

JCU has PC1, PC2 and PC3 facilities available. A number of PC2 and PC3 facilities are registered with the Office of the Gene Technology Regulator (OGTR) and the Department of Aquaculture and Water Resources as Quarantine Approved Arrangements (QAA).

This Procedure does not include biological safety in healthcare or research facilities constructed and operated under their own standards. Where a healthcare or research facility does not have their own standards in place then these standards will apply.

Approved placements will be subject to the host organisation having relevant and adequate Policies and Procedures implemented. In these instances, the student must adhere to the host organisation's Policies and Procedures whist undertaking the placement.

This Procedure does not cover non GMO plants.

3 Definitions

BICON	Department of Agriculture Database system for Import Permits and Approved Arrangements.
Biological Hazard, Biohazard, Biologically Hazardous Material	Any biological agent, substance or material (whether alive or not) present in or arising from living organisms, that are or may be hazardous to the health or well-being of the environment or individuals in the JCU community.
Biological Material	Biological material includes but is not limited to, microorganisms, recombinant DNA, cell lines, animals (live of materials), human tissue or biological fluids, microbial toxins, and synthesised toxins and biologicals.
Biosafety	A combination of systems and practices intended to reduce the risk of accidental exposure to, or release of, agents that may cause an infectious disease in humans, animals, plants, insects or ecosystems.
Dealing	Conduct experiments with GMOs; make, develop, produce, manufacture GMOs; breed; propagate; use GMOs in the manufacturing of non GM products; grow, raise, culture GMOs; import GMOs; transport or store GMOs.
Diagnostic Specimen	Any human or animal material, including (but not limited to) excreta, secreta, blood and its components, sputum, tissue and tissue fluids, submitted for the purposes of diagnosis.
DIR	Dealing with Intentional Release are dealings with GMOs that take place outside of containment facilities. (www.ogtr.gov.au)
DNIR	Dealing Not Involving Intentional Release. Dealings with GMOs that are to be conducted in contained facilities. (www.ogtr.gov.au)
Exempt Dealing	Exempt dealings are a category of dealings with GMOs that have been assessed over time as posing a very low risk. Contained research with very well understood organisms and processes. Must not involve intentional release. (www.ogtr.gov.au)
Gene Technology	Any technique for the modification of genes or other genetic material, but does not include: a) Sexual reproduction; b) Homologous recombination; or c) Mutations that occur naturally or through damage by radiation or chemicals.
GMO	Genetically Modified Organisms
IBC	Institutional Biosafety Committee
Institutional Biosafety Committee (IBC)	Institutional Biosafety Committee, a Committee that is established by an Accredited Organisation, as required by the OGTR.
Microorganism	Microscopic organisms including protozoa and other parasites, fungi, archaea, bacteria, unicellular algae, viruses and viroids.

Notifiable Low Risk Dealing (NLRD)	Notifiable Low Risk Dealings (NLRDs) are described in the Gene Technology Regulations 2001 (the Regulations), and are dealings with GMOs that have been assessed as posing low risk to the health and safety of people and the environment provided certain risk management conditions are met. (www.ogtr.gov.au)
OGTR	Office of the Gene Technology Regulator. The regulator for dealings with GMO.
PC	Physical Containment Level of a facility
PPE	Personal Protective Equipment (includes clothing)
QAA	Quarantine Approved Arrangement. The specific facilities approved by the Regulator to be used for quarantine activities.

4 Duty, Obligations and Responsibilities

Any area of JCU where Biological Material will be used must ensure that appropriate risk assessments, safe operating procedures, regulatory compliance and training are in place.

4.1 Facility Supervisor

The Facility Supervisor is responsible for ensuring:

- safe operating procedures for the equipment and safe work instructions for laboratory practices are followed and documented
- laboratory inductions are completed
- records are maintained for the facility
- appropriate training is provided.

4.2 Teaching Session Supervisor

The Teaching Session Supervisor may be a member of staff or an adjunct and will be responsible for following and enforcing this Procedure (including any biosafety approvals) during an individual teaching session where biological activity occurs.

4.3 Research Project Supervisor

The Research Project Supervisor is responsible for ensuring the requirements of this Procedure have been followed for each project.

4.4 Individuals (JCU Workers, Students, Adjuncts and Volunteers)

All individuals (JCU workers, students, adjuncts and volunteers) are responsible for familiarising themselves with the biological safety requirements for the specific laboratory or facility.

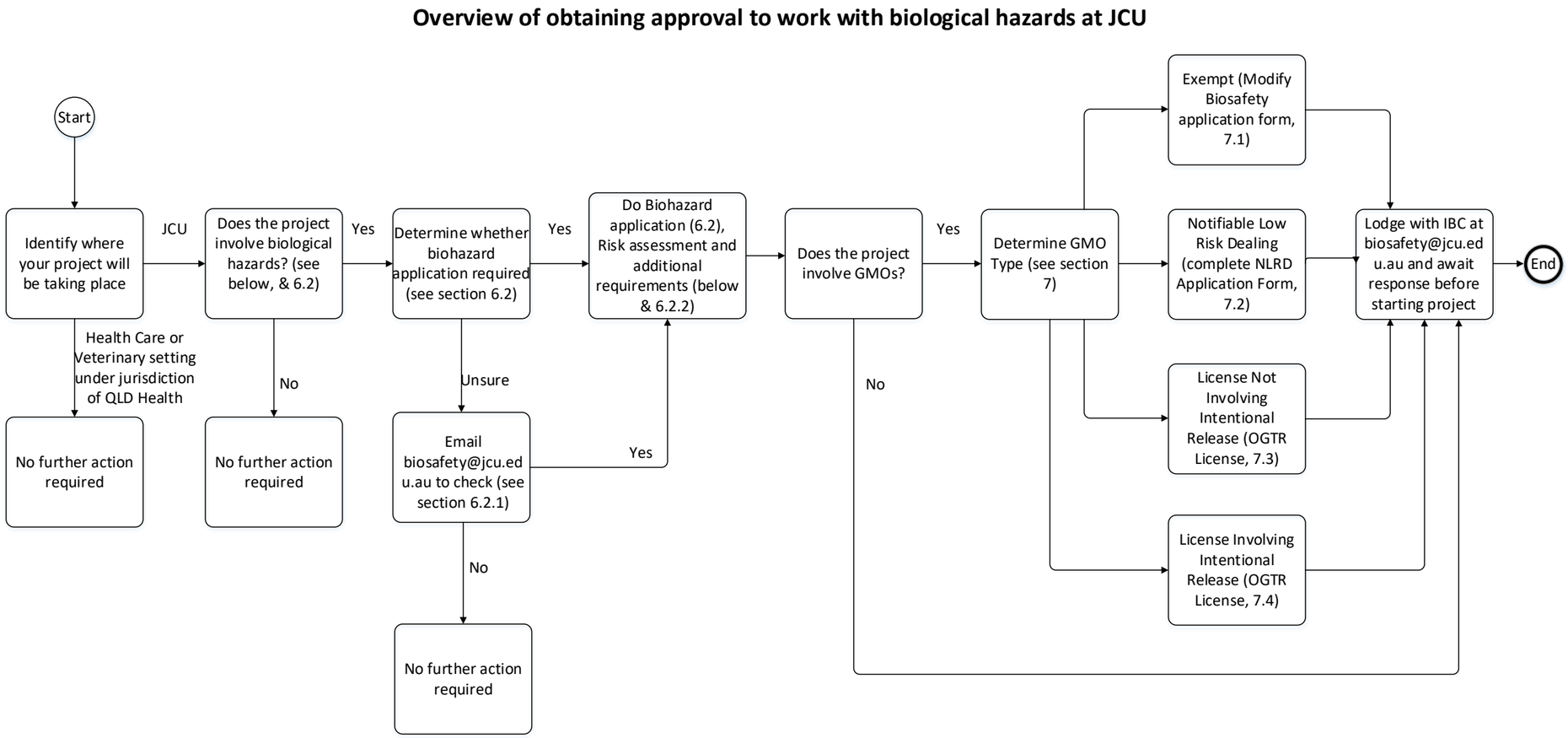
The approved biosafety application requirements outlined in this Procedure must be followed whilst working with Biological Material.

4.5 Contractors

Cannot conduct maintenance activities within a physical containment facility without being issued a decontamination certificate.

If the contractor is conducting the decontamination, the contractor must provide evidence of decontamination processes to the Laboratory Supervisor.

5 Overview of obtaining approval to work with biological hazards at JCU



Biological Hazards Include:

- Genetically modified microorganisms, animals, plants and gene knock-outs
- Materials derived from human source including collecting blood, interviewing at risk populations
- Materials derived from animal sources, in particular those with potential for causing zoonotic infection and horses, bats and animals from overseas
- Purposely infecting animals.
- Working with poisonous or venomous organisms.
- Synthetic toxins/biologicals.
- Working with microorganisms.

Additional requirements include:

- Human Ethics (https://www.jcu.edu.au/research-services/ethics-and-integrity/human-ethics)
- Animal Ethics (https://www.jcu.edu.au/research-services/ethics-and-integrity/animal-ethics)
- Use of Scheduled Drugs and Poisons (HSE-PRO-004 Drugs and Poisons Procedure).
- Use of Carcinogens (substance listed in Schedule 10 WH&S Regulation Qld) (HSE-PRO-004 Drugs and Poisons Procedure).
- Hazardous Chemicals and Dangerous Goods (HSE-PRO-005 Hazardous Chemicals Procedure).
- Radiation sources (HSE-PRO-003 Ionising Radiation Procedure).
- Permits to access geographical locations GBRMPA or National Parks.
- Use of Cytotoxic Drugs.
- Import or Export of Quarantine material.

6 Biosafety Control

The following requirements are general in nature and aimed at controlling biological safety and preventing unintended spread of microorganisms. This Procedure should be read in conjunction with *AS/NZS 2243.3:2010 Safety in laboratories Part 3: Microbiological safety and containment* which provides further information on the topics included within this Procedure.

6.1 Institutional Biosafety Committee

JCU is an Accredited Organisation certified by the OGTR. The University is required to have an IBC in place.

The IBC is a subcommittee to the Health, Safety and Environment Advisory Committee (HSEAC). The current Terms of Reference for the committee are maintained by the HSE Unit.

The IBC oversees compliance of JCU with the OGTR and makes recommendations relating to Biosafety Issues at JCU. Hazards the IBC specifically monitor include:

- Genetically Modified Organisms
- Materials derived from human sources
- Materials derived from animal sources in particular those with zoonotic infection
- Micro-organisms.

The IBC is required to be established as part of the certification of JCU as a suitable organisation to be accredited with the OGTR to allow projects with GMO.

The IBC must have the collective technical and scientific expertise to review and assess all the matters that are likely to be conducted by the organisation.

The following points are requirements of the IBC:

- All members are to be indemnified
- At least one member of the IBC must be an external member
- Conflicts of interest must be declared by members
- The minutes of the IBC are maintained by the HSE Unit and must be retained for a minimum of 3 years from the date of each meeting
- The IBC will determine where expertise or training is lacking and request for external members to be added to the committee and relevant training be provided to IBC members
- Records of decisions on NLRDs, and licensed dealings must be maintained for at least 8 years after the date of assessment.

Related Information:	University Intuitional Biosafety Committee (Sub Committee of the Health, Safety and Environment Advisory Committee) Terms of Reference

6.2 JCU Biosafety Application

A biosafety application is required for projects with Biological Hazards. Hazards include, but are not limited to:

- GMO
  - Genetically modified microorganisms
  - Genetically modified animals and plants
- Materials derived from human source;
  - Collecting blood
  - Interacting with potentially infected individuals, for example, interviewing or taking biological samples
  - Activities conducted outside of facilities being operated under infection and control requirements from Queensland Health
- Materials derived from animal sources, in particular those with potential for causing zoonotic infection and:
  - Dealing with wild animals, such as bats (e.g. Lyssavirus)
  - Dealing with domestic animals such as horses (e.g. Hendra Virus)
  - Dealing with animals outside of Australia (e.g. rabies)
- Purposely infecting animals
- Working with poisonous or venomous organisms
- Synthetic toxins/biologicals
- Working with microorganisms.

All activities must be conducted in the appropriate facilities for the Biosafety risk taking place. For further information consult *AS/NZS 2243.3:2010 Safety in laboratories Part 3: Microbiological safety and containment*.

6.2.1 Determination of nature of biological hazard

If there is uncertainty whether the project requires a biosafety application, the applicant should seek guidance by sending an email to biosafety@jcu.edu.au. The Divisional Biosafety Representative may be able to offer assistance.

The email should include the following information:

- applicants name
- contact details
- name of supervisor
- Division
- College/Institute
- Description of the project.

An initial ruling will be made by an IBC member (Appendix 1) to determine one of the following for the project:

- Confirm that the biosafety application process is relevant, and the full biosafety application is to be completed; or

- That the biosafety application process is not relevant, and the decision will be recorded on a central register maintained on the Biosafety Drive; or
- Further information is required to make the assessment.

6.2.2 Full Biosafety Application

If the project is to proceed under a biosafety application or it was obvious that the application was required, the applicant must then complete the full application for submission (JCU Biosafety Application Approval form). Completed applications are to be sent to biosafety@jcu.edu.au.

The application should include sufficient details to enable the Biosafety representative to review the project methodologies, organisms to be used and proposed activities incorporating any relevant risk assessments.

Risk Assessment

Research, teaching or operational work with Biohazards should only be undertaken when a risk assessment has been developed and the relevant controls implemented. A risk assessment is to be completed in RiskWare.

Section 13 of *AS/NZS 2243.3:2010 Safety in laboratories Part 3: Microbiological safety and containment* is to be consulted to assign risk categories and determine applicable containment facilities that are required for microorganisms.

Human and animal clinical and diagnostic specimens are normally regarded as risk group 2, and shall be handled in a PC2 facility unless a higher risk group is indicated by the risk assessment.

Table 1: Risk Group

Risk Group	Explanation	Example Microorganism
Risk Group 1	Low individual and community risk. Unlikely to cause human or animal disease.	Food grade bacteria
Risk Group 2	Moderate individual risk, limited community risk. Unlikely to be a significant risk to laboratory workers, the community, livestock or the environment. Effective treatment and preventative measures are available.	Salmonella Paratyphi A and B Legionella spp

Risk Group 3	High individual risk, limited to moderate community risk. Usually causes serious human or animal disease, may present a significant risk to laboratory workers, could pose a limited to moderate risk if spread to the community or the environment. Usually effective preventative measures or treatment available.	Australian Bat Lyssavirus Dengue 1, 2, 3 and 4 Hepatitis C
Risk Group 4*	Usually produces life threatening human or animal disease, represents a significant risk to laboratory workers and may be readily transmissible from one individual to another. Effective treatment and preventative measures are not usually available.	Ebola Hendra

The risk assessment should include:

- Identification of the microorganisms and risk group or biological hazard
- The processes and equipment to be used
- Storage requirements and safe handling
- Type of physical containment facility required and available eg. PC 1-4, OGTR certified, Quarantine certified
- Containment equipment required, such as biological safety cabinets
- Provision for handling, decontamination and disposal of wastes
- Required PPE
- Training and experience required
- Health considerations including vaccinations and medical monitoring if required
- Support this with full references of any documents that assisted in arriving at the decision such as journal articles.

The guidelines for healthcare settings can be found on the Queensland Health website www.health.qld.gov.au. The guidelines cover facilities, general management of biological material of human origin and guides for specific communicable diseases.

Guidelines for Veterinary practices can be obtained from the Australian Veterinary Association website www.ava.com.au.

Determine if other requirements apply such as:

- Genetically modified organisms are regulated by the Gene Technology Act (Qld), 2001 and Gene Technology Regulation, (Qld), 2002. These requirements will exist in addition to those for biological safety.
    - The type of dealing to be undertaken must be determined in consultation with the Biosafety representative for your Division.
    - Section 6 of this procedure includes the OGTR process.

- Human Ethics (https://www.jcu.edu.au/research-services/ethics-and-integrity/human-ethics)
- Animal Ethics (https://www.jcu.edu.au/research-services/ethics-and-integrity/animal-ethics)
- Use of Scheduled Drugs and Poisons (HSE-PRO-004 Drugs and Poisons Procedure)
- Use of Carcinogens (substance listed in Schedule 10 WH&S Regulation Qld) (HSE-PRO-004 Drugs and Poisons Procedure)
- Hazardous Chemicals and Dangerous Goods (HSE-PRO-005 Hazardous Chemicals Procedure)
- Radiation sources (HSE-PRO-003 Ionising Radiation Procedure)
- Permits to access geographical locations GBRMPA or National Parks
- Use of Cytotoxic Drugs
- Import or Export of Quarantine material.

The application will be assessed by the IBC representative who may give approval or refer the application to next meeting of the full IBC for assessment.

In considering the application the IBC may seek additional information from the applicant or external sources.

Notification of approval will be sent by email with a copy being sent to biosafety@jcu.edu.au.

Once the application is approved the project can commence. Biosafety applications are valid for 5 years.

Any changes to the approved project activities must be referred to biosafety@jcu.edu.au and any necessary further approvals obtained before the changes are implemented.

A copy of the application is to be kept on the Biosafety Corporate drive.

6.3 Physical Containment Facilities

Physical containment (PC) facilities are used to reduce or prevent release of viable organisms into the outside environment. The facilities also control the introduction of contaminants from outside the facility.

AS/NZS 2243.3:2010 Safety in laboratories Part 3: Microbiological safety and containment identifies the requirements for physical containment facilities 1-4. Additional requirements may be required due to work with GMO, quarantine requirements or based on the project risk assessment.

6.3.1 Summary PC Facility Levels

PC facilities may have additional requirements that are placed on the facility under the OGTR and Quarantine requirements.

Table 2: PC Facility Use

PC Rating:	Hazard level	Use/Controls	Risk Groups
PC1 Laboratory Animal Containment Facility Plant Containment Facility Invertebrate Facility	Low	Student and Undergraduate teaching laboratories. General laboratory conditions, such as sealed floors and benches. Reliant on laboratory practices to control risk.	Risk Group 1
PC2 Laboratory Animal Containment Facility Plant Containment Facility Invertebrate Facility	Moderate	Research, diagnostic facilities. Where infectious aerosols could be present a biological safety cabinet will be used.	Risk Group 2
PC3 Laboratory	High	Research, diagnostic facilities.	Risk Group 3

		Additional controls such as airlocks, access controls, vaccination, additional training.	
PC4 Laboratory	Very High	Highest level of control. Additional controls such as airlocks, access controls, vaccination, additional training, change rooms, shower facilities, and class III biological safety cabinets or fully encapsulated positive pressure suit.	Risk Group 4

** JCU does not currently have PC4 rated facilities.*

6.3.2 Commissioning of non OGTR, non-Biosecurity Australia, PC Facility

When JCU intends to display the PC (1-4) rating of a facility and use the facility for the relevant risk groups, the facility must be inspected to ensure compliance with the intended physical containment rating. PC facilities that will have OGTR or Biosecurity Australia certification will have additional criteria to be met.

PC 1 and 2 facilities can be designed and inspected by JCU personnel using the criteria from *AS/NZS 2243.3:2010 Safety in laboratories Part 3: Microbiological safety and containment.* At least one member of the team is to be from the JCU IBC and have experience relevant to the type of facility. The IBC will approve if a facility is fit for purpose.

PC3 and 4 facilities will require design and initial inspection by a suitable third party with expertise in the type of facility. Reinspection can occur by appropriately experienced and trained JCU personnel.

Facilities PC1-4 that will be Quarantine Approved Arrangements (QAA) must have a third party inspection conducted by an inspector approved by the Department of Agriculture and Water Resources.

Records of these assessments must be kept. Copies of these inspections are to be retained by the person controlling the lab. The facility must be inspected annually by members of the IBC and reassessed to ensure ongoing compliance.

For OGTR facilities see Section 7 of this procedure.

For Biosecurity Australia facilities see Section 8 of this procedure.

6.3.3 Inspection of a non OGTR, non-Biosecurity Australia, PC Facility

Where JCU displays the PC (1-4) rating of a facility and uses the facility for the relevant risk Groups, the facility must be inspected annually to ensure compliance

with the intended physical containment rating provided in *AS/NZS 2243.3:2010 Safety in laboratories Part 3: Microbiological safety and containment.*
The inspection team must have representatives from the IBC. A copy of the assessment will need to be maintained by the person controlling each facility.

6.3.4 JCU Space Management System

The type, category and activities performed within physical containment facilities are to be reviewed and updated in the JCU Estate Directorate Space Management System.

Facility type includes the facility type (example plant, animal, invertebrate, aquaculture), physical containment type, OGTR or Quarantine Certification Level.

The description of the activities conducted within the facility is from the following list:

- Work with materials derived from animal sources such as bodily fluids, tissue
- Work with materials derived from animal sources such as bodily fluids, tissue with Zoonotic Risk
- Work with materials derived from human sources such as bodily fluids, tissue
- Work with genetically modified organisms
- Work with genetically modified plants
- Work with microorganisms
- Work with live aquatic animals
- Work with live terrestrial animals
- Work with live toxin producing animals
- Working with live invertebrates
- Work with risk Group 1 Microorganisms
- Work with risk Group 2 Microorganisms
- Work with risk Group 3 Microorganisms
- Work with risk Group 4 Microorganisms
- Chemically Synthesised toxins/biologicals.

6.4 DSGL and SSBA Materials

Materials that have been identified under the Defence Strategic Goods List (DGSL) or Security Sensitive Biological Agents (SSBA) list are items identified as having potential for being weaponised.

The Defence and Strategic Goods List (DGSL) is the list that specifies goods and technology that are regulated when exported, supplied, brokered or published. A permit is required when exporting, supplying, brokering or publishing DSGL items, unless there is an exemption.

Examples can include publication of research with microorganisms and toxins.

6.5 Biosafety Training

Any person working with biological material in a PC facility and in the field must complete and pass the Biosafety Training that is available on LearnJCU.

A laboratory induction is required to be completed by anyone working within a physical containment facility or laboratory.

Adequate training and instruction may also be required prior to the operation of any specific piece of equipment.

6.6 Equipment

6.6.1 Autoclave

Autoclaves are pressure vessels. The Estate Directorate is to be consulted in regard to potential registration and inspection requirements. If required the autoclave will be registered in the MEX system.

Operators are to be trained in the use of the autoclave. In particular:

- Correct operation
- Correct loading to allow decontamination of the whole load
    - Opening of bags
    - Positioning bags
- Procedures for the temporary holding of material awaiting sterilisation.

The effective operation of autoclaves requires regular confirmation to ensure that sterilisation is occurring, including:

- The use of visual indicators, such as sensitive papers or tapes in each cycle
- Monthly checks by either:
    - Biological indicators placed in several positions of the load
    - Bacterial enzyme indicators placed in several positions of the load
- Annual inspection and calibration of the autoclave is to be conducted by a suitably qualified person
- Records of monthly and yearly checks/inspection must be kept.

Exhausts should be plumbed to vent external to the facility.

6.6.2 Biosafety Cabinets

Biosafety cabinets are used specifically for biological hazards; these cabinets are not the same as chemical fume cabinets. Chemical fume cabinets shall not be used when working with infectious materials.

Anyone using a biosafety cabinet is to be trained in the operating procedures including decontamination procedures.

Any procedure that produces aerosols should be performed in a biosafety cabinet.

Biosafety cabinets are to be inspected and tested against the relevant Australian Standard for the class of cabinet:

- Before the first use
- Annually against the relevant standard

A label is to be attached displaying the inspection date.

Biosafety cabinets shall be decontaminated with formaldehyde gas or an equivalent before testing when they have been used for handling Risk Group 2, 3, or 4 microorganisms.

6.7 Cleaning

Laboratory staff must maintain the physical containment facility in a clean state by:

- Maintaining clear walkways
- Cleaning up spills
- Handling biohazardous and clinical waste
- Cleaning and decontaminating equipment.

Contract cleaners will use a select group of inducted staff for cleaning all research laboratories and OGTR accredited facilities. This cleaning will be limited to:

- Wet mopping of floors
- Window cleaning
- Removal of clearly marked uncontaminated wastes.

Dry sweeping should be avoided due to the potential to cause contamination to work in the facility.

PC2 and PC3 facilities must have dedicated cleaning equipment.

PC3 laboratories will only be cleaned by the laboratory workers.

Duties of the contract cleaners may be handled on a case by case basis (eg within the JCU entities). Provided appropriate risk assessment and induction has been conducted.

6.8 Clinical and Biohazardous Waste

Waste streams generated from facilities with biosafety risk are to be identified and treated/disposed of appropriately (see Appendix 4)

Clinical and biological wastes are materials that are contaminated or potentially contaminated with biological material of risk groups 1-4. This can consist of:

- Sharps including syringes, broken glass, scalpel blades, pipettes. These items should be collected in a rigid puncture proof container that can withstand pressure steam sterilisation
- Solid samples, including plants, invertebrates, animal carcasses, bedding, potting mix, petri dishes, gloves, and PPE
- Contaminated solids for reuse such as glassware
- Contaminated liquids for disposal, such as buffers and culture media
- Mixed class of material contaminated with other items such as radioactive material or hazardous chemicals
    - Radioactive waste should not be pressure sterilised. Waste disposal processes will be documented in the Radiation Safety Protection Plan. Consult the relevant Division Radiation Safety Officer for information
- Material that could contain prions should be collected for decontamination.

Waste streams may consist of:

- Uncontaminated waste:
    - (e.g. cardboard packaging) from PC1 and PC2 facilities may be disposed of in the same manner as household waste.
    - Paper towel used to dry hands after hand washing.
    - Uninfected animal carcases:
        - Uninfected mice into general waste bins
        - Non-infectious animal bedding, fur, clippings

- Non Clinical Biohazardous waste:
    - Waste that requires a form of decontamination or treatment but is not classed as clinical waste.
    - This would include waste with potential for animal or plant disease without risk of human infection.
    - This material would typically be placed in a clear autoclave bag and autoclaved before disposal into general waste streams.
        - Do not label as clinical or biological waste

- Clinical Waste:
    - See appendix 4.
    - Waste that has potential for infection in humans.
    - This waste must be disposed of by a regulated waste company with licenced to dispose of clinical waste.
    - This would include:
        - Human blood
        - Human tissue
        - Sharps

        - Culturing microorganisms that are infectious to humans
    - Double bagged and marked as “biohazardous waste” or “clinical waste” and placed in clinical waste bins.
        - If the material is of low risk no pre-treatment (eg autoclave) is required
        - If high risk autoclaving prior to placing in the clinical waste bin may be conducted

- Other requirements::
    - Waste in OGTR and Biosecurity Australia facilities will have additional requirements that are documented in the facility procedures stating specific waste disposal methods and tracking requirements (see appendix 4).

    - All material from PC3 laboratories must be treated as potentially contaminated. There will be specific procedures in place for the PC3 facility.

Facility / laboratory waste contaminated with biohazardous material is to be disposed of in marked “biohazard bags” placed inside bins marked as ‘biohazardous waste’. The facility must have procedures for storage, transport, decontamination and disposal of biohazardous waste.

Typically, decontamination will include either sterilisation by autoclaves, chemical action (germicides or disinfectants), incineration, or another method allowed by the local authorities.

Decontaminated waste shall be disposed of in accordance with relevant authority requirements.

6.9 Decontamination

Decontamination is required to remove microorganisms, and biological material before a laboratory or piece of equipment can be classed as non-contaminated and biosafety controls can be relaxed for a specified period of time to allow maintenance or other activities.

When maintenance activities are to be conducted within a laboratory on equipment that has been used for biosafety relevant activities, the equipment is to be appropriately cleaned and a decontamination certificate issued.

When equipment that has been used for biosafety relevant activities is to be removed from a laboratory, the equipment is to be appropriately cleaned and have a decontamination certificate attached. Any laboratory specific stickers such as “quarantine” are to be removed from equipment.

When major maintenance / renovation activities occur to a physical containment facility, the facility should be inspected to ensure the intended physical containment standard has been reinstated.

All users of a facility need to be trained in the use of spill kits for biohazards. There will be some facilities (PC3) that have specific personnel who need to be notified to clean up spills.

The decontamination certificate is issued by the laboratory/supervisor/manager (or delegate) for the space or piece of equipment. The decontamination certificate can be located on the JCU Biosafety web page.

Related Information:	Decontamination certificate

6.10 Decommissioning of General Physical Containment Facility

This process is to be completed when a laboratory is decertified. The laboratory is to be cleaned to remove contamination by microorganisms, biological materials, GMO and chemical residue.

The interior fabric (benches, floors and other surfaces) are to be suitably cleaned. Each piece of equipment used for any relevant activity is to be cleaned and have a decontamination certificate attached.

All stickers and signage are to be removed. The status of the facility is to be updated on the Estate Directorate Space Management system.

Additional requirements specific to the laboratory will need to be conducted for OGTR and Biosecurity Australia laboratories.

Related Information:	Decontamination certificate

6.11 Health Management

If work is conducted using human pathogens of Risk Group 3 or 4, each person working in the facility may be subject to an initial medical examination, including:

- Chest X-ray where relevant, and periodic examinations
- Baseline serum sample that is stored for future reference.

Risk Group 4 human pathogens require a system in place for reporting accidents and monitoring employee absenteeism and for the medical surveillance of illnesses that are potentially laboratory associated.

6.11.1 Immunisation.

If working with human or zoonotic pathogens, or samples that may contain human or zoonotic pathogens, a risk assessment is to be performed to determine if vaccinations are required.

The latest edition of The Australian Immunisation Handbook published by the NHMRC should be consulted. The requirements for vaccination are to be included in the laboratory procedures.

7 OGTR

Certain dealings with GMOs are required to be conducted in facilities that meet and are certified as complying with both section 5.3 of this procedure and the OGTR guidelines for physical containment facilities.

Work with any GMO must be conducted in accordance with the *Gene Technology Act (Qld), 2001* and *Gene Technology Regulation (Qld), 2002.*

Work with GMOs is prohibited unless the dealing is:

- Exempt
- A notifiable low risk dealing
- On the Register of GMOs
- Licenced by the OGTR.

7.1 Exempt Dealings with GMOs

Exempt dealings are identified in Schedule 2, Part 1 of the *Gene Technology Regulation, (Qld), 2002*. The only further legislative requirement for exempt dealings is that they do not involve an intentional release of the GMO into the environment. The dealing must still be conducted in a suitable facility for the microbiological risks.

To allow assessment of the application, the project supervisor must:

- submit a completed Biosafety Application Approval form and mark the box indicating that the project is an exempt dealing in the OGTR section; and
- ensure there is an adequate description of the project including host and vector to be used.

Email the above to the IBC Committee at biosafety@jcu.edu.au. This will be reviewed in consultation with the relevant Biosafety Representative for the Division (See Appendix 1).

Exempt dealings are to be conducted in accordance with the OGTR "Guidance Notes for the Containment of Exempt Dealings".

A risk assessment will be required in RiskWare addressing the hazards present in the project.

A record of exempt dealings will be recorded in a register stored on the Biosafety Corporate drive.

Related Information:	Exempt Dealings Register

7.2 Notifiable Low Risk Dealing

Notifiable Low Risk Dealing (NLRD) is identified in Division 2 of the *Gene Technology Regulation, (Qld), 2002*. NLRD do not involve the release of a GMO into the environment.

To conduct an NLRD the project supervisor must:

- Submit a completed NLRD application form to the IBC Committee at biosafety@jcu.edu.au along with the Biosafety Application Approval form. This will be reviewed in consultation with the relevant Biosafety Representative for the Division (See Appendix 1).
- The submission must include:
    - Description of the procedure to be undertaken including host and vector
    - A risk assessment on Riskware covering all aspects of the project including but not limited to:
        - GMO
        - Hazardous chemicals
        - Radiation
        - Biological hazards
        - Disposal of biohazardous waste and hazardous materials
    - Demonstration that the person has the suitable training and experience to undertake the dealing
    - The dealing will be undertaken in an appropriate OGTR registered facility for the relevant risk group as identified in the *Gene Technology Regulation, (Qld), 2002.*

The NLRD acceptance or rejection must be recorded in the IBC minutes. The NLRD must be accepted as an NLRD by the IBC. Work cannot proceed on the NLRD until approved by the IBC.

The NLRD must be added to the JCU NLRD list on the Biosafety Drive by the HSE Unit. The NLRD must have an expiry date.

Related Information:	NLRD Application Form

7.3 Licensed Dealings with GMOs Not Involving an Intentional Release

These dealings require a license from the OGTR, but do not involve any intentional release of the GMO. Such dealings may involve GMOs containing higher risk genes from pathogens, encode toxins, or confer a cancer causing modification or immuno-modulatory function.

These dealings are conducted in a PC2-PC4 rated OGTR certified facility.

Copies of the licences must be stored on the JCU Biosafety Corp drive.

The project owner will need to submit a JCU Biosafety Application Approval form to biosafety@jcu.edu.au.

An application form from the OGTR will need to be submitted through the IBC to the OGTR along with the supporting information.

The project cannot proceed until the OGTR has issued the licence.

7.4 Licensed Dealings with GMOs Involving an Intentional Release

These dealings require a license from the OGTR and can take up to 255 working days to receive an approval.

The project owner will need to submit a JCU Biosafety Application Approval form to biosafety@jcu.edu.au.

An OGTR application from will need to be submitted through the IBC to the OGTR along with the supporting information.

The project cannot proceed until the OGTR has issued the licence.

Copies of the licences must be kept on the JCU Biosafety Corp drive.

Related Information:	Application form for licence for dealings involving release

7.5 Inadvertent GMO Dealings

Inadvertent dealings occur primarily when a person comes into possession of a GMO due to sudden changes such as the termination of employment of the original owner of the GMO.

If a person has inadvertently come into the possession of a GMO then an inadvertent dealings application under section 40A of the Queensland *Gene Technology Act* 2000 (Act) is to be made. Otherwise the person can make an application for a licence under section 40 of the Act.

The intent of inadvertent dealings licence is to allow for appropriate disposal of the GMO.

If a person finds themselves in this situation the Biosafety Representative for the relevant Division must be notified.

7.6 OGTR Certified Physical Containment Facilities

JCU maintains physical containment facilities that are accredited with the OGTR.

AS/NZS 2243.3:2010 Safety in laboratories Part 3: Microbiological safety and containment identifies the requirements for physical containment facilities 1-4. Facilities certified to OGTR requirement will have additional requirements that can be identified in the guidelines for each type of facility and the related PC certification level; the guidelines are available from the OGTR website (www.ogtr.gov.au).

OGTR PC1 and PC2 facilities can be designed and inspected by JCU personnel using the criteria from the OGTR for that type of facility and PC rating. OGTR facilities are inspected on an annual basis by members of the IBC.

OGTR PC3 and PC4 facilities will require design and initial inspection by a suitable third party with expertise in the type of facility. Reinspection can occur by appropriately experienced and trained JCU personnel.

The OGTR guidelines also identify procedural requirements that are required to be in place for OGTR facilities.

Records of the certification of these facilities must be kept on the Biosafety Corporate drive.

The OGTR registration sticker must be displayed at each entry to these facilities.

Access to the physical containment facilities must be controlled and staff must be specifically trained in the requirements for the particular laboratory.

All OGTR certified facilities must be listed on the register of laboratories maintained on the Biosafety Corporate drive (See Appendix 2).

Related Information:	JCU OGTR Certified Laboratories

7.7 OGTR Annual Report

An annual report for accredited organisations is submitted by JCU to the OGTR during the second half of each calendar year. The OGTR will provide the template and due date for the report.

The annual report will be completed by the HSE Biological, Radiation and Chemicals Safety Advisor and reviewed by both the JCU Primary Officer for OGTR and the IBC Chairperson.

The report is then submitted to the Vice Chancellor's Office for signing. Once signed, the JCU Primary or Secondary Contact for OGTR submits the report to the OGTR.

7.8 OGTR Annual Physical Containment Facility Inspections

OGTR certified facilities are to be inspected on an annual basis to monitor compliance with the OGTR certification guideline for the type of facility and containment level.

Members of the IBC will conduct the inspections every year. A consolidated list of findings will be prepared every year for corrective actions. The corrective actions will be divided between those for the Divisions and maintenance issues for the Estate Directorate.

A record of all inspections for each year will be stored on the Biosafety Corporate drive.

The results of the inspections and progress of corrective actions will be reported at the IBC meetings.

The annual inspection of the PC3 facilities is to be submitted to the OGTR by the JCU Primary or Secondary Contact for OGTR.

A copy of the annual report is to be kept on the Biosafety Corporate drive.

7.9 Transport of GMO

Transport must be in accordance with the current OGTR Guidelines for Transport, Storage and Disposal of GMOs.

Related Information:	OGTR guidelines for Transport, Storage and Disposal of GMOs

7.10 Storage of GMO

Storage and labelling of GMO must be in accordance with the current OGTR Guidelines for Transport, Storage and Disposal of GMOs.

All GMOs must be clearly labelled to identify the GMO.

Procedures must be in place to ensure all GMOs can be accounted for. A record must be maintained and available if asked for by the Regulator.

Access to the GMOs must be restricted.

Related Information:	OGTR guidelines for Transport, Storage and Disposal of GMOs

7.11 Spills

Documented procedures must be in place for facilities and projects to decontaminate any spills involving GMOs.

Loss of containment outside of a facility must be reported to the OGTR. An incident must also be lodged in Riskware.

7.12 GMO Decontamination

Decontamination must be undertaken in accordance with the OGTR Guidelines for the Transport, Storage and disposal of GMOs. Specific procedures must be in place for each facility.

Equipment contaminated with, or suspected to be contaminated with, GMOs must be decontaminated before being removed from the facility, except if being transported for the purpose of decontamination in accordance with the OGTR Guidelines for the Transport, Storage and Disposal of GMOs.

All decontamination procedures must be undertaken by trained personnel.

Work benches and surfaces where a procedure involving GMOs has taken place must be decontaminated when the dealings are completed. Equipment directly used in procedures involving GMOs and equipment suspected to be contaminated must be decontaminated when the dealings are completed.

Related Information:	OGTR guidelines for Transport, Storage and Disposal of GMOs

7.13 Disposal of GMO

Storage and Labelling of GMO must be in accordance with the current OGTR guideline for Disposal of GMOs. The method of disposal and decontamination is to be identified in the project risk assessment.

Related Information:	OGTR guidelines for Transport, Storage and Disposal of GMOs

8 Quarantine

Quarantine requirements are monitored by the Department of Agriculture and Water Resources in accordance with the Queensland *Biosecurity Act* 2014.

The Department issues permits for importation and monitors compliance through auditing of Quarantine Approved Arrangements (QAA).

Import permits impose the requirements relating to the specific application. The requirements of a permit must be met in full.

Import permit requirements can range from:

- Initial inspection at the point of entry. In some cases there are no further requirements.
- Import with post entry requirements including the need to use material within a QAA, track usage and disposal.

8.1 Biosecurity Import Conditions

The Department of Agriculture and Water Resources has a Biosecurity Import Conditions (BICON) system for importing.

James Cook University has set up a multi user BICON account administered by the HSE Unit.

Anyone planning on submitting import permit applications will need to register as a 'user' on the system. There are two ways to become a 'user':

1. Receiving an invite from the system administrator. Initially you would request an account from importpermit@jcu.edu.au.
2. When applying in the BICON system selecting the 'account type' as joining an existing 'multi user account', and selecting James Cook University.

Once you have a user account, applications can be submitted to the Department of Agriculture and Water Resources.

Permit applications can either be paid for by credit card or a tax invoice can be generated from the system. Be aware that when an invoice is generated the assessment process will not start until after the invoice is paid.

Any permits in the previous ICON system will not convert over to BICON, and will eventually expire under the old system.

Further information can be found at the following link: "http://www.agriculture.gov.au/import/bicon".

Related Information:	OGTR guidelines for Transport, Storage and Disposal of GMOs

8.2 QAP Facilities

Quarantine Approved Arrangements are the facilities registered with the Department of Agriculture and Water Resources.

The facility must meet the criteria set out in the guidelines for facility types provided from the Department of Agriculture and Water Resources. This includes both the physical and procedural requirements (http://www.agriculture.gov.au/import/general-info/qap/qap-facilities). Quarantine requirements will be in addition or independent to those for OGTR.

Each facility is inspected and approved by the Department of Agriculture and Water. Records of the certification and inspections are to be retained by the laboratory manager.

The QAA registration stickers must be displayed at each entry to the facility.

Facilities are to remain locked when personnel are not in attendance.

The facilities are to be inspected annually by the JCU Institutional Biosafety Committee.

To decommission QAA, the quarantine material must be transferred, stored or destroyed as per permit conditions and the facility must be fully decontaminated. The Department of Agriculture and Water Resources will also need to conduct a final inspection.

8.3 Quarantine Material

Material that has on-going quarantine requirements will have a Quarantine Entry Number (QEN) assigned.

JCU will use the import permit number and a unique sample identifier to track the use of the material including splitting of samples, and disposal.

Quarantine material is to be kept physically separated from other non-quarantine material. The material must be labelled with the QEN and name of the material owner.

The material can only be transferred between QAAs listed on the specific permit. A new application must be lodged with the Department of Agriculture to add QAAs.

8.4 Quarantine Training

Any person wishing to work with quarantine material must undergo the "Quarantine Approved Arrangement for Accredited Persons" (QAA-AP) training for the type of facility.

Anyone working with quarantine material must be trained in the specific permit requirements and the requirements for the facility.

8.5 Fit and Proper Person

To allow any person access to quarantine material and the Quarantine Approved Arrangements, a "Fit and Proper Person" test must be successfully passed. The test is to be applied to:

- Any person working with the material
- Any person who can access quarantine material
- Any person managing operational aspects of a Quarantine Approved Arrangement
- Any person with managing responsibility for the Quarantine Approved Arrangement, such as approving payments of invoices from the regulator.

A record of the test being conducted is to be maintained as evidence.

If a person answers yes to a question, it does not necessarily mean they will be excluded from the facility. Follow up will be required to determine the outcome with the :

- Persons responsible for management of the laboratory; and
- The HSE Biological, Radiation and Chemicals Safety Advisor

Related Information:	HSE-PRO-009b Template "Approved Arrangements" "Fit and Proper Person" Induction Form

8.6 Exporting

If exporting material the requirements of both the Department of Agriculture and Water Resources and the intended receiving country must be met.

Correct shipping and packaging of the material will need to be in place.

8.7 Approved Arrangement Accounts:

A central register of approved arrangements is retained by the JCU HSE Unit. The listing includes account codes to be charged for Quarantine Approved Arrangement compliance costs.

The Quarantine Approved Arrangement list and account codes is provided to JCU Procurement to allow processing of invoices from the Regulator.

9 Biosafety Critical Incidents

Biosafety critical incidents are those that could have high risk consequences for health, the environment or public perception.

Examples of biosafety critical incidents could include:

- Diagnosis or suspected risk group 3 or 4 microorganisms such as Ebola or Anthrax
- Diagnosis or suspected zoonotic diseases such as Hendra or Lyssavirus virus
- Theft of biosecurity sensitive material.

Where a situation is thought to have potential to escalate into an emergency or critical incident, the college or institute management are to be informed. The HSE Unit is also to be notified. Initial discussions will be held to determine the level of risk and the immediate actions.

A staff member with relevant technical knowledge of the IBC should be consulted during any biosafety emergency to assist in determining the probability and level of risk.

A critical incident can only be declared by the Vice-Chancellor or the Chief Incident Coordinator (JCU Chief of Staff).

The following may be considered:

- The James Cook University Critical Incident Policy in particular notification of the Chief Coordinator (JCU Chief of Staff)

- Risk assessment:
  - Probability of the actual biosafety hazard being present
  - Screening tests where a high risk disease is not expected to be confirmed will warrant a different level of response to a diagnostic test where the disease is suspected to be confirmed
  - Consequence of the biosafety hazard
- Key Divisional contacts
  - Including out of normal business hours contacts
- Quarantine of the:
  - Facility
  - Animal
  - Person
- Legislative requirements that may be required to notify government agencies such as OGTR, Queensland Health or Biosecurity Queensland
- Arranging for the collection and shipping of diagnostic samples
- Immediate actions to take:
  - Quarantine
  - Cleaning
  - PPE
  - Identifying locations, people, animals that could be affected

10 Packaging Diagnostic Samples

Biological material/samples that are being transported need to be assessed against the relevant requirements for the mode of transport (road, rail, air or sea) and the class of sample.

Classes of dangerous goods that are relevant under the IATA Dangerous Goods Regulation include:

- Class 6.2 Dangerous Goods, infectious substances:
  - "Category A (UN2814)", could cause permanent disability, or fatal disease to humans or animals. This could include diagnostic samples for Hendra, or samples where a pathogen is known to be present
  - "Category B (UN3373)", are substances that are suspected or are known to contain less virulent pathogens
- Exempt due to minimal likelihood of pathogens and the pathogens are Risk Group 1 (AS/NZS 2243.3:2010 Safety in laboratories Part 3: Microbiological safety and containment). Exempt parcels do still require certain packaging and markings as identified in the IATA Dangerous Goods Regulation.
- Toxins from plants, animals, or microorganisms may be classed under 6.1, Dangerous Goods, Toxic Substances
- Class 9 Dangerous Goods, Miscellaneous Substances for samples packed with dry ice. Exempt quantities exist and exempt quantity packing and marking apply.

In general, the packing and shipping will require:

- Determination of the class of Dangerous Good if any
- Packing by a method relevant for the class of dangerous good or exempt category
- A person who has completed the relevant dangerous goods packing course e.g. such as CASA/IATA approved packager. To package, label and prepare documents.

11 Records

All records must be filed in TRIM. Records must be retained in accordance with the retention and disposal schedules governed by the Queensland State Archives:

- General Retention and Disposal Schedule
- University Sector Retention and Disposal Schedule

12 Related Documents, Legislation and Other Resources

12.1 Related Documents and Other Resources

Documents :	• University Intuitional Biosafety Committee (Sub Committee of the Health, Safety and Environment Advisory Committee) Terms of Reference • HSE-PRO-009a JCU Biosafety Application Approval (form) • HSE-PRO-009b Template "Approved Arrangements" "Fit and Proper Person" Induction Form • Licence application form for GMO dealings involving intentional release. http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/dirform5-htm • Licence application form for GMO dealings not involving intentional relsease. http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/dnir-form2011-htm • Application form for Notifiable Low Risk Dealing (NLRD) http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/4A5F836CFA4873EECA257D4F00836771/$File/NLRDrecordingVer9.pdf
Register	• JCU NLRD Record • JCU OGTR Certified Laboratories • JCU Biosecurity Australia Certified Laboratories

12.2 Regulatory Authorities and Other Relevant Entities

Office of the Gene Technology Regulator www.ogtr.gov.au

Department of Agriculture and Fisheries (Biosecurity) (www.daf.qld.gov.au)

12.3 Related Legislation, Codes of Practice and Procedures

Legislation	• Gene Technology Act (Qld) 2001 • Gene Technology Regulation (Qld) 2002 • Biosecurity Act (Qld) 2014
Standards	AS/NZS 2243.3:2010 Safety in laboratories - Microbiological safety and containment AS 2252.1-2002 Biological safety cabinets - Biological safety cabinets (Class I) for personnel and environment protection AS 2252.4-2010 Controlled environments - Biological safety cabinets Classes I and II - Installation and use (BS 5726:2005, MOD) OGTR guidelines for Transport, Storage and Disposal of GMOs Guideline Clinical and related waste, ESR/2015/1571, version 1.01 26 March 2015

13 Administration

NOTE: Printed copies of this procedure are uncontrolled, and currency can only be assured at the time of printing.

13.1 Approval Details

Policy Sponsor	Deputy Vice Chancellor, Services and Resources
Version no.	1.0 (16-1)
Date for next Major Review	[The procedure review should be scheduled 3 years from the approval date or sooner if required.]

13.2 Revision History

NOTE: A minor amendment will not result in a change of the next major review date.
Approval date - the date the Policy Sponsor approved the establishment, minor or major amendment or disestablishment
Implementation Date - the date the procedure was published in the Policy Library and is the date the procedure takes effect

Version	Approval Date	Implementation Date	Details	Author
18-1	11/07/2018	12/07/2018	Addition of content re Clinical and Biohazardous Waste and minor administrative amendments	HSE Biological, Radiation and Chemicals Safety Advisor
16-2	21/12/2016	22/12/2016	Procedure review – updated to align with current legislation	HSE Biological, Radiation and Chemicals Safety Advisor
16-1	23/12/2015	24/12/2015	Procedure established	HSE Biological, Radiation and Chemicals Safety Advisor

Keywords	Biosafety, Waste, Biohazardous, Biohazard, Clinical Waste

Consultation Committee	HSE Unit, HSEAC Sub Committees and Divisional HSE Committees
Contact Unit	safety@jcu.edu.au

14 Appendices

14.1 Appendix 1: JCU Biosafety Representatives and Institutional Biosafety Committee (IBC)

Composition of Committee	Member and Position Title
Chairperson (Member appointed by HSEAC)	Mr Geoffrey Gorton Director Divisional Operations, Division of Tropical Health & Medicine
Members of the Division of Tropical Health and Medicine: I. Member 1 of 2 – College of Public Health, Medical & Veterinary Sciences II. Member 2 of 2 – College of Public Health, Medical & Veterinary Sciences III. Member 1 of 2 of the College of Medicine and Dentistry (Townsville) IV. Member 2 of 2 of the College of Medicine and Dentistry (Cairns)	 Dr Catherine Rush (or Nominee) Deputy Chair A/Professor Bill Leggat (or Nominee) Dr Lynn Woodward (or Nominee) Research Resource Manager Miss Emma Carson (or Nominee) Laboratory and Technical Support (Dentistry)
Members of the Division of Tropical Environment and Societies: I. Member of the Molecular Ecology & Evolution laboratory, College of Science and Engineering II. Manager, Laboratories and Technical Support Academic, College of Science and Engineering	 Dr Carolyn Smith-Keune (or Nominee) Mrs Susan Kelly (or Nominee) Dr Lynn Van Herwerden (or Nominee)
Member of the ARC Centre of Excellence for Coral Reef Studies	Dr Aurelie Moya/ Dr Peter Cowman (or Nominee) , Senior Research Worker
Member of the Australian Institute of Tropical Health & Medicine: I. Townsville Campus II. Cairns Campus III. PC3 Laboratory	 Dr Lynn Woodward (or Nominee) Mr Phill Walsh (or Nominee) Mr Chris Wright (or Nominee)
Objective Member – External Entity	Mr David Porter Group Laboratory Manager Pathology Queensland Health Support Queensland Department of Health, Queensland Government
Member of the Division of Services and Resources, Estates Directorate	Mr Simon Leavers (or Nominee) Manager, Asset Strategy and Maintenance
Permanent Advisor - HSE Biological, Radiation and Chemical Safety Advisor	Mr Drew Kleier (or Nominee) HSE Biological, Radiation and Chemicals Safety Advisor Health, Safety and Environment Unit
Secretariat	Ms Michelle Nethery (or Nominee) HSE Administrative Officer Health, Safety and Environment Unit

14.2 Appendix 2: OGTR Certified Laboratories

OGTR Cert#	Cert Level	Location	Division	Building	Room	Type
1142	PC2	TSV	DTHM	020-001 , 009	001, 009, 011	Laboratory, Molecular Genetic Lab
1142	PC2	TSV	DTHM	020-011	11	Laboratory, Molecular Genetic Lab
1143	PC2	TSV	DTHM	087-110	110	Laboratory, Virology Lab
1144	PC2	TSV	DTHM	087-115	115	Laboratory Clinical

OGTR Cert#	Cert Level	Location	Division	Building	Room	Type
						Microbiology Lab
2032	PC2	TSV	DTHM	31	31	Research animal house
3029	PC3	TSV	DTHM	087-120	120	Laboratory & airlock
3030	PC2	TSV	DTHM	47 -102, 102A-102J	102, 102A-102J	Laboratory, Med Research lab
4169	PC2	TSV	DTHM	AITHM 48	111, 112, 113A, 113B, 114, 115, 117, 118, 119, 120, C104, C105	Microbiology Laboratory
4165	PC1	TSV	DTHM	86	1	Animal Facility

OGTR Cert#	Cert Level	Location	Division	Building	Room	Type
4200	PC3	TSV	DTHM	48	313, 313A to 313E, 314, 315, 315A to 315D and 320	Laboratory
4212	PC2 Animal Facility	TSV	DTHM	48	31, X301, 301 to 306, 316 to 319 and Corridor C303 and C301	Animal Facility
3197	PC2	CNS	DTHM	E1-103D	103 D	DPHTM Schistosomiasis Lab
3204	PC2	CNS	DTHM	E1-103E	103 E	DPHTM Schistosomiasis Research Facility
3278	PC2	CNS	DTHM	E4.004, E4.005	004, E5.005	Animal Facility
3279	PC2	CNS	DTHM	E4.006 (sterilizer room) and corridor E4.C001	006, C001	QTHA Laboratories
3280	PC2	CNS	DTHM	E4.003, 003A, 003B, 003C	003, 003A-C	QTHA Arthropod Facility
3281	PC2	CNS	DTHM	E4-114A,115,115A,116,122	114A,115,115A,116,122	QTHA Laboratories
3496	PC2	CNS	DTHM	D1-121A	121A	Dentistry Laboratory

OGTR Cert#	Cert Level	Location	Division	Building	Room	Type
4000	PC2	CNS	DTHM	E1	103P	Health and Sciences Building (E1)
NA	NA	CNS	DTES	E1	1.110C, 1.110F, 1.110G	Health and Sciences Building (E1)
NA	NA	CNS	DTES	A2	231	Soils Laboratory

14.3 Appendix 3: Quarantine Certified Laboratories

Cert Level	Quarantine CERT:	QAP Level	Location	Division	Building	Room	Type
PC2	Q2221	5.2	TSV	DTHM	087-008	8	Laboratory, parasitology lab
PC2	Q2223	5.2	TSV	DTHM	087-110	110	Laboratory, Virology Lab
PC2	Q0082	5.2	TSV	DTHM	087-115	115	Laboratory Clinical Microbiology Lab

Cert Level	Quarantine CERT:	QAP Level	Location	Division	Building	Room	Type
PC2			TSV	DTHM	31	31	Research animal house
PC3	Q2078	5.3	TSV	DTHM	087-120	120	Laboratory & airlock
PC2		5.2	TSV	DTHM	AITHM 48	111, 112, 113A, 113B, 114, 115, 117, 118, 119, 120, C104, C105	Microbiology Laboratory
PC2	Q2152	5.2, 7.7	CNS	DTHM	E1-103D	103 D	DPHTM Schistosomisasis Lab
PC2			CNS	DTHM	E1	103P	Health and Sciences Building (E1)
NA	Q1995	5.2	CNS	DTES	E1	1.110C, 1.110F, 1.110G	Health and Sciences Building (E1)
NA	Q1590	5.1	CNS	DTES	A2	231	Soils Laboratory

14.4 Appendix 4: Biohazardous and Clinical Waste

Clinical waste as listed in the EPA document ESR/2015/1571 Version 1.01 26 March 2015, Guideline Clinical and Related Waste		
Type	**Includes**	**Does Not Include**
Animal Waste	• Animal waste means any discarded materials, including carcasses, body parts, blood or bedding, originating from animals contaminated with an agent infectious to humans or from animals inoculated during research, production of biological or pharmaceutical testing with infectious agents. • Biological refers to preparations that are made from living organisms and their products, which are used in diagnosing, immunising or treating humans or animals. This includes but is not limited to serums, vaccines, antigens and antivenins.	• Teeth, hair/fur, claws/hooves or bone fragments are not considered to be animal body parts for the purpose of managing clinical and related waste under the Regulation. • Dead animals at the side of the road or animals put down due to old age or injury do not have to be disposed of as clinical waste. They can be disposed of through local government collection services (if pick-ups are provided) or given to the owner if requested. • General waste such as tongue depressors, cotton wool balls, tissues, bandages, band aids, protective bibs, gloves, overalls, disposable sheets, and shoe protectors with no free flowing blood, are not classed as clinical waste and can go into the general waste stream. Provided the material is first placed within a primary container (eg garbage bag).

Clinical waste as listed in the EPA document ESR/2015/1571 Version 1.01 26 March 2015, Guideline Clinical and Related Waste		
Type	**Includes**	**Does Not Include**
Discarded Sharps	A sharp is an object or device having with sharp points, protuberances or cutting edges that are capable of causing a penetrating injury to humans. This waste includes used hypodermic, intravenous or other medical needles, Pasteur pipettes, disposable dental picks and drill bits, scalpel blades, lancets, scissors, glass slides and broken laboratory glass. In order for an item to be defined as a sharp, it does not have to have been in contact with human blood, body fluids or an infectious agent. However, the area of sharps generation can influence how the waste is managed for disposal. For instance, a hypodermic needle that has been used to give a patient a tetanus injection would be disposed of in a yellow coloured sharps container for clinical waste. However, a sharp generated from an oncology ward which had been used to inject cytotoxic drugs would be disposed of as cytotoxic waste and a sharp which had contained radioactive material would be disposed of as radioactive waste.	• Plastic pipette tips if not contaminated. Using container other than normal sharps container.

Clinical waste as listed in the EPA document ESR/2015/1571 Version 1.01 26 March 2015, Guideline Clinical and Related Waste		
Type	**Includes**	**Does Not Include**
Human Tissue Waste	• Tissue, blood, blood products and other body fluids that are removed from a person during surgery, an autopsy or another medical procedure • Tissue, blood, blood products and other body fluids that are removed from a person during post-operative care or treatment • Specimens of tissue, blood, blood products and other body fluids and containers in which the specimens are kept • Discarded material saturated with, or containing, free-flowing blood and other body fluids. • Human tissue waste includes discarded waste human blood or its components (serum and plasma), containers of free-flowing blood or blood components, or material heavily contaminated with blood or blood components (whether free-flowing or dried). • Waste human blood and its components, including expired stocks from blood banks, is considered to be clinical waste and must be managed according to the legislative requirements for clinical waste. Human body fluids such as saliva, mucus, pleural fluid, cerebrospinal fluid, pericardial fluid and any other fluid that is visibly contaminated with blood, and all body fluids generated from circumstances where there is potential for the presence of infectious agents, are included in this category.	• Tissue does not include human body parts, teeth, hair, nail, gums and bone. • Urine, faeces and vomitus are not generally included as clinical waste, unless they originate from a person with a known infectious disease or are visibly contaminated with blood. • Waste items that may be slightly contaminated with dried blood should not be considered to be clinical waste by generating premises. This may include a light blood smear on a disposable gown or a spot of blood on cotton wool from a blood test. Blocks of tissue that have been fixed for cytological and/or histological examination in paraffin or a similar embedding material that prevents material leaching into the environment may be discarded as general waste. The chemical fixatives used are likely to destroy any potential pathogens in the tissue block. • Sanitary hygiene waste, managed appropriately should not be considered to be clinical waste, unless it has been generated in an isolation area or by a person known to have an infectious disease. Further information on managing sanitary hygiene waste is provided in section 7 of the EPA document Guideline Clinical and Related Waste. Individual premises can, however, still develop their own infection control policies for this waste. • General waste such as tongue depressors, cotton wool balls, tissues, bandages, band aids, protective bibs, gloves, overalls, disposable sheets, and shoe protectors with no

Clinical waste as listed in the EPA document ESR/2015/1571 Version 1.01 26 March 2015, Guideline Clinical and Related Waste		
Type	**Includes**	**Does Not Include**
		free flowing blood, are not classed as clinical waste and can go into the general waste stream. Provided the material is placed in a primary container (example garbage bag) before disposal.

Clinical waste as listed in the EPA document ESR/2015/1571 Version 1.01 26 March 2015, Guideline Clinical and Related Waste		
Type	**Includes**	**Does Not Include**
Laboratory Waste PC1 and PC2	• Laboratory waste means a specimen or culture discarded in the course of dental, medical or veterinary practice or research. This includes wastes contaminated by genetically manipulated material or imported biological material. Laboratory waste also includes cultures and stocks of infectious agents. • This waste includes cultures and stocks of infectious agents (as outlined above), and associated biologicals, cultures and stocks from medical, research or pathological laboratories, wastes from the production of biologicals, discarded live or attenuated vaccines or culture dishes, and devices used to transfer, inoculate or mix cultures. Cultures and stocks refer to systems that are used to grow and maintain infectious agents in vitro. This includes, but is not limited to: • nutrient agars, gels and broths • human and primate cell lines • impure animal cell lines. Culture dishes and devices used to transfer, inoculate or mix cultures refers to items that have come into contact with high concentrations of infectious agents and may include: • plastic or glass plates, flasks, vials, beakers, jars and tubes • inoculation wires and loops • stirring devices • stoppers and plugs • filtering devices • materials used to clean and disinfect items.	• Waste from laboratories that do not conduct testing of blood, body fluids or tissue from humans or animals is not clinical waste. • Non-contaminated waste paper, plastics, and paper products shall be collected as a separate waste stream (AS Standard)

Requirements Independent of the Clinical Waste Disposal		
Source	**Requirement for treatment**	**Source document**
OGTR	• Non-infectious GM animal is deactivated once dead. • Any wastes containing GMOs must be decontaminated prior to disposal if the method of disposal is not also the method of decontamination. • Decontamination may be effected by autoclaving using a combination of temperature and time that has been validated as effective for the decontamination of the GMOs. • PC3 and PC4, prior to disposal, the GMOs to which Part 3.2 applies must be decontaminated inside a relevant facility certified by the Regulator, unless otherwise permitted, in writing, by the Regulator.	OGTR document: Guidelines for the Transport, Storage and Disposal of GMOs

Requirements Independent of the Clinical Waste Disposal		
Source	**Requirement for treatment**	**Source document**
Animal waste in the Microbiological Australian Standard	• Waste shall be segregated, decontaminated where necessary and disposed of according to applicable regulations. • Animal containment facilities should have access to decontamination facilities within their own areas. Waste from low level (PC1 and PC2) animal containment facilities can be decontaminated outside the facility. However, waste shall be contained to prevent dissemination of any infectious microorganisms. Waste from higher level animal containment facilities shall either be pressure steam sterilized in the facility or decontaminated in a closed system to ensure that all infectious microorganisms are destroyed. As a general principle, the biological and physical containment recommended for working with infectious agents in vivo and in vitro are comparable. Infected animals should only be handled by trained staff using procedures designed to protect staff and the environment from exposure to the microorganisms. When housing animals in which microorganisms are to be used, the physical containment levels for work with microorganisms shall follow the containment levels appropriate for the microorganism. Requirements for Animal PC1, Animal PC2, Animal PC3 and Animal PC4 facilities are set out in Clauses 6.4, 6.5, 6.6 and 6.7 of the standard.	AS/NZS 2243.3:2010 Safety in laboratories - Microbiological safety and containment
Animal waste in the Microbiological Australian Standard	• Infectious bedding, cage wastes and cages from small animals shall be decontaminated prior to disposal or reuse as described in Section 12. • Infected carcasses shall be decontaminated prior to disposal. This may be achieved by methods such as alkali digestion, autoclaving, incineration or rendering. • All instruments and containers that have been used in procedures with infectious microorganisms should be decontaminated before cleaning. Any special precautions that are needed, such as decay of radioisotopes, should be taken.	AS/NZS 2243.3:2010 Safety in laboratories - Microbiological safety and containment
PC3 and PC4 Laboratory waste in the Microbiological	PC3 and PC4 waste to be decontaminated inside the facility before being removed.	AS/NZS 2243.3:2010 Safety in laboratories - Microbiological safety and containment

Requirements Independent of the Clinical Waste Disposal		
Source	**Requirement for treatment**	**Source document**
Australian Standard		
General waste paper in PC1 and PC2 laboratories in the Microbiological Australian Standard	Non-contaminated waste paper, plastics, and paper products shall be collected as a waste stream.	AS/NZS 2243.3:2010 Safety in laboratories - Microbiological safety and containment