Risk Management Guidelines - Biologicals

Introduction

These guidelines are designed to assist users with assessing risks and determining appropriate control measures when working with biological hazards. These guidelines must be read in conjunction with the OHS Risk Management Procedure.

All risk assessments must be documented using the online system - SARAH.

There are mandatory controls required by legislation and standards for research with biological and genetically modified material. These controls must be considered when conducting a risk assessment.

When to do a risk assessment

A risk assessment must be undertaken for all activities, which involve biological hazards as defined in the Using Biologicals and Animals Procedure.

How to do a risk assessment

Tutorial videos on how to use SARAH to complete risk assessments, are available on the Risk Management and Safe Work Instructions page.

If the activity that is being assessed is common at Monash University, there may be an existing risk assessment available in SARAH, which could be adopted using the cloning function.

To complete a risk assessment:

1. Follow the OHS Risk Assessment Guide to complete the risk assessment form in SARAH.
2. Describe the activity that is being assessed. Refer to any existing Standard Operating Procedures (SOPs) or protocols relevant to the activity.
3. Determine who are the people that know about the process and the hazards associated with the activity (e.g. Supervisors, Safety Officers, Subject Matter Experts, OHS Consultant/Advisor).
4. Select the most appropriate Mechanism of Injury and the Agency of Injury associated with the risk factor being assessed.
5. Describe how the risks associated with the Mechanism and Agency can lead to injury or disease in the context of the activity that is being assessed. Take into account hazards associated with:
   a. Installation of equipment;
   b. Operation of equipment;
   c. Working in certified facilities;
   d. Handling of biological materials or animals;
   e. Waste generation and disposal;
   f. Transporting samples between labs and/or sites;
g. Decommissioning and disposal of equipment;
h. Other tasks or activities that may need to occur as part of the process (e.g. handling chemicals).

6. Identify:
   a. Any relevant vaccination requirements based on the Immunisation Grid;
   b. Specific First Aid requirements as set out in the First Aid Procedure;
   c. Emergency response and spill containment requirements;
   d. PPE requirements, including a need for respiratory protection where appropriate.

7. Consult with your risk assessment team on the risk factors identified.

8. Examples of available resources include:
   a. Monash University OH&S Biosafety webpages;
   b. Monash University Research Office Biosafety webpage;
   c. Australian Standards (e.g. AS/NZS 2243.3:2010 Safety in laboratories Part 3: Microbiological aspects and containment facilities)
   d. Department of Health - Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials 3rd Edition
   e. OGTR - Guidelines for the Transport, Storage and Disposal of GMOs
   f. EPA - Clinical and related waste – operational guidance
   g. Risk Group Database

9. Identify and describe the existing controls currently in place.

10. Refer to Table 1 for a list of mandatory controls based on the type of organism risk group as classified in AS/NZS 2243.3 (2010) Safety in laboratories - Microbiological safety and containment.

11. From the Risk Matrix in SARAH, select the Likelihood of injury or disease occurring with consideration given to the existing controls. Refer to the table below to identify relevant risk factors.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Ingestion (via splash to face or touching mouth with contaminated hands)</th>
<th>Splash to mucosal surface (e.g. eyes)</th>
<th>Needle Stick Damaged Skin (Direct exposure into blood)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work involving sharps (phlebotomy, injections, surgery)</td>
<td>Unlikely</td>
<td>Possible</td>
<td>Almost Certain</td>
</tr>
<tr>
<td></td>
<td>Inhilation of aerosols</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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12. Select the *Consequence* of the injury with consideration given to the existing controls. Refer to the table below for consequence descriptors.

<table>
<thead>
<tr>
<th>Work involving animal models (rodents, non-human primates)</th>
<th>Possible</th>
<th>Likely</th>
<th>Likely</th>
<th>Almost Certain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work involving large volumes of sample or culture</td>
<td>Almost certain</td>
<td>Likely</td>
<td>Likely</td>
<td>Rare</td>
</tr>
<tr>
<td>Work involving small volumes (pipetting, subculturing)</td>
<td>Unlikely</td>
<td>Possible</td>
<td>Unlikely</td>
<td>Rare</td>
</tr>
</tbody>
</table>

13. The risk rating will be assigned automatically once the *Likelihood* and the *Consequence* are selected. Refer to the Risk Matrix below.
14. Determine if additional controls are required that could further reduce the risk level.

15. Nominate a person responsible and the due date to implement each control.

16. Re-assess the residual risk level with the proposed controls implemented.
Table 1:

<table>
<thead>
<tr>
<th>Organism Group</th>
<th>Mandatory Controls</th>
</tr>
</thead>
</table>
| **Risk Group 1** | Work must be carried out in facilities that meet the PC1 requirements of AS/NZS 2982 and AS/NZS 2243.3.  
  • General waste and infectious waste must be segregated.  
  • Food or drink are not to be consumed or stored in area.  
  • If food/drink is to be used for research purposes, it must be clearly labelled “Not for human consumption”.  
  • Safe Work Procedures.Safe Work Instructions for all procedures, including spill clean-up procedures must be developed.  
  • Minimum PPE to be worn at all times:  
    - laboratory coat/gown,  
    - safety eyewear,  
    - fully enclosed footwear,  
    - long hair tied back or hair net used.  
    - Appropriate gloves against biological hazards as well as any chemicals used, must be worn*. |
| **Risk Group 2** | Work must be carried out in facilities that meet the PC2 requirements of AS/NZS 2982 and AS/NZS 2243.3.  
  • Access to PC2 facilities must be restricted to authorised personnel.  
  • Only work that has been assessed to have a low aerosol risk may be conducted on the bench. All other work must be conducted in a Class II Biosafety cabinet.  
  • Centrifuges that are used for infectious microorganisms shall be fitted with either a sealed rotor or removable buckets for easy decontamination in the event of a spill and samples must be placed in sealable tubes.  
  • Training to include Monash Biosafety training.  
  • All relevant vaccination(s) must be obtained prior to commencing work (e.g. Hepatitis B, Tetanus).  
  • Suitable disinfectant must be available at all times for regular decontamination of work benches e.g. sodium hypochlorite, ethanol.  
  • A secondary unbreakable container, which can be readily decontaminated must be used for the transport of microorganisms between facilities.  
  • General waste and infectious waste must be segregated.  
  • All potentially infectious waste must be steam sterilised before leaving the building or a medical waste contractor must be engaged for infectious waste disposal.  
  • Food or drink are not to be consumed or stored in area.  
  • If food/drink is to be used for research purposes, it must be clearly labelled “Not for human consumption”.  
  • Safe work instructions for all procedures, including spill clean-up procedures must be developed.  
  • Moderate level of supervision is required.  
  • Minimum PPE to be worn at all times:  
    - laboratory coat/gown, |
### Risk Group 3
- Work must be carried out in facilities that meet the requirements of AS/NZS 2982 and AS/NZS 2243.3.
- All work must be conducted in a Class II Biosafety cabinet and PC3 work practices must be adhered to at all times.
- Access to PC3 laboratories must be restricted to authorised and appropriately trained personnel.
- Steam sterilizer (autoclave) must be located within PC3 facility for processing of infectious waste.
- Training to include Monash Biosafety, pathogen specific training and emergency response training including spill management.
- Processes without isolation of hazard: high level of supervision and buddy system is required.
- Processes with isolation of hazard: moderate supervision required.
- Health surveillance where indicated, of those exposed to a potential hazard.
- Centrifuges that are used for infectious microorganisms shall be fitted with either a sealed rotor or removable buckets, for easy decontamination in the event of a spill and samples must be placed in sealable tubes.
- A secondary unbreakable container which can be readily decontaminated must be used for the transport of microorganisms between facilities.
- General waste and infectious waste must be segregated.
- All potentially infectious waste must be steam sterilised before leaving the building or a medical waste contractor must be engaged for infectious waste disposal.
- Food or drink are not to be consumed or stored in area.
- If food/drink is to be used for research purposes, it must be clearly labelled “Not for human consumption”.
- Safe Work Procedures/Safe Work Instructions for all procedures must be developed.
- Minimum PPE to be worn at all times:
  - safety eyewear,
  - fully enclosed footwear,
  - long hair tied back or hair net used.
  - Appropriate gloves against biological hazards as well as any chemicals used, must be worn*.

### Risk Group 4
Work must be carried out in PC4 certified facilities. Monash University does not have PC4 facilities on any of its campuses. There are two (2) PC4 facilities in Victoria. These are: [Australian Animal Health Laboratories](https://www.anah.gov.au) in Geelong and [Victorian Infectious Diseases Reference Laboratory (VIDRL)](https://www.monash.edu.au/ohs) in Melbourne.

### Diagnostic Specimens from animals/humans
- Work with diagnostic specimens must be carried out in facilities that meet the requirements of AS/NZS 2982 and AS/NZS 2243.3.
- All work that presents aerosol risk must be conducted in a Class II Biosafety cabinet.
- Training to include Monash Biosafety training.
- All relevant vaccination(s) must be obtained prior to commencing work (e.g. Hepatitis B, Tetanus).
| (blood, bodily fluids, tissue) | • Centrifuges that are used for diagnostic samples shall be fitted with either a sealed rotor or removable buckets, for easy decontamination in the event of a spill and samples must be placed in sealable tubes.  
• A secondary unbreakable container that can be readily decontaminated must be used for the transport of microorganisms between facilities.  
• General waste and infectious waste must be segregated.  
• All potentially infectious waste must be steam sterilised before leaving the building or a medical waste contractor must be engaged for infectious waste disposal.  
• Food or drink are not to be consumed or stored in area.  
• Safe Work Procedures/Safe Work Instructions for all procedures must be developed.  
• Minimum PPE to be worn at all times:  
  ➢ laboratory coat/gown,  
  ➢ safety eyewear,  
  ➢ fully enclosed footwear,  
  ➢ long hair tied back or hair net used.  
  ➢ Appropriate gloves against biological hazards as well as any chemicals used, must be worn*. |
|---|---|
| GMOs | • Work with GMOs must be carried out in facilities that have been certified by the OGTR.  
• IBC approval must be sought prior to commencing work with GMOs.  
• Appropriate controls must be followed as outlined in Monash Research Office SOPs. |

*Refer to Ansell Chemical Hand Protection search tool.

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