Principles of Laboratory Biosafety and Biosecurity

Risk Assessment for Laboratory Biosecurity and Biosafety
Nashville, TN
6 October 2007

www.biosecurity.sandia.gov

SAND No. 2006-3685C
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company, for the United States Department of Energy's National Nuclear Security Administration under contract DE-AC04-94AL85000.

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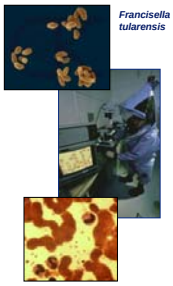
Laboratory Biosafety and Biosecurity

- **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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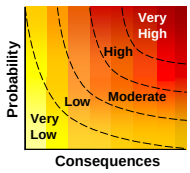
Laboratory Biosafety and Biosecurity Based on Risk Management

- **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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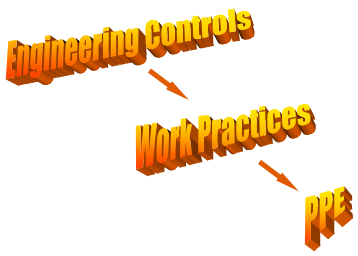
Components of Laboratory Biosafety



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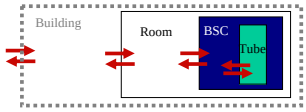
Biosafety: Engineering Controls

- **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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Biosafety: Personal Protective Equipment

- **Types of PPE**
  - Gloves
  - Appropriate footwear
  - Lab coats
  - Eye and face protection
  - Respirator
- **Purpose**
  - Provides a barrier against skin, mucous membrane or respiratory exposure to infectious agents
  - To prevent spread of contamination
- **Limitations**
  - Does not eliminate the hazard
  - Integrity wanes with use (change gloves frequently)
  - Not all gloves created equal – select best glove for the task

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Biosafety Levels

- **Biosafety Level 1**
  - Suitable 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.
  - Examples:
    - *Bacillus subtilis*
    - *Naegleria gruberi*
    - Infectious canine hepatitis virus
    - *E. coli*
- **Biosafety Level 2**
  - Suitable for work involving agents of moderate potential hazard to personnel and the environment
  - Examples:
    - Measles virus
    - Salmonellae
    - Toxoplasma species
    - Hepatitis B virus
- **Biosafety Level 3**
  - Suitable for work with infectious agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.
  - Examples:
    - *Mycobacterium tuberculosis*
    - St. Louis encephalitis virus
    - *Coxiella burnetii*
- **Biosafety Level 4**
  - Suitable for work with dangerous and exotic agents that pose a high individual risk of aerosol transmitted laboratory infections and life-threatening disease.
  - Examples:
    - Ebola Zaire virus
    - Rift Valley Fever virus

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Biosafety Levels, Practices, and Equipment

Table 2. ***Relation of risk groups to biosafety levels, practices and equipment***

RISK GROUP	BIOSAFETY LEVEL	LABORATORY TYPE	LABORATORY PRACTICES	SAFETY EQUIPMENT
1	Basic – Biosafety Level 1	Basic teaching, research	GMT	None; open bench work
2	Basic – Biosafety Level 2	Primary health services, diagnostic services, research	GMT plus protective clothing, biohazard sign	Open bench plus BSC for potential aerosols
3	Containment – Biosafety Level 3	Special diagnostic services, research	As Level 2 plus special clothing, controlled access, directional airflow	BSC and/or other primary devices for all activities
4	Maximum containment – Biosafety Level 4	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC, or positive pressure suits in conjunction with Class II BSCs, double-ended autoclave (through the wall), filtered air

BSC, biological safety cabinet; GMT, good microbiological techniques (see Part IV of this manual)

From: WHO LBM 3rd edition

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Summary of Biosafety Level Requirements

Table 3. Summary of biosafety level requirements

	BIOSAFETY LEVEL			
	1	2	3	4
Isolation[a] of laboratory	No	No	Yes	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation:				
— inward airflow	No	Desirable	Yes	Yes
— controlled ventilating system	No	Desirable	Yes	Yes
— HEPA-filtered air exhaust	No	No	Yes/No[b]	Yes
Double-door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Anteroom	No	No	Yes	—
Anteroom with shower	No	No	Yes/No[c]	No
Effluent treatment	No	No	Yes/No[c]	Yes
Autoclave:				
— on site	No	Desirable	Yes	Yes
— in laboratory room	No	No	Desirable	Yes
— double-ended	No	No	Desirable	Yes
Biological safety cabinets	No	Desirable	Yes	Yes
Personnel safety monitoring capability[d]	No	No	Desirable	Yes

[a] Environmental and functional isolation from general traffic.
[b] Dependent on location of exhaust (see Chapter 4).
[c] Dependent on agent(s) used in the laboratory.
[d] For example, window, closed-circuit television, two-way communication.

From: WHO LBM 3rd edition

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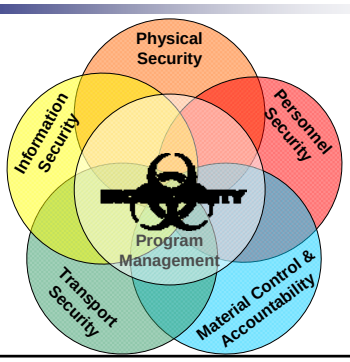
Components of Laboratory Biosecurity



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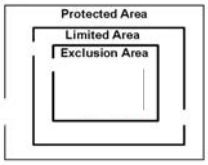
Biosecurity: Physical Security and Personnel Security

- **Physical security – restricts access to authorized individuals**
  - Defined perimeter
  - Access controls
  - Intrusion detection
  - Response
- **Personnel security – determines who is authorized**
  - Personnel screening (background checks)
  - Badges
  - Visitor control



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Biosecurity: MC&A, Transport Security, Information Security

- **Material Control & Accountability (MC&A) – provides awareness of what materials exist where and who is responsible**
  - Physical and procedural controls
  - Inventories
  - Accountable individuals
- **Transport security – MC&A for materials being transferred between laboratories**
  - Knowledge of recipient
  - Physical security of packages
  - Personnel screening for individuals who handle packages
  - Chain of custody
  - Use of reliable carriers
- **Information security – protecting sensitive information from public release**
  - Identification, marking, and control
  - Network and communication security

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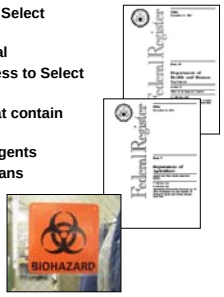
US Select Agent Rule (2005)

- **Facility registration if it possesses one of 80 Select Agents**
- **Facility must designate a Responsible Official**
- **Background checks for individuals with access to Select Agents**
- **Access controls for areas and containers that contain Select Agents**
- **Detailed inventory requirements for Select Agents**
- **Security, safety, and emergency response plans**
- **Safety and security training**
- **Regulation of transfers of Select Agents**
- **Extensive documentation and recordkeeping**
- **Safety and security inspections**



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Select Agents

Heightened Security or Neocolonial Science?

Earthquake Preparedness

Some Countries Are Betting That A Few Seconds Can Save Lives

Science, Vol. 306, 24 December 2004


Bioterrorism

Biosecurity Goes Global

Science, Vol. 305, 17 September 2004

The BWC and Biosecurity

- **Bacteriological (Biological) and Toxin Weapons Convention (BWC) addresses three relevant issues**
  - National Implementing Legislation
  - National Pathogen Security (biosecurity)
  - International Cooperation
- **Recent technical experts meetings to strengthen the BWC.**
  - States Parties agree to pursue national implementation of laboratory and transportation biosecurity (2003)

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UNSCR 1540 and Biosecurity

- **Urges States to take preventative measures to mitigate the threat of WMD proliferation by non-state actors**
- **UNSCR 1540 requires States to**
  - Establish and enforce legal barriers to acquisition of WMD by terrorists and states
  - Submit reports to the 1540 Committee on efforts to comply
- **Paragraph 3 is the key provision that supports biosecurity**
  - "Take and enforce effective measures to establish domestic controls to prevent the proliferation of . . . biological weapons . . .; including by establishing appropriate controls over related materials"
    - Develop and maintain appropriate effective measures to account for and secure such items in production, use, storage or transport
    - Develop and maintain appropriate effective physical protection measures

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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**
- **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
- **However, 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 BiosecurityGuidance, 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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