MACQUARIE University
SYDNEY·AUSTRALIA

Biosafety and Biosecurity Manual

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1. Abbreviations and Definitions

1.1 Abbreviations

AA	Approved Arrangements
AEC	Animal Ethics Committee
BC	Biosecurity Containment
BSC	Biological Safety Cabinet
BICON	Biosecurity Import Conditions
CAF	Central Animal Facility
CBD	Convention on Biological Diversity (United Nations)
DAWE	Department of Agriculture, Water and the Environment
DNIR	Dealings Not Involving Intentional Release
EPA	Environment Protection Authority
GMO	Genetically Modified Organism
HDR	Higher Degree Research
IBC	Institutional Biosafety Committee
NHMRC	National Health and Medical Research Council
NLRD	Notifiable Low Risk Dealing
OGTR	Office of Gene Technology Regulator
PC	Physical Containment
POEO	Protection of the Environment Operations Act
PPE	Personal Protective Equipment
QAP	Quarantine Approved Premises
SMO	Synthetically Modified Organism
SOP	Standard Operating Procedures
SSBA	Security Sensitive Biological Agents
SWI	Safe Work Instructions
WHO	World Health Organisation
WHS	Work Health and Safety

1.2 Definitions

Act means the Gene Technology Act 2000 (Cth);

Approved Arrangement (previously Quarantine Approved Premises and Compliance Agreements) means a voluntary arrangement entered into with the Department of Agriculture, Water and the Environment. These arrangements allow operators to manage biosecurity risks and/or perform the documentary assessment of goods in accordance with departmental requirements;

AEC means the University's Animal Ethics Committee established in accordance with the Guidelines under the Animal Research Act 1985 (NSW), Animal Research Regulation 2010 (NSW) and the Australian Code for the Care and Use of Animals for Scientific Purposes (8th Edition)(the Code);

Animal means any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals encompassing domestic animals, purpose-bred animals, livestock, wildlife), cephalopods and Decapod Crustaceans.

AS/NZS 2243.3:2010 means Standards Australia, "Safety in laboratories Part 3: Microbiological safety and containment" and any modification or replacement thereof;

BC means biosecurity (quarantine) containment and when followed by a numeral is a specified quarantine containment level in accordance with guidelines made by the Department of Agriculture, Water and the Environment;

Biological hazard means any organism or biologically derived infectious agent that is hazardous to humans or animals, or which may negatively impact the environment;

Biosafety means measures relating to the protection of an environment or population, from contamination with or infection by a biological agent;

Biosecurity means the methods that are used to stop a disease or infection from spreading from one person, animal, or place to others;

Containment Level means the degree of physical confinement of GMOS provided by a facility, having regard to the design of the facility, the equipment located or installed in the facility and the procedures generally used within the facility;

Dealing means, as defined in the Act, and in relation to a GMO:

a) conduct experiments with the GMO;
b) make, develop, produce or manufacture the GMO;
c) breed the GMO;
d) propagate the GMO;
e) use the GMO in the course of manufacture of a thing that is not the GMO;
f) grow, raise or culture the GMO;
g) import the GMO;
h) transport the GMO;
i) dispose of the GMO;

and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i);

DIR means Dealings involving Intentional Release as defined in the Gene Technology Regulations 2001;

Disinfectant means a physical or chemical means of killing microorganisms, but not necessarily spores;

Exempt Dealing means activities with GMOs which are classified under the Gene Technology Act as exempt from licence;

Gene Technology Act means the Gene Technology Act 2000 (Cth);

GMO means a genetically modified organism as defined by the Gene Technology Act under s 10;

Guidelines mean the Guidelines for Accreditation of Organisations 2012 and the Explanatory Information on the Guidelines for Accreditation of Organisations v 1.4 issued by the OGTR;

Hazard means a situation or thing that has the potential to harm a person. Hazards at work may include manual tasks, biological, radiation, hazardous chemicals, noise, electricity, machinery and equipment;

High Risk Microorganisms mean Risk Group 2 and above microorganisms, SSBAs and agents requiring containment or approval under the Quarantine Act;

IBC means the University's Institutional Biosafety Committee established in accordance with the Guidelines under s 98 of the Gene Technology Act;

NLRD means a Notifiable Low Risk Dealing as defined in the Gene Technology Regulations 2001;

OGTR means the Office of the Gene Technology Regulator established pursuant to s 26 of the Act;

Organism means any biological entity that is viable; or capable of reproduction; or capable of transferring genetic material;

PC means physical containment and when followed by a numeral is a specified containment level in accordance with guidelines made by the Gene Technology Regulator under s 90 of the Act;

Quarantine Act means the Quarantine Act 1908 (Cth) and, on and from the 16 June 2016, the Biosecurity Act 2015 (Cth) which replaces the Quarantine Act;

Regulations mean the Gene Technology Regulations 2001;

Regulator means the Offic of the Gene Technology Regulator;

Risk control means taking action to eliminate health and safety risks so far as is reasonably practicable, and if that is not possible, minimising the risks so far as is reasonably practicable. Eliminating a hazard will also eliminate any risks associated with that particular hazard;

Risk Group is a numerical classification of infectious microorganisms as defined in the AS/NZS 2243.3:2010;

Risk is the likelihood that harm might occur when exposed to a hazard, as well as the consequence (death, injury or illness;

SSBAs mean security sensitive biological agents pursuant to the National Health Security Act 2007 (Cth), the National Health Security Regulations 2008 and the Security Sensitive Biological Agent Standards 2009;

University means Macquarie University.

2. Introduction

2.1 Purpose and Scope

There are many biological hazards (biohazards) that can be encountered at Macquarie University teaching and research laboratories. Laboratories where biological materials are handled and stored must have the appropriate training, approvals, practices and equipment in place to manage the associated risks. This manual provides information on relevant legislative requirements and safe work practices when working with or being exposed to biological materials. The guidelines within this manual have been developed to complement other biosafety and Work Health and Safety (WHS) management information from:

- Australian Standards AS/NZS2243.3 series (SAI Global available through the MQ library)
- The Office of the Gene Technology Regulator (OGTR)
- Australian Department of Agriculture, Water and the Environment (DAWE)
- Security Sensitive Biological Agents (SSBA) Regulatory Scheme
- The World Health Organisation
- SafeWork NSW

This manual covers basic biological safety requirements and it is expected that individual Faculties and Departments will develop and implement local safety instructions that are designed to meet their specific requirements but remain compatible with these guidelines. This manual should be used in conjunction with the IBC approved information on the WHS SharePoint Hub (Biosafety & Biosecurity) and The Macquarie University Code for the Responsible Conduct of Research.

2.2 Policy

The University Biosafety and Biosecurity Policy is the enabling policy for this guide. Key provisions of the Policy state that Macquarie University will:

- Maintain an appropriately constituted Institutional Biosafety Committee (IBC) who are provided with the resources required for monitoring all biological work at the University.
- Ensure, through the IBC, that all research, teaching and services at the University involving biohazardous materials, genetically modified organisms (GMOs), security sensitive biological agents (SSBAs) and agents requiring quarantine containment are conducted in accordance with the relevant legislation, regulations, guidelines and codes.
- Ensure dealings with GMOs, the use of microorganisms classified as Risk Group 2 and above; animals potentially containing zoonotic microorganisms classified as risk group 2 and above; SSBAs or agents requiring containment or approval under the

Biosecurity (Consequential Amendments and Transitional Provisions) Act 2015, are not commenced without the prior approval of the IBC.

- Ensure it maintains certification of OGTR and quarantine approved facilities.
- Enable the IBC to conduct monitoring inspections, at least annually, of the University's certified laboratories to ensure compliance with the relevant Acts, regulations, guidelines and codes.
- Ensure information is available and training implemented for personnel involved in the acquisition, handling, storage, removal or disposal of biological materials on University premises to ensure that such personnel are aware of potential risks.

Macquarie University expects its staff, HDR candidates, students, researchers, contractors and visitors to adhere to this manual and to the University's Biosafety and Biosecurity Policy to maintain a safe and healthy environment by minimising the risks from biological work procedures. To reach this standard, work with biological material will be guided by current Acts, regulations, Codes of Practice, Australian Standards and University policy and procedures. See Appendix 1 for a detailed list of biosafety legislation.

Macquarie University requires that:

- Biological materials are obtained, transported, stored and disposed of in an ethical and responsible manner.
- Biological materials are handled in a way that will not put at risk the health and safety of any individual, the community and the environment.
- University staff and students comply with training requirements.
- University staff and students are provided with sufficient information, instruction, and supervision to handle microorganisms, biohazardous materials and GMOs safely.

2.3 Objectives

The objectives of this manual are to ensure that:

- All staff, students, researchers, and visitors are aware of the biological hazards, legislative requirements, Australian Standards and University policy and procedures associated with working with microorganisms and biohazardous material.
- Staff, students and researchers are aware of their responsibilities in regard to biological safety at Macquarie University.
- All staff, students, researchers, and visitors receive appropriate training and information that enables them to recognise potential hazards associated with their work.
- All research and teaching involving GMOs, SSBAs, risk group 2 and above microorganisms, clinical and diagnostic samples, animal and human tissues, blood or body fluids, and materials requiring quarantine containment is assessed by the IBC. The use of humans, animals and their tissue, blood or body fluids in research and teaching receives approval from the appropriate (Human or Animal) Ethics Committees prior to commencement of work.
- All research and teaching involving non-pathogenic microorganisms or other biological material or agent unlikely to cause human or animal disease or harm the

environment are risk assessed by the Chief Investigator prior to the commencement of work.

- Microorganisms, clinical and diagnostic samples, animal and human tissues, blood or bodily fluids, and materials requiring quarantine containment is assessed by the IBC.
- Risk management procedures are in place in the event of biological spills.
- Appropriate waste disposal systems are in place for biological materials.

3. Management Structure and Responsibility

3.1 Deputy Vice Chancellor (Research)

The Deputy Vice Chancellor (Research) is responsible to the Vice Chancellor for the Macquarie University IBC and that committee's implementation of requirements as specified by the OGTR and other regulatory bodies.

3.2 Institutional Biosafety Committee

Under OGTR legislation, all work involving GMO's must be reviewed by IBC. The Macquarie University IBC is responsible for:

- Reviewing research, teaching and other applications which involve the use of and dealings with risk group 2 and above microorganisms, animals potentially containing risk group 2 and above zoonotic microorganisms, GMOs, quarantine materials and SSBAs.
- Ensuring that the use of GMOs within the university is conducted in compliance with the Gene Technology Act 2000 and the Gene Technology Regulations 2001.

3.3 University Biosafety Officer

The University Biosafety Officer is authorised to advise and report on biosafety and quarantine matters. The Biosafety Officer assists the IBC in ensuring compliance of OGTR and quarantine approved facilities.

3.4 Deans and Heads of Department

Deans and Heads of Department are responsible for ensuring that all employees and students receive appropriate information and training necessary for them to work and conduct their research safely and in accordance with this manual. They are to ensure that Technical and Facility Managers have resources to develop and implement procedures necessary to ensure that biosafety guidelines are met.

3.5 Laboratory and Facility Managers

Laboratory and Facility Managers are responsible for monitoring laboratory access and authorisation. They are to ensure that staff and students teaching, working or conducting research in their laboratories have undergone the appropriate laboratory safety induction prior to commencing. Managers of certified facilities (OGTR and quarantine) are to maintain all laboratory documentation required for their certification.

3.6 Chief Investigators

Chief Investigators (including Principal Investigators, Academic Supervisors, Research Supervisors and Unit Conveners) are responsible for the health and safety of the undergraduate and postgraduate students they supervise in addition to volunteers and staff employed under them.

They are to ensure that their students and staff have received the appropriate laboratory safety induction and training to enable them to undertake their work safely and that associated risk assessments have been completed.

3.7 Staff, Students and Volunteers

Staff, students and volunteers working with biological hazards must ensure that they follow safety guidelines set out by Macquarie University and their respective Facility Manager and Chief Investigators. They are to ensure that their actions do not put themselves, or any other individual at risk.

4. Health Management

4.1 Immunisation

People working with infectious organisms, blood or bodily fluids or in animal holding facilities should routinely review their need for immunisation against vaccine preventable diseases. Additionally, people who are immunosuppressed, immunocompromised or involved in any of the following activities should consider their need for immunisation:

- Field work
- Working with waste or contaminated water or soil
- Working with animals or inverterbates
- First aid administration

It is mandatory for Chief Investigators to undertake a thorough risk management assessment to identify risks specific to any human pathogen brought into a facility and to which they or other research members may be exposed.

For a comprehensive guide to immunisations please visit:

- MQ Immunisation Policy & Procedures
- The Australian Immunisation Handbook
- World Health Organisation website
- The Australian Federal Government Smart Traveller
- NSW Health occupational immunisation requirements

Tetanus, Hepatitis A, Hepatitis B and Q Fever are notifiable diseases in all states and territories in Australia. In NSW if an employee contracts Q fever it must be reported to SafeWork NSW.

4.1.1 Tetanus

Tetanus is a disease caused by a toxin produced by *Clostridium tetani*. Any tetanus-prone wound can become contaminated with *C. tetani*. Tetanus-prone wounds are those other than clean, minor cuts and include:

- Wounds where disinfection has been delayed by more than 4 hours
- Compound fractures
- Bites
- Deep penetrating wounds
- Wounds containing contamination or foreign bodies (wood, dust, soil, manure)

Those at risk of tetanus include:

- Anyone at risk of scratches, bites and cuts from animals or their cages
- Anyone handling *C. tetani* or its toxin
- Outdoor workers

4.1.2 Hepatitis

Hepatitis A is one of several different hepatitis viruses that can cause infections and damage to the liver. Hepatitis A is caused by the hepatitis A virus and it is highly contagious and can be particularly dangerous for people with pre-existing liver problems. The virus is spread by the faecal oral route and can survive on hands, in food and in water for prolonged periods of time.

Hepatitis B is a potentially life-threatening disease caused by the hepatitis B virus. The Hepatitis B virus is spread through contact with blood and other bodily secretions. Immunisation is an effective way of protecting against hepatitis A and B viruses. Currently for Hepatitis C there is no immunisation or completely effective treatment.
Those at risk of hepatitis infections include anyone who:

- Handles a hepatitis virus
- Is exposed to human faecal material, blood, liver tissue and bile and other bodily secretions
- Works with non-human primates
- First aiders

4.1.3 Q fever

Q fever is amongst the most serious infective hazards and is a WorkCover-reportable illness in NSW. Q fever is a zoonotic infectious disease caused by the bacterium *Coxiella burnetii*, which can be harboured in numerous domesticated and wild animals. *C. burnetii* is highly infectious and is transmitted to humans via aerosols from contaminated body fluids of infected animals.
People considered at risk of exposure are those working with or handling:

- *Coxiella burnetii* as part of their work
- Animals potentially infected, especially pregnant animals, including native animals (e.g. kangaroos), companion animals (cats and dogs) and stock animals (pigs, sheep, cattle)
- Unfixed tissues, including carcasses from potentially infected animals
- Unfixed human samples (blood or tissue) that could be from individuals with Q fever

4.2 Precautions for Pregnant Women

Minimising laboratory risks for pregnant women is especially important due to the sensitivity of the foetus to specific biological agents. All lab workers should know the hazards associated with the materials with which they work and it is important to recognise that an individual's susceptibility to those hazards may change due to factors such as pregnancy. In all cases, a pregnant woman should discuss her laboratory environment with her medical care professional and provide specific information about potential exposures.

4.3 Personal Hygiene

To prevent the spread of laboratory contaminants, it is important to use good microbiological techniques, wear the provided personal protective equipment (PPE) and ensure that hands are

washed after completing a procedure, and before leaving the laboratory. Refer to the World Health Organisation's guidelines for good hand washing technique found on the WHS SharePoint Hub (Biosafety & Biosecurity).

4.4 Exposure incidents

The Action Plan for Exposure to Biohazardous Materials should be implemented when there has been, or there is reason to believe there has been, an exposure to a biological hazard of concern such as a needle-stick injury or a cut, or a mucous membrane exposure to human blood or other body fluids (see the WHS SharePoint Hub (Biosafety & Biosecurity) site for the **Action** Plan).

A *gamma globulin* inoculation (for infection resistance) should be accessed with 24 hours of a needle stick injury where a Hepatitis A infection is a concern.

A needle stick or sharps injury should be reported immediately as per the Action Plan for Exposure to Biohazardous Materials.

Report the incident to your manager or supervisor and the relevant Lab Supervisor if applicable. This should occur as soon as possible after the injury/incident.

Submit a report via MQ online reporting form: https://staff.mq.edu.au/support/other-resources/online-systems/roar as soon as possible, within 24 hours

Refer the incident to the MQ Health Monitoring Advisor as soon as possible via occupationalscreeningandimmunisation@mq.edu.au

5. Research Approval and Risk Management

5.1 The Institutional Biosafety Committee (IBC)

The Macquarie University IBC help to minimise the risks associated with working with biological materials by asking Chief Investigators to complete an online Biosafety Application with an inbuilt risk assessment. Biosafety Applications are maintained by the IBC and are subject to routine monitoring to ensure the specified risk management strategies are being followed. The IBC also confirms that particular laboratories meet a physical containment level under OGTR, quarantine and AS/NZS 2243.3 specifications. The IBC is charged with monitoring all GMO, recombinant and synthetic biology projects and reports to the OGTR. This is done intermittently throughout the financial year or as a bulk-report at the end of the financial year.

At Macquarie University, Biosafety Applications are required for all research, teaching or services that involve the use of biological materials. Biosafety Applications are submitted online and are reviewed by the IBC via an expedited review process between February 1st – November 30th. Outside of this time period, applications are still reviewed but may take longer due to reduced IBC capacity.

5.2 Biosafety Management and Support

Work involving any of the below categories must not commence until IBC approval has been granted and the Macquarie University Biosafety Awareness and Gene Technology courses have been completed:

- Microorganisms classified as risk group 2 and above
- GMOs

- SSBAs
- Agents requiring containment under the Biosecurity Act 2015
- Animals with the potential to carry zoonotic agents classified as risk group 2 and above
- Human and animal clinical and diagnostic samples

A Biosafety Application form for work involving the use of risk group 1 microorganisms (including animals with the potential to carry risk group 1 zoonoses) or other biological material or agent that is unlikely to cause human or animal disease or harm the environment is still required, however it is treated as a **notification** only.

Applications must be submitted via the FoRA (Forms for Research Applications) system using your OneID and password. All applications must be approved by the Chief Investigator prior to an IBC submission.

Biosafety Applications are approved for a period of five years, and for GMO projects approval is under the provision of annual reporting. All biosafety applications are subject to IBC audit and inspection.

The use of humans, animals and their tissue, blood or body fluids in research and teaching may require additional approval from the appropriate Human or Animal Ethics Committees prior to commencement of work.

For more information and supporting resources relating to submitting applications, safety documentation, the review process, and managing approved projects please refer to the Biosafety Management support page located on the University Wiki or the WHS SharePoint Hub – Biosafety & Biosecurity.

For clarification of GMO Dealings visit the OGTR website or the Macquarie University GMO Classification tables.

5.3 Risk management

5.3.1 Hierarchy of control

A risk assessment section has been built into the Biosafety Application. The information requested on the risk assessment section is necessary to give the IBC and Chief Investigator enough information to decide if the work can be carried out safely and, in a laboratory, equipped to meet biosafety needs.

The risk assessment section follows a globally accepted risk management process known as the hierarchy of control. The hierarchy of control creates a systematic approach to manage biological risks safely by providing a structure to select the most effective control measures to eliminate or reduce the risk of hazards associated with a particular research project. The hierarchy of control has six levels of control, the most effective measure is at the top, the least effective at the bottom. As best practice it is recommended to try to incorporate the use of high end controls such as elimination, substitution, isolation and engineering controls as opposed to the use of low end controls such as administrative and the use of personal protective equipment. The hierarchy of control is included in all Risk Assessment Forms to provide a systematic approach for managing the risk associated with biological research hazards.

The hierarchy of control involves the following six steps;

1. Elimination – remove the cause of danger completely (e.g. inactivate infectious source).

2. Substitution – controls the hazard by replacing it with a less risky way to achieve the same outcome (e.g. use of a less pathogenic organism).

3. Engineering /bioengineering controls – Isolate the hazard from people and the environment by using physical or biological safety features to plant or equipment (e.g. Physical containment facility, Class II biosafety cabinet vaccines).

4. Administration – use of administrative controls to lessen the risk (e.g. signage, risk assessments and safe work procedures, training).

5. Personal Protective Equipment (PPE) – provides a personal barrier between the user and the infectious/toxic substance (e.g. gloves, eye protection, lab coat).

Note: The use of PPE to reduce the risk of an hazard should always be the last resort.

For more detailed information please refer to the *SafeWork NSW, Code of Practice: How to manage work health and safety risks.*

5.3.2 Responsibility of the Chief Investigator

The Chief Investigator must ensure:

- Research and technical personnel have read risk assessments before work starts.
- Hard copies of risk assessments are available in the laboratory for reference.
- Research and technical personnel have received sufficient training and/or supervision to allow them to work and handle biological agents and materials in a safe manner.
- Faulty equipment is reported and removed from service where a danger exists.
- Safe Working Procedures are followed.
- Safety rules are followed.
- Emergency equipment is serviced.
- The physical containment level is appropriate for the risk group.
- Incidents, accidents and near miss occurrences are reported to the health and safety unit.
- Regular compliance checks and safety tours are carried out and any findings are documented.
- That they familiarise themselves with the AS/NZ 2243.3 standard.

5.3.3 Responsibility of Research and Technical Personnel

Research and technical personnel include, but is not limited to staff, students, animal care staff, research assistants and volunteers. Research personnel must ensure that they:

- Read the relevant risk assessment and relevant guidance material.
- Follow all relevant Safe Work Procedures and guidelines.

- Report any faulty equipment.
- Attend required training.
- Speak to a supervisor or laboratory manager about any safety concerns.
- Comply with the relevant safety rules and guidelines.

5.3.4 Register of Biological Hazards

The register of biological hazards lists all biologically hazardous materials and microorganisms used and stored in teaching and research laboratories. Hard copies of risk assessments are to be maintained in these laboratories and made available to personnel who conduct work in those laboratories. The register must be updated annually and should also indicate whether any SSBAs are being held.

5.3.5 Inductions

Any person entering a facility must comply with the local processes for induction. The level and detail of the safety induction should depend upon the risk and legislative requirements associated with procedures/work carried out and the materials and equipment stored within the lab. Induction records must be kept and maintained. Access and authorization requirements will be determined on the risk associated with the procedures/work carried out and the materials stored within the laboratory.

5.3.6 Training

All persons handling biological materials or agents are required to complete the following mandatory MQ on-line courses;

- **Biosafety Awareness**
- **Gene Technology**

Access the WorkDay e-learning platform and self-enrol here.

To obtain access to MQ PC2 facilities you will be required to submit proof of completing these courses - a certificate can be downloaded from your WorkDay profile. You may also be required to have completed other MQ laboratory safety courses (and submit proof) including;

- Laboratory Essentials
- Hazardous Chemicals

Every new PC2 User needs to read and understand the local **PC2 Facility Manual** outlining the physical and behavioral requirements and the relevant SOP's and SWI's.

A **local induction** will also be conducted with the relevant Facility Manager (or a delegate of) according to an induction checklist specific for the PC2 facility and based on the local Facility Manual.

Quarantine training is mandatory for individuals working with quarantine materials within any of the University's Approved Arrangements (AA) unless an exception is approved by the Biosafety Officer. For further details contact the AA Facility Manager or the Biosafety Officer. The relevant Facility Manager requires a copy of the certificates once training has been successfully completed.

5.3.7 Laboratory Access and Authorisation

It is a condition of entry that all persons understand the general laboratory safety rules and accept their responsibility under WHS Legislation to adhere to the safety rules at all times. Individual Departments should implement local laboratory safety instructions that are designed to meet their

specific requirements. It is a requirement that inductions are performed for all University laboratories. Induction records are to be maintained by the relevant Laboratory Manager. Access to general laboratories is under the authorisation of the Laboratory Manager or Laboratory Supervisor. Access and authorisation to physical containment facilities is under the direction from the Facility Manager and may be dependent on completion of the on-line courses and local induction. Refer to the respective Facility Manager for further information on access to their laboratories.

5.3.8 Personal Protective Equipment

Personal protective equipment (PPE) is specialised clothing or equipment worn by laboratory personnel for protection against exposure to aerosols, splashes and accidental inoculation. PPE must be worn while working in the laboratory and must not be taken home or worn outside the laboratory. PPE equipment is selected to suit the type of work being performed and the potential risk of exposure. Consult AS/NZS 2243.1:2005 for detailed information regarding the different types of PPE. All PPE is to be removed and hands decontaminated prior to leaving the laboratory or containment facility. The Centre for Disease Control and Prevention has step by step guidelines for safely removing PPE, which can be found on the WHS SharePoint Hub (Biosafety & Biosecurity).

At a minimum, enclosed footwear is mandatory for all University research and teaching laboratories. Within research laboratories a properly fastened laboratory coat that protects the arms and body must be worn at all times unless lesser requirements can be justified by a risk assessment. If applicable, laboratories will supply safety glasses, goggles, face shields and gloves which meet Australian standards and appropriate to the type of work being performed.

5.3.9 Working After Hours

The University defines its business hours as Monday – Friday 7:00 am to 10:00 pm and weekends 8:00 am – 6:00 pm, however Faculties may have differing business hours for their laboratories and clinics. After hours work is defined as the period outside of these business hours as well as Public Holidays. After hours work is defined as the period outside of these business hours as well as Public Holidays. Individuals are advised to check and follow local procedures for working after hours as these may differ across faculties and individual facilities.

5.3.10 Safety Documentation

Safe Work Instructions (SWIs) and Standard Operating Procedures (SOPs) outline the safe way to undertake a task and may be developed for techniques, processes and equipment to minimise any risk to individuals when working with biohazardous materials. Safety documentation is being developed and implemented across the University. Visit the university Wiki and Sharepoint websites below for current approved documents and templates:

Biosafety Management support page

Macquarie University Health and Safety

It is advised that individual research and teaching facilities have a procedure manual which highlights any specific requirements, standard processes and hazards associated with the work space. All staff and students are advised to familiarise themselves with it and consult the relevant Manager with any questions.

6. Standard Precautions

Human error, poor laboratory techniques and misuse of equipment cause the majority of laboratory injuries and laboratory acquired infections. The World Health Organization (WHO) has compiled a chapter of technical methods that are designed to avoid or minimise the most commonly reported problems of this nature. For further detailed information see the WHO Laboratory Biosafety Manual, Chapter 12

The National Health and Medical Research Council (NHMRC) have recommended adoption of the term 'Standard Precautions' as the basic risk minimisation strategy for handling potentially infectious material. Standard precautions are recommended for the care and treatment of all patients in the clinical environment and in the handling of:

- Microbiological agents
- Blood (including dry blood)
- Body fluids, secretions, excretions (excluding sweat)
- Non-intact skin
- Mucous membranes

Standard precautions are work practices required for the basic level of infection control and they include the use of:

- Good microbiological practices (aseptic techniques)
- Good hygiene practices (particularly washing and drying hands before and after patient and sample contact and when leaving the laboratory)
- Use of PPE (including the wearing of gloves, lab coats, gowns, plastic aprons, masks, eye protection)
- Waterproof coverings over any skin breaks
- Appropriate procedures for the handling and disposal of contaminated wastes
- Appropriate procedures for the handling and disposal of sharps

When used in combination with physical containment work practices described in AS/NZS2243.3:2010, this meets the requirements of implementing standard precautions. Specific AS/NZS 2243.3:2010 sections relating to physical containment work practices are listed below:

- Section 5.2.3 and 5.3.6 of a PC1 and PC2 Laboratory ContainmentFacility
- Section 6.4.3 and 6.5.5 of a PC1 and PC2 Animal Containment Facility
- Section 7.2.4 and 7.3.5 of a PC1 and PC2 Plant Containment Facility
- Section 8.2.4 and 8.3.5 of a PC1 and PC2 Invertebrate Containment Facility

Further infection control guidelines can also be found on the Department of Health website.

7. Microorganisms and Biohazardous Materials

7.1 Introduction

The laboratory contains many potential biological hazards. These include working with microorganisms (bacteria, fungi, viruses and parasites), genetically modified organisms, humans, animals, and their associated tissues and biohazardous substances such as prions, human blood,

blood products, body fluids and raw and treated sewerage. The basic approach to working with microorganisms is to regard them as potential pathogens and to handle them with standard microbiological techniques. Such techniques help minimize the risk to laboratory staff, the environment and to maintain purity of strains of isolates. All work with microorganisms and biohazardous materials must be carried out according to the requirements detailed in the AS/NZS 2243.3:2010 Safety in Laboratories, Part 3: Microbiological safety and containment. Compliance with the relevant sections of AS/NZS 2243.3 is considered a minimum requirement for anyone handling microorganisms

Microorganisms vary widely in their infectivity. This is partly due to differences in the portal of entry (skin, ingestion or via the respiratory tract), the physiology of the microorganism, the infectious dose and the ability of the microorganism to overcome intrinsic immune and other host defences.

Laboratory acquired infections may arise through:

- Inhalation through the production of aerosols from processes such as centrifugation, pipetting, opening cultures or flaming contaminated loops.
- Ingestion from accidental splashing into the mouth or contaminated hands.
- Sharps injuries via needle pricks, cuts with contaminated glass, and bites and scratches from animals.
- Transfer through open wounds or across mucosal membranes (eyes, mouth and nose).

7.2 Risk groups

The Australian Standard AS/NZS 2243.3:2010 classifies infectious microorganisms into risk groups. AS/NZS 2243.3:2010 lists risk groups by microorganism type (eg: viruses, bacteria, parasites, fungi) and further divides the lists into human/animal, plant and invertebrate infectious microorganisms. Safe work practices and physical containment levels for each group are detailed within the AS/NZS 2243.3:2010 standard (Table 3.1).

7.2.1 Risk group classification for human and animal infectious microorganisms

Risk group classification for humans and animals is based on the agent's pathogenicity, mode of transmission, host range, the availability of preventative measures and the availability of effective treatment.

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.

7.2.2 Risk group classification for plant infectious microorganisms

The risk grouping of plant infectious microorganisms is primarily concerned with containment of plant pathogens to avoid risk to the environment. Factors considered in relation to the risk from plant infectious microorganisms are the ecological or economic impact; the agents presence in Australia or New Zealand; ease of spread; and the agents host range.

Plant risk group 1 – a microorganism that is unlikely to be a risk to plants, industry, a community or region and is already present and widely distributed.

Plant risk group 2 – a microorganism that is a low to moderate risk to plants, industry, a community or region and is present but not widely distributed.

Pant risk group 3 – a microorganism that is a significant risk to plants, industry, a community or region and is exotic but with limited ability to spread without the assistance of a vector.

Plant risk group 4 – a microorganism that is a highly significant risk to plants, industry, a community or region and is exotic and readily spread naturally without the assistance of a vector.

7.2.3 Risk group classification for invertebrates carrying infectious microorganisms

The risks posed by invertebrates are based on the microorganism that they may be harbouring. Factors considered in relation to their risk are based on; risk to laboratory workers, host range, economical/ecological impact, geographical distribution and ability to disperse. Some examples include viruses in mosquitos, Borrelia in soft ticks and trypanosomes in Triatmid bugs.

Invertebrate risk group 1 – microorganisms that are carried by invertebrates where the microorganisms are unlikely to be a risk to humans or to the environment and are already present and widely distributed.

Invertebrate risk group 2 – microorganisms that are carried by invertebrates where the microorganisms are a low to moderate risk to humans or to the environment and are present but not widely distributed. They have a limited ability to disperse because of low persistence of the microorganism outside the host. They are carried by invertebrates that are un likely to be able to disperse or can be readily controlled.

Invertebrate risk group 3 – microorganisms that are carried by invertebrates where the microorganisms are a significant risk to humans or to the environment and are exotic and have the ability to disperse with or without the aid of a vector. They are carried by invertebrates that are able to disperse.

Invertebrate risk group 4 – microorganisms that are carried by invertebrates where the microorganisms are a highly significant risk to humans or to the environment and are exotic and readily able to disperse with or without the aid of a vector. The microorganisms may be carried by invertebrates that are difficult to detect visually.

7.3 Physical Containment

Containment of microorganisms involves a combination of buildings, engineering, equipment, worker practices and training to handle microorganisms safely. Physical containment is the term used to describe procedures and structures designed to reduce or prevent the release of viable organisms into the outside environment. The physical containment level used relates to the risk group classification of the microorganism, i.e. Physical Containment Level 2 for risk group 2. In some circumstances the physical containment level required for a particular microorganism may depend on the work being performed (e.g. Human Immunodeficiency Virus which is classified as both a risk group 2 and 3 microorganism). There are four classifications of Physical Containment Facilities and are identified by the 'PC' prefix followed by numbers 1 – 4. Not all laboratories operating within the University are certified containment facilities. Certain types of GMO and quarantine related dealings are required to be conducted in a certified facility.

PC1 Facilities – A PC 1 laboratory or facility is suitable for work with microorganisms where the hazard levels are low, and where standard laboratory practice can adequately protect laboratory or facility personnel. This level of laboratory is usually suitable for undergraduate teaching laboratories. Specimens that have been inactivated or fixed may be handled in PC 1 facilities.

PC2 Facilities – A PC2 Laboratory or Facility is required for all work with microorganisms or material likely to contain microorganisms that are classified as risk group 2. If working with specimens containing microorganisms transmissible by the respiratory route or if the work produces a significant risk to humans or the environment from the production of infectious aerosols, a biological safety cabinet must be used.

PC3 Facilities – A PC3 laboratory or facility is required for all work with microorganisms or material likely to contain microorganisms that are classified as risk group 3. A PC3 laboratory or facility provides additional building features and services to minimize the risk of infection to individuals, the community, and the environment.

PC4 Facilities – This is the highest Physical Containment level and due to the highly hazardous nature of this work, rigorous requirements must be adhered to in these facilities. This level of laboratory or facility is required for work with microorganisms classified as risk group 4 microorganisms and other dangerous agents.

Macquarie University does not currently have any PC3 or PC4 facilities and as such Risk Group 3 and 4 organisms cannot be handled or stored on site.

8. Work with Genetically Modified Organisms (GMOs)

8.1 Introduction

Work involving genetic manipulation or the use of genetically modified organisms (GMOs) is regulated by the *Gene Technology Act 2000* and the *Gene Technology Regulations 2001* through the national Office of the Gene Technology Regulator (OGTR). The legislative mandate of the OGTR is to "prevent harm to human health and safety and the environment by regulating use of GMOs in Australia'.

A GMO is defined as:

- An organism that has been modified by gene technology, or
- An organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology, or
- Anything declared by the regulations to be a genetically modified organism, or that belongs to a class of entities declared by the regulations to be genetically modified organisms

Dealings with, in relation to a GMO, means the following:

- Conduct experiments with the GMO
- Make, develop, produce or manufacture the GMO
- Breed the GMO
- Propagate the GMO
- Use the GMO in the course of manufacture of an entity that is not the GMO
- Grow, raise or culture the GMO
- Import, transport or dispose of a GMO

The Macquarie University IBC is accredited by the OGTR to provide on-site monitoring of all teaching and research proposals of work involving the use of GMOs, and to act on behalf of the OGTR and the University to ensure that the Act, regulations and guidelines are followed. All work with GMOs must:

- Have written approval from the IBC before commencement – Record of Assessment (ROA)
- If the GMO is a vertebrate animal, cephalopod or decapod crustacean, then an animal ethics application is also required
- Comply with the *Gene technology Act 2000*, *Gene technology Regulations 2001* and OGTR guidelines

8.2 Types of Dealings

There are a number of different classes of GMO dealings. The type of authorisation required for each class is based on the level of risk that the dealings may pose to people and the environment. These classes of dealings and the respective authorisation processes are described below.

8.2.1 Exempt Dealings

Exempt Dealings are described in Schedule 2 of the Regulations and are a GMO category assessed as posing very low risk. The only legislative requirement for exempt dealings is that they must not involve an intentional release of a GMO into the environment. The OGTR does not require annual reporting of Exempt Dealings.

Exempt Dealings do not require a specified level of containment. If Exempt Dealings occur in uncertified facilities, those facilities must comply with the AS/NZS 2243.3:2010, Part 3: Microbiological Safety and Containment. The regulator has produced *Guidance Notes for the Containment of Exempt Dealings*, to provide guidance to persons conducting Exempt Dealings. Prior to commencement, approval from the IBC is required.

8.2.2 Notifiable Low Risk Dealings

Notifiable Low Risk Dealings (NLRDs) are described in Schedule 3 of the Regulations and are a GMO category assessed as posing low risk to people and the environment provided the risk is properly managed. As a requirement of the Regulations, NLRDS must not be intentionally released and must be reported to the OGTR. NLRDs must be approved by the IBC and it is a condition of approval that the chief investigators complete an Annual Progress Report. NLRDs must be conducted by appropriately trained persons and must be transported, stored and disposed of in accordance with OGTR guidelines. NLRDs must be conducted within an OGTR certified facility. Macquarie University has certified PC2 Facilities where PC1 activities can also be conducted.

8.2.3 Dealings Not Involving Intentional Release

Dealings Not Involving Intentional Release (DNIR) are described in Schedule 3 of the regulations and must be licensed by the regulator. DNIRs are subject to case by case assessments by the OGTR and a license will only be granted once the OGTR is satisfied that any risks posed by the dealings are able to be managed so as to protect the health and safety of people and the environment. Some examples of DNIR dealings are: clinical trials involving GMOs, genetic modifications that may increase the pathogenicity or toxicity of the GMO, and dealings involving pathogens that require PC3 or PC4 containment. Applications for DNIRs are first submitted and approved by the IBC before being passed on to the OGTR. The OGTR has 90 days to approve a license. DNIRs must be conducted in a PC2 or higher OGTR certified facility.

8.2.4 Dealings Involving Intentional Release

Dealings involving Intentional Release (DIRs) are dealings conducted outside containment facilities, for example GM Crops. DIRs must be licensed by the regulator and applications must include a risk assessment and risk management plan. All applications are submitted to the IBC before being passed on to the OGTR. The OGTR has default timeframe of 225 working days to decide on a DIR application. If the project is a 'limited and controlled' release the approval timeframe is 150-170 working days.

9 Synthetically Modified Organisms

Synthetic biology is a multidisciplinary and rapidly evolving field. It can be summarised as the design and construction of new biological parts, devices and systems that do not exist in nature, and the re-design of existing, natural biological systems for research and industrial purposes. The effect of synthetically modified organisms (SMOs) on biological diversity or the environment is not understood.

Currently there is no internationally agreed consensus about a definition of synthetic biology or its potential regulatory and risk assessment challenges. All work with SMO must be approved by the IBC and include detailed risk assessments. 9.1 GMO Physical Containment Facilities

Any person working with GMOs in a laboratory is required to follow the guidelines for containment facilities as set out by the OGTR in addition to all other requirements relating to the Physical Containment level as listed in the AS/NZS2243.3:2010 Section 5.

10. Biosecurity

Biosecurity is a critical part of the government's efforts to prevent, respond to and recover biologicals that threaten the health of humans and animals, the environment, and the economy. Specific laboratory biosecurity processes should be developed by facilities dealing with quarantine materials and SSBAs to ensure security measures are designed to prevent loss, theft, misuse, diversion or intentional release of pathogens or toxins that have the potential to cause significant damage to human health, the environment and the Australian economy.

Biosecurity in Australia is the responsibility of two Federal Government Departments which oversee all importation, exportation and use of biological materials of biosecurity concern:

Department of Agriculture, Water and the Environment – Prevent and control the importation and use of biological materials and are currently acting under the *Biosecurity Act 2015*.

Department of Health – (Formerly Department of Health and Aging) Prevent the deliberate release of harmful biological agents such as viruses, bacteria, fungi and toxins. Currently acting under the *National Health Security Act 2007*, *National Health Security Regulations 2008* and the SSBA Regulatory Scheme.

Strict control measures have been put in place for the importation, exportation and use of these biological materials. Please refer to the specific website for more detailed information.

11. Biosecurity and Quarantine

11.1 Introduction

The Department of Agriculture, Water and the Environment (DAWE) administers the importation and use of biological products to ensure the safe handling, security and disposal of such products in Australia. The aim of the DAWE is to prevent or control entry, establishment or spread of pests and diseases that will or could cause significant damage to humans, animals, plants, the environment or the economy. Imported biological materials should be considered as potentially infectious and handled and disposed of accordingly. The DAWE has specific regulations and requirements regarding the use (import, use, storage, and disposal) of agents requiring containment or approval under the *Biosecurity Act, 2015*.

11.2 Imported Biologicals

Imported biological materials are products containing material from human, animal, plant or microbial origin and include foods, therapeutics, laboratory materials and vaccines.

Imported biological materials are considered to pose a potential quarantine risk. Any person wishing to import biological materials may be required to have a permit to import low risk 'non-prohibited biological products' OR a permit to Import Quarantine Material from the DAWE.

Visit the DAWE and BICON websites for further detailed information. The university has a multi-user BICON account, to join please email biosafety@mq.edu.au.

It is mandatory to keep records of imported goods and should include the following details:

- Date the material was received

- Quarantine entry number and import permit number
- Name of the supplier
- Description of material
- Batch number
- Proposed research and analysis details
- Details of any special treatments
- Date when research or analysis was completed
- Methods and dates of disposal

Items are usually assessed by the DAWE as unrestricted, restricted or prohibited. Persons wanting to use restricted materials are required to obtain a permit for importation and use of the materials. The conditions of use will be detailed on the import permit. Some imported biological materials may need to be stored and handled in Biosecurity Approved Arrangements (AAs; previously termed QAPs).

It is necessary to obtain an *in vivo approval* from the DAWE for the use of restricted imported biological products in non-laboratory animals and plants. Please note that an *in vivo* approval does not act as an import permit.

11.3 Biosecurity Approved Arrangements

Biosecurity AAs are containment facilities that have been approved by the DAWE to hold biological materials that are a concern to the Australian environment and where this is a required condition under the current biological import permit for the material. The DAWE determines the level of quarantine containment required (BC1 – BC4) and this is stated on the import permit. There are several different classes of AAs and each type, and level has certain requirements governing its operation. Class 5 AAs relate to the Facilities at Macquarie University, within this class there are four different sets of criteria (5.1 – 5.4) for corresponding quarantine containment levels (BC1 – BC4). Macquarie University has Class 5 BC1 and BC2 Facilities. Please refer to the AA Facility DAWE information page for detailed information on the regulations associated with the different AA types (microbiological, animal and plant facilities).

All AA users must:

- Obtain DAWE import permits and in vivo approvals as required
- Undertake online DAWE training as advised by the Facility Manager
- Complete the Macquarie University Fit and Proper Person Self Declaration and lodge with the respective Facility Manager
- Comply with DAWE legislation and AS/NZS2243.3:2010 standards
- Ensure that all biological waste is disposed of appropriately
- Comply with conditions as described in the import permit

12. Security Sensitive Biological Agents (SSBAs)

12.1 Introduction

Security-sensitive biological agents (SSBAs) are biological agents that may be deliberately used to harm human and animal health or the Australian economy. They consist of infectious agents, such as

bacteria and viruses, as well as toxins derived from plants or microorganisms. In 2009 the Federal Department of Health (DoH) implemented the SSBA Regulatory Scheme which includes:

- The National Health Security Act 2007
- National Health Security Regulations 2018
- The Security Sensitive Biological Agent Standards

The scheme was implemented to improve the security of biological agents of concern in Australia. The scheme regulates the acquisition, isolation, storage, handling, transport and disposal of SSBAs.

12.2 SSBA Classification

SSBAs are categorised into two lists, Tier 1 and Tier 2. Regulation of Tier 1 list agents came into effect in January 2009 and that of Tier 2 agents in January 2010.

Individuals are in breach of the SSBA Regulatory Scheme if they have not registered their individual SSBA's by 31st January 2010 with the Department of Health. Registration of SSBA's requires the development of numerous documents, review of these documents by a committee, as well as requiring certain levels of security on the individual laboratory where the organisms are stored or used.

Tier 1 Agents	Tier 2 Agents
Abrin (reportable quantity 5mg)	*African swine fever virus*
Bacillus anthracis (Anthrax—virulent strains)	*Capripoxvirus (Sheep pox virus* and *Goat pox virus)*
Botulinum toxin (reportable quantity 0.5mg)	*Classical swine fever virus*
Ebolavirus	*Clostridium botulinum* (Botulism; toxin-producing strains)
Foot-and-mouth disease virus	*Francisella tularensis* (Tularaemia)
Highly pathogenic influenza virus, infecting humans	*Lumpy skin disease virus*
Marburgvirus	*Peste-des-petits-ruminants virus*
Ricin (reportable quantity 5 mg)	*Salmonella* Typhi (Typhoid)
Rinderpest virus	*Vibrio cholerae* (Cholera) (serotypes O1 and O139 only)
SARS coronavirus	*Yellow fever virus* (non-vaccine strains)
Variola virus (Smallpox)	
Yersinia pestis (Plague)	

12.3 Research Approval and Reporting

Handling of any Tier 1 or Tier 2 SSBA must be approved by the IBC and no work with the SSBA can commence until the University and facility have been registered with DoH.

The *National Health Security Act 2007* requires Universities and facilities handling SSBAs to report their holdings to DoH for inclusion on a National Register and comply with relevant security standards. The following events must be reported to the DoH within 2 business days:

- The University starts to handle an SSBA
- The University starts to handle an SSBA that has not previously been included on the National Register
- If a University that is not registered to handle an SSBA at a facility and, as a result of its normal testing procedures, an SSBA is at least presumptively identified

In case of loss, misuse or theft the IBC must be advised immediately.

13. Laboratory Animals

13.1 Introduction

The use of animals or animal tissues for educational or research purposes is regulated in Australia by State Government legislation; the *NSW Animal Research Act 1985* and *Animal Research Regulations 2010* and the Australian code for the care and use of animals for scientific purposes (8th Edition, 2013:NHMRC), which is incorporated by reference into the Animal Research Regulations.

Individuals intending to use animals as part of their teaching or research must be aware of the associated human health risks:

- Allergens (hair, fur, urinary proteins, faeces and parasites)
- Bites, scratches and kicks
- Zoonoses (diseases transmissible from animals to humans)
- Manual handling (lifting and carrying cages, animals and feed)
- Hazardous substances (anaesthetic gases, cytotoxic drugs, radioactive materials)
- Other risks associated with animal houses such as slips (especially in wet animal houses) and contact injuries from needles and sharps

Health surveillance may apply where as a worker you attend a pre-employment medical to ensure the workplace can be reasonably adjusted to accommodate any medical restrictions. This is handled confidentially and implemented in accordance with the University Health Surveillance Program. For more information refer to the Macquarie University Health and Safety webpage.

13.2 Use of Animals at Macquarie University

It is the responsibility of the Animal Ethics Committee (AEC)to ensure, on behalf of the University, that animal research is conducted in accordance with the Australian code for the care and use of animals for scientific purposes (8th Edition, 2013:NHMRC).

At Macquarie University all teaching and research proposals involving the use of live vertebrate animals, cephalopods, or decapod crusteceans must have approval from the AEC before they can proceed. This includes the use of animals in research, teaching, field trials, product testing,

diagnosis, the production of biological products, environmental studies and observational studies of wildlife. Please refer to the Macquarie University Animal Ethics website for application forms, training resources and legislative requirements.

If the project involves the use biohazardous materials, microorganisms classified as risk group 2 and above, GMOs, radioactive isotopes or other hazardous substances approvals will also need to be sought from the relevant committee and/or Officer. If working in one of the University's Animal Facilities individuals must also meet with the facility manager to ensure there is adequate space and resources available to complete the study and to schedule training.

14. Facility Work Practices

14.1 General Rules and Regulations

Laboratories are potentially hazardous work places. Strict adherence to laboratory safety rules and regulations can greatly reduce the risks associated with potential laboratory hazards. It is a condition of entry that all persons must understand the general laboratory safety rules and accepts their responsibility under WHS Legislation to adhere to the safety rules at all times.

All laboratory work shall be carried out with regard to the safety of laboratory occupants. The following requirements apply to all laboratory personnel:

- Individuals shall familiarise themselves with the recommendations and requirements in the laboratory safety manual.
- Individuals shall be familiar with, and shall use, the appropriate safety equipment provided.
- Individuals, who alone know the nature and contents of their experimental materials and apparatus, shall ensure that the apparatus (or the remains, if broken) is decontaminated before maintenance or disposal, and that materials are processed in accordance with laboratory policy before disposal.

Please see the Macquarie University General Laboratory Safety Guidelines and AS/NZS 2243.3 Section 2 for further information. It is recommended that individual Departments develop and implement local laboratory safety guidelines that are designed to meet their specific needs whilst still remaining compatible with these rules.

14.2 Physical Containment (PC) Levels

There are four levels of containment applied to **facilities** certified by the Regulator. These are arranged in order of ascending stringency of containment requirements, which reflect the level of risk. The four levels are PC1, PC2, PC3, and PC4.

MQ does not have PC3 or PC4 facilities. A guide to PC3 and PC4 practices can be found in AS/NZS 2243.3:2010 Section 5, and must be followed in addition to the general laboratory, PC1 and PC2 facility work practices.

14.2.1 PC1 Facility

PC1 work practices are additional to general laboratory work practices. The following practices as described in AS/NZS 2243.3:2010 Section 5 are to be observed when working in a PC1 facility:

- Access to the laboratory is limited
- No food or drink is to be consumed or stored in the laboratory. Eating, drinking, smoking, shaving and the application of cosmetics shall be prohibited
- PPE worn and used in the laboratory shall comply with the requirements in AS/NZS 2243.1.
- Long hair shall be tied back
- All cultures must be clearly labelled and dated
- Do not store cultures for long periods of time on the bench. Transfer cultures to a dedicated storage area, such as refrigerators and cold rooms
- Used sharps, syringes and needles must be placed in the approved yellow sharps bins provided. Before placing into the yellow bins, needles must not be removed, bent, sheared or recapped. The use of sharps shall be restricted in the laboratory for use only when there is no alternative. Take care to prevent the dissemination of material while flaming a wire loop, by drawing the loop from the cooler to the hotter part of the Bunsen burner flame, or by using a hooded or an electric Bunsen burner
- Petri dish cultures of fungi must be sealed to prevent dispersal of spores
- Handle diagnostic kits and control sera with care as the exclusion of all pathogens cannot be guaranteed
- Take care to minimise the production of aerosols whilst working on an open bench
- Take precautions to ensure that reading and writing materials do not become contaminated
- Use self-adhesive labels
- Clean up all spills immediately and decontaminate the area
- Report significant spills and incidents immediately to the facility Manager
- Decontaminate benches at least daily and after each task is completed
- Remove laboratory coats and gowns and store in the facility
- Thoroughly wash hands and under fingernails before leaving the facility

14.2.2 PC2 Facility

The following work practices described in AS/NZS2243.3:2010 Section 5 must be followed in addition to the general laboratory and PC1 facility work practices:

- Instruction and training in handling infectious microorganisms shall be provided to laboratory personnel
- All individuals must receive an induction before they can work in the facility
- Potentially contaminated surfaces must be disinfected before maintenance of equipment is conducted
- Facility shall be inspected at least annually by the IBC to ensure its containment requirement still comply with AS/NZS 2243.3:2010 clause 5.4.4
- All clinical specimens shall be regarded as potentially hazardous. Leaking containers must be handled in a biological safety cabinet and the outside of the container disinfected. Where a replacement sample is obtainable, the leaking specimen shall be sterilised and disposed of
- For work that creates aerosols, such as shaking, mixing, ultrasonic disruption, a biological safety cabinet (BSC) or other equipment designed to contain he aerosol must be used

- A period of at least 5 minutes shall be allowed for aerosols to settle before opening homogeniser or sonicator containers in a BSC
- Special care must be taken when handling human blood, serum, other body fluids and substances that are visibly contaminated with blood, as they may contain viruses. The risk extends to human sera and derivatives used as control reagents
- Any container of viable micro-organisms transported outside the facility must be within a second unbreakable, closed and labelled container (secondary containment) which can be readily decontaminated. There should also be sufficient absorbent material (such as tissue paper) placed around the primary container to absorb any potential spill
- Potentially contaminated, reusable glassware must be pressure steam sterilised or chemically disinfected prior to washing and re-use
- Minor cuts, abrasions and dermatitis should be adequately covered and kept dry
- Bacterial cultures must not be sniffed for odours
- Laboratory work books must be kept separate from all research and experimental processes
- Protective clothing shall not be worn outside the facility and shall be decontaminated or disinfected prior to laundering or disposal

14.2.3 PC3 Facilities

Macquarie University does not have any PC3 facilities.

A guide to PC3 practices can be found in AS/NZS 2243.3:2010 Section 5, and must be followed in addition to the general laboratory, PC1 and PC2 facility work practices.

14.3 Biosecurity Approved Arrangements (AA)

Any person wishing to import microorganisms, animals, human products, plants or soil for their research is required to have an Import Permit from the Department of Agriculture, Water and the Environment (DAWE). The DAWE will assess if the products can be released on arrival or if they need to be used in an AA facility. If they need to be used and stored in an AA facility, conditions set by the DAWE must be met in addition to all other requirements listed in AS/NZS 2243.3:2010 (see section 9 of this manual).

15. Biological Spills

15.1 Introduction

To control the hazards associated with biological spills, every laboratory working with biohazards must develop written emergency spill/clean-up procedures appropriate to the hazards of that material. All laboratories working with biohazards must keep emergency spill/clean-up kits within the laboratory area that are tailored to suit the type of biological material and risk group of the microorganism being used in the work area. AS/NZS 2243.3:2010 provides information on the contents of basic spill kits.

The nature of the spill will determine the type of clean-up response required. Factors include:

- The size of the spill (small or large)

- The risk group classification of the organisms that has been spilled and how infectious it is
- If the spill is confined (in a BSC, incubator, refrigerator) or in the open (bench, floor)
- Whether aerosols are being produced
- If other hazards are involved (chemicals, isotopes, sharps)

Spill clean-up procedures are well documented in AS/NZS 2243.3:2010. Detailed instructions are also available from the Macquarie University Clean up – Biological Spills Safe Working Procedure, also found on the WHS SharePoint Hub (Biosafety & Biosecurity).

15.2 Disinfectants

Characteristics of microorganisms affect their susceptibility to disinfection. All laboratory work areas and benches should be wiped down with 70%w/v (80%v/v) ethanol at the end of each experiment. Refer to AS/NSZ 2243.3 Table F1 for recommended chemical disinfection in microbiological laboratories.

The DAWE also provides a list of broad spectrum disinfectants and sanitisers suitable for use in Approved Arrangements.

16. Laundering of Laboratory Gowns

Reusable laboratory gowns should be laundered on a regular basis. Before being sent to laundry facilities, gowns used in PC2 or higher facilities may need to be autoclaved, unless otherwise specified. Refer to your respective Department for laundry procedures relating to specific laboratories.

17. Disposal of Biological Waste

17.1 Introduction

Biological waste management procedures must be adopted by Macquarie University to protect the health and safety of persons in control of or exposed to biohazardous waste in the workplace and the community in general. Faculties and Departments must develop, implement, maintain and monitor a biological waste management strategy. The waste management strategy adopted by Faculties and Departments must be environmentally responsible and comply with Federal and State legislation and any other regulatory requirements.

Laboratory waste disposal procedures should clearly outline:

- Who is responsible and the training requirements
- The categories into which waste is to be sorted or segregated
- The temporary storage facilities for waste storage
- The collection schedules
- The final disposal arrangements with a NSW Environment Protection Authority (EPA) approved waste disposal contractor
- Records of disposal of waste in accordance with health and government requirements

17.2 Waste Tracking Requirements

The transport of some wastes presents a high risk to the environment and human animal health. These wastes must be tracked when transported into, within or out of NSW. The waste consignor, transporter and receiving facility all have obligations to ensure that the waste is properly tracked. The Protection of the Environment Operations Act 1997 (POEO Act) is the key piece of environment protection legislation administered by the EPA.

Under the POEO Act and the NSW EPAs *Environmental Guidelines: Assessment, Classification and Management of Liquid and Non-liquid Wastes,* wastes classified as Clinical and related waste are subject to special monitoring and reporting requirements. The specific requirements of other biosafety standards and legislation (AS/NZS 2243.3: 2010, OGTR and DAWE) should also be consulted for additional waste handling requirements when required.

Macquarie University maintain waste disposal agreements with EPA-Licenced contractors for the transportation and disposal of waste. All records in regard to waste transportation, facility receipt and disposal are to be retained for 5 years. It is mandatory that all hazardous waste collection and disposal contracts are passed through Macquarie University Research Policy and Contracts to ensure they meet our obligations under the POEO Act.

17.3 Segregation of Laboratory Waste

Laboratories generate many different types of wastes. Each category of waste (chemical, biological, clinical, sharps and radioactive) requires segregation prior to storage and disposal. All personnel handling bagged laboratory wastes must:

- Not compress bags
- Not place hands inside the bag
- Not hold bags close to their body

Under AS/NZS 2243.1:2005 laboratory wastes should at least be sorted into the following categories:

- Non-contaminated paper and plastics which may be disposed of as general waste (AS/NZS 2243.3:2010)
- Non-contaminated broken glass which is placed in a designated container
- Contaminated broken glass which is disposed of in a dedicated container
- Sharps (AS/NZS 2243.3:2010)
- Clinical (AS/NZS 2243.3:2010)
- Biological (AS/NZS 2243.3:2010)
- Cytotoxic
- Animal carcasses (AS/NZS 2243.3:2010, AS/NZS 2243.4:1998)
- Radioactive (AS/NZS 2243.4:1998)
- Drugs of addiction

17.4 Clinical and Biological Waste

Clinical and biological waste has the potential to cause injury, infection or public offence. All laboratory waste contaminated with or potentially contaminated with microorganisms must be decontaminated before final disposal. It is understood that in house decontamination may not be possible for all biological waste generated at Macquarie University. In these circumstances alternative arrangements will be made after consultation with the IBC and Research Policy and

Contracts to ensure the University meets obligations under current legislative requirements. It is recommended that local waste management plans for Faculties and departments are designed and implemented to meet their specific needs but they must be developed in accordance with:

- AS/NZS 2243.3:2010, Section 12 Contaminated materials and waste
- Protection of the Environment Operations Act 1997
- the NSW EPAs Environmental Guidelines: Assessment, Classification and Management of Liquid and Non-liquid Wastes
- OGTR and DAWE guidelines when applicable

Clinical and biological wastes include:

- Clinical specimens or samples of human origin (e.g. blood, body fluids, tissues, other clinical samples, swabs, bandages, wound dressing etc)
- Microbiological waste (petri-dish, other micro-organisms cultures, cell culture materials
- Recombinant DNA waste, genetically modified organisms and materials
- Animal waste (animal tissue and remains, carcasses, bedding and other animal materials)
- Quarantine waste
- Sharps waste
- Cytotoxic and pharmaceutical waste
- Radioactive waste

17.4.1 Microorganisms, clinical or other infectious waste

As defined in AS/NZS 2243.3:2010, wastes contaminated with microorganisms, clinical or other infectious waste can be treated by either two methods depending on local requirements:

Best Practice

Option 1: Wastes able to be rendered non-hazardous are to be done so by autoclaving (pressure steam sterilisation). Wastes are to be sealed in opaque impervious bags that render the waste "unrecognisable". If waste is to be transported outside of the laboratory to autoclave facilities, it is to be done in a secondary sealed, leak-proof, unbreakable container. Although considered non-hazardous after autoclaving, the waste is deposited into the dedicated and locked contaminated waste bins and awaits collection by an EPA approved contractor. Liquid cultures that have been thoroughly decontaminated by pressure steam sterilisation may be disposed of to sewer (sink).

Disposal by this method requires monitoring of the autoclave sterilisation cycles to ensure that the waste is thoroughly decontaminated prior to disposal. Monitoring includes the use of steam indicators (autocloave tape and indicator strips) or chemical or biological indicators.

Option 2: Wastes that cannot be rendered non-hazardous prior to disposal must be sealed in appropriately labelled "yellow contaminated waste bags" at point of generation. These bags must be transported from the laboratory area in a secondary sealed, leak-proof, unbreakable container (garbage bin with sealable lid). Waste bags are to be placed in dedicated and locked contaminated waste bins until collection by an EPA approved contractor for disposal by incineration or autoclaved and shredded.

Disposal by this method is subject to university approval to ensure waste obligations are met and that staff have been trained in the safe handling of hazardous wastes.

17.4.2 GMO waste

OGTR mandates that recombinant DNA or GMOs be rendered non-hazardous before final disposal. For detailed instructions please consult the OGTR *Guidelines for the Transport, Storage and Disposal of GMOs*.

17.4.3 Sharps waste

Sharps must be placed into a sharps container as soon as possible after use. To avoid needlestick injuries, needles must not be re-capped or bent and disposable needles/syringe sets should be discarded as a single unit. Sharps must be disposed of in approved yellow sharps containers which comply with AS4031-1992 *Non-reusable containers for the collection of sharp medical items used in health care areas*. Sharps containers are not be filled past the indicated line and once full, the sharps container must be sealed and placed in a yellow contaminated waste bags before being disposed of in lockable contaminated waste bins. Used sharps containers must not be emptied or reused under any circumstances.

17.4.4 Cytotoxic waste

Cytotoxic waste must be segregated from all other waste streams wherever possible and must be placed into dedicated purple cytotoxic waste bags, lockable bin or the purple cytotoxic sharps containers. If bins are to be used, once full they need to be locked permanently with the side locks, decontaminated on all external surfaces and stored in a dedicated lockable area for disposal contractor. Cytotoxic waste bags and sharps containers must be placed into a purple cytotoxic clinical waste bin for contractor. Disposal is by incineration at 1100˚C.

17.4.5 Animal carcasses

17.4.5.1 Non-Biohazardous animal carcasses

Non-biohazardous animal carcasses are those that; are used for dissection purposes only in teaching; are surplus to experimental requirements; do not contain any GMOs, SMOs or SSBAs; or those that are not mandated under quarantine regulations. The EPA classifies non-biohazardous animal carcasses as putrescible (organic) waste which means they can be disposed of, without treatment, directly for deep burial at a landfill facility. Animals suitable for this disposal are required to be packaged into black garbage bags and de-identified of any labelling. Carcasses are to be refrigerated at 4˚C or frozen until collected.

17.4.5.2 GMO animal carcasses

GMO animals that do not contain any hazardous or GMO microorganisms are rendered non-biohazardous through euthanasia. Such carcasses can then be disposed of as non-biohazardous. Animals suitable for this disposal are required to be packaged into black garbage bags and de-identified of any labelling. Carcasses are to be refrigerated at 4˚C or frozen until collected.

17.4.5.3 Biohazardous and quarantine regulated animal carcasses

Imported animals or animal carcasses contaminated, or potentially contaminated with biohazardous materials, GMOs, SMOs or imported biologicals must be rendered non-hazardous prior to disposal. If facilities exist, animal carcasses may be rendered safe by autoclaving on site prior to landfill disposal.

Disposal by this method requires monitoring of the autoclave sterilisation cycles to ensure that the waste is thoroughly decontaminated prior to disposal.

If in-house autoclaving is not available, animal carcasses are to be double bagged and held in the freezer before being transported by an approved transporter to the designated waste disposal contractor for high temperature incineration or other methods approved by the Department of Agriculture, Water and the Environment. For materials and animals regulated by quarantine the methods of disposal must be consistent with the import permit.

Disposal by this method is subject to university approval to ensure waste obligations are met under OGTR and EPA legislation

17.4.5.4 Perfused animal carcasses and animal treated with cytotoxic drugs

Animals and animal tissues perfused with formaldehyde or paraformaldehyde or from animals that were treated with cytotoxic drugs are deemed non-biohazardous. However, these animals are unable to be autoclaved due to the generation of toxic fumes. Perfused animals and animal tissues must be placed in plastic bags with a label indicating the chemical hazard and segregated from non-perfused materials. Animals treated with cytotoxic drugs are to be disposed of as cytotoxic waste. Carcasses are to be refrigerated at 4˚C or frozen until collected.

17.4.6 Drugs of addiction

Drugs of addiction are substances which are addiction producing or potentially addiction producing. Possession and use are strictly limited. Destruction of a drug of addiction may be carried out only by or under the direct personal supervision of a person authorised by the NSW Ministry of Health such as Pharmaceutical Services Senior Pharmaceutical Officers, a police officer or another authorised individual. The destruction is to be recorded in the facilities drug register, and show the date, the name of the person who carried out the task and their registration number. Please refer to the local Facility Manager for the disposal procedure of empty containers used to store drugs of addiction.

18. Appendix 1: Biosafety Legislation

Commonwealth Legislation
Biological Controls Act 1984
Biosecurity Act 2015
Crimes (Biological Weapons) Act 1976
Crimes (Biological Weapons) Regulations 2019
Gene Technology Act 2000
Gene Technology Regulations 2001
National Health Security Act 2007
National Health Security Regulations 2018
Prohibition of Human Cloning Act 2002
Biosecurity (Consequential Amendments and Transitional Provisions) Act 2015
Research Involving Human Embryos Act 2002
NSW Legislation
Anatomy Act 1977
Animal Research Act 1985
Animal Research Regulation 2010
Biological Control Act 1985
Gene Technology (NSW) Act 2003
Human Tissue Act 1983
Human Cloning for Reproduction and Other Prohibited Practices Act 2003
NSW Work Health and Safety Act 2011
NSW Work Health and Safety Regulations 2011
Protection of the Environment Operations Act 1997
Public Health Act 1991
Public Health (Microbial Control) Regulation 2000
Research Involving Human Embryos (NSW) Act 2003
Australian Standards
AS/NZS 2243.3:2010 Microbiological Safety and Containment
AS/NZS 2243.1:2005 Safety in Laboratories – Planning and Operational Aspects
AS/NZS 2982:2010 Laboratory Design and Construction
AS/NZS 3816:1998 Management of Clinical and related wastes
AS/NZS 4501.1:2008 Occupational Protective Clothing
AS/NZS 4501.2:2006 Occupational Protective clothing
Other
SafeWork NSW
SafeWork NSW – Pregnancy at Work – Guide 2002
Australian Immunisation Procedures Handbook (10th Edition, NHMRC)
World Health Organisation Biosafety Manual

19. Appendix 2: Document History

Approved by: Macquarie University Institutional Biosafety Committee

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Major Review date [5 years]: November 2020

Version Number	Activity	Date
1.3	Document Approved	November 2015
1.4	Document amended to reflect new approval system and Biosecurity Act 2015	October 2017
1.5	Websites updated	June 2018
1.6	Document amended to add *Abbreviations and Definitions* section and amend content	September 2021