Key Risk Area (KRA)

KRA 1.2 Biological Management

1. Purpose

The University of Newcastle (**University**) is committed to providing a safe and healthy work and study environment, so far as is reasonably practicable. This document provides the framework for conducting activities with biological material to manage safety, security and compliance requirements.

2. Scope

This document applies to all health, safety and wellbeing activities of staff, students, visitors (including volunteers, contractors and other workers), Council members, and other persons interacting with the University; the operations of staff of University aligned Research Centres and controlled entities; and all activities conducted by or on behalf of the University on and outside of the University's campuses.

This policy does not apply to the use of biological material that is not hazardous in domestic settings (e.g., plant and animal materials used in the preparation of food for human consumption); or biologicals used in standard clinical practice not related to research or teaching activities.

3. Guidelines

3.1. Risk Assessment

Specific risks associated with biological material include infection risks to humans and animals and the risk to the environment.

The University has a risk management process to ensure that all University activities including research work and teaching practicals have safety approval where appropriate. Each time a new project/activity is planned to be undertaken, or when there is a variation to an existing one, it is the responsibility of the Principal Investigator or Responsible Supervisor to ensure that an appropriate safety review application is submitted. Applications must be submitted via Tick@lab if the project or activity involves biological materials including:

- Micro-organisms or Biological toxins,

- Laboratory and non-laboratory animals, cell lines and tissues or body fluids,
- Human body fluids, human cell lines or tissues not screened for pathogens,
- Security sensitive biological agents,
- Genetically modified organisms (GMOs).

The Safety Protocol will then be reviewed and assessed by the Institutional Biosafety Committee (IBC) in line with biological risk management principles and relevant regulatory requirements.

3.2. Biological Risk Group Classification

Biological material including most microorganisms are classified according to their biological risk profile under a risk group:

Risk Group 1 (low individual and community risk)
A microorganism that is unlikely to cause human or animal disease.

Risk Group 2 (moderate individual risk, limited community risk)
A microorganism that is unlikely to be a significant risk to laboratory workers, the community, livestock, or the environment; laboratory exposures may cause infection, but effective treatment and preventative measures are available, and the risk of spread is limited.

Risk Group 3 (high individual risk, limited to moderate community risk)
A microorganism that usually causes serious human or animal disease and may present a significant risk to laboratory workers. It could present a limited to moderate risk if spread in the community or the environment, but there are usually effective preventative measures or treatment available.

Risk Group 4 (high individual and community risk)
A microorganism that 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.

Refer to AS/NZS 2243.3:2022 Safety in Laboratories: Part 3 – Microbiological Safety and Containment or the resources below to identify pathogen risk groups and access Safety Data Sheets (SDSs):

- American Biological Safety Association (ABSA) risk group classification for infectious agents

- List of Security Sensitive Biological Agents (SSBAs) Canadian Public Health Agency Pathogen SDS's and Risk Assessments

Note- The biological material handled at the University is up to risk group 2 (moderate individual risk, limited community risk).

3.3. Physical Containment (PC) Facilities

Control strategies for handling microorganisms and other biological material (clinical samples, animal tissue and fluids etc.) are clearly outlined in AS/NZS 2243.3:2022. The primary control is containment of the material to within appropriate facilities where the risk category of the material (risk group 1-4) matches the physical containment level (PC1-4) of the facility.

The physical containment level of a facility dictates the storage, handling/behavioural and disposal requirements for material handled in the facility, so staff, other workers and students working in these facilities must be inducted and trained in line with the measures identified in the standard (AS/NZS 2243.3:2022). The measures are in themselves a system of risk control strategies.

The Engineering specifications and requirements for PC facilities are listed in AS/NZS2243.3:2022.

3.3.1. Work Practices in Physical Containment (PC) Facilities - PC1 Work Practices

- Access to the laboratory shall be limited to authorised persons.
- Food/drink shall not be brought into the laboratory or stored in laboratory refrigerators.
- Eating, drinking, smoking, shaving and the application of cosmetics shall be prohibited in laboratories. **Note:** This includes offices within the containment facility boundary.
- PPE worn and used in the laboratory includes enclosed shoes, lab coat or gown and safety glasses. **Note:** A rear-fastening gown is preferable.
- Minimise the production of aerosols, particularly where work is carried out on the open bench.
- Minimise the dissemination of microbiological material while flaming a wire loop, by drawing the loop gradually from the cooler to the hotter parts of the Bunsen burner flame, or by using a hooded or an ‘electric’ Bunsen burner. **Note:** Disposable loops may be used as an alternative.

- Clearly identify and date cultures. Minimise the time cultures are kept on the bench (transfer to a dedicated storage area, such as a refrigerator or cold room).
- Do not mouth pipette. Do not use pipettes that require forced expulsion to deliver the nominal volume.
- Diagnostic kits, control sera and products manufactured from microbiological sources must be handled with care as infectious microorganisms may be still present.
- As airborne fungal spores can spread in a similar manner to aerosols, cover or seal cultures of spore producing fungi as appropriate to prevent dispersal.
- Always use local exhaust ventilation* or a fume cupboard when determined as appropriate by a risk assessment of any work with toxic, volatile, corrosive or odoriferous substances. Biosafety cabinets are not designed for this purpose.
- Items such as door handles, fridges, telephones, keyboards, reading and writing materials shall be regularly decontaminated.
- Decontaminate work benches at least daily and after all work involving microorganisms.
- Staff shall be trained in the clean-up of microbiological spills. Spills shall be contained, any affected persons attended to and the area cleaned up and decontaminated with appropriate disinfectant.
- Segregate wastes (e.g. broken glassware, biological and radioactive substances) and dispose of according to applicable regulations, using the most appropriate and effective method for the materials concerned.
- Remove laboratory gowns and decontaminate hands before moving to areas outside laboratories.
- All stored Biological material must be recorded on the Biological Register for the Facility and all freezers and locations where biological material is stored must be labelled with a Biohazard Signage. Registers should be reviewed at predetermined intervals based on risk and at a level and frequency whereby materials can be accounted for in an appropriate manner and the facility must have measures in place to minimise the quantities of biological agents and toxins that are retained onsite.
- *AS/NZS 2982.2010 Laboratory Design and Construction should be consulted for local exhaust ventilation requirements.*

3.3.2. Work Practices in Physical Containment (PC) Facilities – PC2 Work Practices

In addition to the work practices described for PC1 laboratories, the following work practices apply:

- Laboratory doors shall be closed when the laboratory is operating.

- All clinical and diagnostic specimens shall be regarded as potentially hazardous. Leaking containers shall be handled in a biological safety cabinet and the outside of the container decontaminated.
- The use of sharps such as syringes, needles and scalpels shall be minimised, as sharps injuries constitute a large portion of laboratory accidents.
- Needles and syringes or other sharp instruments shall be restricted in the laboratory for use only when there is no alternative.
- Sharps shall be disposed of in sharps containers. Before disposal, needles shall not be removed, bent, sheared, or replaced in a sheath or guard, unless the recapping/removal procedure can be carried out by a safe method with suitable equipment.
- As glass equipment such as pipettes have the potential to become sharps during an accident, plasticware should be substituted for glassware whenever possible.
- Where infectious material is being injected under high pressure, Luer-lock fittings should be used.
- For manipulations of Risk Group 2 microorganisms transmissible by the respiratory route or work producing a significant risk from aerosol production, a biological safety cabinet or other equipment designed to contain the aerosol shall be used.
- A period of at least 5 min shall be allowed for aerosols to settle before opening homogeniser or sonicator containers in a biological safety cabinet (BSC).
- Large items of equipment can interfere with the airflow pattern in a Class II BSC and correct operation of the cabinet should be validated with the equipment in situ.
- When working with infectious or potentially infectious prions, a laminar flow cytotoxic drug safety cabinet shall be used.
- Bacterial cultures shall not be actively sniffed for odours. NOTE: This has been a common cause of laboratory acquired infections.
- Seal cultures of spore producing fungi as appropriate to prevent dispersal.
- Any container of viable microorganisms, including any waste that may contain viable organisms, shall be transported outside the laboratory within a second unbreakable and closed container, which can be readily decontaminated.
- Potentially contaminated re-usable laboratory ware shall be collected and disinfected or decontaminated prior to washing and re-use. For chemical disinfection, pipettes shall be placed vertically in an appropriate disinfectant solution, tip-first and fully immersed, to minimise the production of aerosols. If pipettes are to be thermally decontaminated in a steam steriliser, they shall be fully immersed, vertically in a fluid, such as a detergent.

- **Note:** Thermal decontamination of pipettes that are not fully immersed in a liquid, i.e. are empty, can only be achieved in a pre-vacuum steam steriliser.
- Gloves shall be worn when working in a biological safety cabinet, when handling human blood and body fluids, and when conducting procedures with materials that contain or potentially contain human Risk Group 2 microorganisms.
- PPE shall be removed and hands decontaminated in a predetermined appropriate order, before leaving the laboratory.
- Appropriate protocols for laundering or decontaminating PPE should be implemented.
- Laboratory staff shall advise maintenance and service personnel of the special microbiological hazards in the laboratory.
- All potentially contaminated equipment and adjacent surfaces shall be decontaminated prior to maintenance or removal from the area.
- A control program against pest insects, birds and animals shall be instituted.

3.4. Training

Refer to HSG 4.2 Health, Safety and Wellbeing Induction, Training and Competency.

3.5. Biological Specimens (Human and Animal Specimens)

Human and animal specimens which include tissue and body fluids are normally regarded as risk group 2 and shall be handled in a PC2 facility unless a risk assessment identifies otherwise.

3.5.1. Workers Performing Phlebotomy

It is recommended that researchers conducting projects where blood collection from study participants is required consider the options of engaging a certified Phlebotomist or Nurse/Mid Wife trained in venepuncture or using a Pathology service first before looking to train staff to undertake this activity.

Venepuncture due to its invasive nature carries specific risks to the patient/participant. Researchers (including nurses and mid wives) undertaking blood collection are expected to have completed accredited/certified training (HLTPAT002 Perform venous blood collections or HLT37215 Certificate III in Pathology Collection) or comparable training that includes infection control, risk identification and management, clinical requirements, practical component and competency assessment delivered by a certified trainer (such as a Nurse/Hospital Educator or other certified trainer- Certificate IV TAE40116).

Those trained in phlebotomy must be regularly conducting venepuncture to retain their skills and expertise. The University does not recommend anyone is trained where limited and irregular venepuncture will be performed by them. If staff have been trained but have not used their skills for an extended period of time, a training refresher session is highly recommended but at a minimum there is a requirement of confirmation of competency via one (1) observation of a successful blood collection by an independent assessor (currently this is the HMRI Clinical Research Facility Manager).

3.5.2. Standard (Universal) Precautions

Standard (Universal) body substance precautions assume that all human blood and body substances are potential sources of infection, independent of risk and are therefore handled as if infectious. Universal Precautions are expected to be observed for all workers handling biological material.

3.6. Animal Handling Precautions

If work involves animals workers must consider and manage zoonosis risk including:

- Q fever risk where workers have contact with abattoirs or at-risk animals, including native animals, farm and feral animals or handle non-lab animal products of conception (such as placental tissue and birth fluids). Inhalation of dust in areas frequented by at risk animals may also pose a Q fever infection risk. Note- Q fever vaccination is expensive and can only proceed after pre-screening indicates a worker has no existing antibodies to the Q fever bacterium Coxiella burnetii.
- Workers who come into regular contact with bats (flying foxes and microbats) are recommended to receive rabies vaccine.
- Workers who work with poultry or pigs are recommended to receive influenza vaccine.
- Workers who work with horses need to consider Hendra virus risk which at this time is addressed with the vaccination of horses being handled.

3.7. Biosecurity Material

The *Biosecurity Act 2015* commenced on 16 June 2015 and later wholly replaced the *Quarantine Act 1908* (Cth) as the primary piece of biosecurity legislation in Australia.

Biosecurity is a critical part of the government's efforts to prevent, respond to and recover from pests and diseases that threaten the economy and environment.

3.7.1. Importing into Australia

To help protect Australia's unique environment from unwanted pests and diseases, the Department of Agriculture, Fisheries and Forestry regulates products imported into Australia. The importation of some products is, by law, subject to certain biosecurity import conditions. Some products are not permitted entry while other products are only allowed into Australia subject to meeting import conditions that mitigate the biosecurity risk. This may include a requirement for an import permit.

You can use the Biosecurity Import Conditions system (BICON) to determine whether a commodity intended for import into Australia:

- is permitted
- is subject to import conditions
- requires supporting documentation
- requires treatment
- needs an import permit.

It is your responsibility to comply with the department's import conditions when importing into Australia. BICON will identify whether your goods require an import permit. You can apply, track and manage your BICON import permits online using your BICON registered user account.

3.7.2. Approved Arrangements

Approved arrangements, previously Quarantine Approved Premises and Compliance Agreements, are voluntary arrangements entered into with the Department of Agriculture, Fisheries and Forestry.

These arrangements allow operators to manage biosecurity risks and/or perform the documentary assessment of goods in accordance with departmental requirements, using their own sites, facilities, equipment and people, and without constant supervision by the department and with occasional compliance monitoring or auditing.

The Department of Agriculture, Fisheries and Forestry has set conditions for how activities can be performed under an approved arrangement. Some conditions are specific to the class of approved arrangement you are operating, and some apply across multiple arrangement classes.

The class of an approved arrangement is based on the:

- type of activities taking place in the arrangement
- associated biosecurity risks.

Any University activity being planned that would fall under an approved arrangement is required to have safety approval via the safety review system noting facilities falling under an approved arrangement whilst aligning with the PC classifications under AS/NZS 2243.3:2022

have extra regulatory requirements relating to registration and record keeping that is regulated by Department of Agriculture, Fisheries and Forestry.

3.8. Genetically Modified Organisms

The Office of the Gene Technology Regulator (OGTR) regulates use of Genetically Modified Organisms (GMOs) in Australia.

The Regulatory System covers the classes of Genetically Modified Organism/Material (GMO's) individually known as dealings, organisations working with GMOs (accredited organisations) and certification of facilities where GMOs are handled and stored (Physical Containment Facilities).

Specific risks associated with GMO material include infection risks to humans and animals and the risk to the environment should the GMO escape containment. Some GMOs are pathogenic (cause disease), and others may contaminate the environment by introducing modified traits into plants, animals, micro-organisms etc which would not normally be present. GMOs are classified taking into account their risk group (AS/NZS 2243.3:2022) and the Gene Technology classification framework. Refer to KRA 1.8 Gene Technology for further Information.

3.9. Security Sensitive Biological Agents (The SSBA Regulatory Scheme)

The deliberate release of harmful biological agents can cause significant harm to human health, the environment and our economy.

The Security Sensitive Biological Agents (SSBA) Regulatory Scheme aims to:

- designate SSBAs that are of security concern to Australia
- limit opportunities for acts of bioterrorism or biocrime to occur using SSBAs
- maintain access to SSBAs for those with a legitimate need to handle SSBAs within secure laboratories
- provide a legislative framework to regulate the handling of SSBAs.

Legitimate biological research involving SSBAs can have a range of therapeutic benefits, but might also have the potential to be misused to threaten public health or national security. The scientific community refers to this as 'dual-use' biological research.

Part 3 of the *National Health Security Act 2007* (Cth) (NHS Act) establishes the SSBA Regulatory Scheme.

The *National Health Security Regulations 2018* (Cth) (NHS Regulations) give detail about operations and requirements of the scheme.

The SSBA Standards outline how confirmed and suspected SSBAs and sensitive information associated with SSBAs, must be securely:

- handled
- stored
- disposed of
- transported.

3.9.1. Reporting and registering

The aim of the Security Sensitive Biological Agent (SSBA) Regulatory Scheme is to limit opportunities for acts of bioterrorism or biocrime to occur using harmful biological agents. The regulatory scheme was developed using risk management principles to achieve a balance between counter-terrorism concerns and the interests of the regulated community. The regulatory scheme aims to maintain full access to SSBAs for those with a legitimate need.

The administration of the SSBA Regulatory Scheme resides within the Department of Health and Aged Care portfolio. The scheme is built around a two-tiered List of SSBAs and requires all entities and facilities handling SSBAs to comply with the *National Health Security Act 2007* (Cth), the *National Health Security Regulations 2018* (Cth) and the SSBA Standards.

Any worker planning to obtain, handle or store SSBAs on an ongoing basis must submit their risk assessment and procedural documentation for Safety Review by the IBC to determine if the work can be accommodated safely at the University before applying to register the SSBA with the Department of Health and Aged Care (Health).

The Minister for Health and Aged Care determines which biological agents are of security concern to Australia and the list of SSBAs is regularly reviewed to make sure it is up to date. View the list. Further information is available via the Security Sensitive Biological Agents (SSBA) Regulatory Scheme.

3.10. Health Management

A Position Screening Health and Safety Risk Assessment must be completed for all new Workers and existing workers commencing new roles or activities to identify potential workplace exposures, any reasonable adjustments required and future health monitoring needs.

3.10.1. Immunisation

Workers who handle or collect clinical samples human tissue, blood, body fluids or sewage and First Aid Officers are expected to have completed Hepatitis B immunisation with seroconversion confirmed through a blood test.

For workers in groups handling biological agents or toxins (e.g. when working with Diptheria Toxin) immunisation is required with Tetanus-Diptheria Toxoid (Td) or its equivalent (such as Tetanus-Diptheria-acellular- pertussis (Tdap) a suitable vaccine.

Workers who work with animals should be up to date with routinely recommended vaccines for adults, such as dT-containing and MMR vaccines.

Individual assessment of Q fever risk is required where workers have contact with abattoirs or at-risk animals, including native animals, farm and feral animals or handle non-lab animal products of conception (such as placental tissue and birth fluids) to determine if vaccination is required. Inhalation of dust in areas frequented by at risk animals may also pose a Q fever infection risk.
Note- Q fever vaccination is expensive and can only proceed after pre-screening indicates a worker has no existing antibodies to the Q fever bacterium *Coxiella burnetii.*

Workers who come into regular contact with bats (flying foxes and microbats) are recommended to receive rabies vaccine.

Workers who work with poultry or pigs are recommended to receive influenza vaccine.

Health Monitoring records are held in the University Health Service Medical database.
Refer to HSG 8.5 Health Monitoring for further information.

3.10.2. Health Screening

Any suspected exposure to human body fluids of tissues via a splash or penetrating injury must be reported via the incident reporting system and medical review undertaken via referral to the University Health Service, Clinical Placement Organisation Staff Health Office or other Medical Provider as soon as possible to determine if follow-up screening needs to be commenced.

The University takes a precautionary approach with potential exposures involving fixed cells and tissues still considered for screening.

3.11. Transport of Biological Material

Procedures for the safe and secure transport of cultures, specimens, samples and contaminated and potentially contaminated materials must include;

- ensuring transport requirements are identified and implemented, including legislated requirements, national and international guidelines;
- ensuring transport between organisations and locations is in accordance with legal requirements for the transport of dangerous goods, International Air Transport Association requirements and when applicable the Office of the Gene Technology Regulator (Genetically Modified Material) and/or Department of Agriculture, Fisheries and Forestry (Biosecurity Material);
- ensuring adequate packaging systems (double containment), materials, labels, PPE and documentation are available and used as part of the transportation process;
- selecting a reliable, trustworthy carrier that is qualified to handle the package safely and securely;
- checking and confirming whether a request received for biological agents, and toxins or material that may contain viable biological agents and toxins, is being made by an approved and suitably equipped facility, and equivalent controls are applied to importation of material to the facility;
- the need is identified for formal documented transfer forms signed by the responsible management representative authorizing movement of materials and document control that allows traceability of material movements;
- identifying and implementing adequate and proportionate emergency response and contingency plans associated with transportation, including adequate precautions for handling suspicious packages, Quarantine/Biosecurity and GM material;
- The IATA Dangerous Goods Regulations describe the markings and, if required, the labels required on specified packages for air transport.

3.12. Biological Waste Management

3.12.1. Solid Clinical Waste

This waste (excluding categories mentioned below) is placed into yellow contaminated waste bags (double bag or use wet bags to prevent holes or leaks). When ¾ full they must be sealed with tape and placed in the yellow clinical waste whiz bin in the area for collection by a licenced waste contractor.

3.12.2. Sharps (e.g. broken contaminated glass, contaminated glass, glass pipettes, needles, scalpels, slides)

This waste is placed in sharps bins after use and should only be filled up to the line shown on the bin. The full bin must be sealed and placed in a yellow contaminated/clinical waste whiz bin in the area. All full yellow whiz bins are to be locked and they are removed weekly by the licenced waste contractor. All contaminated glass, both broken and unbroken, must be disposed in contaminated sharps bins.

3.12.3. Cell Culture and Liquid Microbial Waste (Including Genetically Modified Waste)

This waste must be autoclaved or diluted in bleach at a final concentration of 0.5% for a minimum of 30 minutes before being washed down the sink with water.

3.12.4. Solid Microbiological Waste (Including Genetically Modified Material)

Solid waste containing microorganisms, infectious material or genetically modified material must be placed into autoclavable contaminated waste bags or sealed in autoclavable vessels and autoclaved. The bags are then placed in a yellow contaminated/clinical waste wheelie bin located in the autoclave room for disposal through the waste contractor.

3.12.5. Animal Carcasses/Tissue

This waste is placed into black plastic body bags, (provided by the facility) and transported to a dedicated freezer usually located in the animal facility area for storage prior to disposal.

All Genetically Modified and risk group 2 culture waste must be inactivated/sterilised before disposal. Sterilisation of liquid waste can be by disinfection (e.g. bleach treatment) or autoclaving and all solid waste is autoclaved. All solid waste is then placed in the yellow biological/clinical waste bins and collected by a licenced waste contractor for disposal as clinical waste.

3.13. Incident Management and Reporting

HSG 5.1 Health, Safety and Wellbeing Incident Notification and Investigation

HSG 5.2 First Aid PDF

HSG 5.3 Emergency Response

3.14. Raising Concerns

Any member of the University community who has concerns about a breach of the KRA should contact the Health, Safety and Wellbeing Team directly and lodge a report in the online Incident / Hazard Reporting System (AIMS).

When working with biological material if there is an incident or unexplained symptoms or illness is experienced, seek medical attention and report the event using the online Incident / Hazard Reporting System (AIMS).

3.15. Regulatory Framework

Legislation

Gene Technology

Gene Technology (New South Wales) Act 2003 (NSW)

This Act, consisting of 20 sections divided into six Parts, adopts in New South Wales an approach to the regulation of genetically modified organisms in line with the decisions and regulation of the Commonwealth of Australia. For this purpose, the Act applies the *Gene Technology Act 2000* (Cth) as a law of the State and makes contraventions punishable as an offence.

Biosecurity

Biosecurity Act 2015 (Cth), *Export Control Act 2020* (Cth), *Imported Food Control Act 1992* (Cth)

The Department of Agriculture, Fisheries and Forestry administers the *Biosecurity Act 2015* (Cth) (except to the extent administered by the Department of Health and Aged Care), *Export Control Act 1982* (Cth), *Imported Food Control Act 1992* (Cth) and various other Acts in order to protect Australia's animal, plant and human health status and to maintain market access for Australian food and other agricultural exports. If you import or export goods to/from Australia or are associated with the movements of vessels or aircraft to Australia, you should be aware of your responsibilities under Australian law.

There are two regulations made under the *Biosecurity Act 2015* (Cth):

• The *Biosecurity Regulations 2016* (Cth) (administered by Department of Agriculture, Fisheries and Forestry); and

• The *Biosecurity (Human Health) Regulations 2016* (Cth) (administered by the Department of Health and Aged Care).

Australian and International Standards

AS/NZS 2243.3:2022- Safety in laboratories Part 3: Microbiological safety and containment

AS/NZS 2243.3:2022 in addition to provision of detail regarding classification of biological material and physical containment facilities including requirements for construction and

operation. It also categorises microbiological agents into risk groups based on their individual and community risk and provides guidance on handling, storing and culturing. Information includes handling and storage requirements, signage, risk classification of micro-organisms and biological material, handling, storage, disposal of microbiological material, classification of facilities (physical containment from PC1 to PC4), behavioural aspects, infection control strategies and emergency procedures for incidents involving biological material.

Compliance with Australian/New Zealand Standard 2243.3:2022 Safety in Laboratories – Microbiological Safety and Containment may be relevant to the University's compliance with the laws regulating biological materials, such as where compliance with this Standard is a condition for the issue of import permits and other approvals relating to gene technology and imported biological materials.

ISO 35001:2019 - Biorisk management for laboratories and other related organisations

The ISO 35001:2019 biorisk management system establishes the biorisk management principles that enable laboratories and related facilities to achieve their biosafety and biosecurity objectives. ISO 35001:2019 also defines the essential components of a biorisk management system framework to be integrated into the overall governance, strategy and planning, management, reporting processes, policies, values, and culture of a laboratory or other related facility. ISO 35001:2019 describes a comprehensive biorisk management process that mitigates biorisks (biosafety and biosecurity risks); and provides guidance on the implementation and use of the standard, where appropriate. The biorisk management system is based on a management system approach, which enables an organization to effectively identify, assess, control, and evaluate the biosafety and biosecurity risks inherent to its activities.

World Health Organisation (WHO)

The WHO Laboratory Biosafety Manual (4th ed.) provides information and fundamental concepts to encourage the development of management systems and codes of practice for handling pathogenic microorganisms in laboratories. The manual complements AS/NZS 2243.3:2022 and is a useful reference which may be used to guide the implementation of systems and controls within the framework.

4. Definitions

In the context of the Health and Safety Management System Framework:

Biocontainment	System for confining microorganisms or organisms or other entities within a defined space.
Biohazard	A biohazard is a potential source of harm caused by biological risk group agents or toxins. Biohazards, which may provoke infection, allergy or toxicity in humans, animals or plants are classified in AS/NZS 2243.3:2022.
Biological safety officer	A person who is competent in the assessment and control of biohazards and has responsibility and authority for oversight of the control of biohazards.
Biorisk	Combination of the probability of occurrence of harm and the severity of that harm where the source of harm is a biohazard.
Biosafety	Biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biohazards, or their accidental release i.e. all the prevention measures carried out to avoid infection with pathogenic organisms and/or toxins and their release to the environment.
Biosecurity	Institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of biohazards. Laboratory biosecurity describes the protection, control and accountability for biohazards within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorised access or intentional unauthorised release.
Competent person	A person who has, through training, qualification or experience, acquired the knowledge and skills to carry out a specific task.
Containment	The act of restricting an organism or prion to a secure place to prevent escape, through a combination of physical components and operational practices and procedures. A containment facility is an example of a secure place. Physical components include buildings, engineering, equipment and systems.
Containment facility	A place that is designed, built and operated for the purpose of containment. A containment facility may include a combination of buildings, rooms and laboratories for holding microorganisms, animals, invertebrate and plants within a physical containment barrier. This may also include airlocks, access and support rooms, and interconnecting corridors.
Decontamination	A physical or chemical process that kills or removes pathogenic microorganisms, but does not necessarily result in sterility.
Gene Technology	Gene technology (also known as genetic engineering or genetic modification) provides ways to make changes to genes – the sets

	of instructions in the cells of all living creatures. There is a large amount of overlap between 'gene technology' and the newer term 'synthetic biology'.
GMO	A genetically modified organism (GMO), which is: - an organism that has been modified using gene technology; or - an organism that has inherited particular traits from an organism, being traits that occurred in the initial organism because of gene technology; or - anything that is, or that belongs to a class of things which is, declared to be a GMO under the *Gene Technology Regulations 2001* (Cth), other than the exceptions contained in the *Gene Technology Act 2000* (Cth) (i.e. certain human beings and organisms declared not to be GMOs).
IBC	An Institutional Biosafety Committee (IBC) established as such in accordance with written guidelines issued by the OGTR pursuant to the *Gene Technology Act 2000* (Cth). IBCs play an integral role in assisting compliance with Australia's national gene technology regulatory scheme laws. (refer to KRA 1.8).
Immunisation	A process where a person is made immune or resistant to an infectious microorganism through the administration of a vaccine.
Infectious microorganism	A microorganism capable of invading a susceptible host and multiplying in it, which may or may not cause a disease.
Leader / Supervisor	Any member of the University who is responsible for supervising staff and/or undergraduate or postgraduate students and/or for leading research projects.
Microorganism	A microscopic organism including protozoa, fungi, archaea, bacteria, unicellular algae, viruses and viroids.
OGTR	Office of the Gene Technology Regulator.
Pathogen	An infectious organism, usually microscopic, capable of causing disease in the host.
PPE	Personal protective equipment, which is anything used or worn by a person to minimise risk to the person's health and safety, including air supplied respiratory equipment.
Prion	A proteinaceous infectious particle that lacks nucleic acids, which can cause scrapie and other related neuro-degenerative diseases of humans and animals.
Risk Group	Organisms are classified into a risk group (RG1 to RG4) based on the criteria in AS/NZS 2243.3:2022.

Worker	As defined in the *Work Health and Safety Act 2011* (NSW). This definition includes (without limitation) employees (or staff), conjoints, students on work experience, contractors and sub-contractors and their employees, and volunteers.

5. Responsibilities

A comprehensive list of health, safety and wellbeing responsibilities is provided in HSG 1.2 Roles and Responsibilities Guideline.

Specific responsibilities under this Guideline include:

Nominated CEO or equivalent

- Ensure the University complies with the health, safety and compliance obligations related to conducting activities involving Biological material;
- Develop effective processes and standards, and advise and direct workers in the proper use and management of Biological material;
- Maintain and resource the system required for reviewing research, teaching and other activities involving biological material to ensure that safety and regulatory requirements are met;
- Provide relevant induction and training in the regulatory requirements of conducting activities involving biological material.

Infrastructure and Facilities Services (IFS)

- Ongoing servicing and maintenance of University Physical Containment facilities and related fixed infrastructure and fittings included; autoclaves, backflow prevention, pest control, handwash sinks, eyewash station;
- Ensure any maintenance or repair work to be conducted in the facility is discussed with the Biological Safety Officer to determine if it requires additional risk control strategies to maintain containment before the work proceeds.

Supervisors and Leaders

- Ensure workers who report to them are aware of this KRA;
- Ensure all work activities involving biological material have current safety approval which includes the IBC assessment before they are commenced;
- Report issues of non-compliance of workers in accordance with the KRA;
- Ensure a register of biological materials stored onsite is maintained;
- Support suitable representation of workers who report to them as members of the Institutional Biosafety Committee reflecting the volume of Gene Technology and Biological work conducted by their workers.

Institutional Biosafety Committee

- Assist the University to meet its compliance and safety responsibilities related to biological activities defined under AS/NZS 2243.3:2022 including with Australia's national gene technology regulatory scheme laws (refer to KRA 1.8);
- Provide advice on monitoring and surveillance of the continuing implementation of standards and guidelines;
- Review risk assessments and implications of microbiological components of research and teaching proposals before they commence;
- Participate in inspections of Physical Containment facilities;
- Review safety audits;
- Provide relevant work health and safety and compliance related biological advice.

Biological Safety Officer

- Provide advice and guidance to the University and its workers relating to biosafety, biorisk, biosecurity and biocontainment;
- Assist the University to meet its compliance and safety responsibilities related to biological activities as defined under AS/NZS 2243.3:2022;
- Provide advice on monitoring and surveillance of the continuing implementation of standards and guidelines;
- Participate in inspections of Physical Containment facilities;
- Review safety audits.

Health, Safety and Wellbeing Team

- Monitor the effectiveness of this KRA and support its implementation;
- Implement and maintain procedures to support this KRA;
- Provide training programs and assessment of workers to support this KRA;
- Overall monitoring and surveillance of the continuing implementation of standards
- and guidelines;
- Ensure that appropriate records are kept, including personnel training, immunisations;
- Provide relevant work health and safety and compliance related biological advice;
- Service the Institutional Biosafety Committee (IBC) and administer the safety review system;
- Conduct commissioning and decommissioning inspections of Physical Containment facilities;
- Conduct annual inspections of PC2 facilities and inspect PC1 facilities as required;

- Review any reports relating to non-compliance including breaches of containment and notify the OGTR as required by the Gene Technology legislation.

Local Safety Contact Person /Facility Manager

- The person with overall responsibility for operation of the laboratory or facility shall ensure that safe procedures are documented, put into practice, and reviewed and updated regularly;
- The person shall implement initial and continuing induction and training programs, ensure personnel are supervised and that maintenance is carried out in accordance with safe procedures;
- The person shall ensure that casual visitors have restricted access to the laboratory or facility;
- Ensure the local register of biological materials stored is maintained;
- Assist Supervisors and Leaders to ensure workers and students comply with this KRA;
- Report issues of non-compliance of workers in accordance with the KRA;
- Ensure any planned maintenance or repair work to be conducted in the facility is discussed with the Organisation Primary Contact Officer/s before the work proceeds.

Workers and students

- Staff members (or employees), students, visitors, contractors and other workers must comply with reasonable health and safety instructions, policies and procedures including this KRA, and exercise caution when working with biological material;
- Check and ensure work they undertake with biological material has safety clearance before the work is commenced and conduct work activities according to any conditions of approval and only in facilities and with equipment that meet the appropriate biosafety requirements and in accordance with the supporting process;
- Meet the conditions of any licence, permit or approval issued by the Office of the Gene Technology Regulator, Department of Agriculture, Fisheries and Forestry or Department of Health and Aged Care;
- Report any biosafety or compliance issues to Supervisors, their Leader or the Health, Safety and Wellbeing Team, in addition to lodging a report in the online Incident / Hazard Reporting System (AIMS).

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6. References & Related Documents

The following documentation is referenced in, or applicable to this Key Risk Area:

HSG 1.2 Roles and Responsibilities

HSG 8.5 Health Monitoring PDF, 466.33 KB

HSG 5.2 First Aid PDF, 344.09 KB

HSG 5.3 Emergency Response PDF, 252.05 KB

HSG 4.2 Health, Safety and Wellbeing Induction, Training and Competency PDF, 241.82 KB

KRA 1.5: Personal Protective Equipment (PPE) (PDF, 71 KB)

KRA 1.7: Laboratory Safety (PDF, 132KB)

KRA 1.8 Gene Technology

Institutional Biosafety Committee Terms of Reference

Work Health and Safety Act 2011 (NSW)

Work Health and Safety Regulation 2017 (NSW)

Gene Technology Act 2000 (Cth)

Gene Technology Regulations 2001 (Cth)

Biosecurity Act 2015 (Cth)

Biosecurity Regulation 2016 (Cth) (administered by the Department of Agriculture, Fisheries and Forestry); and

Biosecurity (Human Health) Regulation 2016 (Cth) (administered by the Department of Health and Aged Care)

National Health Security Act 2007 (Cth)

National Health Security Regulations 2018 (Cth)

AS 2243.1:2021 Safety in Laboratories, Part 1: Planning and operational aspects

AS/NZS 2243.3:2022 Safety in Laboratories, Part 3: Microbiological safety and containment

AS/NZS 2243.6:2010 Safety in Laboratories, Part 6: Plant and equipment aspects

AS/NZS 2982:2010 Laboratory design and construction

AS 3816:2018 Management of clinical and related wastes

ISO 35001:2019 Biorisk management for laboratories and other related organisations

Department of Health and Aged Care: Security Sensitive Biological Agent (SSBA) Standards (2013): for the handling, storage, disposal and transport of SSBAs and suspected SSBAs

Security Sensitive Biological Agents (SSBA) Regulatory Scheme

Safe Work Australia: – National Hazard Exposure Worker Surveillance: Exposure to biological hazards and the provision of controls against biological hazards in Australian workplaces (March 2020)

Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health and Aged Care, Canberra, 2022, immunisationhandbook.health.gov.au

Department of Agriculture, Fisheries and Forestry: Australian Biosecurity Import Conditions (BICON)

NOHSC National Code of Practice for the Control of Work-related Exposure to hepatitis and HIV (Blood-borne) Viruses (NOHSC 2010 (2003))

NHMRC Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019)
NSW Health Guideline: Work Health and Safety - Blood and Body Substances Occupational Exposure Prevention (2018)
WHO Laboratory Biosafety Manual (4th ed.)

7. Amendment History

Version	Date of Issue	Approval	Section(s) Modified	Details of Amendment
1	October 2023	CPCO		Original version with latest amendment, which combines existing information on the University web and sharepoint sites

8. Appendices

Nil