Containment Facility Internal Certification Policy (MPF1195)

RELEVANT LEGISLATION

Government legislation:

- Occupational Health and Safety Act 2004 (Vic)
- University of Melbourne Act 2009 (Vic)

University legislation:

- Statute 1.7 – University Governance

SCOPE

This policy applies to all work areas of the University where hazardous infectious agents or potentially hazardous biological material (including diagnostic samples) that might reasonably be expected to contain these agents, are stored, used, handled, transported or disposed.

POLICY

1. Suitability of facilities and work practices

1.1. The University will ensure that work with hazardous infectious agents or potentially hazardous biological material is conducted in facilities that are structurally designed to reduce the risk of unintentional release of the agents.

1.2. The University will ensure the appropriateness of facility attributes used for work with hazardous infectious agents or potentially hazardous biological material.

1.3. The University will ensure that appropriate work practices are in place to reduce the risk of unintentional infection of laboratory personnel working with hazardous infectious agents or potentially hazardous biological material and the risk of unintentional release of the agents.

2. Certification of facilities

2.1. The University will certify facilities used for work with hazardous infectious agents or potentially hazardous biological material in accordance with requirements determined by the Gene Technology and Biosafety Committee. These will be based on the following as relevant for the type of facility:

- Australian/New Zealand Standard, Safety in Laboratories, Part 3: Microbiological safety and containment (AS/NZS 2243.3 – Current Version)
- Office of the Gene Technology Regulator (OGTR) guidance notes for Physical Containment Level 1 (PC1) facilities in which dealings with Genetically Modified Organisms (GMOs) that are classified as exempt are conducted.

2.2. Facilities that are currently certified by the Office of the Gene Technology Regulator (OGTR) or approved by the Department of Agriculture, Fisheries and Forestry (DAFF) do not need to be certified under this policy.

SCHEDULES
• Schedule A – Facilities that require certification under this policy

RELATED DOCUMENTS

• Australian/New Zealand Standards, 2243.3: Safety in Laboratories Part 3: Microbiological safety and containment (available through University Library)
• Containment Facility Internal Certification Procedure
• Infectious Agent Project Approval Policy
• Infectious Agent Project Approval Procedure
• Infectious Agent Reporting Policy
• Infectious Agent Reporting Procedure

DEFINITIONS

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>biological material</td>
<td>Any material such as tissue (including organs and bone), cell lines or body fluids sourced from a living organism. Samples (for example, unscreened human blood or blood products) are included in this definition.</td>
</tr>
<tr>
<td>Dealing Not Involving Release (DNIR)</td>
<td>Dealings with GMOs as defined in the Gene Technology Regulations 2001.</td>
</tr>
<tr>
<td>Exempt Dealings</td>
<td>Dealings with GMOs as defined in the Gene Technology Regulations 2001.</td>
</tr>
<tr>
<td>hazardous infectious agent</td>
<td>A bacterium, fungus, virus or other agent able to cause disease in an otherwise healthy host (for example, human, animal or plant).</td>
</tr>
<tr>
<td>infectious agent</td>
<td>An infectious agent is a bacterium, fungus, virus or other agent that is able to invade and replicate in a host organism (for example, human, animal or plant) and which may or may not cause a disease.</td>
</tr>
<tr>
<td>Notifiable Low Risk Dealing (NLRD)</td>
<td>Dealings with GMOs as defined in the Gene Technology Regulations 2001.</td>
</tr>
<tr>
<td>Standard Operating Procedure (SOP)</td>
<td>A detailed, written instruction to achieve uniformity of the performance of a specific task. The term Standard Work Procedure (SWP) is interchangeable with SOP.</td>
</tr>
</tbody>
</table>

RESPONSIBLE OFFICER

The Director, Office for Research Ethics and Integrity is responsible for the development, compliance monitoring and review of this policy and any associated guidelines.

IMPLEMENTATION OFFICER

The Biosecurity and Biosafety Officer, Office for Research Ethics and Integrity is responsible for the promulgation and implementation of this policy in accordance with the scope outlined above. Enquiries about interpretation of this policy should be directed to the implementation officer.

REVIEW
This policy is to be reviewed by 30 November 2015.

**VERSION HISTORY**

<table>
<thead>
<tr>
<th>Version</th>
<th>Approved By</th>
<th>Approval Date</th>
<th>Effective Date</th>
<th>Sections Modified</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Senior Vice-Principal</td>
<td>1 Aug 2013</td>
<td>1 Aug 2013</td>
<td>N/A</td>
</tr>
</tbody>
</table>