1. CONTENTS

SECTION 1 - BACKGROUND ............................................................................................................. 4
1. INTRODUCTION ......................................................................................................................... 4
2. LEGAL AND OPERATIONAL FRAMEWORK ............................................................................ 4
3. DEFINITIONS ............................................................................................................................. 4
4. BIOSAFETY POLICY .................................................................................................................. 6
5. RESPONSIBILITIES – UNIVERSITY OF SOUTH AUSTRALIA ............................................ 6
6. INSTITUTIONAL BIOSAFETY COMMITTEE - BACKGROUND ............................................. 7

SECTION 2: INSTITUTIONAL BIOSAFETY COMMITTEE: TERMS OF REFERENCE ............ 8
7. RESPONSIBILITIES OF THE INSTITUTIONAL BIOSAFETY COMMITTEE ....................... 8
8. COMMITTEE MEMBERSHIP ..................................................................................................... 9
9. TERM OF OFFICE, MEETINGS AND QUORUM ................................................................ 9
10. CONFIDENTIALITY & SECURITY ......................................................................................... 9
11. CONFLICT OF INTEREST ....................................................................................................... 10
12. INDEMNIFICATION OF COMMITTEE MEMBERS ............................................................... 10
13. REVOCATION OF MEMBERSHIP ........................................................................................ 11
14. COMPLAINTS RESOLUTION .................................................................................................. 12
15. RETENTION OF RECORDS ..................................................................................................... 12
16. SHARING OF EXPERTISE BETWEEN INSTITUTIONAL BIOSAFETY COMMITTEES ................................................................. 12

SECTION 3: WORKING WITH BIOHAZARDOUS MATERIALS ........................................... 13
17. MICROBIOLOGICAL RISK GROUPS ..................................................................................... 13
18. WORKING WITH HUMAN, ANIMAL OR PLANT CELLS, TISSUES OR SPECIMENS ................................................................. 14
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>19.</td>
<td>CONTAINMENT FACILITIES FOR MICROBIOLOGICAL WORK</td>
<td>15</td>
</tr>
<tr>
<td>20.</td>
<td>IBC APPROVAL FOR BIOHAZARDOUS OR INFECTIOUS MATERIAL</td>
<td>16</td>
</tr>
<tr>
<td>21.</td>
<td>CONTAINMENT FACILITIES FOR GMO WORK</td>
<td>17</td>
</tr>
<tr>
<td>22.</td>
<td>WORKING WITH GMOs</td>
<td>18</td>
</tr>
<tr>
<td>23.</td>
<td>GMO LICENCES</td>
<td>23</td>
</tr>
<tr>
<td>24.</td>
<td>IBC APPROVAL FOR GM WORK</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>SECTION 4: WORKING WITH GENETICALLY MODIFIED ORGANISMS (GMOs)</td>
<td>17</td>
</tr>
<tr>
<td>25.</td>
<td>IMPORTATION OF BIOLOGICAL MATERIAL</td>
<td>26</td>
</tr>
<tr>
<td>26.</td>
<td>TRAINING IN BIOSAFETY</td>
<td>28</td>
</tr>
<tr>
<td>27.</td>
<td>AUDITING OF BIOHAZARD FACILITIES</td>
<td>29</td>
</tr>
<tr>
<td>28.</td>
<td>REPORTING</td>
<td>29</td>
</tr>
<tr>
<td>29.</td>
<td>CLEANING AND WASTE DISPOSAL</td>
<td>30</td>
</tr>
<tr>
<td>30.</td>
<td>STORAGE OF BIOHAZARDOUS MATERIALS AND GMOs</td>
<td>31</td>
</tr>
<tr>
<td>31.</td>
<td>TRANSPORT OF BIOHAZARDOUS MATERIALS AND GMOs</td>
<td>32</td>
</tr>
<tr>
<td>32.</td>
<td>BIOHAZARD EMERGENCY PLAN</td>
<td>33</td>
</tr>
<tr>
<td>33.</td>
<td>REVIEW OF BIO-SAFETY MANUAL</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>SECTION 5: ASSOCIATED ACTIVITIES</td>
<td>26</td>
</tr>
<tr>
<td>34.</td>
<td>Appendix 1 – Biological Hazard Risk Assessment Form</td>
<td>36</td>
</tr>
<tr>
<td>35.</td>
<td>Appendix 2 – Extract from NHMRC Immunisation Handbook</td>
<td>39</td>
</tr>
<tr>
<td>36.</td>
<td>Appendix 3 – List of Exempt Dealings</td>
<td>41</td>
</tr>
<tr>
<td>37.</td>
<td>Appendix 4 – Host/Vector Systems for Exempt Dealings (Table 5)</td>
<td>43</td>
</tr>
<tr>
<td>38.</td>
<td>Appendix 5 – Kinds of Dealings suitable for at least NLRD-PC1(Tables 6 and 7)</td>
<td>45</td>
</tr>
<tr>
<td>39.</td>
<td>Appendix 6 – Dealings requiring a Licence (as per Schedule 3 Part 3 of the Act) (Table 8)</td>
<td>49</td>
</tr>
<tr>
<td>40.</td>
<td>Appendix 7 – Viral Vector Flow Chart</td>
<td>52</td>
</tr>
<tr>
<td>41.</td>
<td>Appendix 8 – PC Facility Induction Checklist</td>
<td>57</td>
</tr>
<tr>
<td>42.</td>
<td>Appendix 9 – Response to Spill or Unintentional Release of</td>
<td></td>
</tr>
</tbody>
</table>
We would like to thank the Chair and the executive officer of the Flinders University IBC for allowing us access to their Biosafety Manual as an aid in preparing this document.
SECTION 1 - BACKGROUND

1. INTRODUCTION

In accordance with the requirements of the Work Health and Safety Act 2012 (SA), University of South Australia is required to exercise a duty of care towards staff, students, contractors and visitors. General principles guiding safe work at the University are provided in the University’s Health Safety and Injury Management Policy, Procedures and Guidance Notes at:

Safety and Wellbeing

The Office of the Gene Technology Regulator (OGTR) has specific requirements in relation to practices and procedures involving Genetically Modified Organisms (GMOs). The University of South Australia is an OGTR-accredited organisation.

The OGTR focus is on the containment of GMOs and animals, plants and microbes that contain GMOs, through a registration and licensing system. Transport and storage of GMOs are also an OGTR consideration. Further information is available at:

Office of the Gene Technology Regulator (OGTR)

This Manual summarizes the operation of the University of South Australia Biosafety management system and provides links to other relevant information and resources.

2. LEGAL AND OPERATIONAL FRAMEWORK


The management system requirements of SafeWork SA, Safe Work Australia, Return to Work SA, Work Health and Safety Act 2012 (SA), Work Health and Safety Regulations 2012 (SA) and the OGTR are based on principles as found in the Standards ISO 9000 (Quality Assurance Systems) and ISO 14000 (Environment Management Systems).

3. DEFINITIONS

Accreditation

Organisations may be OGTR-accredited under Section 92 of the Gene Technology Act 2000. In order to gain accreditation, the organisation must show that it is able to establish and maintain, or have access to, an Institutional Biosafety Committee able to assess, approve and supervise Dealings.

Biohazard

Any material of biological origin which has the capacity to be detrimental to other biological organisms. Biohazard includes:

- Microorganisms (including bacteria, parasites, fungi, viruses and prions) infectious to
humans, animals and plants

• Organisms or microorganisms capable of producing toxins detrimental to humans, animals and plants
• Biological material of human, animal or plant origin transfected with infectious or toxin-producing microorganisms
• Biological material of human, animal or plant origin naturally containing infectious or toxin-producing microorganisms
• Any object or material contaminated with infectious or bio-toxic\(^1\) material, including sharp objects

**Certification**

OGTR-accredited organisations may apply under Part 7 Division 2 of the Gene Technology Act 2000 to have facilities certified to specified Physical Containment (PC) levels. All Dealings, apart from Exempt Dealings, must be carried out in appropriate certified facilities.

**Dealing**

• Any experiments or activities involving making, developing, producing, manufacturing, breeding, propagating, growing, raising, culturing, importing or exporting a GMO.
• The use of a GMO in manufacturing a product that is not a GMO.
• Storage, transport or disposal of a GMO.

**DIR**

Dealing with Intentional Release (OGTR classification) - a Dealing that includes the intentional release of a GMO into the environment. Each DIR requires an individual licence, specific to the work, from the OGTR.

**DNIR**

Dealing with No Intentional Release (OGTR classification) - a Dealing that does not include the intentional release of a GMO into the environment. Each DNIR requires an individual licence, specific to the work, from the OGTR.

**Exempt Dealing**

Exempt Dealings are classified as Dealings under the Act, but they do not require a licence specific to the work and do not need to be reported to the OGTR.

**Gene Technology**

• Any technique used for the modification of genes or other genetic material.
• Genetically Modified Organism (GMO)
• An organism that has been modified by gene technology.

\(^{1}\) Only toxins of a biological nature are included in this Biosafety Manual. Use of chemical toxins is regulated by the Chemical and Nanomaterials Committee and use of ionising radiation by the Radiation Safety Committee.
IBC
Institutional Biosafety Committee

NLRD
Notifiable Low Risk Dealing (OGTR classification) - a Dealing that must be undertaken in an OGTR-certified PC facility, does not require an individual licence specific to the work but does need to be reported to the OGTR by the accredited organisation.

OGTR
Office of the Gene Technology Regulator

Organism
A biological entity that is viable, capable of reproduction or capable of transforming genetic material.

PC
Physical Containment - specialised containment facilities incorporating structural and behavioural measures to prevent contamination of personnel or the environment.

4. BIOSAFETY POLICY

University of South Australia (hereafter referred to as the University) has a duty of care to all staff, students, volunteers, contractors and visitors. The University aims to meet all requirements of the Work Health and Safety Act 2012, the Gene Technology Act, 2000, and all other relevant legislation.

In order to meet that aim, the University provides human, physical and financial resources to support Biosafety work and uses specialist expertise as required. An Institutional Biosafety Committee (IBC) has been established to ensure that activities involving biohazards are planned and executed in such a way that every reasonable precaution is taken to protect the health and safety of each employee, the public, and environment, and to prevent damage to property.

The University also aims to ensure that applications to conduct or participate in research utilising GMOs and biohazardous materials are examined in detail prior to such approval and that safety guidelines laid down for particular research projects are adhered to in the conduct of that research.

The University has established contingency plans for dealing with biosafety incidents and accidents. These are outlined in Section 4:31 of this manual.

The Biological Hazards and Genetically Modified Organisms Policy (Policy No. RES-4.3) will be reviewed at least every 3 years and when required to maintain currency with changes in relevant legislation.

5. RESPONSIBILITIES – UNIVERSITY OF SOUTH AUSTRALIA

The Vice-Chancellor (University of South Australia) has the ultimate responsibility for meeting the requirements of the Work Health and Safety Act 2012, Gene Technology Act, 2000, and
associated Regulations and Standards.

The University’s Deputy Vice-Chancellor: Research & Innovation (DVCRI) is responsible for ensuring that Biosafety is managed safely at the University and in accordance with all legislative requirements, and that resources are available to meet those requirements.

The Director: Human Resources has overall responsibility for the health, safety and welfare of University staff, students and volunteers, as well as for contractors and visitors to the University.

The Pro Vice Chancellors are responsible for ensuring allocation of resources to enable compliance with legislative requirements and University policies and procedures within each Division.

The Directors/Heads of Schools/Institutes/Units have specific delegated responsibility for ensuring that University requirements are met within the sectors under their leadership.

Supervisors must ensure that:

- Sufficient project reviews are undertaken to ensure that all biological manipulations, in progress and intended, are approved by the Institutional Biosafety Committee.
- Approval for Biosafety work is obtained from the Institutional Biosafety Committee prior to commencement of any project involving biohazards or GMOs
- Staff under their supervision are consulted when new Biosafety work is planned
- OGTR rules are posted in OGTR-certified areas
- Personnel working with biohazards are familiar with the University Biosafety Manual and the Policy and Procedures therein and
  - adhere to the requirements of the Biosafety Manual
  - have received training in all aspects of biosafety work
  - have received specific training with regards to working with GMOs, if indicated

All persons undertaking biosafety work have an obligation to ensure that:

- Their activities do not risk their own safety
- They do not expose other personnel to risk
- They comply with all requirements detailed in the University Biosafety Manual and the Policy and Procedures therein

6. INSTITUTIONAL BIOSAFETY COMMITTEE - BACKGROUND

6.1 Role of the Committee

The role of the Institutional Biosafety Committee (IBC) is to oversee research and teaching activity involving genetically-modified organisms and Risk Group 2 biohazardous material, to assist the University in fulfilling its duty of care and meet the aims of the Biosafety Policy.

6.2 Reporting Structure

The IBC reports directly to the DVCRI.
SECTION 2: INSTITUTIONAL BIOSAFETY COMMITTEE: TERMS OF REFERENCE

7. RESPONSIBILITIES OF THE INSTITUTIONAL BIOSAFETY COMMITTEE

The terms of reference for the University of South Australia Institutional Biosafety Committee are:

7.1 To undertake the assessment, review and approval of all University activities involving the use of biological hazards, Genetically-modified Organisms and pathogenic organisms (including assessing the qualifications and experience of those involved).

7.2 To provide advice to the University community on potential hazards and their management.

7.3 To inspect physical containment facilities such as laboratories against the requirements of the Office of the Gene Technology Regulator (OGTR) at least once per year.

7.4 To ensure that biological and physical containment facilities at all levels meet, and continue to meet, the safety requirements set down in the “Handbook on the Regulation of Gene Technology in Australia” produced by the OGTR and/or Standards Australia AS/NZS 2243.3: 2010 “Safety in Laboratories: Part 3: Microbiological safety and containment”.

7.5 To maintain a register of IBC approved experiments and activities and those involved in using University containment facilities.

7.6 To communicate changes in Gene Technology Regulations and Australia/New Zealand Standards of Safety in Laboratories (AS2243.3) or similar guidelines.

7.7 To make inspections of laboratories or other work areas to ensure that appropriate safety requirements are being met.

7.8 To make regular reports to the Research Integrity, Accountability and Compliance Committee. These reports will include:

- a list of the titles of projects and/or activities considered since the last report
- the names of those involved
- the location of the projects and/or activities
- their approval status
- the level of containment

7.9 To assist the University to prepare annual reports to the OGTR as required under the Gene Technology Regulations.

7.10 To prepare and retain minutes of all meetings and copies of all correspondence to researchers and others regarding requirements and other matters.

7.11 To consider any other matter relevant to biological safety referred to it by the Research Integrity, Accountability and Compliance Committee.
8. COMMITTEE MEMBERSHIP

8.1 The composition of the Committee is such that it can competently carry out its duties.

8.2 All members are invited to join the Committee by the DVCRI and have equal voting rights.

8.3 The Committee should include at least the following members:

• Two molecular biologists with the requisite knowledge and expertise to assess, evaluate and oversee work involving the use of gene technology.
• One virologist and/or microbiologist with the requisite knowledge and expertise to assess, evaluate and oversee work involving the use of microorganisms.
• One researcher currently using gene technology in his/her research.
• A representative of the University Occupational Health and Safety Unit.
• A representative of the Facilities Management Unit.
• A representative of the Animal Ethics Committee.
• An independent member (i.e. a person with no personal, pecuniary or research association with the University).
• A Chairperson will be appointed by the DVCRI from the membership of the Committee.
• A Deputy Chairperson should be nominated by the Chair and elected by and from the Committee membership.
• An Executive Officer (non-voting member) will be appointed by Research Services Unit (RSU).
• Any other person or persons may be recruited by the Committee to assist in its function or to provide special expertise, to a maximum voting membership of 8 persons.

9. TERM OF OFFICE, MEETINGS AND QUORUM

9.1 The term of office for members is 3 years, with eligibility for further terms.

9.2 The IBC will meet as required but generally four times a year.

9.3 A quorum shall be half the membership plus one.

10. CONFIDENTIALITY & SECURITY

10.1 Maintaining confidentiality and security is essential to protecting the approval process as well as privacy, innovation, the integrity of research and the reputation and safety of individuals and Institutions.

10.2 Members of the IBC must sign a Confidentiality Agreement which protects information, conversations, deliberations or decisions from being disclosed outside of the Committee itself.

10.3 Any visitors, guests or observers present at AEC meetings must also sign Confidentiality Agreements.

10.4 Information may be sought by IBC members from contacts outside the IBC with regards to specific issues, but applicants must not be identified nor information divulged which could
identify projects or applicants or which could be regarded as socially, scientifically or commercially sensitive. Those contacts must also be informed of the sensitive nature of such an enquiry and the corresponding confidentiality restrictions and be asked to be mindful of such, to exercise absolute discretion and not to discuss the nature of any conversations or information gained with other persons except in conjunction with IBC business or purposes.

10.4 Current institutional Confidentiality Agreements signed by IBC members cover in situations where expert advice was sought and provided by a member of another (SA-based) IBC. If the IBC deemed this not sufficient, then a standard one-way Confidentiality Agreement would be requested to be signed by the person providing assistance.

10.5 It is up to members to seek advice from the Chair if they are unsure of how to balance their responsibilities with regards to confidentiality and security.

10.6 University of South Australia Information Technology (IT) policies, procedures and guidelines must be adhered to:

- When using IT facilities or equipment.
- When accessing University of South Australia webpages or shared sites.

10.7 Should any confidential information (or any storage device containing confidential information) pertaining to the AEC be lost or stolen, the EO must be notified immediately.

11. CONFLICT OF INTEREST

11.1 A member of the IBC will not take part in the assessment/approval of a project/activity where the member is involved in that project/activity.

11.2 Any conflicts of interest must be declared prior to out-of-session assessment of applications and Minuted at the subsequent full Committee meeting that ratifies the assessment outcome.

12. INDEMNIFICATION OF COMMITTEE MEMBERS

The University shall indemnify individual members who serve on the IBC for any costs arising as the result of legal action against individual members, as a result of work that they undertake as a committee member.
13. **REVOCATION OF MEMBERSHIP**

13.1 In certain circumstances, the Committee may resolve to recommend to the DVCRI that a member be removed from the Committee. This may occur where the member:

- Has a real or apparent conflict of interest with the interests of the Committee.
- Behaves in a way which brings the Committee into disrepute.
- Impedes the Committee from fulfilling its Terms of Reference.
- Engages in misconduct.
- Incurs a criminal record.
- Incurs termination of employment due to misconduct.
- Has a poor attendance record (i.e. misses three meetings in a row without leave of absence, without good cause or without notifying the Executive Officer).
- Fails to meet confidentiality requirements.
- Consistently fails to review applications and documents distributed for review by the Executive Officer.
- Uses information for purposes other than those intended.
- Behaves in a manner which impairs the effectiveness of the Committee.
- Demonstrates mental or physical incompetence.

13.2 Prior to making a resolution to recommend removal, the Chair will meet with the member to outline the basis for the recommendation and will provide the member with reasonable opportunity, not exceeding two weeks, to be heard or to make a written submission in response. Following receipt of the member’s response, the Committee may:

- Resolve to recommend that the member be removed from the Committee.
- Resolve to retain the member.

13.3 Where the Committee resolves that a member be removed, the Chair of the Committee will take this recommendation to the DVCRI. The granting of such a request is at the discretion of the DVCRI. Should it be granted the member’s membership will cease immediately on notification by the DVCRI to this effect.

- The DVCRI may prohibit a member from being on property under his or her control (thus preventing that member from attending IBC meetings) whilst a resolution to recommend removal is considered, or in the case that criminal charges or allegations of misconduct are being investigated.
- A member may submit a complaint or grievance, in accordance with Section 2:14, about any step in this process.
14. COMPLAINTS RESOLUTION

Where complaints are made against the decisions of the IBC, the Chairperson will refer the matter to the DVCRI for resolution.

15. RETENTION OF RECORDS

The IBC will keep/maintain records of all approvals for:

15.1 Microbiological work, Risk Group 2 and higher

15.2 All genetic manipulation work that is classified by the IBC as:

- Exempt Dealings
- Notifiable Low Risk Dealings (NLRD)
- Dealings Not Involving Intentional Release (DNIR)
- Dealings Involving Intentional Release (DIR)
- Stored GMOs if not part of an approved Dealing
- Stored microbiological materials that fall within the scope of this manual

16. SHARING OF EXPERTISE BETWEEN INSTITUTIONAL BIOSAFETY COMMITTEES

16.1 For specific applications which are outside of the expertise of the IBC assistance can be sought from members of alternative IBCs in the South Australian IBC Network. This follows an agreement between the Chairs of member IBCs of this Network.

16.2 Requests for such external advice may be sought directly by the IBC Chair (or EO) approaching another IBC Chair as required.

16.3 A standard one-way Confidentiality Agreement may need to be signed by the person providing advice where institutional Confidentiality Agreements signed by IBC members do not adequately cover this arrangement.
SECTION 3: WORKING WITH BIOHAZARDOUS MATERIALS

17. MICROBIOLOGICAL RISK GROUPS

In Australia and New Zealand, the following classifications of micro-organisms are used, which are based on the pathogenicity of the agent, the mode of transmission and the availability of preventive measures and treatment.

17.1 Human and Animal Infectious Microorganisms

Risk Group 1 (low individual and community risk) – a microorganism that is unlikely to cause disease in humans or animals.

Risk Group 2 (moderate individual risk, limited community risk) – a microorganism that can cause human or animal disease, but 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 preventive measures are available, and the risk of spread is limited.

Risk Group 3 (high individual risk, limited to moderate community risk) – a microorganism that usually causes serious human or animal disease and may present a significant risk to laboratory workers. It could present a risk if spread in the community or the environment, but there are usually effective preventive 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 is readily transmissible from one individual to another. Effective treatment and preventive measures are not usually available.

17.2 Plant Infectious Microorganisms

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 already 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 a limited ability to spread without the assistance of a vector.

Plant Risk Group 3 - 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.

17.3 Invertebrates Carrying Microorganisms

Invertebrate Risk Group 1 - microorganisms 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 carried by invertebrates where the microorganisms are a low to moderate risk to humans or to the environment and are already present but not widely distributed. They have a limited ability to disperse because of low persistence of the

---

2 AS/NZS 2243.3:2010, Section 3
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 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 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. They may be carried by invertebrates that are difficult to detect visually.

18. WORKING WITH HUMAN, ANIMAL OR PLANT CELLS, TISSUES OR SPECIMENS

Human, animal or plant standard cell lines (e.g. bought from a commercial supplier) are considered to be in Risk Group 1, unless otherwise indicated by the supplier.

Human or animal clinical or diagnostic specimens (i.e. a specimen that has been obtained purely for the purpose of diagnosing or monitoring a disease or condition) are considered to be in Risk Group 2, unless a higher Risk Group is indicated by the source or clinical history of the samples.

Work with human, animal or plant cells or tissues has the potential to be hazardous, dependent on the source of the material and the likelihood that it contains micro-organisms or biotoxins. PC1 laboratories can be adequate for working with this material if good microbiological practices are followed, but a documented Risk Assessment should be carried out prior to use to determine what PC level is appropriate.

Preparation of primary cells from human or animal organs or tissues should be done in PC2 containment.

All cells and tissues must be decontaminated prior to disposal.

Facilities within the University are not currently equipped to work with Risk Groups 3 and 4 microorganisms.

For examples of microbiological organisms in each of the Risk Groups, refer to Australian Standard 2243.3:2010 “Safety in Laboratories: Part 3: Microbiological safety and containment”. The Standard may be accessed through the SAI Global public database, Standards Online, via the University library.
19. CONTAINMENT FACILITIES FOR MICROBIOLOGICAL WORK

18.1 Physical Containment Levels

There are four physical containment levels corresponding to Risk Groups 1 – 4, as defined in Section 1:17 (above).

All work performed in a laboratory or facility of a specific containment level must follow the procedures set out for that level of containment, but it is important to note that the laboratory must comply with the Australian Standard 2243.3:2010 “Safety in Laboratories: Part 3” but does not necessarily require certification. The Standard may be accessed through the SAI Global public database, Standards Online, via the University library.

Animals and plants inoculated with organisms from the above Risk Groups must be housed in containment facilities appropriate to the physical containment level.

A summary of each Containment Level is provided below. Comprehensive information about the requirements for each Level is detailed in Australian Standard 2243.3:2010 “Safety in Laboratories: Part 3: Microbiological safety and containment”.

18.2 Physical Containment Level 1 (PC1)

This level of facility with its practices and equipment is appropriate for general and teaching laboratories.

A Physical Containment Level 1 laboratory is suitable for work with microorganisms where the hazard levels are low, and where laboratory personnel can be adequately protected by standard laboratory practice. The organisms used are not known to cause disease in healthy adults (i.e. organisms are in Risk Group 1).

Work may be carried out on the open bench. Specimens that have been inactivated or fixed may be carried out in PC1 facilities.

18.3 Physical Containment Level 2 (PC2)

This level of facility with its practices and equipment is applicable to clinical, diagnostic, teaching and other premises where work is carried out with microorganisms or material likely to contain microorganisms, which may be present in the community, where the microorganism may be associated with animal, plant or human disease of moderate severity, (i.e. Risk Group 2 microorganisms).

With good microbiological techniques, work with these agents may be carried out on the open bench. If there is a significant risk from the production of aerosols, a biological safety cabinet should be used.
18.4 Physical Containment Level 3 (PC3)

This level of facility with its practices and equipment is applicable to clinical, diagnostic and other premises where work is carried out with indigenous or exotic microorganisms, and where there is a risk of serious infection to humans, animals or plants. Work with Risk Group 3 microorganisms must be carried out in Physical Containment Level 3 facilities.

A Physical Containment Level 3 laboratory provides safeguards to minimize the risk of infection to individuals, the community and the environment. **PC3 facilities are not available within the University at present.**

18.5 Physical Containment Level 4 (PC4)

This level of facility with its practices and equipment is applicable to work with highly infectious microorganisms, including Risk Group 4 microorganisms that pose a high individual risk of life-threatening disease and may be readily spread to the community.

PC4 facilities are not available within the University at present.

20. **IBC APPROVAL FOR BIOHAZARDOUS OR INFECTIOUS MATERIAL**

19.1 IBC Approval Procedures

Work specified as Risk Group 1 (refer Section 3:17) does not require approval from the IBC. However, PC1 procedures must be followed when working with these organisms.

All work specified as Risk Group 2 (Section 3:17) must be approved by the IBC and must be carried out in a PC2 microbiological facility. Procedures required for a PC2 microbiological facility, as set out in Australian Standard 2243.3:2010 “Safety in Laboratories: Part 3: Microbiological safety and containment” must be followed. Microbiological facilities are not certified but are audited by the IBC (refer to Section 3:18).

IBC approval must be obtained for Storage of all microbiological organisms of Risk Group 2 (if not part of an approved project)

The IBC must be notified of the importation or acquisition of all microbiological organisms of Risk Group 2 (if not part of an approved project)

To obtain approval from the IBC:

- Complete the Biohazard Application Form for the proposed project, acquisition or storage
- Submit form to the Executive Officer (EO) of the IBC via email to biosafety@unisa.edu.au
- Applications will be checked by the (EO) then distributed to the Committee members. Applications are assessed and approved “out of session”.
- The application form and information for obtaining IBC approval is available for download from the IBC web page: [Biosafety and Gene Technology](#)
There are currently no facilities within the University equipped for working with risk groups 3 and 4 microorganisms.

SECTION 4: WORKING WITH GENETICALLY MODIFIED ORGANISMS (GMOS)

21. CONTAINMENT FACILITIES FOR GMO WORK

20.1 OGTR Containment Levels

Four levels of containment facilities are defined for working with GMOs. These are PC1 to PC4 and these classifications harmonise with the Physical Containment classifications for microbiological work (Section 3:18). That is, for any one containment level, similar risk factors are associated with either microbiological work or work with GMOs. However, work with GMOs may need to be undertaken in OGTR-certified facilities.

The OGTR has strict rules for working with GMOs and the Certification of containment facilities.

20.2 Certification of Containment Facilities

The Gene Technology Act requires NLRD PC1, NLRD PC2, DNIR and DIR Dealings to be conducted within an OGTR-certified facility.

The University currently has both Physical Containment Level 1 & Level 2 OGTR-certified animal, arthropod and laboratory facilities.

To be granted Certification, a facility must meet each of the requirements specific for that classification of certification.

Facilities are certified for a 5 year period. At the conclusion of this time a request for recertification can be submitted. Certified laboratories will have signage on the door specifying the certification and the approval period.

Certified facilities are inspected annually.

Personnel using OGTR-certified facilities must be trained in the requirements of that facility, and the training must be documented.

OGTR-certified facilities may be audited / inspected by the OGTR at any time.

For OGTR-certification of PC1 and PC2 animal, arthropod and laboratory facilities, both the Australian Standard 2243.3:2010 “Safety in Laboratories: Part 3: Microbiological safety and containment” and OGTR “Guidelines for Certification of a Physical Containment (TYPE) Facility” requirements must be adhered to. The Standard may be accessed through the SAI Global public database, Standards Online, via the University library. OGTR Guidelines for each type of facility may be downloaded from the OGTR website:

OGTR Certification Guidelines for PC Facilities

There are currently no facilities certified to work with GMOs at PC3 and PC3 level within the University.
22. WORKING WITH GMOS

All work involving GMOS comes under the control of the OGTR as set out in the Gene Technology Act 2000 and Gene Technology Regulations 2001 (updated September 2011).

The requirements of the OGTR are detailed on the OGTR website at www.ogtr.gov.au

Limited extracts from the site are reproduced below but researchers wishing to work with a GMO (designated by the OGTR as a ‘dealing’) should access the site and consult the Gene Technology Act 2000 and the Gene Technology Regulations 2001.

All work involving GMOS must be approved by the IBC; any work involving a DNIR or DIR must also be licenced by the OGTR.

21.1 What is a GMO?

A GMO is an organism that has been modified by the use of gene technology.

Organisms that are not classed by the OGTR as GMOS are shown in Table 1.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description of organism</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species)</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>A whole animal, or a human being, modified by the introduction of naked recombinant nucleic acid (such as a DNA vaccine) into its somatic cells</td>
<td>IF: the introduced nucleic acid is incapable of giving rise to infectious agents</td>
</tr>
<tr>
<td>3</td>
<td>Naked plasmid DNA that is incapable of giving rise to infectious agents when introduced into a host cell</td>
<td>-</td>
</tr>
<tr>
<td>6</td>
<td>An organism that results from an exchange of DNA</td>
<td>IF: the donor species is also the host species AND the vector DNA does not contain any heterologous DNA</td>
</tr>
<tr>
<td>7</td>
<td>An organism that results from an exchange of DNA between the donor species and the host species</td>
<td>IF: such exchange can occur by naturally occurring processes AND the donor species and the host species are micro-organisms that satisfy the criteria in AS/NZS 2243.3:2010 (Safety in laboratories, Part 3) for classification as Risk Group 1 AND are known to exchange nucleic acid by a natural physiological process AND the vector used in the exchange does not contain heterologous DNA</td>
</tr>
</tbody>
</table>
from any organism other than an organism that is involved in the exchange

Table 1: Organisms that are not GMOs (from Schedule 1 of the Act)
21.2 What is Gene Technology?

Gene technology is any technique used for the modification of genes or other genetic material.

Techniques that are not classed by the OGTR as gene technology are shown in Table 2.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description of technique</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Somatic cell nuclear transfer</td>
<td>IF: the transfer does not involve genetically modified material</td>
</tr>
<tr>
<td>2</td>
<td>Electromagnetic radiation induced mutagenesis</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>Particle radiation induced mutagenesis</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>Chemical induced mutagenesis</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>Fusion of animal cells, or human cells</td>
<td>IF: the fused cells are unable to form a viable whole animal or human</td>
</tr>
<tr>
<td>6</td>
<td>Protoplast fusion, including fusion of plant protoplasts</td>
<td>-</td>
</tr>
<tr>
<td>7</td>
<td>Embryo rescue</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>In vitro fertilisation</td>
<td>-</td>
</tr>
<tr>
<td>9</td>
<td>Zygote implantation</td>
<td>-</td>
</tr>
</tbody>
</table>
| 10   | A natural process  
Examples of natural processes include conjugation, transduction, transformation and transposon mutagenesis | IF: the process does not involve genetically modified material |

Table 2: Techniques that are not gene technology (from Schedule 1A of the Act)

21.3 What is a Dealing?

A Dealing includes any of the activities listed in Table 3:

- The term 'dealings', in relation to a genetically modified organism (GMO) is defined in the Gene Technology Act 2000 (the Act).
- ‘Deal with’, in relation to a GMO, means the following:
  - conduct experiments with the GMO
  - make, develop, produce or manufacture the GMO
  - breed the GMO
  - propagate the GMO
  - use the GMO in the course of manufacture of a thing that is not the GMO
  - grow, raise or culture the GMO
  - import the GMO
  - transport the GMO
  - dispose of the GMO
  - possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs in Tables 4-8.

Table 3: OGTR definition of Dealings
21.4 What is an Exempt Dealing?

Exempt Dealings are classified as Dealings under the Act but do not require a licence specific to the work.

Exempt dealings must be approved by the IBC but do not need to be reported to the OGTR.

There is no prescribed PC facility requirement for Exempts dealings, but the OGTR strongly suggests that all Exempt Dealings be carried out under PC1 conditions, a view that is supported by the IBC.

Activities described as Exempt Dealings are shown in Table 4 in Appendix 3.

21.5 What is a Host/Vector System?

The OGTR specifies which host/vector systems may be used for Exempt Dealings.

A vector system is the means by which donor nucleic acid is introduced into a host cell.

The host is the type of cell into which donor nucleic acid is introduced.

Vector systems can include plasmids, non-conjugative plasmids, bacteriophages or viruses.

- Non-conjugative plasmid means a plasmid that is not self-transmissible, and includes, but is not limited to, non-conjugative forms of the following plasmids:
  - bacterial artificial chromosomes (BACs)
  - cosmids
  - P1 artificial chromosomes (PACs)
  - yeast artificial chromosomes (YACs)

Donor nucleic acid may also be introduced into the host using a non-vector system, which means a system by which donor nucleic acid is or was introduced (for example, by electroporation or particle bombardment) into a host cell:

- in the absence of a nucleic acid-based vector
- using a nucleic acid-based vector in the course of a previous dealing and the vector is:
  - no longer present
  - present but cannot be remobilised from a host cell

Approved host/vector systems are detailed in Table 5 in Appendix 4.
21.6 What is a Notifiable Low Risk Dealing?

Notifiable Low Risk Dealings (NLRDs) are classified as Dealings under the Act but do not require a licence specific to the work.

NLRDs must be approved by the IBC and need to be reported to the OGTR by the accredited organisation; the OGTR will assign its own identification numbers to reported NLRDs; this information, including the name of the accredited organisation and the title of the Dealing, is made publicly available on the OGTR website.

There are prescribed PC facility requirements for NLRDs (PC1 or PC2 only).

Classifications of NLRDs are shown in Tables 6 and 7 in Appendix 5.

21.7 Dealings that are NOT Notifiable Low Risk Dealings

A Dealing that is not an Exempt Dealing or a Notifiable Low Risk Dealing can only be undertaken by a person who is licensed, under the Act, for the Dealing.

A person may only apply for a license after seeking approval for the project from the IBC.

Dealings NOT involving an intentional release of GMOs into the environment (DNIRs) are dealings with GMOs in contained facilities which do not meet the criteria for classification as Exempt Dealings or Notifiable Low Risk Dealings. These dealings must be licensed by the Gene Technology Regulator (the Regulator).

Dealings with a GMO licensed as a DNIR must not involve release into the environment.

The contained facilities used for conducting DNIRs must be certified and typically range from Physical Containment Level 2 (PC2) to Physical Containment Level 4 (PC4). The appropriate level of containment is determined by the Risk Group classification of the wild type (non-genetically modified parent) organism as outlined in the Australian/New Zealand Standard (AS/NZS 2243.3:2010) AND the risk(s) identified for dealings with the specific GMO.

The kinds of dealings with GMOs that are classified as DNIRs are described in Schedule 3, Part 3 of the Gene Technology Regulations 2001 (the Regulations) and are higher risk dealings than NLRDs.

In general, DNIRs consist of dealings with GM pathogenic organisms, or GM organisms containing higher risk genes from pathogens or genes that encode toxins or confer an oncogenic modification or immuno-modulatory function.

Dealings involving an Intentional Release of GMOs into the Australian environment (DIRs) are dealings with GMOs outside contained facilities. These can range from small scale field trials (limited and controlled releases) of GMOs to general/commercial release of GMOs.

Dealings considered to carry a higher risk than those categorised as NLRDs, which may be undertaken only under a licence from the OGTR, are shown in Table 8 in Appendix 6.
21.8 Dealings with Viral Vectors

Dealings with viral vectors can be classified in the DNIR, NLRD, and exempt categories, therefore guidance on the correct classification of contained dealings with viral vectors has been developed – see the flow chart in Appendix 7.

21.9 New and Emerging Technologies in Genetic Engineering

Certain new and emerging technologies are not covered by the Gene Technology Act 2000 or the Gene Technology Regulations 2001. These include siRNAs and other nucleic acids such as DNA oligonucleotides, and gene editing techniques including CRISPR/Cas, ZFN and TALEN.

The most recent advice from the Office of the Gene Technology Regulator is that the responsible IBC should be approving and reporting on these procedures, regardless of the nature of the editing being proposed. All South Australian IBCs have agreed to adopt this position.

As such, the IBC must be notified of any work involving cells containing introduced nucleic acids, even if the nucleic acid is not in a vector and therefore non-replicative (e.g. siRNAs and DNA oligonucleotides). Likewise, any gene editing conducted using (for instance) CRISPR/Cas, ZFN and TALEN must first be approved by the IBC.

Researchers undertaking this type of work should submit a GMO Dealing Application to the IBC.

23. GMO LICENCES

22.1 Licence Legislation

A GMO licence is a legal instrument issued by the Gene Technology Regulator (the Regulator) under the Gene Technology Act 2000 (the Act) that sets down the conditions under which specified dealings with genetically modified organisms (GMOs) must be undertaken. Licences may be issued for Dealings Not involving Intentional Releases (DNIRs), Dealings involving Intentional Releases (DIRs) or Inadvertent Dealings.

A person who deals with a GMO without a licence is guilty of an offence, punishable under Section 32 of the Act if:

- the person deals with a GMO, knowing that it is a GMO; and
- the dealing with the GMO by the person is not authorised by a GMO licence, and the person knows or is reckless as to that fact; and
- the dealing with the GMO is not specified in an Emergency Dealing Determination, and the person knows or is reckless as to that fact; and
- the dealing is not a Notifiable Low Risk Dealing, and the person knows or is reckless as to that fact; and
- the dealing is not an Exempt Dealing, and the person knows or is reckless as to that fact; and
- the dealing is not included on the GMO Register, and the person knows or is
reckless as to that fact.
24. IBC APPROVAL FOR GM WORK

23.1 IBC Approval Procedures

IBC approval must be obtained for:

- All procedures involving GMOs
- Storage of all GMOs (if not part of an approved Dealing)

The IBC must be notified of:

- The importation or acquisition of all GMOs (if not part of an approved Dealing)

NOTE: UniSA is currently not accredited by the OGTR for any GMO work at PC3 or PC4 level.

23.2 To obtain approval from the IBC:

- Complete the forms appropriate for the proposed project, Dealing, acquisition or storage
- The application forms and information for obtaining IBC approval is available for download from the IBC webpage: [Biosafety and Gene Technology](#)
- Submit forms to the Executive Officer (EO) of the IBC via email to biosafety@unisa.edu.au
- Applications will be checked by the EO then distributed to the Committee members. Applications are assessed and approved “out of session”.

Applications for a License from the OGTR for a Dealing Not involving Intentional Release (DNIR) or a Dealing involving Intentional Release (DIR) must first be approved by the IBC. To obtain IBC approval, submit completed DNIR or DIR form, downloaded from [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/forms-1](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/forms-1)

For assistance with OGTR applications, contact the Chair or Executive Officer of the IBC (contact details are on the IBC webpage, as above).


Failure to comply with appropriate PC operating procedures and/or licensing conditions will lead to revocation of approval by the IBC and/or revocation of licence by the OGTR.

23.3 Minor modifications to approved dealings

The OGTR allows the minor modifications to be made to Licensed Dealings; these can be found in Appendix 11. The IBC allow the same minor modifications to be made to approved Exempt and NLR Dealings, with the exception that NLRDs can only be approved for a maximum of 5
years. To apply for approval of a minor modification use the application form on the IBC website (http://w3.unisa.edu.au/res/ethics/safety/genesafety.asp).

23.4 Cross-Institutional Projects

All South Australian IBCs (with the exception of the University of Adelaide) have agreed to accept approval from a single IBC where employees of one Institution are working in a certified facility operated by another Institution, thereby avoiding the unnecessary duplication of IBC review.

Researchers should submit an application to the IBC which oversees the facilities where the work is being conducted, rather than their home organisation’s IBC. For example, a UniSA researcher who plans to work with GMOs in a facility operated by SA Pathology should submit an application to the SA Pathology IBC. Once the dealing has been approved, the SA Pathology IBC will provide copies of all relevant documentation to the UniSA IBC for recordkeeping purposes, but the UniSA IBC will not undertake their own review.

However, if relevant work on a project is being conducted on the premises of two (or more) institutions, the IBCs of both organisations must each review and approve the work, as each IBC has responsibility for work conducted in their own certified facilities. Separate applications covering the entirety of the project should be submitted to both IBCs.

SECTION 5: ASSOCIATED ACTIVITIES

25. IMPORTATION OF BIOLOGICAL MATERIALS

24.1 Permits

Imported biological materials pose a potential quarantine risk, particularly if they are used in animal experimentation. Imported biological materials should be considered as potentially infectious, and handled and disposed of accordingly.

Biosecurity in Australia is the responsibility of the Federal Department of Agriculture, Fisheries and Forestry (DAFF). DAFF has quite specific and strict regulations and requirements regarding the use of imported biological materials. DAFF regulations take into account assessments of the risks associated with the types of materials. Items are usually assessed as unrestricted, restricted or prohibited. Persons wanting to use restricted materials are required to obtain a permit for importation and use of the materials. All imports under DAFF permits must abide by the conditions listed on the permit.

For further information about DAFF import permits and application forms, refer to the DAFF webpages at http://www.daff.gov.au/biosecurity

24.2 Notification

The IBC must be notified of all materials imported via DAFF, or materials brought into UniSA or acquired by staff/students by other means, that fall within the scope of this manual (i.e. microbiological Risk Group 2 or higher and all GMOs). Notification must be made by way of the appropriate IBC application form (see RSU website: http://w3.unisa.edu.au/res/ethics/safety/biosafety.asp).
Biological materials acquired from outside institutions will often require a Material Transfer Agreement (MTA). All MTAs must be forwarded to the RSU for processing.

For further information about MTAs refer to the Research Services Unit website: http://w3.unisa.edu.au/res/contracts/legal.asp
26. TRAINING IN BIOSAFETY

25.1 Induction and Training

Biosafety induction into facilities and ongoing training in working with GMOs or Biohazards to the required PC level is the responsibility of the person nominated as ‘Responsible Person’ for that facility:

- For contractors or visitors
- For facility staff

The approved Project Supervisor is responsible for biosafety induction and ongoing training to the required PC level for all project personnel. A checklist for laboratory induction (which specifies appropriate levels of induction for not only researchers but also contractors and others who only enter facilities infrequently) appears in Appendix 8.

The Institutional Biosafety Committee offers a biosafety training session annually, usually in April. All University staff and HDR students who work with Risk Group 2 biohazards or genetically modified organisms are strongly encouraged to attend this session at least once every 3 years.

The University’s Safety & Wellbeing Team and the IBC also provide online training courses in biosafety and gene technology. These modules are designed to supplement local face-to-face induction and training programs, and can be accessed via the Biosafety Training webpage: http://w3.unisa.edu.au/res/ethics/safety/biosafetytraining.asp. Researchers are encouraged to check this page regularly for updates.

25.2 Records of Training

Records of biosafety training, including training in OGTR requirements, must be kept by the person nominated as the “Responsible Person” for the facility where the work is carried out. These will be required to be produced during the annual audit of the area.

It is recommended that all project supervisors retain a copy of the IBC certificate issued to all staff and students who have attended a training session.

25.3 Immunisation requirements

Where laboratory personnel are working with infectious or potentially infectious microorganisms immunisation may be recommended (especially if pregnant, considering pregnancy, immune-compromised or immune-suppressed). Refer to the University’s Safety Management System (http://w3.unisa.edu.au/safetyandwellbeing/default.asp) for detailed information, including University policies and guidelines for managing these hazards and risks. The School of Pharmacy and Biological Sciences has developed a school-based policy and provides guidelines regarding vaccinations for its researchers.

Appendix 2 shows an extract of the NHMRC Immunisation Handbook showing recommended vaccinations for persons at increased risk of certain occupationally acquired vaccine-preventable diseases.

25.4 Access to PC2 Facilities
Routine access to Animal Facilities is only provided to persons that have undergone the Induction and Training required by the Facility Management.

Routine access to PC facilities is only provided to persons that have:

- Undertaken General Laboratory Safety Induction
- Undertaken PC Facility Induction (Appendix 8)
- Been issued with the required personal protective equipment
- Been authorised as a laboratory user by the IBC

Where access to PC facilities is required for the purposes of maintenance or cleaning, this will only be provided to persons that have:

- Undertaken the Cleaner/Maintenance Induction (Appendix 8)
- Demonstrated that they have any required personal protective equipment
- Been authorised by the nominated Responsible Person for the facility

Names of authorised persons will be maintained by the nominated Responsible Person for the facility, and a record of inductions kept in the Induction folder.

PC2 facilities shall be kept locked at all times when not in use. Only authorised persons shall be provided with a key or key card access to the laboratory.

**Working safely is a condition of access to PC facilities, and repeated failure to observe safe working practices and procedures will result in the withdrawal of access privileges.**

27. **AUDITING OF BIOHAZARD FACILITIES**

26.1 Compliance Auditing

Compliance auditing will take place in two forms:

- The IBC will perform an arranged audit of all OGTR-certified PC1 and PC2 facilities at UniSA on an annual basis. The IBC will perform an arranged audit of all microbiological facilities using Risk Group 2 organisms for compliance with PC2 microbiological procedures on an annual basis.
- The Chair of the IBC (or delegate) will meet with Project Supervisors at least annually to conduct a progress interview of all current NLRDs, DNIRs and DIRs.

26.2 The IBC may also conduct un-announced inspections/audits of facilities and procedures.

26.3 The IBC may investigate any occurrence involving a spill or unintentional release of microorganisms or GMOs.

26.4 The IBC will also undertake investigation where there is a notification of a breach of the OGTR legislation.

28. **REPORTING**
27.1 Reporting to the OGTR

The IBC has the responsibility for reporting to the OGTR:

- The membership of the IBC
- Details of current NLRD, DNIR and DIR projects
- Details of certified containment laboratories, animal facilities and plant facilities
- Annual report as an accredited organisation

27.2 Reporting to the Institution

The IBC has the responsibility for reporting to the DVCRI:

- Activities of the IBC, by way of Institutional Annual Report
- Copy of the annual report submitted to OGTR
- Copy of the annual report submitted to the Director, Human Resources

29. CLEANING AND WASTE DISPOSAL

28.1 Cleaning of PC Facilities

All facilities must be kept clean and tidy at all times. Workbenches should be cleared and surfaces decontaminated at the end of each day.

Items for sterilisation should be collected regularly. Where possible, facilities should be equipped with a “dunk bucket”, containing a detergent or antimicrobial agent, for decontaminating glassware and plasticware prior to washing up/sterilisation.

Contaminated waste should be disposed of on a regular basis. Waste for removal must be double-bagged and the exterior bag surface decontaminated before being removed from the facility.

Walls should be cleaned periodically or when visibly dirty by washing with a detergent solution. Open shelves should be periodically cleaned of dust to reduce the risk of contamination of work areas.

Only trained personnel shall be permitted to clean facilities. Floors should be cleaned after normal working hours, preferably by wet mopping with a detergent solution. Sweeping, dry mopping and vacuuming should be avoided as these procedures produce airborne dust.

28.2 Waste Disposal

All waste must be segregated at the point of generation into:

- General waste – non-infectious material, paper, plastics, paper products*
- Sharps – syringes, needles, broken glass, scalp blades. These must be collected in a puncture-resistant container
• Infectious waste – includes microbiologically contaminated materials such as culture bottles, used gloves, tissue samples. These must be collected into a sturdy bin or plastic bag and must be disposed of by incineration by a commercial waste contractor.

• Microbiological Waste - waste containing live organisms from a PC2 microbiological facility must be treated by either steam sterilisation** or chemical disinfectant treatment***, e.g. 0.5-1% sodium hypochlorite solution (for liquid waste). After treatment, waste can then be disposed by the general waste stream (solid) or by the sewer system (liquid).

• GMO Waste - includes contaminated materials such as culture bottles, used gloves or tissue samples. Waste must be collected in specially-marked plastic bags. Before removal from the facility, waste must be double-bagged and the exterior wiped with disinfectant. Bags must be placed in specified bins for collection and disposal by a commercial waste contractor.

*NO WASTE GENERATED IN A PC2 FACILITY OR INVOLVING WORK WITH GMOs MAY BE TREATED AS GENERAL WASTE*

**Where steam sterilisation is used, the temperature cycle must be monitored and the steam steriliser tested on a monthly basis. Refer to Australian Standard 2243.3:2010 Safety in Laboratories: Part 3: Microbiological Aspects and Containment Facilities.

*** Refer to Australian Standard 2243.3: 2010 Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities, for a full listing of chemical disinfectants.

30. STORAGE OF BIOHAZARDOUS MATERIALS AND GMOS

29.1 Microbiological Materials

Risk Group 1

• Microbiological samples must be clearly labelled and stored in leak-proof containers

Risk Group 2

• Microbiological samples must be clearly labelled and stored in a leak-proof container within a second unbreakable container.

• Secondary containers must be in a secured area to prevent access by unauthorised persons

GMO materials - Exempt & NLRD

• Only GMOs with IBC approval may be stored within any facilities coming under the jurisdiction of the UniSA IBC

• All GMOs must be stored in sealed unbreakable primary containers and then in a secondary container that is labelled with a biohazard symbol, description of contents, date of storage and the contact details for the person responsible for
• Secondary containers must be locked when not in use or located in a secure area that prevents access to the container by persons not authorised to access the contents

Dealings Not Involving or Involving Intentional Release (DNIR or DIR)
• For all completed projects, a storage form must be filled out and submitted to the IBC. The form can be downloaded from:
• All the GMOs must be stored in sealed unbreakable primary containers
• Primary containers must be stored in a secondary container that is labelled with a biohazard symbol description of contents, date of storage and the contact details for the person responsible for the contents
• Secondary containers must be locked when not in use or located in a secure area that prevents access to the container by persons not authorised to access the contents

NOTE: Storage of GMOs classified as DNIR or DIR must be licensed by the OGTR and any licensing conditions must be met.

31. TRANSPORT OF BIOHAZARDOUS MATERIALS AND GMOS

30.1 Within the Facility

No special conditions are required for transporting materials within a facility, i.e. within the walls that constitute the Physical Containment.

30.2 Within the Organisation

Precautions must be taken to ensure the biohazard materials and GMOs do not contaminate the environment. The material should be transported in a sealed unbreakable container, appropriately labelled.

Where the material is PC2 (microbiological or GMO), a secondary sealed outer container must also be used.

30.3 Between Organisations

Stringent procedures have been developed for safe transport of biological, hazardous and dangerous materials by air, rail and road. For full details, refer to Australian Standard 2243.3: 2010 Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities, Section 13 and references therein.


For materials that are not commercially available a Materials Transfer Agreement is also required and must be fully executed prior to transfer (see RSU website:
32. BIOHAZARD EMERGENCY PLAN

Refer also to Appendix 9, “Biohazard – GMO spill or unintentional release flow chart”. These flowcharts are also located in each laboratory where GMO research and high risk microbiological research is conducted.

31.1 Containment Failure

Where there has been a failure to contain biohazardous material or GMOs within a Room/Laboratory/Plant house/Animal facility:

- Immediately notify the Project Supervisor.
- Immediately notify the Chair or Executive Officer of the IBC.
- Immediately notify the nominated Responsible Person for the facility.
- Immediately notify Security, University of South Australia, advising the nature of the incident.

31.2 First Aid Procedures

In case of accidental personal contamination/exposure to any Risk Group 2 biohazardous material or GMO:

- Immediately notify the Project Supervisor.
- Immediately notify the Chair or Executive Officer of the IBC.
- Immediately notify the nominated Responsible Person for the facility.
- Seek medical help if required.

31.3 Biohazard Spills

31.3.1 Spills inside a biological safety cabinet

- Leave the cabinet ON to retain aerosols. Put on gloves.
- Wet inert absorbent material with disinfectant
- Avoid creating aerosols by slowly placing absorbent material wetted with disinfectant over the spill and leave for about 10 minutes.
- Remove the absorbent material and dispose of in correct manner (Section 4:28 of the Biosafety Manual).
- Wipe the floor of the cabinet and any other contaminated surfaces with
• For large spills, or any highly infectious material, decontaminate the cabinet with gaseous sterilant.

31.3.2 Spills outside a safety cabinet but in a room, lab or plant house

31.3.2.1 Low risk microbiological material (unlikely to cause untreatable disease or unpreventable contamination to humans, animals or plants):

• Put on gloves.
• Wet inert absorbent material with disinfectant
• Avoid creating aerosols by slowly placing absorbent material wetted with disinfectant over the spill and leave for about 10 minutes.
• After about 10 minutes, collect material and dispose of in the correct manner (Section 4:28 of the Biosafety Manual).
• Wipe the area with fresh disinfectant.

31.3.2.2 High risk microbiological materials (causes serious disease in humans, animals or plants)

• Do not breathe the aerosol!
• Evacuate the area and close the doors for at least 30 minutes
• Advise others working in the area, including the nominated responsible person for the facility
• Remove and dispose of contaminated clothing
• Assemble several personnel to clean up spill
• Put on clean protective apparel, including mask and gloves
• Wet inert absorbent material with disinfectant
• Avoid creating aerosols by slowly placing absorbent material wetted with disinfectant over the spill and leave for 10 minutes
• Dispose of all contaminated material (Section 28 of the Biosafety Manual)
• Wipe over area with fresh disinfectant
• Discard protective apparel and gloves

31.4 GMO Spills

Follow the procedure for high risk microbiological materials with the following additional step:

• Dispose of all contaminated material as per Section 4:28 of the Biosafety Manual
FOR ANY SPILL, COMPLETE AN ONLINE INCIDENT REPORT FORM WITHIN 12 HOURS

31.5 Investigation of Biohazard-related Injuries or Illness

Incidents, injuries or illnesses related to biosafety will be investigated by:

- A line manager, lab manager or the Divisional safety consultant. A member of the University of South Australia Health Safety & Injury Management Unit
- Any other person or persons as required.

33. REVIEW OF BIO-SAFETY MANUAL

This manual shall be reviewed regularly by the IBC.
34. Appendix 1 – Biological Hazard Risk Assessment Form

## BIOHAZARD RISK ASSESSMENT

**NAME:** .................................................................  **DATE:** .................................................................

**TITLE & DURATION OF ACTIVITY OR PROJECT:** .........................................................................................

**FACILITY TO BE USED (Campus, Building and Room Number):** ............................................................

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Action Required</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSESSING THE BIOHAZARD</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Does your activity or project involve the use of micro-organisms?</td>
<td></td>
<td></td>
<td>If “Yes”, this is a biohazard. Go to Question 3</td>
</tr>
<tr>
<td>2. Does your activity or project involve the use of animals (including invertebrates), plants, soils or other materials that have the potential to spread micro-organisms to humans or the environment?</td>
<td></td>
<td></td>
<td>If “Yes”, this is a biohazard. Go to Question 3</td>
</tr>
<tr>
<td>3. Have the Risk Groups for all biohazards to be used in the activity or project been determined?</td>
<td></td>
<td></td>
<td>If “No” consult “AS/NZS 2143.3:2010” Section 3 - Degree of Hazard from Micro-organisms</td>
</tr>
<tr>
<td>4. Is every biohazard to be used in the activity or project classified as Risk Group 1?</td>
<td></td>
<td></td>
<td>If “No”, apply for approval from the Institutional Biosafety Committee before commencing the activity or project</td>
</tr>
<tr>
<td>5. Does your activity or project involve the use of animals (including invertebrates), plants or other organisms that have the potential to produce toxins harmful to humans or the environment?</td>
<td></td>
<td></td>
<td>If “Yes”, apply for approval from the Institutional Biosafety Committee before commencing the activity or project</td>
</tr>
<tr>
<td>6. Does your activity or project involve the use of gene technology?</td>
<td></td>
<td></td>
<td>If “Yes”, apply for approval from the Institutional Biosafety Committee before commencing the activity or project</td>
</tr>
<tr>
<td>7. Does your activity or project involve the import, export or use of animals (including invertebrates), plants, soils or other materials</td>
<td></td>
<td></td>
<td>If “Yes”, ensure correct biosecurity Australia permit has been obtained and that all approval conditions are</td>
</tr>
</tbody>
</table>

---

*The Standard AS/NZS 2143:2010 Part 3: Microbiological safety and containment* may be accessed through the SAI Global public database, Standards Online, via the University library.*
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Action Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>that require quarantine approval?</td>
<td></td>
<td></td>
<td>adhered to before commencing the activity or project</td>
</tr>
<tr>
<td>RISK GROUP 1 BIOHAZARDS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Has the correct signage been placed outside the laboratory entrances indicating physical containment levels, entry requirements and warning symbols?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Has the biohazard symbol been attached to equipment containing biological hazardous material (e.g. fridges, freezers, liquid nitrogen dewars)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Does the laboratory have a copy of the University Biosafety Manual readily accessible to all staff, students or other personnel?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Is access to the laboratory limited to laboratory staff or students and persons specified by laboratory management?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Are laboratory doors able to be closed when work is in progress?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Are spaces under benches, biosafety cabinets and equipment free from clutter and accessible for cleaning?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Are aisles and exits free of trip hazards and obstructions to allow unimpeded passage?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Will laboratory gowns and gloves be worn at all times while work is being conducted in the laboratory?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Are eye wash stations or single use packs of sterile eye irrigation fluid provided within the laboratory?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Are safety glasses and face shields available if required?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Will procedures generating aerosols be carried out in a biosafety cabinet?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19. Are biosafety cabinets serviced annually?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. Are work surfaces routinely decontaminated with 70% ethanol or other appropriate disinfectant?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. Are plunge buckets containing Virkon or other suitable decontaminant available?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. Are emergency procedures, including spills, evacuation and first aid procedures, displayed in the laboratory?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Yes</td>
<td>No</td>
<td>Action Required</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----</td>
<td>----</td>
<td>-----------------</td>
</tr>
<tr>
<td>23. Is a spill kit (containing an appropriate disinfectant to decontaminate the biohazard being used, paper towels, gloves, forceps for broken glass, biohazard bags and any other appropriate material) available in the case of a spill?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24. Are all staff members, students or other personnel involved in the activity or project trained in the handling of pathogenic or infectious organisms?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25. Are all staff members, students or other personnel involved in the activity or project trained in the requirements of PC1 facilities?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>26. Is all training documented and the records kept?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27. Have all staff members, students or other personnel involved in the activity or project been informed of the potential risks of working with the biohazard whilst pregnant, considering pregnancy, immunocompromised or immunosuppressed?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28. Have all staff members, students or other personnel involved in the activity or project been informed of the immunisation recommendations(^2) for the type of work they will be doing?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^2\) The Australian Immunisation Handbook, 10th Edition 2013 (Department of Health & Ageing)
### 35. Appendix 2 – Extract from NHMRC Immunisation Handbook

From Table 3.3.7: Recommended vaccinations for persons at increased risk of certain occupationally acquired vaccine-preventable diseases

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Workers (HCW)</td>
<td></td>
</tr>
</tbody>
</table>
| All HCW Includes all workers and students directly involved in patient care or the handling of human tissues | Hepatitis B  
Influenza  
MMR (if non-immune)†  
Pertussis (dTpa)  
Varicella (if non-immune) |
| HCW who work in remote Indigenous communities or with Indigenous children in NT, Qld, SA and WA, and other specified healthcare workers in some jurisdictions | Vaccines listed for ‘All HCW’, plus hepatitis A |
| HCW who may be at high risk of exposure to drug-resistant cases of tuberculosis (dependent on state or territory guidelines) | Vaccines listed for ‘All HCW’, plus consider BCG |
| Persons who work with children | | |
| All persons working with children, including:  
• staff and students working in early childhood education and care  
• correctional staff working where infants/children cohabitate with mothers  
• school teachers (including student teachers)  
• outside school hours carers  
• child counselling services workers  
• youth services workers | Influenza  
MMR (if non-immune)  
Pertussis (dTpa)  
Varicella (if non-immune) |
| Staff working in early childhood education and care | Vaccines listed for ‘Persons who work with children’, plus Hepatitis A |
| Laboratory Personnel | | |
| Laboratory personnel handling veterinary specimens or working with Q fever organism (*Coxiella burnetii*) | Q fever |
| Laboratory personnel handling either bat tissues or lyssaviruses (including rabies virus and Australian bat lyssavirus) | Rabies |
| Laboratory personnel routinely working with these organisms: *Bacillus anthracis*  
Vaccinia poxviruses  
Poliomyelitis virus  
*Salmonella enterica* subspecies *enterica* serovar Typhi (S. Typhi)  
Yellow fever virus  
*Neisseria meningitidis*  
Japanese encephalitis virus  
Seasonal Influenza Virus† | Anthrax  
Smallpox  
Poliomyelitis (IPV)  
Typhoid  
Yellow fever  
Quadrivalent meningococcal conjugate vaccine (4vMenCV)  
Japanese encephalitis  
Influenza |
<table>
<thead>
<tr>
<th>Occupation</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persons who work with animals</strong></td>
<td></td>
</tr>
<tr>
<td>Veterinarians</td>
<td>Influenza</td>
</tr>
<tr>
<td></td>
<td>Q fever</td>
</tr>
<tr>
<td></td>
<td>Rabies</td>
</tr>
<tr>
<td>Wildlife and zoo workers who have contact with at-risk animals, including</td>
<td>Q fever</td>
</tr>
<tr>
<td>kangaroos and bandicoots</td>
<td></td>
</tr>
<tr>
<td>Persons who come into regular contact with bats (both ‘flying foxes’ and</td>
<td>Rabies</td>
</tr>
<tr>
<td>microbats), bat handlers, bat scientists, wildlife officers, zoo curators</td>
<td></td>
</tr>
<tr>
<td>Poultry workers and others handling poultry</td>
<td>Influenza</td>
</tr>
<tr>
<td><strong>Other persons exposed to human tissue, blood, body fluids or sewage</strong></td>
<td></td>
</tr>
<tr>
<td>Workers who have regular contact with human tissue, blood or body fluids</td>
<td>Hepatitis B</td>
</tr>
<tr>
<td>and/or used needles or syringes</td>
<td></td>
</tr>
<tr>
<td>Plumbers or other workers in regular contact with untreated sewage</td>
<td>Hepatitis A</td>
</tr>
<tr>
<td></td>
<td>Tetanus (dT or dTpa)</td>
</tr>
</tbody>
</table>

*University of South Australia addition*
36. Appendix 3 – List of Exempt Dealings
(From Schedule 2 Part 1 of the Act) (Table 4)

<table>
<thead>
<tr>
<th>Item</th>
<th>Description of Dealing</th>
<th>Conditions</th>
</tr>
</thead>
</table>
| 2    | A dealing with a genetically modified Caenorhabditis elegans | UNLESS:  
an advantage is conferred on the animal by the genetic modification  OR  
as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent |
| 3    | A dealing with an animal into which genetically modified somatic cells have been introduced | IF:  
the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification  AND  
the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells |
| 3A   | A dealing with an animal whose somatic cells have been genetically modified in vivo by a replication-defective viral vector | IF:  
the in vivo modification occurred as part of a previous dealing  AND  
the replication defective viral vector is no longer in the animal  AND  
no germ line cells have been genetically modified  AND  
the somatic cells cannot give rise to infectious agents as a result of the genetic modification  AND  
the animal is not infected with a virus that can recombine with the genetically modified nucleic acid in the somatic cells of the animal |
<table>
<thead>
<tr>
<th>Item</th>
<th>Description of Dealing</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>A dealing involving a host/vector system mentioned in Table 5 AND producing no more than 25 litres of GMO culture in each vessel containing the resultant culture</td>
<td>AND THE DONOR NUCLEIC ACID: must satisfy either of the following requirements: (i) it must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy human beings, animals, plants or fungi OR (ii) it must be characterised and the information derived from its characterisation show that it is unlikely to increase the capacity of the host or vector to cause harm. Example: Donor nucleic acid would not comply with subparagraph (ii) if its characterisation shows that, in relation to the capacity of the host or vector to cause harm, it provides an advantage or adds a potential host species or mode of transmission or increases its virulence, pathogenicity or transmissibility. AND: (b) must not code for a toxin with an LD50 of less than 100 µg/kg AND (c) must not code for a toxin with an LD50 of 100 µg/kg or more, if the intention is to express the toxin at high levels AND (d) must not be uncharacterised nucleic acid from a toxin-producing organism AND (e) must not include a viral sequence unless the donor nucleic acid: (i) is missing at least 1 gene essential for viral multiplication that: (A) is not available in the cell into which the nucleic acid is introduced AND (B) will not become available during the dealing AND (ii) cannot restore replication competence to the vector.</td>
</tr>
<tr>
<td>5</td>
<td>A dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in Item 1 of Table 5</td>
<td>IF THE DONOR NUCLEIC ACID is not derived from either: (a) a pathogen OR (b) a toxin-producing organism</td>
</tr>
</tbody>
</table>

Table 4: List of Exempt Dealings (from Schedule 2 Part 1 of the Act)
### Appendix 4 – Host/Vector Systems for Exempt Dealings (Table 5)

(As per Schedule 2 Part 2 of the Act)

<table>
<thead>
<tr>
<th>Item</th>
<th>Class</th>
<th>Host</th>
<th>Vector</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bacteria</td>
<td>Escherichia coli K12, E. coli B or E. coli C or E. coli Nissle 1917 – any derivative that does not contain: (a) generalised transducing phages OR (b) genes able to complement the conjugation defect in a non-conjugative plasmid</td>
<td>1. Non-conjugative plasmids</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. Bacteriophage (a) lambda (b) lambdoid (c) Fd or F1 (eg M13)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3. None (non-vector systems)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bacillus – specified species – asporogenic strains with a reversion frequency of less than 10–7: (a) B. amyloliquefaciens (b) B. licheniformis (c) B. pumilus (d) B. subtilis (e) B. thuringiensis</td>
<td>1. Non-conjugative plasmids</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. Plasmids and phages whose host range does not include B. cereus, B. anthracis or any other pathogenic strain of Bacillus</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3. None (non-vector systems)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pseudomonas putida – strain KT 2440</td>
<td>1. Non-conjugative plasmids including certified plasmids: pKT 262, pKT 263, pKT 264</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. None (non-vector systems)</td>
</tr>
<tr>
<td></td>
<td>Streptomycyes – specified species: (a) S. aureofaciens (b) S. coelicolor (c) S. cyaneus (d) S. griseus (e) S. lividans (f) S. parvulus (g) S. rimosus (h) S. venezuelae</td>
<td>1. Non-conjugative plasmids</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. Certified plasmids: SCP2, SLP1, SLP2, PJJ101 and derivatives</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3. Actinophage phi C31 and derivatives</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4. None (non-vector systems)</td>
</tr>
<tr>
<td></td>
<td>Agrobacterium radiobacter Agrobacterium rhizogenes — disarmed strains Agrobacterium tumefaciens — disarmed strains</td>
<td>1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. None (non-vector systems)</td>
</tr>
</tbody>
</table>
| 1 | Bacteria (cont’d) | Lactobacillus  
Lactococcus lactis  
Oenococcus oeni syn. Leuconostoc oeni  
Pediococcus  
Photobacterium angustum  
Pseudoalteromonas tunicata  
Rhizobium (including the genus Allorhizobium)  
Sphingopyxis alaskensis syn. Sphingomonas alaskensis  
Streptococcus thermophiles  
Synechococcus – specified strains:  
(a) PCC 7002  
(b) PCC 7942  
(c) WH 8102  
Synechocystis species – strain PCC 6803  
Vibrio cholerae CVD103-HgR | 1. Non-conjugative plasmids  
2. None (non-vector systems) |
| 2 | Fungi | Neurospora crassa – laboratory strains  
Pichia pastoris  
Saccharomyces cerevisiae  
Schizosaccharomyces pombe  
Kluyveromyces lactis  
Trichoderma reesei  
Yarrowia lipolytica | 1. All vectors  
2. None (non-vector systems) |
| 3 | Slime moulds | Dictyostelium species | 1. Dictyostelium shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2  
2. None (non-vector systems) |
| 4 | Tissue culture | Any of the following if they cannot spontaneously generate a whole animal:  
(a) animal or human cell cultures (including packaging cell lines);  
(b) isolated cells, isolated tissues or isolated organs, whether animal or human;  
(c) early non-human mammalian embryos cultured in vitro  
Either of the following if they are not intended, and are not likely without human intervention, to vegetatively propagate, flower or regenerate into a whole plant:  
(a) plant cell cultures;  
(b) isolated plant tissues or organs | 1. Non-conjugative plasmids  
2. Non-viral vectors, or defective viral vectors unable to transduce human cells  
3. Baculovirus (Autographa california nuclear polyhedrosis virus), polyhedrin minus  
4. None (non-vector systems) |

Table 5: Host/Vector Systems for Exempt Dealings (as per Schedule 2 Part 2 of the Act)
38. Appendix 5 – Kinds of Dealings suitable for at least NLRD-PC1 (Tables 6 and 7).

NOTE: Unless the Dealing also involves any items from Table 8, which require individual licences, specific to the work, from the OGTR (as per Schedule 3 Part 1 of the Act)

<table>
<thead>
<tr>
<th>Item</th>
<th>Dealing</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1a.</td>
<td>A Dealing involving:</td>
<td>UNLESS:</td>
</tr>
<tr>
<td></td>
<td>a genetically-modified laboratory guinea pig OR</td>
<td>i.  an advantage is conferred on the animal by the genetic modification OR</td>
</tr>
<tr>
<td></td>
<td>a genetically-modified laboratory mouse OR</td>
<td>ii. the animal is capable of secreting or producing an infectious agent as a result of the genetic modification</td>
</tr>
<tr>
<td></td>
<td>a genetically-modified laboratory rabbit OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a genetically-modified laboratory rat</td>
<td></td>
</tr>
<tr>
<td>1.1c.</td>
<td>A Dealing involving:</td>
<td>IF THE DONOR NUCLEIC ACID:</td>
</tr>
<tr>
<td></td>
<td>a replication-defective vector derived from Human adenovirus or Adeno-associated virus in a host mentioned in Item 4 of Table 5</td>
<td>i.  cannot restore replication competence to the vector AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ii.  does not:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A.  confer an oncogenic modification in humans OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B.  encode a protein with immunomodulatory activity in humans</td>
</tr>
</tbody>
</table>

Table 6: Kinds of Dealings suitable for at least NLRD-PC1* (from Schedule 3 Part 1 of the Act)

* Unless the Dealing also involves any items from Table 8, which require individual licences, specific to the work, from the OGTR
Table 7: Kinds of Dealings suitable for at least NLRD-PC2, unless the Dealing also involves any items from Table 8, which require individual licences specific to the work from the OGTR (as per Schedule 3 Part 2 of the Act)

<table>
<thead>
<tr>
<th>Item</th>
<th>Dealing</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1a.</td>
<td>A Dealing involving whole animals (including non-vertebrates)</td>
<td>THAT DOES NOT involve a genetically-modified laboratory guinea pig OR a genetically-modified laboratory mouse OR a genetically-modified laboratory rabbit OR a genetically-modified laboratory rat OR genetically-modified Caenorhabditis elegans AND IT DOES involve genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism</td>
</tr>
<tr>
<td>2.1aa.</td>
<td>A Dealing involving a genetically-modified laboratory guinea pig OR a genetically-modified laboratory mouse OR a genetically-modified laboratory rabbit OR a genetically-modified laboratory rat OR genetically-modified Caenorhabditis elegans</td>
<td>IF: the genetic modification confers an advantage on the animal AND the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification</td>
</tr>
<tr>
<td>2.1b.</td>
<td>A Dealing involving a genetically-modified plant</td>
<td></td>
</tr>
<tr>
<td>2.1c.</td>
<td>A Dealing involving a host/vector system not mentioned in Table 5 or in Item 1.1(c) of Table 6</td>
<td>AS LONG AS neither host nor vector has been implicated in, or has a history of causing, disease in otherwise healthy: human beings OR animals OR plants OR fungi</td>
</tr>
</tbody>
</table>
| 2.1d. | A Dealing involving a host and vector not mentioned in Table 5 | IF: the host or vector has been implicated in, or has a history of causing, disease in otherwise healthy: human beings OR animals OR plants OR fungi AND the donor nucleic acid is characterised AND the characterisation of the donor nucleic acid shows that it is unlikely to increase the capacity of the host or vector to cause harmExample: Donor nucleic acid would increase the capacity of the host or vector to cause harm, if it: (a) provides an advantage or (b) adds a potential host species or mode of transmission or
<table>
<thead>
<tr>
<th>Item</th>
<th>Dealing</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1e.</td>
<td>A Dealing involving a host/vector system mentioned in Table 5</td>
<td>IF THE DONOR NUCLEIC ACID: encodes a pathogenic determinant OR is uncharacterised nucleic acid from an organism that has been implicated in, or has a history of causing, disease in otherwise healthy:  A. human beings OR B. animals OR C. plants OR D. fungi</td>
</tr>
<tr>
<td>2.1f.</td>
<td>A Dealing involving a host/vector system mentioned in Table 5 AND producing more than 25 litres of GMO culture in each vessel containing the resultant culture</td>
<td>IF: the dealing is undertaken in a facility that is certified by the Regulator as a large scale facility AND the donor nucleic acid satisfies the conditions set out in Item 4 of Table 4</td>
</tr>
<tr>
<td>2.1g.</td>
<td>A Dealing involving complementation of knocked-out genes</td>
<td>IF: the complementation is unlikely to increase the capacity of the GMO to cause harm compared to the capacity of the parent organism before the genes were knocked out Example: A dealing would not comply with paragraph 2.1g if it involved complementation that, in relation to the parent organism: a. provides an advantage or b. adds a potential host species or mode of transmission or c. increases its virulence, pathogenicity or transmissibility</td>
</tr>
<tr>
<td>2.1h</td>
<td>A Dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in Item 1 of Table 5</td>
<td>IF THE DONOR NUCLEIC ACID: is derived from either: a pathogen OR a toxin-producing organism</td>
</tr>
<tr>
<td>2.1i.</td>
<td>A Dealing involving the introduction of a <strong>replication-defective viral vector unable to transduce human cells into a host not mentioned in Table 5</strong></td>
<td>IF: the donor nucleic acid cannot restore replication competence to the vector</td>
</tr>
<tr>
<td>2.1j.</td>
<td>A Dealing involving the introduction of a <strong>replication-defective non-retroviral vector able to transduce human cells, other than a dealing mentioned in Item 1.1 (c) of Table 6, into a host mentioned in Table 5</strong></td>
<td>IF: the donor nucleic acid cannot restore replication competence to the vector</td>
</tr>
</tbody>
</table>
2.1k. A Dealing involving the introduction of a **replication-defective non-retroviral vector** able to transduce human cells into a host not mentioned in Table 5

**IF:** the donor nucleic acid cannot restore replication competence to the vector AND the donor nucleic acid does not: confer an oncogenic modification in humans or encode a protein with immunomodulatory activity in humans

2.1l. A Dealing involving the introduction of a **replication defective retroviral vector** able to transduce human cells into a host mentioned in Table 5

**IF:** all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble into a virion without these functions being supplied in trans AND viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination AND either: the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA OR the packaging cell line and packaging plasmids express only viral genes gagpol, rev and an envelope protein gene, or a subset of these

2.1m. A Dealing involving the introduction of a **replication defective retroviral vector** able to transduce human cells into a host not mentioned in Table 5

**IF:** the donor nucleic acid does not: confer an oncogenic modification in humans OR encode a protein with immunomodulatory activity in humans AND all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble into a virion without these functions being supplied in trans AND viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination AND either: the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA OR the packaging cell line and packaging plasmids express only viral genes gagpol, rev and an envelope protein gene, or a subset of these

---

**Table 7: Kinds of Dealings suitable for at least NLRD-PC2* (from Schedule 3 Part 2.1 of the Act)**

*Unless the Dealing also involves any items from Table 8, which require individual licences specific to the work from the OGTR*
39. Appendix 6 –Dealings requiring a Licence (as per Schedule 3 Part 3 of the Act) (Table 8)

**Note 1** The following list qualifies the list in Parts 1 and 2, and is not an exhaustive list of dealings that are not Notifiable Low Risk Dealings.

**Note 2** A Dealing that is not a Notifiable Low Risk Dealing, or an Exempt Dealing, can be undertaken only by a person who is licensed, under the Act, for the dealing (see Act, section 32).

<table>
<thead>
<tr>
<th>Item 3.1</th>
<th>Dealing</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>A dealing involving cloning of nucleic acid encoding a toxin having an LD₅₀ of less than 100 µg/kg</td>
<td>Other than a dealing mentioned in paragraph 2.1 (h) of Table 7</td>
</tr>
<tr>
<td>(b)</td>
<td>A dealing involving high level expression of toxin genes, even if the LD₅₀ is 100 µg/kg or more</td>
<td></td>
</tr>
<tr>
<td>(c)</td>
<td>A dealing involving cloning of uncharacterised nucleic acid from a toxin-producing organism</td>
<td>Other than a dealing mentioned in paragraph 2.1 (h) of Table 7</td>
</tr>
<tr>
<td>(d)</td>
<td>A dealing involving the introduction of a replication defective viral vector</td>
<td>INTO A HOST not mentioned in Table 5, other than a dealing mentioned in paragraph 2.1 (i) of Table 7, IF THE DONOR NUCLEIC ACID: (i) confers an oncogenic modification in humans OR (ii) encodes a protein with immunomodulatory activity in humans</td>
</tr>
<tr>
<td>(e)</td>
<td>A dealing involving the introduction of a replication competent virus or viral vector</td>
<td>Other than a vector mentioned in Table 5, IF THE DONOR NUCLEIC ACID: (i) confers an oncogenic modification in humans OR (ii) encodes a protein with immunomodulatory activity in humans</td>
</tr>
</tbody>
</table>
| (f) | A dealing involving, as host or vector, a micro-organism | IF:  
(i) the micro-organism has been implicated in, or has a history of causing disease in otherwise healthy:  
(A) human beings OR  
(B) animals OR  
(C) plants OR  
(D) fungi  
AND  
(ii) NONE of the following sub-subparagraphs apply:  
(A) the host/vector system is a system mentioned in Table 5  
(B) the donor nucleic acid is characterised and its character shows that it is unlikely to increase the capacity of the host or vector to cause harm  
(C) the dealing is mentioned in paragraph 2.1 (g) of Table 7  
Example  
Donor nucleic acid would not comply with sub-subparagraph (B) if, in relation to capacity of the host or vector to cause harm, it:  
(a) provides an advantage; or  
(b) adds a potential host species or mode of transmission; or  
(c) increases its virulence, pathogenicity or transmissibility. |
| (g) | A dealing involving the introduction, into a micro-organism, of nucleic acid encoding pathogenic determinant | UNLESS:  
(i) the dealing is a dealing mentioned in paragraph 2.1 (g) of Table 7 OR  
(ii) the micro-organism is a host mentioned in Table 5 |
| (h) | A dealing involving the introduction, into a micro-organism, genes whose expressed products are likely to increase the capacity of the micro-organism to induce an autoimmune response | Other than a host mentioned in Table 5 |
| (i) | A dealing involving use of a viral or viroid genome, or fragments of a viral or viroid genome, to produce a novel replication competent virus with an increased capacity to cause harm compared to the capacity of the parent or donor organism | Example  
A dealing would comply with paragraph (i) if it produces a novel replication competent virus that has a higher capacity to cause harm to any potential host species than the parent organism because the new virus has:  
(a) an advantage; or  
(b) a new potential host species or mode of transmissibility; or  
(c) increased virulence, pathogenicity or transmissibility.
<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>(j)</td>
<td>A dealing with a replication defective retroviral vector (including a lentiviral vector) able to transduce human cells</td>
<td>Other than a dealing mentioned in paragraph 2.1 (l) or (m) of Table 7</td>
</tr>
<tr>
<td>(k)</td>
<td>A dealing involving a genetically modified animal, plant or fungus that is capable of secreting or producing infectious agents as a result of the genetic modification</td>
<td></td>
</tr>
<tr>
<td>(l)</td>
<td>A dealing producing, in each vessel containing the resultant GMO culture, more than 25 litres of that culture</td>
<td>Other than a dealing mentioned in paragraph 2.1 (f) of Table 7</td>
</tr>
<tr>
<td>(m)</td>
<td>A dealing that is inconsistent with a policy principle issued by the Ministerial Council</td>
<td></td>
</tr>
</tbody>
</table>
| (n) | A dealing involving the intentional introduction of a GMO into a human being | UNLESS the GMO:  
(i) is a human somatic cell AND  
(ii) cannot secrete or produce infectious agents as a result of the genetic modification AND  
(iii) if it was generated using viral vectors:  
(A) has been tested for the presence of viruses likely to recombine with the genetically modified nucleic acid in the somatic cells AND  
(B) the testing did not detect a virus mentioned in sub-subparagraph (A) AND  
(C) the viral vector used to generate the GMO as part of a previous dealing is no longer present in the somatic cells |
| (o) | A dealing involving a genetically modified pathogenic organism | IF the practical treatment of any disease or abnormality caused by the organism would be impaired by the genetic modification |
| (p) | A dealing involving a micro-organism that satisfies the criteria in AS/NZS 2234.3:2010 for classification as Risk Group 4 | |

Table 8 – Dealings requiring a DNIR or DIR Licence (as per Schedule 3 Part 3 of the Act)
40. Appendix 7 – Viral Vector Flow Chart

Guidance flowchart for the classification of contained dealings with viral vectors according to the Gene Technology Regulations 2001 as amended*

1. Print this form and use a pen or highlighter to mark your selections and path through the flowchart.
2. Scan the completed flowchart and submit it to the IBC with your completed application form.

- **parent virus meets criteria for Risk Group 4 microorganism in AS/NZS 2243.3:2010**
  - Yes → DNIR 3.1 (p)
  - No → genetic modification impairs treatment of disease caused by virus / viral vector
    - Yes → DNIR 3.1 (o)
    - No → virus / viral vector is being introduced into a human
      - Yes → DNIR 3.1 (n)
      - No → genetic modification may produce a novel replication competent virus
        - Yes → DNIR 3.1 (f)
        - No → genetic modification may induce an autoimmune response
          - Yes → DNIR 3.1 (h)
          - No → genetic modification may result in the production of a toxin
            - Yes → DNIR 3.1 (a), (b) or (c)
            - No → Go to virus characteristics

* Effective from 1 September 2011, incorporating amendments up to the Gene Technology Amendment Regulations 2011 (No. 1). This table provides guidance only and does not constitute legal advice. Users must refer to the complete applicable conditions and exclusions in the Gene Technology Regulations 2001, as amended.

Website: www.gtr.gov.au  Telephone: 1800 181 030  Updated August 2011
**Virus characteristics**

1. **vector is a replication competent virus**
   - Yes → Go to **Replication competent viruses**
   - No

2. **genetic modification restores replication competence**
   - Yes → Go to **Replication competent viruses**
   - No

3. **vector is a retrovirus (including lentivirus)**
   - Yes → Go to **Replication defective retroviruses**
   - No

4. **Go to Replication defective non-retroviruses**
Replication competent viruses

virus is non-pathogenic plant virus or Baculovirus (ACNPV)

No

may confer an oncogenic modification or have an immunomodulatory effect in humans

Yes

modification involves a pathogenic determinant

No

DNIR 3.1 (c) in vitro

exempt

in vitro

NLRD 2.1 (f) >25L per vessel

No

DNIR 3.1 (e)

modification involves a pathogenic determinant

virus is a pathogen

Yes

Yes

DNIR 3.1 (f)

No

DNIR 3.1 (g)

NLRD 2.1 (d)

virus is a pathogen

No

NLRD 2.1 (c)
Replication defective retroviruses

- **vector can transduce human cells**
  - No: **in vitro dealings only**
    - Yes: modification involves a pathogenic determinant
      - Yes: exempt
        - NLRD 2.1 (f)
        - >25L per vessel
      - No: NLRD 2.1 (e)
  - Yes: accessory genes are present and vector is not self inactivating
    - Yes: may confer an oncogenic modification or have an immunomodulatory effect in humans
      - Yes: DNIR 3.1 (g)
      - No: DNIR 3.1 (d) & (j)
    - No: NLRD 2.1 (i)

- **in vitro dealings only**
  - No: NLRD 2.1 (m)
  - Yes: may confer an oncogenic modification or have an immunomodulatory effect in humans
    - Yes: DNIR 3.1 (d) & (j)
    - No: NLRD 2.1 (i)
41. Appendix 8 – PC Facility Induction Checklist

PC Facility Induction Check List

I Level A Induction - Introduction and Orientation
(Contractors and cleaners require Level A induction only)

Tours of labs and facilities:

- Floor orientation – card/keys/egress/security/toilets
- Building evacuation
- Eyewash/Safety showers
- First Aid – location of kits/trained personnel
- Explanation of PC and why we do induction (Biological Hazards/OGTR)
- No eating/drinking or wearing headphones in labs
- Food refrigerator access outside facility
- Don’t place paper/books/tools on benches
- Wearing of PPE – glasses/gowns/shoes (where to find them)
- Appropriate locations to wear gowns
- When finished in area remove gown/glasses and wash hands
- Consult technical staff if any questions/issues/unsure

II Level B Induction
(People using facilities occasionally require Level A and Level B induction only)

- Allocation/laundering of gown if necessary

- Facility-specific WH&S induction MUST BE COMPLETED before work commences:
  - Location of SDSs
  - Risk assessments/SOPs for new chemicals/equipment/plant
  - Biological/chemical/GMO spills procedures
  - Fire Extinguishers and blankets
• Tour of appropriate areas
  o Facility: ________________________________
    ▪ Research Labs/Tissue Culture areas (TC training if required) □
    ▪ Booking of tissue culture labs or equipment □
    ▪ Autoclave area/prep/wash-up □
    ▪ Hot Room/Cold Room/Freezer Room □
    ▪ Other ________________________________ □
  o Stores □

• Access to autoclaving
  o Transport of contaminated material for autoclave & non autoclave □
  o Clean material for autoclaving drop-off/pickup □

III Level C Induction
(Summer Scholarship students, HDR students and new staff require all levels of induction)

• Allocation of locker if necessary   Locker Number .....................

WH&S:
• The following online courses MUST BE COMPLETED before work commences:
  o Basic Compulsory: Work Health and Safety fundamentals □
  o South Australian Work Health & Safety Legislation □
  o Ergonomics □
  o Manual tasks for workers □
  o Bullying and Harassment □
  o Incident Investigation (HDR and staff only) □
  o Working Safely with Hazardous Chemicals □
  o Risk Management for workers □
  o Chemical spills management □
  o Environmental Awareness □
  o Biosafety 1 (Biosafety Principles) □
  o Biosafety 2 (Gene Technology) If working with Genetically Modified Organisms □

Facility-specific OHS induction MUST BE COMPLETED before work commences:
• Location of MSDSs and use of Chemwatch GoldFFX  
• Risk assessments/SOPs for new chemicals/equipment/plant  
• Biological/chemical/GMO spills procedures  
• Fire Extinguishers and blankets

• Training in safe and appropriate use of equipment/facilities
  o Chemical storage cabinets
  o Understanding of how to work in PC1 or 2, i.e.:
    ▪ Working safely with organisms  
    ▪ Safe use of Bunsen burners  
    ▪ Class 2 Biosafety cabinet (BSC)  
    ▪ Fume hood  
    ▪ Bench centrifuge  
    ▪ Balances  
    ▪ Hot plate stirrers  
    ▪ Water baths  
    ▪ Pipettes  
    ▪ Incubators  
    ▪ Other__________________________________________

• General House Keeping
  o End of day clean-up
  o Procedures for cleaning work area – daily, weekly
  o Disposal of waste
    ▪ Solvents
    ▪ Biological hazard waste
    ▪ Sharps
    ▪ GMO waste
  o Washing glassware
  o Items for dishwasher
  o Access to:
    ▪ PC facility
    ▪ Stores
    ▪ Location of common keys
• Working alone policy

• Ordering
  o Location of catalogues
  o Order forms – including risk assessment requirements

• General Stores
  o List of available items

• Storage
  o Correct labelling of solutions, cultures and GMOs
  o Storage of solutions, cultures and GMOs
  o Storage of chemicals and reagents
  o Corrosives and flammables
  o Labelling and location of cultures (4°C and -80°C)
  o Storage of GMOs

• Media Preparation and Autoclaving
  o Preparation of media
  o Access to autoclaving
  o Transport of contaminated material for autoclave & non autoclave
  o Clean material for autoclaving
  o Collection of material after autoclaving

• Molecular Techniques
  o Orientation of equipment and facilities

• Transport of GMOs
PC Facility Induction Check List

By signing this form you agree to adhere to PC facility requirements, as explained during the induction, at all times whilst working in the facility.

Level of Induction Performed: ________________________________

Name: ____________________________________________________

Status: Contractor / Cleaner / Occasional User / Summer Student / HDR Student / Staff Member

Employer: ________________________________________________

Signature: ________________________________________________

Date: _____________________________________________________

Inductor: _________________________________________________

Locker No.: _______________________________________________
42. Appendix 9 – Response to Spill or Unintentional Release of Biohazardous Material or GMO

Notify everyone working in the area

Is it safe to Contain and Decontaminate?

Yes

Contain and Decontaminate
(See Appendix 10)

Notify either the IBC Chair or Executive Officer

No

Evacuate the area

Notify Security on Ext. 88888
(Wait for Response Team)

Notify either the IBC Chair or Executive Officer
43. Appendix 10 – Dealing with Spill of Biohazardous Material or GMO

**Inside Biological Safety Cabinet**

- Leave the cabinet ON to retain aerosols
- Put on gloves
- Wet inert absorbent material with disinfectant
- Avoid creating aerosols and slowly place absorbent material wetted with disinfectant over the spill and leave for about 10 minutes
- Remove the absorbent material and dispose of in correct manner (Section 4:28 of the Biosafety Manual)
- Wipe the floor of the cabinet and any other contaminated surfaces with disinfectant
- For large spills, or spills of highly infectious material, decontaminate the cabinet with gaseous sterilant

**Outside Biological Safety Cabinet**

**Low-risk Biohazardous Material**

- Put on gloves
- Wet inert absorbent material with disinfectant
- Avoid creating aerosols and slowly place absorbent material wetted with disinfectant over the spill and leave for about 10 minutes
- After about 10 minutes, collect material and dispose of in the correct manner (Section 27 of the Biosafety Manual)
- Wipe the area with fresh disinfectant

**High-risk Biohazardous Material**

- Do not breathe the aerosol!
- Evacuate the area and close the doors for at least 30 minutes
- Advise others working in the area, your supervisor and the nominated Responsible Person for the facility
- Remove and dispose of contaminated clothing
- Assemble several personnel to clean up spill
- Put on clean protective apparel, including mask and gloves
- Wet inert absorbent material with disinfectant
• Avoid creating aerosols and slowly place absorbent material wetted with disinfectant over the spill and leave for 10 minutes
• Dispose of all contaminated material (Section 4:28 of the Biosafety Manual)
• Wipe over area with fresh disinfectant
• Discard protective apparel and gloves

Genetically Modified Organisms

Genetically-modified Organisms

Follow the procedure for high risk microbiological materials with the following additional step:
• Dispose of all contaminated material as per Section 4:28 of the Biosafety Manual
44. Appendix 11 - OGTR Policy on Scope for Variations of GMO Licences

Policy on Scope for Variation of GMO Licences
Section 71 of the Gene Technology Act 2000 (the Act) provides for the Gene Technology Regulator (the Regulator) to vary the conditions of licences authorising dealings with genetically modified organisms (GMOs), either on the Regulator’s initiative or on application from the licence holder.

The tables below provide guidance to licence holders/applicants on the OGTR’s policy for determining whether or not applications to extend the authority of GMO licences (for either intentional release or contained dealings) will be considered as variations or would warrant new GMO licence applications. The tables each identify three categories of proposed changes: those that are likely to be considered as variations; those likely to require a new licence application; and those that do not clearly fall into either of these categories and therefore require more specific consideration.

This policy is a guide only and is based on the OGTR’s interpretation of the relevant provisions of the Act. The Regulator will not apply the policy inflexibly and will have regard to the merits of each individual application. The Regulator will apply the risk assessment process used in current risk assessment and risk management plans (RARMPs), based on the Risk Analysis Framework, to identify any additional risks that were not previously identified in the RARMP prepared for the licence. Licence applicants and licence holders who are concerned about the application of the policy in particular circumstances are encouraged to contact the Office for further advice and information. No conclusions can be drawn about whether a particular application for variation will be approved as this will be assessed on a case by case basis.

The Act requires that the Regulator must not vary a licence:
- for dealings not involving an intentional release of GMOs (DNIR) so as to authorise dealings involving intentional release (subsection 71(2));
- for dealings involving intentional release (DIR) under ‘limited and controlled’ conditions (s50A) unless the variation would also meet the conditions for a ‘limited and controlled’ release (subsection 71(2A)); or
  - if satisfied that the RARMP prepared in respect of the original application for the licence did not cover the risks posed by the dealings to be authorised by the varied licence (section 71(2B)).

The Regulator must also be satisfied that any risks posed by the dealings authorised under the varied licence are able to be managed so as to protect the health and safety of people and the environment (section 71 (4)).

The Regulator may request further information from a licence holder in regard to a variation application, and may take any other appropriate action. For example the Regulator may consult the Gene Technology Technical Advisory Committee or a local council where an intentional release is proposed to occur.
### Categories of proposed changes to licences authorising Dealings Not involving Intentional Release of a GMO (DNIR licences)

<table>
<thead>
<tr>
<th>Unlikely to give rise to additional risks, and therefore likely to be considered as a variation to a licence</th>
<th>Case specific</th>
<th>May give rise to additional risks, and therefore likely to require a new DNIR application</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Addition of related gene or related parent organism</td>
<td>• Addition of new genes unrelated to original introduced genes but within the purpose described in the original licence application</td>
<td>• Addition of a GMO unrelated to original dealing</td>
</tr>
<tr>
<td>• Changes to transport of GMOs (including import)</td>
<td>• Add a new dealing for a related purpose to that of the original dealings</td>
<td></td>
</tr>
<tr>
<td>• Minor changes to management protocols (eg change of decontamination method)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Change facility (at same type and level or greater)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Extension of period of the licence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• New project supervisor</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>