



Version	Approved by	Approval date	Effective date	Next full review
1.0	Vice-Chancellor	26 May 2022	26 May 2022	May 2025
Policy Statement				
Purpose	To provide a framework for the safety and security of all employees, contractors, volunteers, students, and members of the public when dealing with, or coming into contact with, potentially biohazardous material.			
Scope	<p>This policy applies across the University to employees, students, contractors, visitors and volunteers who:</p> <ul style="list-style-type: none"> • may handle or are potentially exposed to biological hazards • work in or need to service facilities where biohazardous materials are being used (including clinics, biological teaching and research laboratories, plant, insect, animal and aquatic facilities) • supervise personnel who handle biological hazards or work in these facilities. <p>This policy does not apply to the use of biological material that is not hazardous (e.g., plant and animal materials used in the preparation of food for human consumption; and biologicals used in standard clinical practice).</p>			
Policy Provisions				

1. Policy Statement

UNSW will provide a world-class campus environment that promotes health and safety and wellbeing. Our objective is that no person will come to harm while working, studying, visiting or transiting through UNSW. UNSW is committed to managing the risk to humans, animals and the environment of unintentional release of, or exposure to:

- biological hazards
- genetically modified organisms
- biological material that is controlled, regulated or prohibited
- biological material of security concern

As biosafety is a specific application of the safety policy, this policy is to be read in conjunction with the [Health and Safety Policy](#).

2. Biorisk and Biosecurity Management

UNSW must establish, document, implement, communicate, maintain, and continually improve a biorisk management system, including the processes needed, in accordance with the requirements of this Biosafety Policy and the relevant supporting documents.

- 2.1 UNSW provides appropriate and commissioned engineered controlled biological physical containment facilities for the containment, handling, storage and disposal of the type of organism or process being undertaken, and these facilities are inspected regularly as per regulatory requirements.
- 2.2 UNSW will enable workers to comply with legislative requirements, mandatory codes and Standards that are applicable to their work with biological materials, or in areas where work with biological material is undertaken.
- 2.3 UNSW must appropriately manage the import of biological material which involve any Risk Group 1 organisms and above, as determined by AS/NZS2243.3, or Security Sensitive Biological Agents ([SSBA](#)), GMOs or any material which is governed by the [Biosecurity legislation](#), as set out in the relevant legislation.

- 2.4 UNSW is an accredited organisation under the *Gene Technology Act 2000* (Cth) and will continue to meet the requirements and conditions described in the [Guidelines for Accreditation of Organisations of the Office of the Gene Technology Regulator](#) (OGTR). All intended dealings of any genetically modified material shall be risk assessed and approved by the Gene Technology Research Committee (GTRC) before any material is brought into UNSW and prior to any work commencing. Furthermore, all intended work with Risk Group 3 organisms shall be risk assessed and approved by the GTRC before any material is brought into UNSW and prior to any work commencing. The Pro Vice-Chancellor Research & Enterprise (PVCRE) is the signatory for these approved proposals. See [Regulated Biological Materials Research Procedure](#) for Terms of Reference.
- 2.5 Resources will be provided to enable all work with Risk Group 2 organisms, as defined by AS/NZS 2243.3, to be risk assessed and authorised at a local level by trained and authorised members of staff prior to commencing any work with biological materials.
- 2.6 UNSW will resource, maintain and update a centralised Biohazardous Material Register of all Biohazardous Materials, including Risk Group 1 organisms and above as defined by AS/NZS 2243.3, or Security Sensitive Biological Agents ([SSBA](#)), GMOs or any material which is governed by the [Biosecurity legislation](#), currently held at all identified and documented locations where related UNSW work is carried out.
- 2.7 UNSW will establish, document, and maintain procedures to define, report, record and analyse any incident involving biological materials, including any noncompliance with the relevant governing Acts, Regulations and Standards. Records of the nature of the incident and any subsequent action taken must be maintained and appropriate processes put in place to encourage learning from incidents involving biological materials
- 2.8 Training (central and local), information and advice will be provided on the requirements, procedures and guidelines that apply to any work with biological materials, including biohazardous materials (Risk Group 1 and above) and GMOs. All training must be successfully completed, competency assessed and documented **prior** to work commencement. Each area will determine the level of competency required as determined by the risk involved and will put in place documented criteria for assessment. The required training should be revisited and renewed within the appropriate timeframe, depending on the training. ([Central: Training | Safety \(unsw.edu.au\)](#))
- 2.9 UNSW will define and document the roles and responsibilities of competent people, in particular for those who identify, control and manage biosafety, biosecurity and work associated with the risk management of biological materials.
- 2.10 UNSW will meet its statutory obligations set out under State and Federal law in relation to working with biological material including the provision of the appropriate Personal Protective Equipment (PPE) as outlined in [HS659 Personal Protective Equipment Guideline](#).
- 2.11 UNSW must ensure that all Human and Animal ethical permissions have been assessed and approved through the [UNSW RECS](#).
- 2.12 UNSW maintains health monitoring guidelines which include appropriate vaccination, and allergen monitoring ([HS091 Health Monitoring Guideline](#)).
- 2.13 UNSW has established waste treatment and disposal processes that follow appropriate legislation for storage, transport, and disposal. [HS321 Laboratory Hazardous Waste Disposal Guideline](#)
- 2.14 UNSW will determine a three-year planned audit program for all biosafety and biorisk documented policy, procedure, guidelines and resources and their implementation in all governed areas in UNSW.

3. Regulatory Framework

UNSW must ensure that all work involving biological material as defined shall be conducted as required by the appropriate aligned legislation as outlined in the [Appendix - Regulatory Framework](#).

Accountabilities	
Responsible Officer	Director, UNSW Risk and Safety
Contact Officer	Senior Manager, UNSW Safety and Injury Management
Supporting Information	
Legislative Compliance	<p>This policy supports the University's compliance with the following legislation:</p> <p>Biosecurity Act 2015 (Cth)</p> <p>Gene Technology Act 2000 (Cth)</p> <p>National Health Security Act 2007 (Cth)</p> <p>All work involving biological material must be conducted as required by the appropriate aligned legislation in the Appendix - Regulatory Framework</p>
Aligned Document	Health and Safety Policy
Supporting Documents	<p>UNSW Biosafety website: Biological Safety (unsw.edu.au)</p> <p>Biosafety Management</p> <p>Biosafety Risk Management Procedure</p> <p>HSMS Review Procedure (HS319)</p> <p>Regulated Biological Materials Research Procedure</p> <p>Risk Management Procedure (HS329)</p> <p>UNSW RECS</p>
Related Documents	See Appendix - Regulatory Framework
Superseded Documents	Nil
File Number	2022/032986
Definitions and Acronyms	
Biological/Biohazardous material	A biological hazard 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 2243.3:
Biosafety	The application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards. Biosafety defines the containment conditions under which infectious agents can be safely manipulated.
Biosafety Advisor/Officer /Coordinator	A Competent individual who is designated to provide advice, guidance and assurance on biorisk management. The role shall report directly to Senior Management and have delegated authority to prohibit work in the event that it is considered necessary to do so. The role should be independent of those responsible for implementing the programme of work. (ISO 35001:2019)
Biorisk	Biorisk is the effect of uncertainty expressed by the combination of the consequences of an event (including changes of circumstances) and the associated "likelihood" of occurrence where biological material is the source of harm.
Biosecurity	The measures taken to minimise the risk of infectious diseases caused by viruses, bacteria or other microorganisms, insects & pests, entering, emerging, establishing or spreading in Australia, potentially harming the Australian population, our food security and economy.
Genetically Modified Organism (GMO)	A Genetically Modified Organism is an organism which has; <ul style="list-style-type: none"> a. been modified by gene technology; b. a mutation that involved the introduction of foreign nucleic acids; c. inherited particular traits from an organism (the <i>initial organism</i>), being traits

	<p>that occurred in the initial organism because of gene technology; or d. anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;</p> <p>but <i>does not</i> include: e. a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or f. an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.</p>			
GTRC	<p>Gene Technology Research Committee The GTRC is the University's primary body responsible for ensuring all practices involving gene technology, biosecurity-regulated materials and biologically-hazardous materials of Risk Group 3 and above are conducted in accordance with the governing legislation including the Gene Technology Act 2000, Gene Technology Regulations 2001 and ASNZS 2243.3.</p>			
IATA	<p>The International Air Transport Association (IATA) The 63rd edition of the Dangerous Goods Regulations includes the provisions on competency-based training and assessment (CBTA) as agreed by the ICAO Dangerous Goods Panel in DGP/27 (September 2019). There is a two-year transition period and therefore, the training provisions from the 61st edition may continue to be used until 31 December 2022. The IATA Dangerous Goods Regulations describe the markings and, if required, the labels required on packages for air transport</p>			
IBC	<p>Institutional Biosafety Committee The IBC is the University's primary body responsible for ensuring all practices involving biological material adhere to the Australian and International Standards. This includes AS2243.3 Safety in Laboratories – Microbiological Safety and Containment and ISO 35001, Biorisk Management and other codes of practice, and licensing requirements.</p>			
Import Permit	<p>A permit issued by the Department of Agriculture, Water and Environment (BICON) for the import of conditionally prohibited materials to Australia.</p>			
OGTR	<p>Office of the Gene Technology Regulator (DoH)</p>			
Physical Containment (PC) Facility	<p>A physical containment facility (PC facility) is a facility that involves the combination of building, engineering, equipment and practises to handle microorganisms safely and to protect users and the environment as described in AS/NZ 2243.3</p>			
PC1-4	<p>Physical Containment level 1 to level 4 (lowest containment level through to highest) • As described in AS/NZS 2243.3, for handling material that may contain microorganisms of the corresponding Risk Group level. • As described by the OGTR to explain the categories of organisms and types of dealings intended to be contained in each facility type. These levels are intended to harmonise as closely as possible with the Risk Group levels</p>			
PPE	<p>Personal Protective Equipment</p>			
Risk Group	<p>Risk Groups are classifications for microorganisms that are infectious for humans, animals and plants, based on pathogenicity, host range, mode of transmission, plus availability of effective preventative measures and effective treatment. Risk groups are designated from 1 (the lowest risk) to 4 (the highest risk).</p>			
SSBA	<p>Security Sensitive Biological Agents as defined by the DoH. The SSBA Regulatory Scheme builds on Australia's obligations under the Biological and Toxins Weapons Convention and UN Security Council Resolution 1540.</p>			
Revision History				
Version	Approved by	Approval date	Effective date	Sections modified
1.0	Vice-Chancellor	26 May 2022	26 May 2022	This is a new policy

Appendix: Regulatory Framework

Legislation

Gene Technology

Gene Technology (Licence Charges) Act 2000, *Gene Technology (New South Wales) Act 2003 No 11* ([OGTR](#))

This Act, consisting of 20 sections divided into six Parts, aims at adopting 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](#) and the [Gene Technology \(Licence Charges\) Act 2000](#)* of the Commonwealth as a law of the State. The Act contains provisions on offences and penalties and on the administrative laws.

Biosecurity

[Biosecurity Act 2015](#), [Export Control Act 2020](#), [Imported Food Control Act 1992](#)

The Department of Agriculture, Water and the Environment administers the *Biosecurity Act 2015*, *Export Control Act 1982*, *Imported Food Control Act 1992* 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 Act:

- The [Biosecurity Regulations 2016](#) (administered by the Department of Agriculture, Water and the Environment); and
- The [Biosecurity \(Human Health\) Regulations 2016](#) (administered by the Department of Health).

Australian Standards

AS/NZS 2243.3-2010 Safety in laboratories Part 3: Microbiological safety and containment

Compliance with *Australian/New Zealand Standard 2243.3 Safety in Laboratories – Microbiological Safety and Containment* (“AS2243.3”) is enforced by both the Biosecurity Regulations 2016 and the Gene Technology Regulations 2001 and provides an outline of requirements for construction and operation of containment facilities. It also categorises microbiological agents into risk groups based on their individual and community risk. 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 biorisk management system establishes the biorisk management principles that enable laboratories and related facilities to achieve their biosafety and biosecurity objectives. ISO 35001 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 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 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 AS2243.3 and is a useful reference which may be used to guide the implementation of systems and controls within the framework.

The International Air Transport Association (IATA)

The 63rd edition of the [Dangerous Goods Regulations](#) includes the provisions on competency-based training and assessment (CBTA) as agreed by the ICAO Dangerous Goods Panel in DGP/27 (September 2019). There is a two-year transition period and therefore, the training provisions from the 61st edition may continue to be used until 31 December 2022. The IATA Dangerous Goods Regulations describe the markings and, if required, the labels required on packages for air transport

NHMRC Guidelines

The National Health and Medical Research Council Act (1992) enables NHMRC to issue evidence-based guidelines in areas relating to human health. NHMRC guidelines are based on a review of the available evidence and follow transparent development and decision-making processes. They are informed by the judgement of evidence by experts, and the views of consumers, community groups and other people affected by the guidelines. In regard to ethical issues, NHMRC guidelines reflect the community's range of attitudes and concerns. There are robust processes in place to [manage conflict of interest](#) and to use the best available scientific methods for making recommendations such as the use of [GRADE](#) (an internationally recognised approach to rate the [certainty of evidence](#) and the strength of recommendations).

To support the development of the highest quality guidelines, NHMRC also provides:

- [Standards for Guidelines](#) which apply to all guidelines containing recommendations for clinical practice, public health and environmental health.
- The [Guidelines for Guidelines Handbook](#), containing practical and in-depth information on how to develop guidelines that meet the NHMRC Standards
- The [Clinical Practice Guidelines in Development Register](#), which allows developers to share information about their guideline in development
- The [Australian Clinical Practice Guidelines Portal](#), which allows Australian clinicians and consumers to find clinical practice guidelines through a single website
- an approval program for certain high quality national guidelines which have been developed to rigorous standards.

Australian guidelines for the prevention and control of infection in health care

The Guidelines provide a nationally accepted approach to infection prevention and control, focusing on core principles and priority areas for action. They provide a basis for healthcare workers and healthcare facilities to develop detailed protocols and processes for infection prevention and control specific to local settings.

This approach is underpinned by a risk-management framework to ensure the basic principles of infection prevention and control can be applied to a wide range of healthcare settings including hospitals, day procedure units, office-based practice, long-term care facilities, remote area health services, home and community nursing and emergency services.

It is recognised that the level of risk may differ according to the different types of facility and therefore some recommendations should be justified by risk assessment. When implementing these recommendations all healthcare facilities need to consider the risk of transmission of infection and implement according to their specific setting and circumstances.

The evidence base for the Guidelines addresses the highest level of risk of infection transmission in the healthcare setting and has predominantly been drawn from the acute-care setting. The recommendations should be read in the context of the evidence base and the advice on the practical application of the recommendations.

The Australian Immunisation Handbook

The handbook provides clinical advice for health professionals on the safest and most effective use of vaccines in their practice.

These recommendations are developed by the [Australian Technical Advisory Group on Immunisation](#) (ATAGI) and approved by the [National Health and Medical Research Council](#) (NHMRC).