Risk Assessment
Risk Management
Biological Risk (Definition)

- “Probability of exposure occurring and resulting in an adverse effect.”
  - Johnson (2001)
Biological Risk Assessment

• Process used to identify:
  – Hazardous characteristics of a known infectious agent or potentially infectious materials;
  – The activities that can result in a person’s exposure to an agent or material;
  – The likelihood that such exposure will cause a LAI; and
  – The probable consequences of such as infection.
Biological Risk Assessment

(Agent Hazards) + (Lab Procedure Hazards)
Biological Risk Assessment

- Challenges:
  - Qualitative process – involves uncertainty
  - Involves both objective and subjective factors.
  - Individual risk may vary
  - Expertise of many fields may be needed.
CDC/NIH BMBL, 5th edition
Why comply with guidelines...?

• OSHA’s General Duty Clause
  – Requires an employer to:
    “furnish to each of his employees…a place of employment…free from recognized hazards that are likely to cause death or serious physical harm…”

• In New York State, NYSDOH CLEP Safety Standards have adopted elements of BMBL.

• Compliance with BMBL required by select agent regulations.
Biological Risk Assessment Process (BMBL 5th edition)

Five step process:

**Risk Assessment**

1) Perform comprehensive hazard evaluation and determine initial BSL/ABSL

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

**Risk Management**

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

4) Evaluate staff proficiency and safety equipment integrity

5) Review with knowledgeable individuals
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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.
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.
Agent Hazards

What else do you need to know?
- History of Laboratory-acquired infection (LAI).
- Probable routes of transmission of LAI.
- Infective dose
- Stability in the environment.
- Host range.
- Is it endemic?
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

SECTION VIII
Agent Summary Statements

Section VIII-A: Bacterial Agents
Agent: Bacillus anthracis

Bacillus anthracis, a gram-positive, non-hemolytic, and non-motile bacterium, is the etiologic agent of anthrax, an acute bacterial disease of mammals, including humans. Like all members of the genus Bacillus, under adverse conditions, B. anthracis has the ability to produce spores that allow the organism to persist for long periods of time until the return of more favorable conditions. Early historical reports of anthrax date back to at least 1250 BC. The study of anthrax and B. anthracis in the 1800s contributed greatly to our current understanding of infectious disease. Much of Koch's postulates were derived from work on identifying the etiologic agent of anthrax. Louis Pasteur developed the first attenuated live vaccine for anthrax.

Most mammals are susceptible to anthrax; it most often affects herbivores that ingest spores from contaminated soil and, to a lesser extent, carnivores that scavenge on the carcases of diseased animals. Anthrax still occurs frequently in parts of central Asia and Africa. In the United States, it occurs sporadically in animals in parts of the West, Midwest, and Southeast.

The infectious dose varies greatly from species to species and also is strain-dependent. The inhalation anthrax infectious dose (ID) for humans primarily has been extrapolated from inhalation challenges of anthrax primates (CDP), or studies done in contaminated units. Estimates vary greatly, but the lethal dose (LD) is likely within the range of 2,500-55,000 spores. It is believed that very few spores (10 or less) are required for cutaneous anthrax.

Occupational Infections

Occupational infections are possible when in contact with contaminated animals, animal products, or pure cultures of B. anthracis, and may include scrub, vesiculobullous, and laboratory workers. Numerous cases of laboratory-acquired anthrax (primarily cutaneous) have been reported.[13] Recent cases include suspected cutaneous anthrax in a laboratory worker in Texas and a cutaneous case in a North Dakota man who disposed of five cows that died of anthrax.[14]

Natural Modes of Infection

The clinical forms of anthrax in humans that result from different routes of infection are 1) cutaneous (via broken skin), 2) gastrointestinal (via ingestion), and 3)
Material Safety Data Sheets

• What about MSDSs for infectious agents?
  – 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

- **Unknown specimens**
  - Often not sufficient information to make an appropriate assessment of risk in Clinical/Diagnostic setting.
  
  - Need to establish “triggers” in laboratory procedures where probability of risk goes up.
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Lab Procedure Hazards

- Agent concentration/volume.
- Manipulations/equipment that produce droplets and aerosols.
- Manipulations involving sharps.
- Manipulations with high potential for spills and splashes.
- Exposure to zoonotic diseases of experimental animals.
Lab Procedure Hazards

- “Procedures that impart energy to a microbial suspension will produce aerosols”. (BMBL)

- Procedures that create aerosols:
  - Centrifuging (without primary containment).
  - Sonicating/blending
  - Pipetting
  - Vortexing
Lab Procedure Hazards

• “Potential risk from exposure to droplet contamination requires as much attention in a risk assessment as the respirable component of aerosols.” (BMBL)
Lab Procedure Hazards

• Are sharps used in any procedures?
  – Needles and syringes
  – Scalpels
  – Pasteur pipettes
  – Glass culture tubes
Lab Procedure Hazards

• Manipulations with high potential for spills and splashes
  – Culturing high volumes and high titers of an agent.
  – In vitro experiments using loose fitting coverings (e.g., Cell culture plates and flasks).
  – Pouring or decanting fluids.
  – Necropsies of infected animals (e.g., Rabies lab).
Biological Risk Assessment Process (BMBL 5th edition)

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Risk Management

(Capability of Staff & Equipment to Control Hazards)
Risk Management

• **Safe Work Practices**
  – The risk assessment/management process should identify any potential deficiencies in the practices of the laboratory workers.
  – **Evaluate:**
    • Training
    • Technical proficiency in practices and equipment
    • Experience with agents
    • Demonstration of good habits
    • Ability to respond to emergencies
Risk Management

• Safety Equipment
  – Ensure that safety equipment is working properly.
  – Ensure that staff are properly trained in:
    • Correct use of equipment;
    • Proper procedure;
    • Inspection frequency;
    • Potential malfunctions; and
    • Recertification frequency, if applicable.
Risk Management

• Recommended laboratory practices.
  – Biosafety Level 1
  – Biosafety Level 2
  – Biosafety Level 3
  – Biosafety Level 4

• Section VIII-G: Toxins Summary Statements

• Appendix I: Guidelines for Work with Biological Toxins.
Risk Management

• Laboratory Biosafety Level Criteria:
  – Laboratory Practice and Technique.
    • Standard Practices
    • Special Practices
  – Safety Equipment (Primary Barriers and PPE).
  – Facility Design and Construction (Secondary Barriers).
NYSDOH CLEP Standards -
Safety Standard 1: Biohazard Risk Assessment and Biosafety Program

• Laboratory shall conduct an infectious agent risk assessment for each permit category.

• Implement risk-based biosafety program.
  – Described in laboratory safety manual;
  – Reviewed annually and revised as necessary;
  – Minimally meets BSL-2 criteria;
  – Incorporates use of BSC and appropriate PPE; and
  – Includes procedures to be implemented when high-risk pathogens are suspected (as applicable).
NYSDOH CLEP Standards -
Safety Standard 2: Employee Occupational Exposure Plan

• Laboratory shall establish an employee infectious agent “medical response plan” appropriate for the testing and procedures performed by the laboratory
  – Immediate notification of lab director of exposures or reports of symptoms consistent with LAI;
  – Medical risk assessment;
  – Diagnostic testing and treatment protocols;
  – Root cause investigation; and
  – Documentation of corrective/preventive action.
Questions?

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