Biosafety and Laboratory Preparedness

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Biosafety and Laboratory Preparedness

- Risk assessment for biological research
- Regulatory considerations for biosafety
- Laboratory preparedness
Risk Assessment for Biological Research

Factors in Risk Assessment:

- Agent-related factors
- Experiment-related factors
- Host-related factors
Agent-related factors

Countries / organizations have developed agent risk classification systems

- Summary at http://www.absa.org/resriskgroup.html

Classification systems may take the following factors into consideration:

- Pathogenicity of the organism / disease caused
- Mode of transmission and host range
- Availability of effective preventive measures
- Availability of effective treatment
- Other factors
## NIH Risk Groups

<table>
<thead>
<tr>
<th>Risk Group 1  (RG1)</th>
<th>Agents that are not associated with disease in healthy adult humans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk Group 2  (RG2)</td>
<td>Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are <em>often</em> available</td>
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<tr>
<td>Risk Group 3  (RG3)</td>
<td>Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions <em>may be</em> available (high individual risk but low community risk)</td>
</tr>
<tr>
<td>Risk Group 4  (RG4)</td>
<td>Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are <em>not usually</em> available (high individual risk and high community risk)</td>
</tr>
</tbody>
</table>
Experiment-related factors

Some factors that may affect the biosafety level chosen for a project:

- Agent risk group
- Sample characteristics
- Planned procedures
- Scale of culture growth
- Animal use
Biosafety Levels

(1) BIOSAFETY LEVEL 1 - for work involving well-characterized agents not known to cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment.

(2) BIOSAFETY LEVEL 2 - for work involving agents of moderate potential hazard to personnel and the environment.

(3) BIOSAFETY LEVEL 3 - for facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.

(4) BIOSAFETY LEVEL 4 - required for work with dangerous and exotic agents which pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease.

CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (4th Edition 1999)
Host-related factors

Occupational health / medical surveillance programs may need to consider:

- Age
- General health and nutritional status
- Use of medications
- Pregnancy
- Immune status for specific agent
- Other factors
“NIH Guidelines for Recombinant DNA Research”

If institution receives NIH funding, it must follow these guidelines

Require an Institutional Biosafety Committee to review rDNA research

http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm
“Biosafety in Microbiological and Biomedical Laboratories”

- Published by CDC/NIH
- Prescribes lab practices and techniques, equipment and facility design for biosafety level 1-4 and animal biosafety level 1-4
- Agent summary statements
“OSHA Bloodborne Pathogen Standard”

US Occupational Safety and Health Administration

Standard covers work with human blood or other potentially infectious materials

Requires an Exposure Control Plan, training of employees, offer of hepatitis B vaccine


State regulations supercede in some cases
Other Regulatory Considerations

- Other OSHA regulations (respiratory protection, injury and illness reporting, etc.)
- Import / export permits through CDC or USDA/APHIS
- Select agent regulations
- State and local regulations may govern waste disposal, require local research oversight
Awareness of Routes of Exposure

- Injection (sharps or non-intact skin)
- Ingestion
- Mucous membranes (eyes/nose/mouth)
- Inhalation (aerosols)
Attire in MIT labs

Lab Attire
- Closed toed shoes
- Pants or long skirt
- Safety glasses
- Lab coats / gloves provided in labs as needed
Practices in MIT labs

- No eating, drinking, smoking
- Wash hands after removing gloves and before exiting
Lab Emergencies

- To report any emergency, dial 100 from any MIT phone
- In event of exposure to biological material, please wash well in sink, eyewash or shower
- Report injury or exposure to MIT personnel
- Seek medical attention
Lab Evacuations

- Follow instructions of MIT personnel
- If evacuation alarm sounds, please exit building via stairs
- Gather in a safe place for a headcount
Conclusion

- Risk assessment for biological research
- Regulatory considerations for biosafety
- Laboratory preparedness

Have a safe experience!