Charles Sturt University

Biosafety Manual

Booklet 2 -
Risk Assessments and Applications

IN THIS BOOKLET

1. Research Approval and Risk Management

1.1. The Institutional Biosafety Committee (IBC)

The Charles Sturt University IBC helps to minimise the risks associated with working with biological materials by annually inspecting certain laboratories and facilities to ensure that they meet a physical containment level two and above under OGTR, quarantine and AS/NZS 2243.3 specifications. Any work involving any of the following must not commence until IBC approval has been granted:

- Work with GMO's
- Work with human biological specimens where work falls outside of the university 'Human Biological Specimens Laboratory Use Policy'. This can be found at https://policy.csu.edu.au/document/view-current.php?id=196 as per section 3.1 of booklet 1
- Biological products requiring containment or approval under the Quarantine Act 1908
- Security Sensitive Biological Agents (SSBAs)

The IBC has a website which provides a variety of information. The IBC is contactable for advice and guidance - email: biosafety@csu.edu.au

1.2. Risk Assessment, Safe Work Procedures, Working with GMOs and Application Forms

Risk assessment	A completed risk assessment form is required for all work involving biological materials, for each project (teaching or research). The information requested on the risk assessment form and the process of completing one is necessary to allow the chief investigator/ subject coordinator to find and document enough information to decide if the work can be carried out safely in a laboratory/ facility equipped to meet specific biosafety needs. Risk assessment forms are available online from the technical services http://science.csu.edu.au/technical or e-mail techsupportunit@csu.edu.au
Applications to work with GMOs	The IBC is charged with assessing and monitoring all GMOs, recombinant and synthetic biology projects and reports annually to the OGTR. Work with GMOs are defined by the OGTR as 'dealings' and there are four main types of dealings. Application forms for Exempt and Notifiable Low Risk Dealings working are available online from the IBC website https://research.csu.edu.au/integrity-ethics-compliance/biosafety. For clarification of dealing classes please consult the OGTR website and section 4.2 below of this manual. Applications must be made to the IBC to conduct any dealings with GMOs and approval needs to be granted before any work can commence.
Application to work with unscreened human biological specimens	Applications for an exemption to the human biological specimen's policy may be made to the IBC using the form provided on the IBC website at any time and emailed to the governance officer biosafety@csu.edu.au . a. a detailed risk assessment should accompany each application (including copies of all relevant protocols). b. confirmation of approvals from other compliance committees (for example, the Human Research Ethics Committee) **must** accompany the application. Names and contact details of all involved in the project together with confirmation that required vaccinations/ serological testing for those workers has been cited and recorded. c. applicants must provide sufficient information to enable the committee to make an informed decision. d. if the applicant is applying for an ongoing exemption (for example, for some undergraduate practical classes), they shall nominate the time period (session times) for such exemptions (for a maximum of three years). Heads of school, facility managers and applicants shall be notified in writing of the committee's decision.
Safe Work procedures	Safe work procedures (SWPs) 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. Safe work procedures are being developed and implemented across the University. Visit the Technical Services website for some current SWPs: http://science.csu.edu.au/technical or e-mail techsupportunit@csu.edu.au It is advised that individual research and teaching facilities maintain a current SWP manual containing all SWPs pertaining to that facility. All staff and students are advised to familiarise themselves with it and

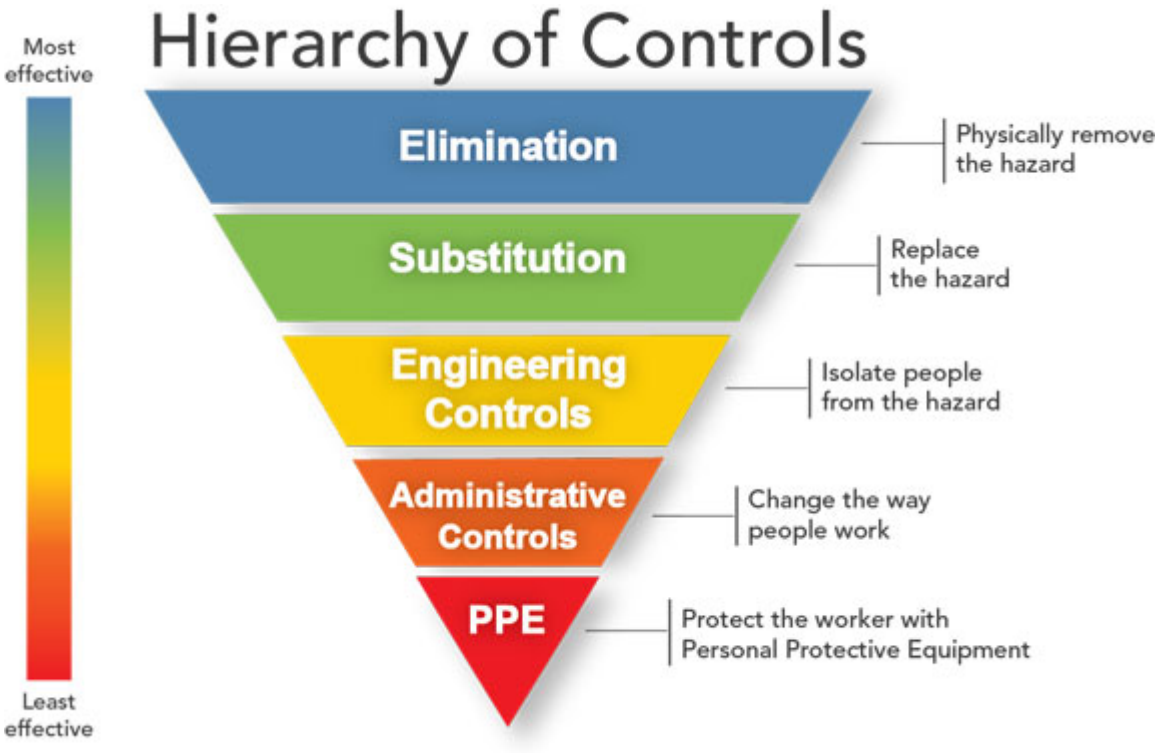
	consult the relevant manager with any questions.

1.3. Risk management

1.3.1. Hierarchy of control

The risk assessment form 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 or teaching exercise. 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. In completing risk assessments this hierarchy should be considered.

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. isolation – separates the hazard from the people at risk by isolating it (e.g. Class II biosafety cabinet).
4. engineering /bioengineering –Add physical or biological safety features to plant or equipment (e.g. Physical containment facility, vaccines).
5. administration – use of administrative controls to lessen the risk (e.g. signage, risk assessments and safe work procedures, training).
6. Personal Protective Equipment (PPE) – provides a personal barrier between the user and the infectious/toxic substance (e.g. gloves, eye protection, and laboratory coat).

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

Responsibility of the chief investigator/ subject coordinator and/ or convener or person in charge of the research/ teaching activity/ project	YOU must ensure: a. research and technical personnel have read risk assessments and safe work procedures before work starts. b. hard copies of risk assessments and safe work procedures are available in the laboratory for reference. c. all personnel involved researchers/ students/ visitors have received sufficient training and/or supervision to allow them to work and handle biological agents and materials in a safe manner. d. that they are inducted into the facility in which the work will be conducted. e. faulty equipment is reported and removed from service where a danger exists. f. safe work procedures are followed. g. safety rules are followed. h. emergency equipment is available and serviced. i. the physical containment level is appropriate for the risk group. j. incidents, accidents and near miss occurrences are reported to work health and safety. k. 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.
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. THEY must ensure that they: a. read the relevant risk assessment and relevant guidance material. b. follow all relevant safe work procedures and guidelines. c. report any faulty equipment. d. attend required training. Speak to a supervisor or laboratory manager about any safety concerns. Comply with the relevant safety rules and guidelines.

1.4. Register of biological hazards and list of microorganisms

The register of biological hazards lists all biologically hazardous materials, microorganisms, GMOs and SSBAs used and stored in teaching and research laboratories. Copies of risk assessments and safe work procedures are to be maintained in these laboratories and made available to personnel who conduct work in those laboratories (hardcopy or electronic). The register must be updated annually and a copy should be kept at the entrance to the facility for access by emergency services in case of accident or incident.

1.5. 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 or facility. Induction records must be kept and maintained by the laboratory or facility manager. Access and authorization requirements will be determined on the risk associated with the procedures/work carried out and the materials stored within the laboratory/ facility.

1.6. Training

In order to reduce the inherent risks associated with biohazards, training, hazard awareness, knowledge of the biological agent, good habits, caution, attentiveness and concern for the health of co-workers are prerequisites for all individuals.

The IBC administers online biological safety training modules 1 and 2. Module 1 deal with general biological hazards in laboratories and facilities and module 2 deals with compliance with the OGTR regulations and working with GMOs. Both modules outline the legislative framework for research using biological agents, and potential risks associated with biological research. Both modules are available through the Biosafety interact site at https://interact2.csu.edu.au/webapps/blackboard/execute/content/blankPage?cmd=view&content_id=_1460157_1&course_id=_21887_1

Module 1 is mandatory on induction for anyone conducting research in a laboratory or facility at CSU which contains biological hazards.
Module 2 is mandatory for individuals working in laboratories with GMO's in OGTR certified facilities whether or not they work with GMOs and regardless of whether any GMOs are handled in those facilities.

It is expected that individuals repeat these every three years. On completion of each module a certificate is produced which should be printed and stored as evidence of completion. The laboratory or facility manager is required to record completion of these before access is granted. For further information please contact your supervisor, facility manager or the university IBC (biosafety@csu.edu.au). In addition CSU has a Workplace Health and Safety unit for advice and guidance ohs@csu.edu.au.

Quarantine training is mandatory for individuals working with quarantine materials or those working within the universities Quarantine Approved Premises (QAP). For further details contact the QAP Facility Manager. The university IBC and QAP manager are required to keep training records of all users once training has been successfully completed.

1.7. 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 laboratories/ facilities / schools 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 laboratory or facility manager. Access to any laboratories is under the authorisation of the facility manager. Refer to the respective facility manager for further information on access to their laboratories.

1.8. Personal protective equipment

Personal protective equipment (PPE) is specialised clothing or equipment worn by laboratory/ clinical personnel for protection against exposure to aerosols, splashes and accidental inoculation. PPE must be worn while working in the laboratory/ clinics or facilities where this is required and must not be taken home or worn outside of those facilities. 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. Appendix 4 details a step by step process for safely removing PPE.

At a minimum, enclosed footwear is mandatory for all university research and teaching laboratories and clinics. 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. Laboratories will supply safety glasses, goggles, face shields and gloves which meet Australian standards and appropriate to the type of work being performed.

1.9. Working after hours

The university defines its business hours as Monday – Friday 9:00 am to 5:00 pm. After hours work is defined as the period outside of these business hours and includes public holidays. All individuals occupying a building after hours are required to advise Security of their presence in the building and an estimate of their length of stay. Phone numbers and contact details for security on different campuses can be found at: http://www.csu.edu.au/contacts/security .

NOTE: Except under special circumstances, with permission of the supervisor and laboratory or facility manager, undergraduate students including honours students are not normally allowed into laboratories unsupervised.

2. 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 use list of best practice standard 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 at http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf

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. These are at https://www.nhmrc.gov.au/health-advice/public-health/preventing-infection. Standard precautions are recommended for the care and treatment of all patients in the clinical environment and in the handling of specimens containing:

- microbiological agents
- blood (including dry blood), body fluids, secretions, excretions (excluding sweat)
- non intact skin and 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 - **Safety in laboratories Microbiological safety and containment** sections relating to standard work practices in different types of physical containment facilities are listed below:

- section 5.2.3 and 5.3.6 of a PC1 and PC2 Laboratory Containment Facility
- 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

The IBC recommends all laboratory users review this standard. Further infection control guidelines can also be found on the Department of Health website.

3. Risk Groups

The Australian Standard AS/NZS 2243.3:2010 classifies infectious microorganisms into risk groups by microorganism type (e.g. 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 also detailed within the standard. A list of risk group 2, 3 and 4 organisms can be found in Appendix 1. *Note that risk grouping is not an exact science and risk groups can vary for some organisms between countries. When the grouping is ambiguous the definition of the risk group helps to determine. If in doubt then assume a higher risk grouping rather than a lower one.*

3.1. 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. **Diagnostic specimens** are generally regarded as belonging to Risk Group 2. This applies to all clinical specimens processed in medical /veterinary microbiology laboratories as well as other pathology laboratories including haematology and biochemistry.
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.

3.2. 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 agent's 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.
Plant 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.

3.3. 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 unlikely 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

3.4. 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 and laboratory acquired infections. **Physical containment levels are not just about the physical space but also about procedures and behavioural requirements of workers.** In general 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 and whether its pathogenicity is reduced in anyway compared to type strains (e.g. Human Immunodeficiency Virus which is classified as both a risk group 2 and 3 microorganism). There are four classifications of Physical Containment level term PC1 – 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. Details of the requirements for certification of laboratories and facilities at particular levels can be found in the Australian standard AS/NZS 2243.3: 2010 Safety in Laboratories Part 3. Microbiological safety and containment.

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

4. Work with Genetically Modified Organisms (GMOs)

4.1. 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 and amendments* 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:

a. An organism that has been modified by gene technology, or
b. 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
c. 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:

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 an entity that is not the GMO
f. grow, raise or culture the GMO
g. import, transport or dispose of a GMO

The university's 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:

a. have written approval from the IBC before commencement
b. if the GMO is a vertebrate animal or cephalopod, then an animal ethics application is also required
c. comply with the *Gene technology Act 2000*, *Gene technology Regulations 2001* and OGTR guidelines and any subsequent amendments to the act and regulations.

4.2. 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.

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 to the OGTR by the university IBC. 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. Application forms for Exempt dealings can be found on the Biosafety website.
Notifiable Low Risk Dealings (NLRD)	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. NLRDs must be approved by the IBC. 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. CSU has certified PC2 Facilities. Application forms for Notifiable Low Risk Dealings can be found on the Biosafety website.

Dealings Not Involving Intentional Release (DNIR)	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 produced jointly by the chief investigator and the IBC and are approved by the IBC before being passed on to the OGTR. The application documentation should be obtained directly from the OGTR website. Once submitted the OGTR has 90 days to review the application. Then a licence is granted directly by the OGTR. Usually the process requires further information the OGTR may request. DNIRs must be conducted in a PC2 or higher OGTR certified facility.
Dealings Involving Intentional Release (DIR)	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. Applications for DIRs are produced jointly by the chief investigator and the IBC and are approved by the IBC before being passed on to the OGTR. The application documentation should be obtained directly from the OGTR website. 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.
Synthetically modified organisms (SMO)	Synthetic biology is a multidisciplinary and rapidly evolving field. It can be summarised as the design and construction of new biological parts, devices, systems or whole organisms 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 or scope of synthetic biology or its potential regulatory and risk assessment challenges. It includes GMOs with modular proteins, bacteria with completely synthesised genomes, gene drives and DNA sequence mutations produced by CRISPR technology that are mutations that could potentially occur in nature but do not. The United Nation's Convention on Biological Diversity (CBD) has formerly urged for regulation and that member countries (which includes Australia) follow a precautionary approach to synthetic biology. The CBDs decision on synthetic biology urges all member countries to: a. follow a precautionary approach to synthetic biology. b. set up systems to regulate the environmental release of any synthetic biology organisms or products. These regulations must ensure that activities in one country cannot harm the environment of another. c. ensure that no synthetic biology organisms are released for field trials without a formal prior risk assessment. d. submit synthetic biology organisms, components and products to scientific assessments that consider risks to conservation and sustainable use of biodiversity as well as human health, food security and socio-economic considerations. e. encourage research funds to assess the safety of synthetic biology as well the socio-economic impacts of the technology. Support developing countries to develop their capacity to assess synthetic biology.

5. 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 Security Sensitive Biological Agents (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 Primary Industries – Prevent and control the importation and use of biological materials and are currently acting under the Biosecurity Act 2015 implemented in 2016.

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.

Department of Defence – Under the Defence trade Act of 2012 and the Defence Trade Controls Amendment Bill 2015 the department of defence prevents and regulates:

- intangible supply of technology relating to defence and strategic goods, such as supply by electronic means; and
- brokering the supply of Defence and Strategic Goods (DSGL) goods and technology.

The aim of the act and bill are to strengthen Australia's export controls, and to stop technology that can be used in conventional and weapons of mass destruction from getting into the wrong hands. Some examples of intangible means are email, fax, telephone, video conferencing, providing access to electronic files, or presentations that contain DSGL technology. The provisions apply equally to the industry, university and research sectors. For example it is prohibited to export from Australia goods or information that may enhance another countries defence of weapons capability and this includes biological materials and information. For example it may be illegal to supply DNA sequences from organisms that could potentially be used as biological weapons. Such events might be the unintentional emailing of sensitive research data to research collaborators overseas. Charles Sturt University has a Defence Trade Control Act 2012 – Compliance and Administration Policy and Committee which can provide further advice on exports and export permit applications for DSGL goods and technology. Email dtcc@csu.edu.au .

6. Quarantine Biological Material

6.1. Introduction

The Department of Agriculture administers the importation and use of biological products to ensure the safe handling, security and disposal of such products in Australia under the Biosecurity Act 2015. The aim of the Department of Agriculture 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 Department of Agriculture has specific regulations and requirements regarding the use (import, use, storage, and disposal) of agents requiring containment or approval under the Biosecurity Act 2015.

6.2. Imported biologicals

Imported biological materials are considered to pose a potential quarantine risk. Imported biological materials are products containing material from human, animal, plant or microbial origin and include foods, therapeutics, laboratory materials and vaccines. Any person wishing to import biological materials may be required to have a Permit to Import Quarantine Material from the Department of Agriculture. Please see http://www.agriculture.gov.au/import/goods/biological for further details to determine if you need a permit.

If biologicals are purchased from suppliers based in Australia that import biologicals from overseas then they usually have the import permits in place and those goods purchased need only to be used under the conditions specified by the retailer. Examples where a permit may be required are to import microorganisms, antibodies or plasmids from companies based overseas directly.

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

a. date the material was received
b. quarantine entry number and import permit number
c. name of the supplier
d. description of material
e. batch number
f. proposed research and analysis details
g. details of any special treatments
h. date when research or analysis was completed
i. methods and dates of disposal

Items are usually assessed by the DAWR 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 kept in Quarantine Approved Premises (QAP). It is necessary to obtain an *in vivo approval* from the Department of Agriculture for the use of restricted imported biological products in non-laboratory animals and plants. Please note that an in vivo approval is not an import permit.

6.3. Quarantine approved premises

Quarantine Approved Premises (QAPs) are containment facilities that have been approved by the Department of Agriculture to hold biological materials that are a concern to the Australian environment. The Department of Agriculture determines the level of quarantine containment required (QC1 – QC4) and this is stated on the import permit. There are several different classes of QAP and each type, and level of QAP has certain requirements governing its operation. Class 5 QAPs relate to the QAP Facilities at Charles Sturt University, within this class there are four different sets of criteria (5.1 – 5.4) for corresponding quarantine containment levels (QC1 – QC4). Charles Sturt University has a facility which is built to the standard of a Class 5 QC2 QAP (Laboratory and Glasshouse). At the date of writing this facility in the NaLSH on Wagga Wagga campus is not yet approved for use as a Quarantine facility and advice on work that can be conducted there should be obtained from the facility manager.

All QAP users must:

a. obtain Department of Agriculture import permits and in vivo approvals as required
b. undertake online Quarantine training as advised by the facility manager
c. comply with Department of Agriculture legislation and AS/NZS2243.3:2010 standards
d. ensure that all biological waste is disposed of appropriately
e. comply with conditions as described in the import permit

Note: *The QAP is comprised of a laboratory and plant facility that are additionally OGTR certified and therefore associated regulations must be complied with also.*

7. Security Sensitive Biological Agents (SSBAs)

7.1. 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 Regulation, 2008
- 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.

7.2. 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. It is necessary to apply for registration to the DoH before working with an SSBA. The list of SSBAs below is correct as of March 2016 and may change with amendments. Safety guidelines and regulations for working and reporting on SSBAs can be obtained from Department of Health Security Sensitive Biological Agents (SSBA) at http://www.health.gov.au/ssba .

More detailed guidelines for working or handlings SSBAs under the legislation can be found in Appendix 2 (Booklet 3).

Tier 1 SSBAs (with toxin thresholds*)	**Tier 2 SSBAs**
Abrin (5 mg)	*African swine fever virus*
Bacillus anthracis (Anthrax – virulent strains)	*Capripoxvirus* (Sheep pox virus and Goat pox virus)
Botulinum toxin (0.5 mg)	*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 (5 mg)	*Yellow fever virus* (non-vaccine strains)
Rinderpest virus	

SARS coronavirus
Variola virus (Smallpox)
Yersinia pestis (Plague)

Notes

a. The agents above only refer to infectious, viable and pathogenic organisms or active toxins.
b. 'Highly pathogenic influenza virus infecting humans' includes influenza viral strains that fulfil all the criteria listed below:
c. considered highly pathogenic in usual host animal;
d. proven infection of humans; and
e. involved in an outbreak of human disease.

Examples of such viral strains include the 1918 pandemic Influenza virus A and Influenza virus A H5N1.

f. 'Botulinum toxin' does not refer to a form approved for therapeutic use under the Therapeutic Goods Act 1989. For example, the forms of Botulinum toxin approved for therapeutic use and known under their commercial names Botox™ or Dysport™.
g. the List is not a legislative instrument.
h. genes and DNA of SSBAs are not regulated.

8. Laboratory Animals

8.1. 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:

a. allergens (hair, fur, urinary proteins, faeces and parasites)
b. bites, scratches and kicks
c. zoonoses (diseases transmissible from animals to humans)
d. manual handling (lifting and carrying cages, animals and feed)
e. hazardous substances (anaesthetic gases, cytotoxic drugs, radioactive materials)
f. other risks associated with animal houses such as slips (especially in wet animal houses) and contact injuries from needles and sharps

8.2. Use of animals at Charles Sturt University

It is the responsibility of the Animal Care and Ethics Committee (ACEC) 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 CSU all teaching and research proposals involving the use of live vertebrate animals or cephalopods must have approval from the ACEC before they can proceed. This includes the use of animals in research, teaching, field trials,

product testing and production of biological products, environmental studies and observational studies of wildlife. Please refer to the CSU Animal Ethics website for application forms, training resources and legislative requirements https://research.csu.edu.au/integrity-ethics-compliance/animal.

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.

9. Facility Work Practices

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: a. individuals shall familiarise themselves with the recommendations and requirements in the laboratory safety manual. b. individuals shall be familiar with, and shall use, the appropriate safety equipment and PPE provided. c. 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 General Laboratory Safety Guidelines as per AS/NZS 2243.3:2010 Section 2 for further information. It is recommended that individual facilities develop and implement local laboratory safety guidelines that are designed to meet their specific needs whilst still remaining compatible with these rules.
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: a. access to the laboratory is limited b. 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 c. PPE worn and used in the laboratory shall comply with the requirements in AS/NZS 2243.1. d. long hair shall be tied back e. all cultures must be clearly labelled and dated f. 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 g. 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 h. petri dish cultures of fungi must be sealed to prevent dispersal of spores i. handle diagnostic kits and control sera with care as the exclusion of all pathogens cannot be guaranteed

	j. take care to minimise the production of aerosols whilst working on an open bench k. take precautions to ensure that reading and writing materials do not become contaminated l. use self-adhesive labels m. clean up all spills immediately and decontaminate the area n. report significant spills and incidents immediately to the facility manager o. decontaminate benches at least daily and after each task is completed p. remove laboratory coats and gowns and store in the facility Thoroughly wash hands and under fingernails before leaving the facility
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: a. instruction and training in handling infectious microorganisms shall be provided to laboratory personnel b. all individuals must receive an induction before they can work in the facility c. potentially contaminated surfaces must be disinfected before maintenance of equipment is conducted d. 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 e. 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 f. for work that creates aerosols, such as shaking, mixing, ultrasonic disruption, a biological safety cabinet (BSC) or other equipment designed to contain the aerosol must be used g. a period of at least 5 minutes shall be allowed for aerosols to settle before opening homogenizer or sonicator containers in a BSC h. 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 i. 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 j. potentially contaminated, reusable glassware must be pressure steam sterilised or chemically disinfected prior to washing and re-use k. minor cuts, abrasions and dermatitis should be adequately covered and kept dry l. bacterial cultures must not be sniffed for odours m. laboratory work books must be kept separate from all research and experimental processes n. protective clothing shall not be worn outside the facility and shall be decontaminated or disinfected prior to laundering or disposal
PC3 facilities	The following practices as described in AS/NZS 2243.3:2010 Section 5 must be followed in addition to the general laboratory, PC1 and PC2 facility work practices: *Note: CSU has a small laboratory which is built to PC3 specifications however it is currently operated and certified only at PC2. The laboratory is currently within the Veterinary Diagnostic Laboratory on Wagga campus. This laboratory is* ***not currently certified at PC3*** *at the time of writing this manual.*

	a. 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 b. the laboratory management shall establish policies and written procedures whereby only persons who have been advised of the biohazard, and who meet any medical requirements, shall enter the laboratory c. an effective emergency evacuation plan is in place d. all laboratory staff have specific training in handling pathogenic organisms and in the use of safety equipment and controls e. all laboratory procedures with risk group 3 infectious materials, shall be conducted in a BSC of Class I, Class II or Class III f. outer clothing and personal effects shall not be taken into the containment facility g. no one shall enter the laboratory for cleaning, servicing of equipment, repairs or other activities before the relevant, potentially contaminated surfaces have been decontaminated and authorisation has been obtained from the facility manager h. dedicated cleaning equipment shall be stored within the facility i. viable biological materials to be removed from the containment laboratory shall be transferred to a non-breakable, sealed primary container , the external surface of which is decontaminated before enclosure in a non-breakable sealed secondary container j. laboratory wastes shall be rendered safe, preferably by decontamination in a pressure steam steriliser before professional disposal k. if a double ended pressure seam steriliser is installed across the barrier, it shall be decontaminated after each exposure to the laboratory environment l. protective clothing shall be removed in a predetermined appropriate order (note: in most circumstances this involves removing the gloves then decontaminating the hands followed by removal of eye protection, gown and respiratory protection, taking care not to touch potentially contaminated parts of PPE when doing so, then decontaminating hands again. m. measures shall be taken to ensure no microbiological contamination is removed from the facility on footwear In the event of a power failure, entry to the facility shall be restricted until services have been restored.
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.
Quarantine approved premises (QAP)	Any person wishing to import microorganisms, animals, human products, plants or soil for their research is required to have a an Import Permit from the Department of Agriculture (DA). The DA will assess if the products can be released on arrival or if they need to be used in a QAP facility. If they need to be used and stored in a QAP facility, conditions set by the DA must be met in addition to all other requirements listed in AS/NZS 2243.3:2010.

10. Biological Spills

10.1. 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/ facilities 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 and factors include:

a. the size of the spill (small or large)
b. the risk group classification of the organisms that has been spilled and how infectious it is
c. if the spill is confined (in a BSC, incubator, refrigerator) or in the open (bench, floor)
d. whether aerosols are being produced
e. 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 'Biological Spills Safe Working Procedure and in Appendix 5' (Booklet 3).

10.2. 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 or other approved disinfectant. The Department of Agriculture also provides a list of QAP approved disinfectants.

11. Laundering of Laboratory Gowns

Laboratory gowns should be laundered on a regular basis. Before being sent for laundering, gowns used in PC2 or higher facilities must be autoclaved, unless otherwise specified. Refer to your respective laboratory/ facility for specific laundry procedures.

12. Disposal of Biological Waste

12.1. Introduction

Biological waste management procedures must be adopted by CSU 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 must be environmentally responsible and comply with Federal and State legislation and any other regulatory requirements.
Laboratory waste disposal procedures should clearly outline:

a. who is responsible and the training requirements
b. the categories into which waste is to be sorted or segregated
c. the temporary storage facilities for waste storage
d. the collection schedule
e. the final disposal arrangements with a NSW Environment Protection Authority (EPA) approved waste disposal contractor
f. records of disposal of waste in accordance with health and government requirements

12.2. 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 Department of Agriculture) should also be consulted for additional waste handling requirements when required.
CSU maintains waste disposal agreements with EPA-Licenced contractors for the transportation and disposal of waste. All records in regards 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 comply with the POEO Act.**

12.3. 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

12.4. 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 CSU. In these circumstances alternative arrangements will be made after consultation with facility managers and Technical Services to ensure the University meets obligations under current legislative requirements. It is recommended that local waste management plans 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 (POEO Act)
- the NSW EPAs *Environmental Guidelines: Assessment, Classification and Management of Liquid and Non-liquid Wastes*
- OGTR and Department of Agriculture guidelines when applicable

Clinical and biological wastes include:

a. clinical specimens or samples of human origin (e.g. blood, body fluids, tissues, other clinical samples, swabs, bandages, wound dressing etc.)

b. microbiological waste (petri-dish, other micro-organisms cultures, cell culture materials
c. recombinant DNA waste, genetically modified organisms and materials
d. animal waste (animal tissue and remains, carcasses, bedding and other animal materials)
e. quarantine waste
f. sharps waste
g. cytotoxic and pharmaceutical waste
h. radioactive waste

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 the 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 (autoclave tape and 3M Thermolog® strips) or chemical or biological indicators (spore tests). Typically a Thermolog strip is included in each autoclave cycle to verify effectiveness. This is included in the records book for each run. Note: Autoclave tape is a useful indicator tape to show that items have been autoclaved but should not be relied upon to indicate effectiveness of the treatment.*** **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.***
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* (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/tsd-guidelines-toc/$FILE/tsd-guidelines.pdf). GMO 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 double bagged and sealed in suitable 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 GMO cultures that have been thoroughly decontaminated by pressure steam sterilisation may be disposed of to the 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 (autoclave tape and 3M Thermolog® strips) or chemical or biological indicators (spore tests). Typically a Thermolog strip is included in each autoclave cycle to verify effectiveness. This is included in the records book for each run. Note: Autoclave tape is a useful indicator tape to show that items have been autoclaved but should not be relied upon to indicate effectiveness of the treatment. Records of autoclave runs must be kept for at least 12 months and the autoclave must be checked and calibrated annually with records kept for at least 5 years.*** **Option 2**: Wastes (microbial, plant and animal) can be decontaminated by other methods but the effectiveness of these methods must be demonstrated and records kept as described in OGTR *Guidelines for the Transport, Storage and Disposal of GMOs* . ***Disposal by this method is subject to university approval to ensure waste obligations are met under OGTR and EPA legislation.***
Sharps waste	Sharps must be placed into a sharps container as soon as possible after use. To avoid needle stick injuries, needles must not normally 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 decontaminated by autoclaving prior to disposal in lockable contaminated waste bins. Used sharps containers must not be emptied or reused under any circumstances. In some circumstances and if necessary depending on the type of work you are doing recapping of needles can be achieved using a range of commercially available devices that hold the needle cap to allow reinsertion of the needle or using the 'one hand scoop method' for recapping. ***If recapping is necessary a safe work procedure must be written and adhered to by staff conducting these techniques.*** Needle stick injuries are one of the most common injuries in laboratories and clinics and frequently result from recapping needles. Recapping is best avoided if at all possible.
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.

12.5. Animal carcasses

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, SSBAs or infectious organisms; 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. Carcasses are to be refrigerated at 4˚C or frozen until collected.
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.
Biohazardous and quarantine regulated animal carcasses	Imported animals or animal carcasses contaminated, or potentially contaminated with biohazardous materials, GMOs, SMOs, SSBAs, infectious organisms 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 and Water Resources. For materials and animals regulated by quarantine the methods of disposal must be consistent with the import permit. ***Disposal by this method is subject must ensure CSUs waste obligations are met under OGTR and EPA legislation.***
Perfused animal carcasses	Animals and animal tissues perfused with formaldehyde or paraformaldehyde 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. Carcasses are to be refrigerated at 4˚C or frozen until collected.

12.6. 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 facility manager for the disposal procedure of empty containers used to store drugs of addiction.