Procedure: Biological safety

Purpose

This procedure seeks to provide the University a structured approach to preventing exposure of workers to hazards presented by biological materials and to protect the public and the environment from unintended release of biological material. The procedure seeks to ensure compliance with the *Work Health and Safety Act 2011* (Cth) and the *Work Health and Safety Regulations 2011* (Cth) and The University's Work Health & Safety (WHS) Management System. This procedure is linked to The University's Work health and safety policy and is one of the Safe Work Procedures within the WHS Management System.

Definitions

Approved arrangement is an arrangement, approved by the Department of Agriculture and Water Resources (DAWR) that provides the capacity to carry out specified activities to manage biosecurity risks associated with specified goods, premises or other materials.

BICON is the Australian Government's database of Biosecurity import conditions. It is used to determine what import conditions exist, if an import permit is required and is used to complete and submit an application for a permit.

Biologically hazardous material is any biological agent, substance or material (whether alive or not) present in or arising from living organisms. They are or may be hazardous to the health or well-being of the public, the environment or individuals in The University community. These hazards include, but are not limited to:

- microorganisms (such as bacteria, fungi, protozoa, viruses);
- animals (including their tissues, dander, blood or body fluids and excreta);
- plants and insects (including fluids, hairs, or parts of a whole organism);
- human blood, tissues, body fluids and excreta (or components of these);
- materials that have been contaminated or are potentially contaminated with infectious microorganisms;
- imported biological materials;
- products and by-products (including any of the items listed above) that could be toxic, allergenic or hazardous in other ways; and

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- any material that has contacted with biologically hazardous material.

Biosafety is a combination of systems and practices intended to reduce the risk of accidental exposure to, or release of, agents that may cause an infectious disease in humans, animals, plants, insects or cause harm to ecosystems.

Biosafety and Biosecurity Officers are local area representatives appointed by a school or facility to coordinate and advise on the local use of biological agents. They also liaise between local areas and the University or external stakeholders.

Biosecurity containment facilities (BC1, BC2, BC3 and BC4) are approved arrangements licensed by the Department of Agriculture and Water Resources under the *Biosecurity Act 2015* (Cth).

Biosecurity risk is the likelihood of a biological agent, disease or pest entering, establishing itself or spreading in Australian territory, and the potential for the biological agent, disease or pest to cause harm to human, animal or plant health, the environment or produce negative economic consequences.

Biosecurity controls are measures to manage biosecurity risks.

DAWR is the Department of Agriculture and Water Resources, or any successor Commonwealth entity managing the Biosecurity Act 2015 (Cth).

DoH is the Australian Government's Department of Health.

Gene Technology is any technique used to modify genes or other genetic material, but does not include sexual reproduction, homologous recombination, mutations that occur naturally or through damage by radiation or chemicals, or any other technique specified in the Gene Technology Regulations 2001 (Cth).

Genetically Modified Organism (GMO) refers to:

- an organism that has been modified by gene technology; or
- an organism that has inherited particular traits from an organism (the initial organism), 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 organisms declared by the Regulations to be genetically modified;

A GMO does not include:

- a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or

- an organism declared by the Regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the Regulations not to be genetically modified organisms.

IBC refers to the Institutional Biosafety Committee at the University. IBCs play important roles for organisations undertaking work with GMOs, by helping organisations to meet the requirements of the Gene Technology legislation.

Infectious agent refers to any agent capable of producing infection, e.g. bacteria, parasites, fungi, viruses and prions existing on their own or in biological material.

Local area refers to a College, Research School or Service Division of the University.

OGTR is the Office of the Gene Technology Regulator.

Pathogen is a microorganism capable of causing disease in a host.

Physical Containment (PC1, PC2, PC3 and PC4) refers to Physical Containment level 1 to level 4 (lowest containment level through to highest).

Physical Containment (PC) facility is the laboratory, room, facility or building that has been constructed and equipped to specific *Australian Standard/New Zealand Standard 2243.3:2010 Safety in laboratories Microbiological safety and containment (AS/NZS 2243.3)* requirements to physically contain microorganisms, animals, plants, insects or biological hazards and to protect people and the environment. It is a place where research and teaching involving biohazards is undertaken (which includes laboratories, animal houses, plant houses, invertebrate rooms, and constant temperature rooms).

GMOs dealings can only be carried out in an OGTR certified physical containment facility.

Research Group or Laboratory Leaders are responsible for allocating tasks to workers, students or visitors, and the oversight of research facilities or research projects.

Risk group as described in AS/NZS 2243.3 is the classification of microorganisms based on criteria such as the pathogenicity of the agent, the mode of transmission, host range, availability and effectiveness of preventative measures, and availability of treatment. Risk Group 1 to Risk Group 4 (lowest to highest risk) are to be handled in the corresponding level of Physical Containment; the risk group classifications in AS/NZS 2243.3 describe infectious microorganisms for humans and animals, plants and invertebrates.

SSBA refers to Security Sensitive Biological Agents according to the Department of Health.

Vector is an insect/other organism that transmits a pathogenic fungus, virus, bacterium, etc. or any agent that acts as a carrier or transporter of genetic material such as a virus or plasmid that conveys a genetically engineered segment of DNA into a host cell.

Worker is defined as anyone who carries out work for the University. A worker includes staff, volunteers, contractors, students and visitors at the University.

Procedure

Scope

1. This procedure outlines the requirements for workers who carry out work, research or study at the University in a clinical environment, laboratory, research facility, plant facility or animal facility, and who may handle or are potentially exposed to biological materials and associated hazards (as listed above in definitions).

2. This procedure assists workers identify biological hazards and meet various relevant legislative and regulatory requirements. The University will follow the relevant legislation, regulations and standards, such as those prescribed by the OGTR, the DAWR, the DoH and Australian Standards (AS).

Responsibilities

3. College Deans, Research School and Service Division Directors, or their nominees, are responsible for:

- ensuring that every research or teaching using biological agents is approved;
- ensuring that containment facilities are appropriate for all teaching and research activities involving biohazards or biosecurity risks;
- ensuring that facilities are registered and certified as required;
- ensuring that training needs are identified, all persons are appropriately trained and that training records are kept for handling of quarantine material;
- ensuring that systems to meet the objectives set forth in this procedure are established and maintained. This responsibility extends to all aspects of biological research involving all individuals who enter or work in a PC Facility or Approved Arrangement or who collaborate in undertaking research or teaching;
- appointing a containment Facility Manager for all containment facilities or delegating the responsibilities of a Facility Manager to the School Manager; and
- appointing a Biosafety (and if required a Biosecurity) officer for the area.

4. The School or Facility manager is responsible for ensuring:

- all approved arrangements are registered with the University WHS consultant in the Work Environment Group (WEG);

- updated Biological and Facility registers for biosecurity material are collected and forwarded bi- annually to the University WHS consultant in WEG;
- that appropriate immunisation is provided for all workers and records are retained as per the Immunisation procedure;
- that plant or equipment is decontaminated before contractors are brought in to service or repair plant or equipment;
- that arrangements are in place for biological wastes generated in the containment facility that they manage to be stored, decontaminated and disposed of appropriately.
- that a facility is fully decommissioned after it ceases functioning as a containment facility; and
- that departing workers make their work space safe and reassign responsibility for the control of any remaining biological, chemical and plant or equipment hazards to others before leaving the University as per the Vacating research facilities procedure.

5. Research group or laboratory leaders are responsible for:
   - ensuring all biological work complies with this University procedure;
   - obtaining all required legislative approvals, licences and certificates;
   - assessing the risk of exposure of workers and students to biological hazards and ensuring that the identified controls are implemented and maintained;
   - assessing the risk of exposure of workers and students to vaccine-preventable diseases and identifying the subsequent need for immunisation;
   - implementing and maintaining a register of all biological hazards within their control;
   - keeping up-to-date registers of material subject to biosecurity controls and making these available to external regulators or the University on request;
   - ensuring that biological wastes generated by their activities, or the part of containment facility that they supervise, are stored, decontaminated and disposed of according to University and local area Hazardous Waste Disposal Procedures; and
   - making their work space safe and reassigning responsibility for the control of any remaining biological, chemical and plant or equipment hazards to others before they leave the University.
6. Biosafety and biosecurity officers are responsible for:
   - coordinating the biosafety and biosecurity activities in their local area;

- liaising as needed with the IBC or the WEG WHS Consultant to ensure communication between outside regulatory bodies, the University and researchers; and
- assisting with and providing advice on the requirements for the safe use, movement, storage and disposal of biological agents in their facility.

7. The WHS Consultant in the WEG is responsible for:

- maintaining the University Register of Material subject to biosecurity controls and the University Register of Permits to import (once developed);
- maintaining the University register of Approved Arrangements; and
- reporting to the University Legal office on permits for importing and holdings of material subject to biosecurity controls when required to do so.

8. It is the responsibility of all workers to:

- ensure all biological work is carried out according to University procedures;
- follow all directions from supervisors to comply with the University and local area safety procedures; and
- understand and comply with the controls for the safe use of any biological material.

Regulatory processes

9. All work, research, teaching or study involving microbiological organisms, diagnostic samples, human and animal tissues, blood or bodily fluids, plant materials, insects and general biological hazards must follow the requirements of this procedure relevant to the use of the material.

10. The biological materials used at the University may be subject to one or more of the following regulatory processes/agencies and AS to control associated hazards.

Australian standards (AS)

11. AS/NZS 2243.3 Safety in the Laboratories (Series): Part 3: Microbiological safety and containment applies wherever work using animals, plants, insects, microorganisms (including prions) is undertaken in diagnostic, research, teaching, quality control or regulatory analysis.

OGTR

12. When working with GMOs, workers must follow the legislative requirements of the Gene Technology Act 2000, Gene Technology Regulations 2001 and Guidelines issued by the OGTR.

13. This includes research leaders having applications for their work assessed by the IBC, ensuring that their facility provides a level of containment appropriate for their work, and where applicable, that their facility is certified with the OGTR before research begins.

Department of Agriculture and Water Resources (DAWR)

14. When working with imported materials for research or teaching all workers must follow the specific biosecurity requirements established under the *Biosecurity Act 2015* (Cth) administered by the DAWR.

15. Biological material and items potentially contaminated with biological material may require a permit to import, and the permit may require the imported material to be kept within a prescribed Biocontainment (BC) facility (termed an Approved Arrangement) registered with the DAWR.

16. Specific record-keeping, training and security requirements need to be followed for all material subject to biosecurity controls. Contact the local area Biosafety or Biosecurity Officers for further information on DAWR requirements.

Security Sensitive Biological Agents (SSBAs)

17. SSBAs are biological agents such as viruses, bacteria and toxins that if they were deliberately released, would have the potential to cause significant damage to human health, the environment and the Australian economy. SSBAs are regulated under the *National Health Security Act 2007* (Cth) by the *SSBA Regulatory Scheme.* Consult the current list of SSBAs to determine if the material that is intended to be used is included.

18. Prior to working with any listed SSBAs, contact the local area WHS officer for information regarding the approval process. Most SSBAs have extra requirements such as more stringent physical containment requirements (PC3 or PC4) or cytotoxic laboratory facilities, as well as upgraded security.

19. At present the University does not conduct, or have facilities approved for work with SSBAs.

Other requirements at the University

20. There may be other requirements, such as complying with University Radiation safety procedure, Human and animal ethics procedures, and the Transport of hazardous Biological Materials.

Working with GMOs

21. The University is an accredited organisation registered with the OGTR. It has established an Institutional Biosafety Committee (IBC) to approve and oversee research using GMO's. The IBC also conducts annual inspections of OGTR- certified facilities.

22. The four different categories of genetic modification according to the *Gene Technology Regulations 2001* (Cth) are:

a. Exempt Dealings.

b. Notifiable Low Risk Dealings (NLRDs).

c. Dealing Not Involving Intentional Release (DNIRs).

d. Dealing Involving Intentional Release (DIRs).

Exempt Dealings

23. Exempt Dealings are defined in Part 1 of Schedule 2 of the *Gene Technology Regulations 2001* (Cth) and involve host/vector systems listed in Part 2 of Schedule 2. They consist of genetic modified dealings that pose a very low risk.

24. Researchers must submit a description of their Exempt Dealings to the IBC for approval before commencing work on the dealing to ensure that the dealing has been correctly classified.

25. Dealings in the exempt category are required to comply with the OGTR Guidance Notes for Exempt Dealings.

Notifiable Low Risk Dealings (NLRD)

26. NLRDs are defined in Parts 1 and 2 of Schedule 3 of the *Gene Technology Regulations 2001* (Cth). They comprise GM dealings that pose low risk.

27. Researchers must submit an application for IBC approval of their NLRD and have been notified of IBC approval before commencing work on the dealing.

Dealings Not Involving Release (DNIRs)

28. Dealings that are not NLRDs and therefore require a DNIR licence are defined in Part 3 of Schedule 3 of the *Gene Technology Regulations 2001* (Cth). They comprise GM dealings that pose a moderate risk.

29. Researchers must submit an application for a DNIR licence to the OGTR via the IBC and must not commence work on the dealing until a licence has been received from the OGTR. They must have a signed and dated record of notifications of licence conditions in the facility manual.

Dealing Involving Intentional Release (DIRs)

30. Dealings that are not DNIR and therefore require a DIR licence are defined in the *Gene Technology Act 2000 (section 48-67)* (Cth). They comprise GM dealings that pose a significant risk.

31. Each DIR licence application is subject to comprehensive, science-based, case-by-case analysis process by the OGTR.

32. Researchers must submit an application for a DNIR licence to the OGTR via the IBC and must not commence work on the dealing until a licence has been received from the OGTR. Researchers must have a signed and dated record of notifications of licence conditions recorded in their facility manual.

Applications for approval to work with GMOs

33. The research leader must submit their application for approval before research commences. Application forms are available on the University IBC website. The application must include hazard assessments and standard operating procedures that include risk management measures for any procedures that could result in exposure of a worker to a GM microorganism risk group 2 or above.

34. The researcher should submit their application to the IBC via rdna.officer@anu.edu.au for approval, or in the case of a DNIR, for assessment by the IBC prior to onward submission to the OGTR.

35. The IBC will notify the researcher of the outcome of their application. If unsure of the dealing category of GMOs, contact the IBC Secretary via rdna.officer@anu.edu.au for advice prior to application submission.

Training requirements for work with non-exempt GMOs

36. All workers working on an IBC-approved or OGTR-licenced dealing must undertake biological safety training and gene technology practices training or any other training deemed to be necessary by the IBC or the research leader.

37. All workers working on an IBC-approved or OGTR-licenced dealing involving the handling or injection of rodents must also undertake training in rodent care and handling, and injection techniques as appropriate.

38. Training must be recorded in the facility manuals for the facilities in which the dealings are undertaken and must be renewed every five years.

Transport of GMOs

39. Transport of GMOs outside of an OGTR-certified containment facility must comply with the OGTR Guidelines for Transport, Storage and Disposal of GMOs.

40. The outermost transport container must be labelled GMO and labelled with the name and contact details of the worker responsible for the GMOs transportation.

Storage of GMOs

41. GMOs may be stored either within or outside of certified facilities, provided storage complies with the OGTR Guidelines for Transport, Storage and Disposal of GMOs.

42. Whole, viable GM plants or animals must not be stored outside of a certified facility without written permission from the Regulator.

43. GMOs must not be stored in a site that is prone to flooding, storm surges or other natural disasters.

Disposal of GMOs

44. Disposal of GMO waste must comply with the OGTR Guidelines for Transport, Storage and Disposal of GMOs.

Facility manuals

45. Each OGTR certified facility must contain a facility manual. The facility manual is to include the following documents:

- training records;
- additional training records for NLRD applications;
- local area standard operating procedures for GM waste transport, sterilisation and spill procedures;
- risk assessments;
- IBC annual inspection reports;
- OGTR certification documentation; and
- any other relevant document.

Termination of dealings

46. On termination of a dealing the researcher should notify the IBC Secretary via rdna.officer@anu.edu.au.

47. When the dealing has ceased all GMOs must be either destroyed or transferred to another researcher with appropriate approvals to conduct further dealings with the GMOs. If the GMOs are to be kept in storage then the dealing has not ceased and NLRD approval must be in place.

OGTR- certification of facilities

48. Exempt dealings require PC1 containment but do not require facility certification. Work in uncertified PC1 facilities must be carried out in accordance with the AS/NZS 2243.3: Microbiological safety and containment and the OGTR Guidance notes for Exempt Dealings. Uncertified PC1 facilities are not inspected by the IBC.

49. If undertaking research work that is part of a NLRD or a Licenced Dealing, work must be carried out in the appropriate facility (either a PC1 or PC2 facility) that has been certified by the OGTR. The IBC must inspect the facility and the IBC Secretary will complete a certification application and submit it to the OGTR. Information required for certification, including a floor plan of the facility with containment boundaries and entrances/exits clearly marked, must be submitted to the IBC Secretary via rdna.officer@anu.edu.au. At present, the University does not have any OGTR-certified PC1 facilities.

50. The IBC will notify the researcher regarding the outcome of the certification application.

Physical containment classification

51. Physical Containment 1 (PC1) laboratory or facility is suitable for work with microorganisms where the hazard levels are low, and where laboratory or facility workers can be adequately protected by standard laboratory practice. The organisms used should generally be classified as Risk Group 1 according to AS/NZS 2243.3. OGTR certification is not required for PC1 facilities unless PC1 NLRD work is to be undertaken. At present, the University does not have any OGTR-certified PC1 facilities.

52. Physical Containment 2 (PC2) laboratory or facility where its practises and equipment are used for research, diagnostic and other premises, and where work is carried out using microorganisms or material that contain microorganisms that are classified as Risk Group 2 according to AS/NZS 2243.3. If work produces a significant risk to workers or the environment from the production of infectious aerosols, a biological safety cabinet should be used. OGTR certification is mandatory to work in PC2 with GMOs at the University.

53. Physical Containment 3 (PC3) laboratory or facility where its practises and equipment are used for research, diagnostic and other premises, and where work is carried out using microorganisms or material that contain microorganisms that are classified as Risk Group 3 according to AS/NZS 2243.3. The University currently does not have any OGTR-certified PC3 laboratory or facility. If planned work requires the use of Risk Group 3 material, contact the IBC Secretary via rdna.officer@anu.edu.au for further information.

54. Physical Containment 4 (PC4) laboratory or facility where its practises and equipment are used for research, diagnostic and other premises and where work is carried out with microorganisms or material that contain microorganisms that are classified as Risk Group 4 according to AS/NZS 2243.3. The University currently does not have any OGTR certified PC4 laboratory or facility. If planned work requires the use of Risk Group 4 material contact the IBC Secretary via rdna.officer@anu.edu.au for further information.

Inspections of OGTR- certified facilities

55. Uncertified PC1 facilities are managed at the local level by local area biosafety officer or facility managers and are not inspected by the IBC.

56. OGTR- Certified PC2 facilities are inspected annually by the IBC. Inspection dates will be announced several weeks before the inspections.

57. Current OGTR PC2 facility guidelines can be found on the OGTR website.

Suspension of OGTR- certified facilities

58. If temporary suspension of PC2 certification is required (e.g. to modify the containment facility), an application can be made to the OGTR via the IBC Secretary to suspend a certification. A request for suspension must be submitted to the IBC Secretary via rdna.officer@anu.edu.au. Alterations that might affect the integrity of containment are not allowed in an OGTR Certified Facility until formal notification of suspension has been received from the OGTR. Work may not recommence in the facility until it has been inspected by the IBC and the suspension lifted by the OGTR.

Surrender of OGTR- certified facilities

59. If PC2 certification is no longer required, the University must surrender the facility certification. Advise the IBC Secretary via rdna.officer@anu.edu.au.

60. The following actions should be taken to remove GMOs requiring containment from the facility, either by transportation to another certified facility or by destruction the following actions should be taken:

- All surfaces and equipment in the facility that were used to handle GMOs must be decontaminated. Facilities to be surrendered must be completely free of laboratory debris.
- No structural modification or demolition is permitted in facilities awaiting decertification. Alterations that affect the integrity of containment are not allowed in an OGTR Certified Facility until formal notification of decertification has been received from the OGTR.
- OGTR stickers **must not be** removed from the facility until formal notification of decertification has been received from the OGTR.

61. When the facility is ready for surrender, the IBC Secretary will arrange an inspection of the area. Once inspection is complete, the IBC Secretary will advise the regulator that the transport, storage and disposal of GMOs have been done in accordance with the guidelines and the facility is free of all GMOs. The OGTR will then notify the IBC Secretary when the surrender of the certification is effective.

62. The IBC Secretary will notify the facility manager of the completed surrender. All OGTR stickers must be removed from the facility at this time.

Working with material subject to biosecurity controls

63. The importation and use of biological, animals and plant material is subject to biosecurity regulations at the University.

64. DAWR is the regulatory authority for the University. DAWR provides biosecurity inspection services for the arrival of imported organisms and products into Australia, and inspection and certification for a range of animal and plant products exported from Australia. DAWR also monitors products being imported that may pose a risk to Australia's plant, animal and human health – including their subsequent derivatives.

Import of biosecurity material

65. Import permits are legal documents and all permit users must abide strictly by the exact permit conditions relevant to any material being imported that is subject to biosecurity controls. If the permit conditions on the permit do not match the intended import then the permit must be amended. Note that the person or business (generally ANU) that is "named" on the permit is held ultimately responsible for everything imported under that permit (even if others use it). Therefore any permit holder must ensure that all users of material imported under the permit abide by the permit conditions.

66. To determine if an import permit is required, contact the local area Biosecurity Officer or the Biosecurity Import Condition System (BICON).

67. The University is required to maintain a register of all import permits issued and any subsequent variations. To enable this, all permit applications must only be made from sub-accounts set up under either the ANU multi-user BICON account, or the multi-user BICON account of a Research School.

68. A record of all permit use, and a listing detailing all material held that is subject to biosecurity control, shall be submitted to the WEG upon request.

Exporting of Material Subject to Biosecurity Controls

69. To export Biosecurity material, verify the requirements with the country of import. Once requirements are established contact the local area Biosafety/Biosecurity Officer who will assist in the completion of the required DAWR export documentation.

Approved Arrangements

70. Approved Arrangements (AAs) are DAWR approved laboratories or facilities to carry out research using material subject to Biosecurity. AAs will have a bright yellow sign on the entrance door stating "Biosecurity Area". AAs fall into different classes. University AAs are mainly class 5.2 for laboratories and their requirements are detailed within the Approved Arrangement requirements for 5.2: Biosecurity containment level 2 (BC2).

71. All biosecurity material must be kept segregated (physically or temporally) from non-biosecurity material at all times. Physical barriers, labelling, locked and signed storage areas, designated workspace areas and standard operating procedures are required. All work practices must follow the AS/NZS 2243.3 and the requirements of the Biosecurity Class specific criteria.

72. AAs are inspected by DAWR at least annually. It is also recommended that spot checks for compliance are carried out by the local area Biosecurity officer.

73. AAs must have a facility manual. As a minimum the facility manual is to include::

- import permits for specified AAs;
- training records;
- contact details;
- local procedures required by an import permit;
- details (identity, quantity, location) of all biosecurity material and any derivatives;
- movement details for biosecurity material including removal for disposal by an approved method; and
- other relevant documents according to permit requirement.

DAWR certified facilities

Registrations

74. To apply for Approved Arrangements, download the forms and other relevant documentation from the DAWR website.

75. The principal researcher will send the complete forms to the local area Biosecurity Officer.

76. The Biosecurity Officer will check the forms for completeness and forward it to DAWR for approval. The approval process can take up to 120 days.

77. Once approved, the local area Biosecurity officer must ensure that appropriate signage and procedures are in place for the class of facility approved. They also are to provide the WEG Consultant details of the new AA.

Inspections

78. DAWR auditors will inspect the AAs at least annually to measure the compliance against BC class criteria and permit conditions.

79. Local area Biosecurity Officers are expected to conduct spot inspections in addition to annual DAWR inspections.

Decommissioning

80. Before decommissioning, a DAWR Approved Arrangements needs to be inspected as the final “close-out” inspection.

81. All Biosecurity material must be transferred or destroyed as per permit conditions.

82. Approved Arrangement Facilities being decommissioned must be decontaminated by a DAWR approved disinfection method and records kept.

Management of Biosecurity waste

83. Biosecurity waste must be kept separate to non- biosecurity waste. It must be double bagged, held in rigid, lidded, pest-proof bins labelled “Quarantine” or “Biosecurity Waste” and must remain within the AAs until removed to an autoclave room for disposal or treatment.

84. The allowable disposal methods (e.g. autoclaving, high temperature incineration, chemical sterilisation) are stipulated in the permit conditions. After autoclaving, the material is no longer classified as being "subject to Biosecurity controls" and can be disposed of as biological or clinical waste.

85. Waste disposal by autoclaving must be fully documented in an Autoclave Log. Autoclaves must be calibrated annually, with the proof/printout/graph of the complete sterilisation time available for auditing, along with any monthly spore tests (biological indicator).

Transfer and transport of Biosecurity material

86. Biosecurity material may be transferred between any nominated AAs listed on the permit. If the particular AA to be transferred to is not listed on the permit, the permit will need to be varied through the BICON system. The required forms can be accessed on the DAWR webpage. Material cannot be transferred until approval is received from DAWR. Contact the local area Biosecurity Officer for further information.

87. If transferring material to another group or organisation they are to be provided with a copy of the import permit and required to sign an agreement stating that they will abide by the conditions on the permit and all other DAWR requirements.

88. Transport of Biosecurity material must follow the usual transport requirement for biologicals (e.g. double containment - sealed primary containment with the secondary

containment being sealed and unbreakable; full labelling with "Biosecurity Material" and contact details for the laboratory and a copy of the permit).

Training requirements for work with materials subject to Biosecurity controls

89. Any workers using materials subject to Biosecurity controls are required to complete the University Biological Safety course and obtain training in Approved Arrangements for Accredited Persons (Classes 1 to 8), or be under the *direct supervision* of a person who has such training. Both training requirements must be kept up to date.

Immunisation

90. All workers are expected to adhere to the requirements of the Immunisation procedure. Refer to the procedure for further detail on the Vaccinia virus.

Cessation of an individual's work

91. The Vacating research facilities departure checklist assists workers in ensuring that their laboratory space is left in a satisfactory and safe condition prior to departure following completion of a research project. All biological materials, chemicals and hazardous equipment must be disposed of according to the University's Chemical Management procedure or the responsibility for the control of the hazard and all relevant documentation be assigned to another person.

Emergency procedures

92. Biological laboratories should have a dedicated biological spill kit suited to the hazards present. The following are examples of default procedures to be taken to minimise contamination after the spill. Local areas may have procedures more appropriate to their specific conditions or organisms in use – in this case these procedures take precedence and are to be followed.

Minor spill (low aerosol, PC1/ PC2)

93. Default procedures include, but not limited to:

- wearing disposable gloves;
- barricading the spill area and alerting users;
- soaking absorbent material such as paper towels in disinfectant and placing over spill area;
- placing towels in yellow, labelled plastic bags as biological waste for disposal; and
- cleaning spill area with fresh towels soaked in disinfectant.

Major spill (high aerosol production)

94. Default procedures include, but not limited to:

- wearing disposable gloves;
- wearing Personal Protective Equipment from the spill kit;
- attending to injured or contaminated persons and removing them from exposure;
- preventing contaminated persons from spreading the contamination;
- alerting other workers in area;
- barricading the area and waiting at least 20 minutes for aerosols to settle;
- covering the spill with absorbent material;
- pouring a freshly prepared 1in 10 dilution of bleach (12.5% available chlorine) around the edges of the spill and then into the spill, avoiding splashing; and
- PPE and other material used for the clean-up is disposed of as biological waste.

Incident reporting requirements

95. Any loss or release of a biological agent outside of containment, either confirmed or suspected (including the loss of a culture down the sink or an animal that is unaccounted for) is to be reported as an incident via the Workplace safety incident and hazard reporting tool and investigated locally as per the WHS Incident management procedure.

96. If the biological agent has been genetically modified or infected with a genetically modified agent, the OGTR must be notified through the IBC Secretary via rdna.officer@anu.edu.au as soon as possible after the incident has been dealt with.

97. Any exposure of a worker to a GM risk group micro-organism e.g. via a needle stick injury, must also be reported to the OGTR via the IBC Secretary by contacting rdna.officer@anu.edu.au as soon as possible after the incident has been dealt with.

98. If the biological agent is subject to biosecurity controls then DAWR must be notified via the local Biosecurity office or the WEG.

99. Any illness or injury sustained in association with ANU research or teaching activities must be reported using the Workplace safety incident and hazard reporting tool as per the WHS Incident management procedure.

Sources

Legal and other requirements
Work Health & Safety Act 2011 (Cth)

Work Health & Safety Regulations 2011 (Cth)
Biosecurity Act 2015 (Cth)
Gene Technology Regulations 2001 (Cth)
Gene Technology Act 2000 (Cth)
National Health Security Act 2007 (Cth)
Australian Standard/New Zealand Standard *2243.3:2010 Safety in laboratories Microbiological safety and containment*

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