Biological Risk Assessment

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Risk Assessment Webinar
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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)

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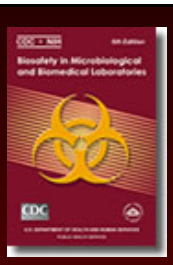
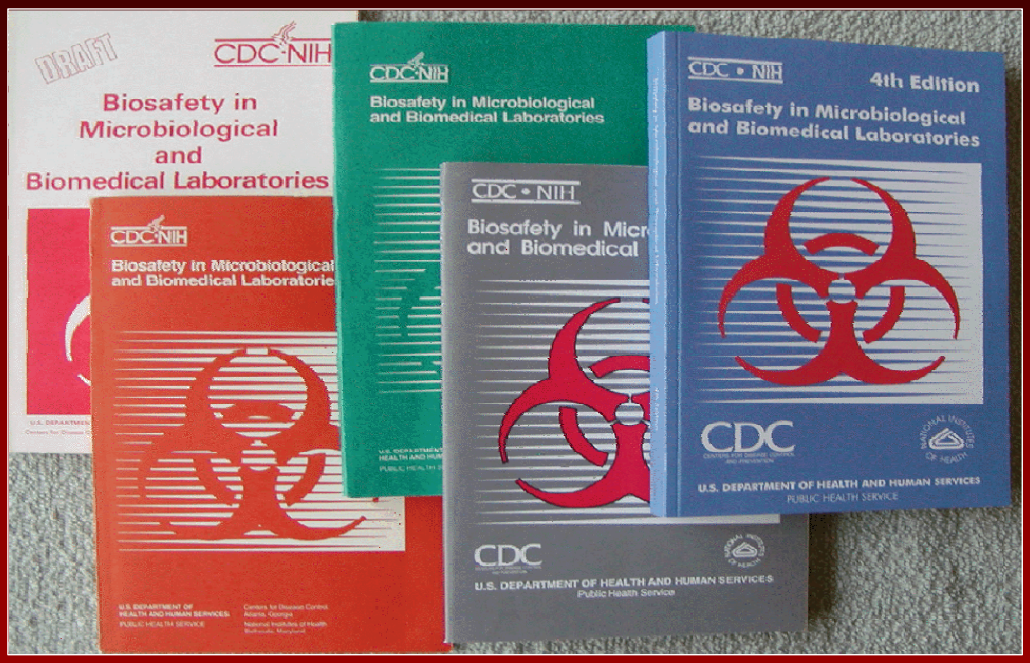


Evolution of CDC/NIH BMBL



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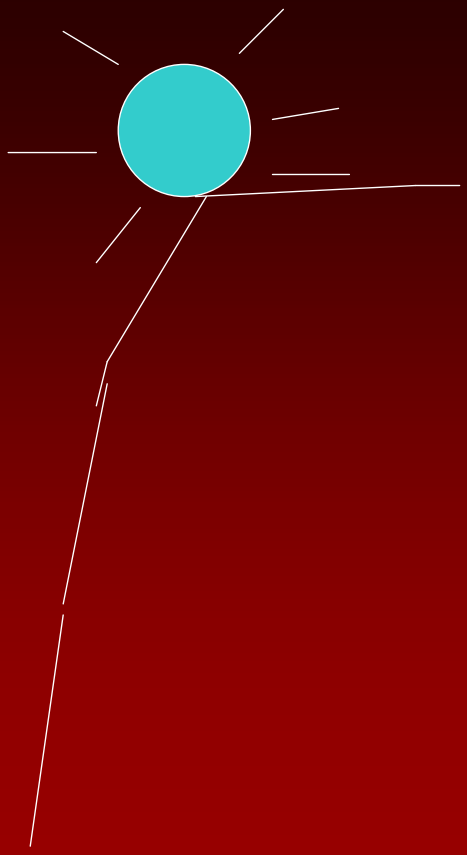
- The CDC/NIH Booklet “Biosafety in Microbiological and Biomedical Laboratories (BMBL)”, 5th Edition (2007)
- NYS DOH CLEP – Safety Standards (Effective November 1, 2010)
  - Revised to be consistent with BMBL
- CDC/APHIS - Select Agent Regulations: Possession, use, and transfer of select agents.

Risk Assessment



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Biosafety Risk Assessment and Management Process

Five step process:

Risk Assessment

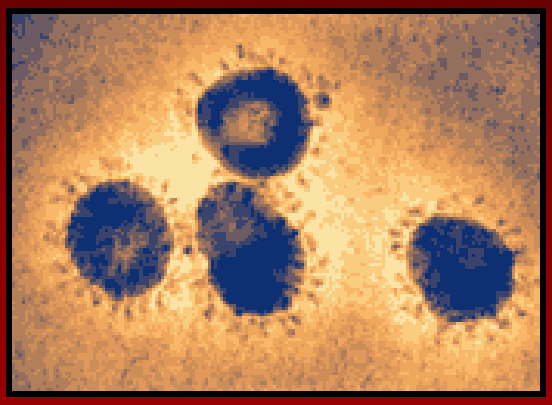
1) Perform comprehensive hazard evaluation and determine initial biosafety level (BSL).
2) Identify laboratory procedure hazards
    1) Determining risk
    2) Determining acceptability of risk

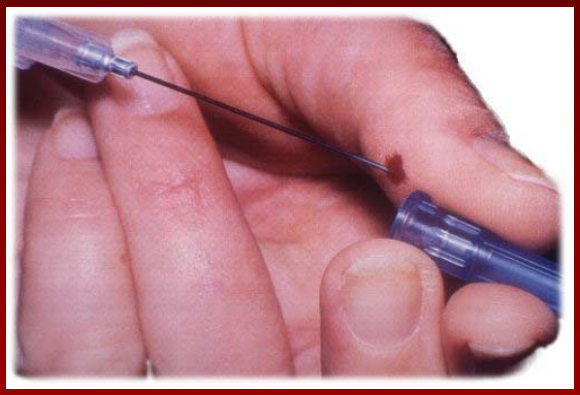
Risk Management

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)





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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.
  - History of Laboratory-acquired infection (LAI)

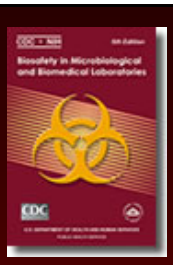
Determine the proper risk group

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.

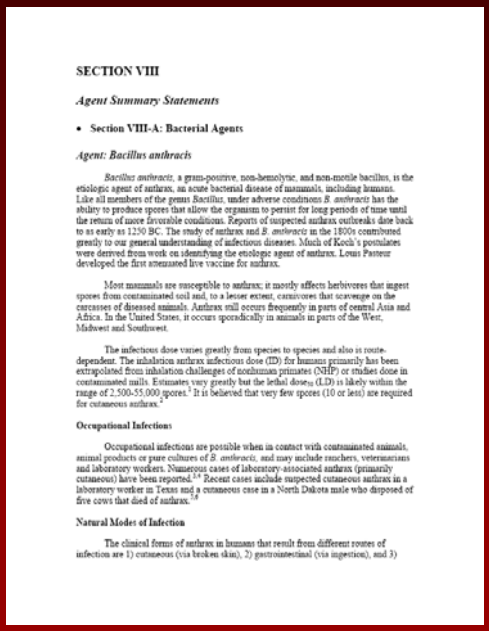
RISK GROUP 4: Agents are likely to cause serious or lethal disease. Effective preventive or treatment options are not usually available.



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



SECTION VIII

Agent Summary Statements

- **Section VIII-A: Bacterial Agents**

Agent: Bacillus anthracis

Bacillus anthracis, a gram-positive, non-hemolytic, and non-motile bacillus, 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. Reports of suspected anthrax outbreaks date back to as early as 1250 BC. The study of anthrax and *B. anthracis* in the 1800s contributed greatly to our general understanding of infectious diseases. 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 mostly affects herbivores that ingest spores from contaminated soil and, to a lesser extent, carnivores that scavenge on the carcasses 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 Southwest.

The infectious dose varies greatly from species to species and also is route-dependent. The inhalation anthrax infectious dose (ID) for humans primarily has been extrapolated from inhalation challenges of nonhuman primates (NHP) or studies done in contaminated mills. Estimates vary greatly but the lethal dose$_{50}$ (LD) is likely within the range of 2,500-55,000 spores.[4] It is believed that very few spores (10 or less) are required for cutaneous anthrax.[5]

Occupational Infections

Occupational infections are possible when in contact with contaminated animals, animal products or pure cultures of *B. anthracis*, and may include ranchers, veterinarians and laboratory workers. Numerous cases of laboratory-associated anthrax (primarily cutaneous) have been reported.[3,6] Recent cases include suspected cutaneous anthrax in a laboratory worker in Texas and a cutaneous case in a North Dakota male who disposed of five cows that died of anthrax.[7,8]

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

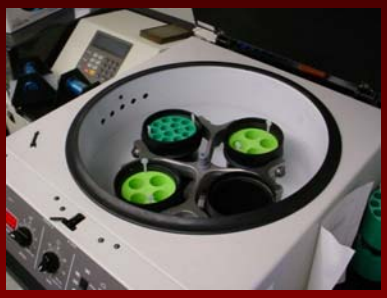
- MSDSs are available for certain infectious agents.
  - Health Canada Office of Laboratory Security
  - MSDS content:
    - Section 1: Infectious Agent
    - Section 2: Health Hazard
    - Section 3: Dissemination
    - Section 4: Viability
    - Section 5: Medical
    - Section 6: Laboratory Hazards
    - 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



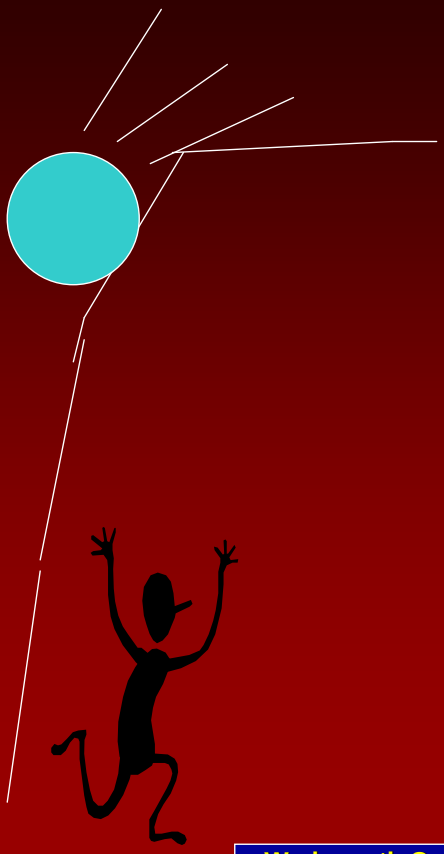
Lab Procedure Hazards

- Assess automated systems and other emerging technology for exposure risks.

Lab Procedure Hazards

- 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



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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!

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