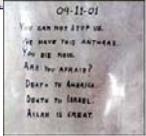


Anthrax

- In 2005 natural outbreaks have occurred in the North America, South America, Asia, and Europe**
 - Thousands of cattle, sheep, horses, llamas and wild bison have been affected
 - High zoonotic potential
- In 2001 *Bacillus anthracis* spores were maliciously released through the United States postal system in 2001**
 - Resulting in 5 deaths and 22 additional illnesses
 - The attack has increased U.S. awareness of the biological weapons and bioterrorist threat
 - Suspicion that the material was obtained from a bioscience laboratory
 - As result, the U.S. has imposed new rules that are designed to improve the security and agent accountability of legitimate bioscience research laboratories



Bacillus anthracis






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Laboratory Biosafety and Biosecurity

- Biosafety**
 - Objective: reduce or eliminate accidental exposure to or release of potentially hazardous agents
- Biosecurity**
 - Objective: protect biological agents against theft and sabotage by those who intend to pursue bioterrorism or biological weapons proliferation
- Common strategy**
 - Implement graded levels of protection based on a risk management methodology
- Control of certain biological materials is necessary, but how that is achieved must be carefully considered**
 - Biosecurity and biosafety should be integrated systems that avoid compromising necessary infectious disease research and diagnostics



Francisella tularensis





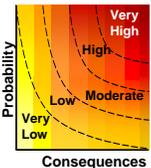
Yersinia pestis




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Laboratory Biosafety and Biosecurity Based on Risk Management

- Safety and security in a biological environment will never be perfect
- Most biological agents can be contracted or isolated from natural sources
- Critical not to compromise legitimate bioscience operations
- Management must distinguish between "acceptable" and "unacceptable" risks
 - Ensure that protection for an agent, and the cost, is proportional to the risk of accidental release/exposure or theft and misuse of that material



- Protect against unacceptable risk scenarios
- Develop incident response plans for acceptable risk scenarios




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Components of Laboratory Biosafety

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Biosafety: Engineering Controls

- **Primary barriers – contain the agent at the source**
 - Biological safety cabinet
 - Animal caging
 - Specialized lab equipment (centrifuges, fermenters, etc.)
- **Secondary barriers – contain the agent within the room or facility in case an agent escapes from the primary barriers**
 - Building & Room Construction
 - HVAC Issues:
 - Directional airflow
 - Exhaust filtration
 - Other Engineering Controls:
 - Solid waste treatment
 - Wastewater treatment

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Biosafety: Work Practices

- Good microbiological technique
- Wash hands often
- No mouth pipetting
- No eating or drinking in lab
- Minimize aerosol generation
- Careful pipetting technique
- Decontaminate work surfaces
- Safe sharps handling
- Training
- Written procedures

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Laboratory Biosecurity Supports Laboratory Biosafety

- **Laboratory biosecurity supports the laboratory biosafety agenda of preventing disease in people, animals, and plants and minimizing the risk of worker injury**
- **Safe and secure laboratories help**
 - Ensure the containment of hazardous infectious substances in laboratories
 - Maintain citizens' confidence in the activities of the bioscience research community
 - Increase transparency to investors in the biomedical and biotechnology industries
 - Protect valuable research and commercial assets
 - Reduce the risks of crime and bioterrorism





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Conclusions

- **Biosafety has historically been based on guidance and best practices**
- **Biosecurity is much newer and regulations, guidelines, and implementation methodologies are evolving**
- **Infectious diseases pose significant threats to public and agricultural health**
- **The "internationalization" of laboratory biosecurity practices is an important development**
 - Securing dangerous pathogens in one or a few countries is insufficient to mitigate the threat of bioterrorism or biological weapons proliferation
- **Managing risks in the laboratory is dependent on both biosafety and biosecurity**
 - Helps reduce the threat of infectious disease
 - Established international guidance on laboratory biosafety and evolving international expectations for laboratory biosecurity
- **The US Select Agent Rule is not universally applicable**
 - Laboratory biosecurity guidelines and requirements need to reflect local and national concerns and priorities

"Infectious diseases make no distinctions among people and recognize no borders"
President George Bush, November 2001



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Resources

- **Laboratory Biosafety and Biosecurity Guidance**
 - Laboratory Biosecurity Handbook, 2007, CRC Press
 - WHO Laboratory Biosafety Manual, 3rd edition (Ch 9 is Laboratory Biosecurity)
 - WHO/FAO/OIE joint guidance – *Biorisk Management: Laboratory Biosecurity Guidance, 2006*
 - CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*
 - 5th edition, 2006, extensive recommendations on biosecurity
 - Canada's *Laboratory Biosafety Guidelines*, 3rd edition
- **Transport of Infectious Substances**
 - IATA guidance
 - WHO guidance
- **On the Web**
 - Biosecurity Engagement Program: www.BEPstate.net
 - American Biological Safety Association: www.absa.org
 - Sandia National Laboratories: www.biosecurity.sandia.gov
 - European Biosafety Association: www.ebsa.be
 - Asia-Pacific Biosafety Association: www.a-pba.org




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