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Biosafety and Laboratory Preparedness

GEM4 Summer School 2006

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Biosafety and Laboratory Preparedness

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

Risk Assessment for Biological Research

Risk Assessment

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

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

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
- ◆ <http://www.cdc.gov/OD/ohs/biosfty/bmbl4/bmbl4toc.htm>

"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
- ◆ 29 CFR 1910.1030 -- <http://www.osha.gov/SLTC/bloodborne pathogens/standards.html>
- ◆ 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!