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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

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 *often* available
Risk Group 3 (RG3)	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* 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 *not usually* 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/bloodbornepathogens/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!