Biological Risk Assessment

David Hill
Director, Safety and Security
Wadsworth Center
New York State Department of Health

Risk Assessment Webinar
June 15, 2011
Biohazard Risk Assessment

• What is it?
  - Agent-based qualitative risk estimate.
    • Safe when risk associated with task is considered to be acceptable.

• What needs to be reviewed?
  - From accessioning to waste disposal.

• Most important component is professional judgment.
Why do it and document it?

Standards & guidelines driving biohazard risk assessments:

- OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030)
  - “Exposure control plans shall be update at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure.”

- “Document annual consideration and implementation of appropriate and effective safer medical devices designed to eliminate or minimize occupational exposure.” (Needlestick Safety and Prevention Act, 2000)
Why do it and document it?

Standards & guidelines driving biohazard risk assessments:

- OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030)
- The CDC/NIH Booklet “Biosafety in Microbiological and Biomedical Laboratories (BMBL)”, 5th Edition (2007)
Evolution of CDC/NIH BMBL
Why do it and document it?

Standards & guidelines driving biohazard risk assessments:

- OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030)
- The CDC/NIH Booklet “Biosafety in Microbiological and Biomedical Laboratories (BMBL)”, 5th Edition (2007)
- NYS DOH CLEP – Safety Standards (Effective November 1, 2010)
  - Revised to be consistent with BMBL
- CDC/APHIS - Select Agent Regulations: Possession, use, and transfer of select agents.
Risk Assessment
Biosafety Risk Assessment and Management Process

Five step process:

Risk Assessment

1) Perform comprehensive hazard evaluation and determine initial biosafety level (BSL).

2) Identify laboratory procedure hazards
   1) Determining risk
   2) Determining acceptability of risk

Risk Management

3) Determine final containment (BSL) with any additional safety enhancements

4) Evaluate staff proficiency and safety equipment integrity

5) Review with knowledgeable individuals
Biosafety Risk Assessment

(Agent Hazards) + (Lab Procedure Hazards)
Agent Hazards

• What are the principle hazardous characteristics of an agent?
  - Its capability to infect and cause disease
  - The severity of the disease
  - Availability of preventative measures and treatments for the disease
  - Route of transmission
    • Transmission via aerosol is most serious hazard.
      - Infective dose and agent stability key factors.
    - History of Laboratory-acquired infection (LAI)
Determine the proper risk group

**RISK GROUP 1:** Agents are not associated with disease in healthy human adults

**RISK GROUP 2:** Agents associated with human diseases that are rarely serious. Effective preventive or treatment options are often available.

**RISK GROUP 3:** Agents are associated with serious or potentially lethal diseases for which effective preventive or treatment options may be available.

**RISK GROUP 4:** Agents are likely to cause serious or lethal disease. Effective preventive or treatment options are not usually available.
Section VIII
Agent Summary Statements

- Good Source of Info:
  - Agent
  - Occupational Infections
  - Natural Modes of Infection
  - Laboratory Safety
  - Containment Recommendations
  - Special Issues
    - Vaccines
    - Select Agent
    - Transfer of Agent
    - Post Exposure Treatment
Material Safety Data Sheets

- **MSDSs are available for certain infectious agents.**
  - Health Canada Office of Laboratory Security
  - **MSDS content:**
    - Section 1: Infectious Agent
    - Section 2: Health Hazard
    - Section 3: Dissemination
    - Section 4: Viability
    - Section 5: Medical
    - Section 6: Laboratory Hazards
    - Section 7: Recommended Precautions
    - Section 8: Handling Information
    - Section 9: Miscellaneous Information
Agent Hazards

- What about clinical specimens with unknown risks?
  - Past experience
    - Have you seen high risk agents in your lab?
  - Medical data on patient if available.
  - Geographic origin of specimen
  - Ad hoc guidelines during outbreaks (e.g., West Nile Virus, SARS-CoV, etc).
Lab Procedure Hazards

- Assess specific tasks within each method or procedure.
- Consider all sources and routes of exposure:
  - Manipulations that produce droplets and aerosols
    - Pipetting, blenders, centrifuges (without primary containment), sonicators, and vortex mixers
  - Manipulations involving sharps
  - Manipulations with high potential for spills and splashes
  - New/emerging technologies
Lab Procedure Hazards

- Assess automated systems and other emerging technology for exposure risks.
Important to define what constitutes an “exposure incident” or “occupational exposure” in advance of incidents.

- *Exposure incident* (OSHA BBP): “means a specific eye, mouth, or other mucous membrane, non-intact skin, or parenteral contact with blood or OPIM...”

- *Occupational exposure* (CDC/APHIS Select Agent Regulations): “Any event that results in any person...not being appropriately protected in the presence of an agent or toxin...”
Risk Management
Biosafety Risk Assessment and Management Process

Five step process:

1) Perform comprehensive hazard evaluation and determine initial biosafety level (BSL).
2) Identify laboratory procedure hazards
   1) Determining risk
   2) Determining acceptability of risk

3) Determine final containment (BSL) with any additional safety enhancements
4) Evaluate staff proficiency and safety equipment integrity
5) Review with knowledgeable individuals
Managing Risks

- **OSHA Bloodborne Pathogen Standard**
  - Shall establish a written Exposure Control Plan

- **CDC/NIH BMBL**
  - A laboratory-specific biosafety manual must be prepared and adopted as policy
  - Four recommended laboratory practices
    - Biosafety levels 1 - 4

- **NYSDOH CLEP Standard**
  - Shall describe use of biosafety equipment, practices, and procedures in laboratory’s safety manual.
  - Minimally meet biosafety level 2
    - Describe additional procedures for suspected high risk pathogens.
Thank You!

David Hill
Director, Safety and Security
Wadsworth Center
(518) 486-3874
Email: djh08@health.state.ny.us