4.0  RISK GROUPS AND BIOSAFETY LEVELS

Risk Groups

Biohazardous agents are classified into Risk Groups by regulating agencies such as the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). The classification of many biohazardous agents can be found in the CDC *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), the NIH *Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guide), or from the American Biological Safety Association (ABSA) *Risk Group Database*. The risks are generically defined as follows; see Appendix D for specific definitions from several agencies.

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>RG 1</td>
<td>Well characterized agents that are not known to cause disease in healthy adults, or agents that present a minimal risk to the environment.</td>
</tr>
<tr>
<td>RG 2</td>
<td>Agents that are known to cause disease in healthy adults which is rarely serious and for which prevention or treatment options are available, or agents that pose a moderate risk to the environment.</td>
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<tr>
<td>RG 3</td>
<td>Agents that are known to cause serious or fatal disease, particularly by the inhalation route, and for which there may be preventive or treatment options available, or agents that pose a high risk to the environment.</td>
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<tr>
<td>RG 4</td>
<td>Agents that are likely to cause serious or fatal disease for which prevention or treatment options are not usually available, or those agents that pose a serious threat to the environment.</td>
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</tbody>
</table>

Biosafety Levels

The same regulatory groups have created Biosafety Levels (BSL) that define a set of laboratory practices, facilities and equipment that are appropriate to contain and safely work with the different Risk Groups. The determination of appropriate biosafety level for a project or for a laboratory is made by evaluating the agents in use and the specific procedures and experiments being performed with those agents. Unless specified by regulation, the determination of Biosafety Level for a project or laboratory is made by the Ohio University IBC in conjunction with the PI. In general, the Biosafety Level will be the same as the highest Risk Group for the agents involved. The following table gives an overview of Biosafety Levels; it is taken from the CDC BMBL 5th Edition, 2007. For a detailed description of Biosafety Levels, see the BMBL.
<table>
<thead>
<tr>
<th>BSL</th>
<th>AGENTS</th>
<th>PRACTICES</th>
<th>PRIMARY BARRIERS AND SAFETY EQUIPMENT</th>
<th>FACILITIES (SECONDARY BARRIERS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Not known to consistently cause disease in healthy adults (RG1)</td>
<td>Standard Microbiological Practices</td>
<td>None required</td>
<td>Laboratory bench and sink required</td>
</tr>
</tbody>
</table>
| 2   | • Agents associated with human disease  
• Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure (RG2) | BSL-1 practice plus:  
• Limited access  
• Biohazard warning signs  
• "Sharps" precautions  
• Biosafety manual defining any needed waste decontamination or medical surveillance policies | Primary barriers:  
• Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials  
PPE*:  
• Laboratory coats; gloves; face protection as needed | BSL-1 plus:  
• Autoclave available |
| 3   | • Indigenous or exotic agents with potential for aerosol transmission  
• Disease may have serious or lethal consequences (RG3) | BSL-2 practice plus:  
• Controlled access  
• Decontamination of all waste  
• Decontamination of laboratory clothing before laundering  
• Baseline serum | Primary barriers:  
• Class I or II BSCs or other physical containment devices used for all open manipulation of agents  
PPE:  
• Protective laboratory clothing; gloves; respiratory protection as needed | BSL-2 plus:  
• Physical separation from access corridors  
• Self-closing, double-door access  
• Exhaust air not recirculated  
• Negative airflow into laboratory |
| 4   | • Dangerous/exotic agents which pose high risk of life threatening disease  
• Aerosol-transmitted laboratory infections have occurred; or related agents with unknown risk of transmission (RG4) | BSL-3 practices plus:  
• Clothing change before entering  
• Shower on exit  
• All material decontaminated on exit from facility | Primary barriers:  
• All procedures conducted in Class III BSCs or Class I or II BSCs in combination with  
full-body, air-supplied, positive pressure personnel suit | BSL-3 plus:  
• Separate building or isolated zone  
• Dedicated supply and exhaust, vacuum, and decontamination systems  
• Other requirements outlined in the text |

* PPE – Personal Protective Equipment