



# Principles of Laboratory Biosecurity



**International Biological Threat Reduction  
Global Security Center  
Sandia National Laboratories  
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# Strengthening Biological Risk Management



## ***Vision for Integrated BioRisk Management:***

- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs and establish accountability through development of Country "report cards"



# Laboratory Biosafety and Biosecurity

## Laboratory Biosafety

- A set of preventive measures designed to reduce the risk of accidental exposure to or release of a biological hazard

## Laboratory Biosecurity

- A set of preventive measures designed to reduce the risk of intentional removal (theft) of a valuable biological material

## Common strategy

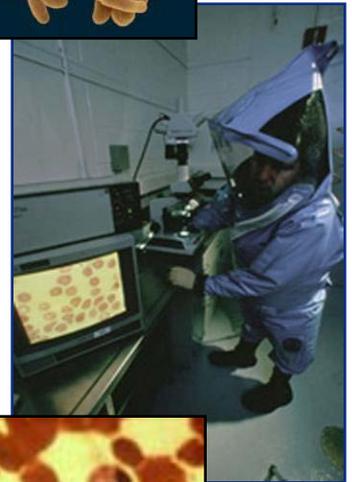
- Implement graded levels of protection based on a risk management methodology

## 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*



# 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





# National Oversight of Biosecurity and Biosafety

- **Countries use a mixture of regulations and guidance**
  - Performance-based vs. prescriptive
    - A performance approach generally defines what result is intended, leaving how to achieve the result up to the user.
    - Prescriptive approaches outline specific requirements that must be done
- **Many models for regulation**
- **Laboratory biosafety standards and practices generally more advanced than laboratory biosecurity**
- **Many countries just beginning to address these issues at a national level**
- **Resources:**
  - Interpol
    - <http://www.interpol.int/Public/BioTerrorism/NationalLaws/>
  - OECD
    - <http://www.biosecuritycodes.org/leg.htm>



# Examples of National Oversight

- **Canada**

- Human Pathogens Importation Regulations Act
  - Overseen by Office of Laboratory Security (within Health Canada)
  - Controls and tracks use of imported dangerous pathogens, including biosecurity requirements
- Have introduced legislation to extend controls on imported pathogens to any laboratory with those pathogens
- Has national laboratory biosafety guidelines
  - Addresses biosafety and biosecurity
- Office of Laboratory Security certifies BSL3 and BSL4 facilities to a national standard

- **United Kingdom**

- Anti-Terrorism, Crime, and Security Act of 2001
  - Part 7 requires Security of Pathogens and Toxins – implementation requires close coordination of laboratories and local police
- Guidance developed by Advisory Committee on Dangerous Pathogens
- Need to notify Health & Safety Executive first time hazard group 2, 3, or 4 pathogens are used on premises; notification is also required of the subsequent use of certain agents

- **Singapore**

- Biological Agents and Toxins Act (BATA; 2005)
  - Framework for regulating biological activities in Singapore
  - Addresses: Possession, Use, Import/Export, Transfer, Transport, Biosafety
  - Up to \$1 million fine and life imprisonment
- Have adopted the WHO LBM as the Singapore standard

RISK PERCEPTION

RISK ASSESSMENT

RISK MANAGEMENT





# Risk Perception in Laboratories

## Biosafety risks: laboratory-acquired infections

- **History of lab-acquired infections**
  - Often attributed to carelessness or poor technique
  - Relatively few cases can be attributed to direct accident (mouth pipetting and sharps injuries)
  - Exposure to airborne pathogens generally presumed to be most plausible cause
  - Brucellosis is most common
- **Sporadic infections in community as a result**
  - 1973 and 1978—England had 3 secondary cases of smallpox
  - 1950—2 cases of Q fever in household of scientist
  - 1990—1 documented case of Monkey B virus from animal handler to wife
  - SARS—including 3 generations (9 cases)

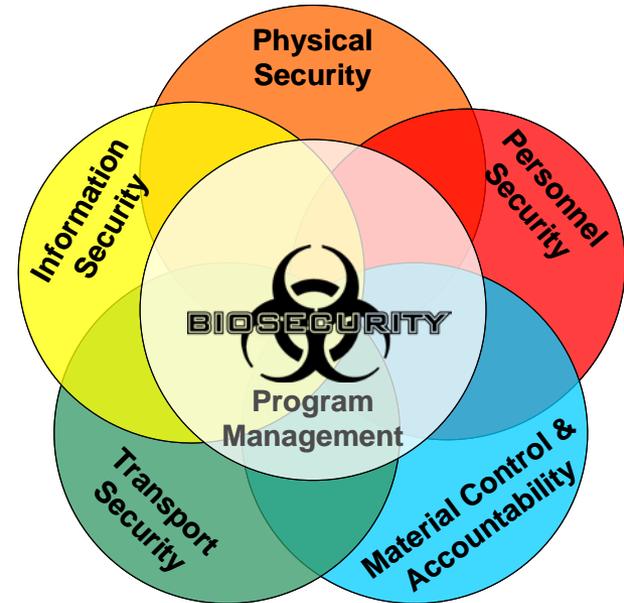
## Biosecurity risks: laboratories as sources of material for malicious use

- **Bioterrorism has emerged as a threat to international security**
  - 1984 Rajneeshee religious cult attacks
  - 1990s Aum Shinrikyo attempts
  - 2001 Anthrax attacks in the US
- **Examples of illicit acquisition**
  - 1990s—Aum Shinrikyo ordered *Clostridium botulinum* from a pharmaceutical company
  - 1995—Larry Wayne Harris, a white-supremacist, ordered 3 vials of *Yersinia pestis* from the ATCC
  - 1995—Laboratory technician Diane Thompson removed *Shigella dysenteriae* Type 2 from hospital's collection and infected co-workers



# Biosecurity System

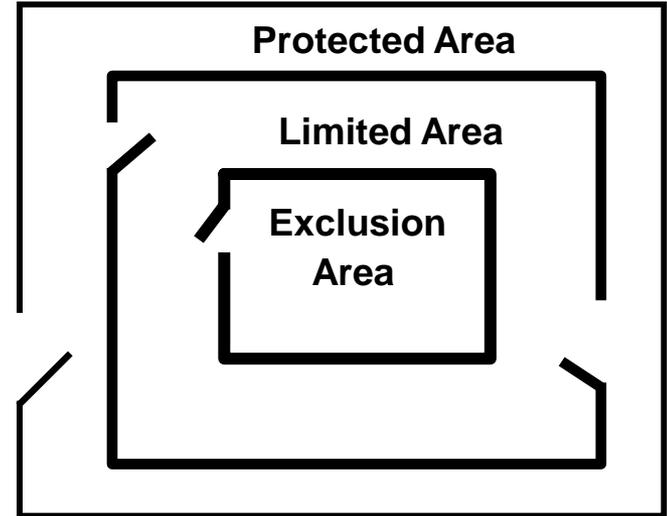
- **Biosecurity system components**
  - Physical security
  - Personnel security
  - Material handling and control measures
  - Transport security
  - Information security
  - Program management practices
- **Each component implemented based on results of risk assessment**
- **In general, biosecurity for**
  - Moderate risk focuses on the insider
  - High risk focuses on both the insider and the outsider





# Physical Security

- **Aims to limit access to authorized individuals**
- **Moderate**
  - Store and use pathogens (and infected animals) within Limited Areas
  - Restrict access using controlled keys and secured windows
  - Control visitors
- **High**
  - Store and use pathogens (and infected animals) within Exclusion Areas
  - Electronic Intrusion Detection System and/or guards
  - Controlled and authenticated key
    - **Something you *have* (key) plus something you *know* (PIN)**
  - Restrict and control visitors
  - Maintain records of entry/exit





# Personnel Security

- **Determines who should be authorized to have access**
- **Moderate**
  - Background investigation
    - **Criminal history**
    - **Verifiable compliance with rules and regulations**
  - Drug test
- **High**
  - Moderate plus
    - **Personal and associate interviews**
    - **Credit history**
    - **Terrorist/extremist/criminal affiliation**
    - **Periodically reinvestigate**





# Material Control & Accountability

- **Determine what materials exist, where they are, and who is responsible for those materials**
- **Moderate**
  - Seed stocks cataloged and records stored securely
    - **Transfers in and out**
    - **Source**
    - **Strain**
    - **Form**
    - **Responsible individual**
  - Working stocks, including infected animal status, tracked through laboratory notebooks
- **High**
  - Moderate plus
    - **Increased control over working stocks**
    - **Increased verification over destruction**





# Transport Security

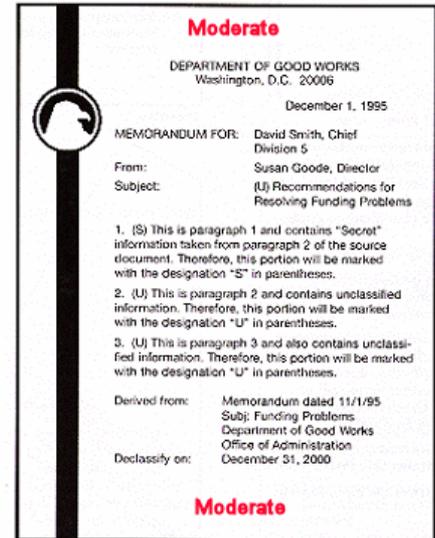
- **Aims to deter theft while materials are outside of laboratories by implementing biosecurity measures during the transport process**
- **Moderate**
  - Internal transport personnel screened
  - Recipient screened for legitimacy
  - Safe receipt notification
- **High**
  - Moderate plus
    - **Chain of custody**
    - **Physical controls on storage containers**





# Information Security

- Measures to protect information that is too sensitive for public distribution
- Examples include:
  - Risk assessments
  - Access authorizations
  - Security plans
- Identification
  - A review & approval process
- Control
  - Storage
  - Communication security
    - Phone, fax, email
  - Network security
    - User authentication, firewalls, virus protection, layered network access, wireless access



## Marking





# Goals: Biorisk Management

- **Effective laboratory biosafety and laboratory biosecurity working together:**
  - Reduce the risk of injury, infection and death of employees and the public
  - Reduce the risk of environmental contamination
  - Reduce the risk of theft or intentional misuse of biological agents
  - May promote conformation with local and global practices and regulations
  - Ensure that biological materials are used safely and securely





# New International Laboratory Biorisk Management Standard

- **CEN Workshop Agreement, 2008 – laboratory biorisk management standard**
  - <http://www.cen.eu/cenorm/sectors/technicalcommitteesworkshops/workshops/ws31.asp>
- **Based on international best practices**
  - Risk-based approach
  - World Health Organization – *Laboratory Biosafety Manual, 3<sup>rd</sup> edition*
  - WHO/FAO/OIE joint guidance – *Biorisk Management: Laboratory Biosecurity Guidance, 2006*
  - Relies on a “Plan-Do-Check-Act” approach with the goal of continuous improvement
- **Developed by consensus, initiated by leading professional organizations**
  - European Biological Safety Association
  - American Biological Safety Association
  - Asia Pacific Biosafety Association





# 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**
  - Limits the number of individuals who may be exposed to the hazards
  - Limits access to those who are professionally qualified and properly trained to be there
  - Access control procedures and records can be used to support investigations of laboratory safety or security incidents

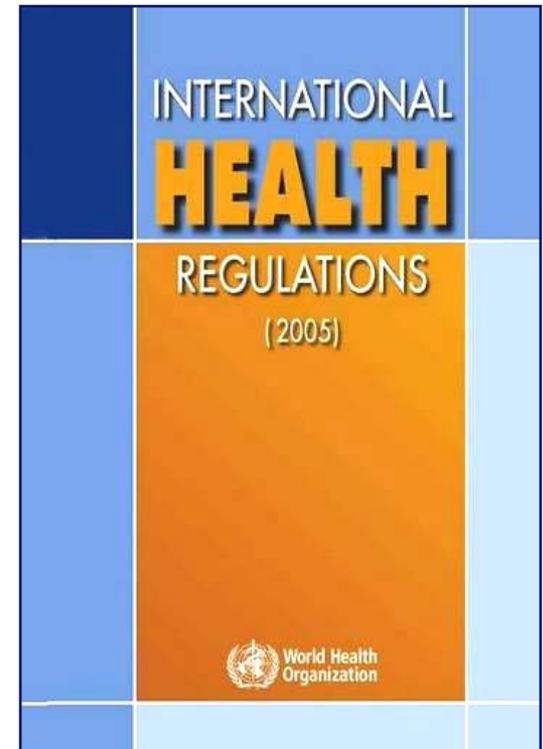


Laboratory Biosecurity



# International Calls for Improving Laboratory Biosafety and Biosecurity

- **International Health Regulations, 2005**
- **Organization for Economic Cooperation and Development, “Best Practice Guidelines for Biological Resource Centers,” published 2007**
- **Biological Weapons Convention Experts Group meetings in 2003 and 2008 address biosecurity**
- **United Nations Security Council Resolution 1540 (2004) requires States to establish and enforce legal barriers to acquisition of WMD by terrorists and states, including laboratory biosecurity measures**



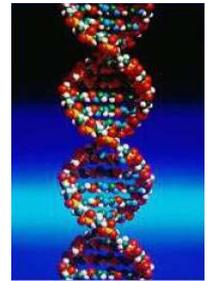
**CEN Work Agreement Biorisk Management Standard 15793, published 2008**





# Biosecurity: Materials, Equipment, and Expertise?

- **Current US and international efforts are predominately focused on materials but...**
  - Policy makers are looking at possible controls for equipment and expertise
    - **E.g. Denmark's new regulations**
- **National Academies Report on “Biotechnology in an Age of Terrorism” (Fink Report) defines 7 experiments of concern:**
  - Experiments that would
    - **Demonstrate how to render a vaccine ineffective**
    - **Confer resistance to therapeutically useful antibiotics or antiviral agents**
    - **Enhance the virulence of a pathogen or render a nonpathogen virulent**
    - **Increase transmissibility of a pathogen**
    - **Alter the host range of a pathogen**
    - **Enable the evasion of diagnostic/detection modalities**
    - **Enable the weaponization of a biological agent or toxin**





## World At Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism

*“...given the high level of know-how needed to use disease as a weapon to cause mass casualties, the United States should be less concerned that terrorists will become biologists and far more concerned that biologists will become terrorists.”*

## CONFRONTING 21<sup>ST</sup> CENTURY THREATS – [www.barackobama.com](http://www.barackobama.com)

*“We must not fixate on fighting the last war. The central concern is that as biological science and related technologies accelerate....bioweapons become ever more globally available”*

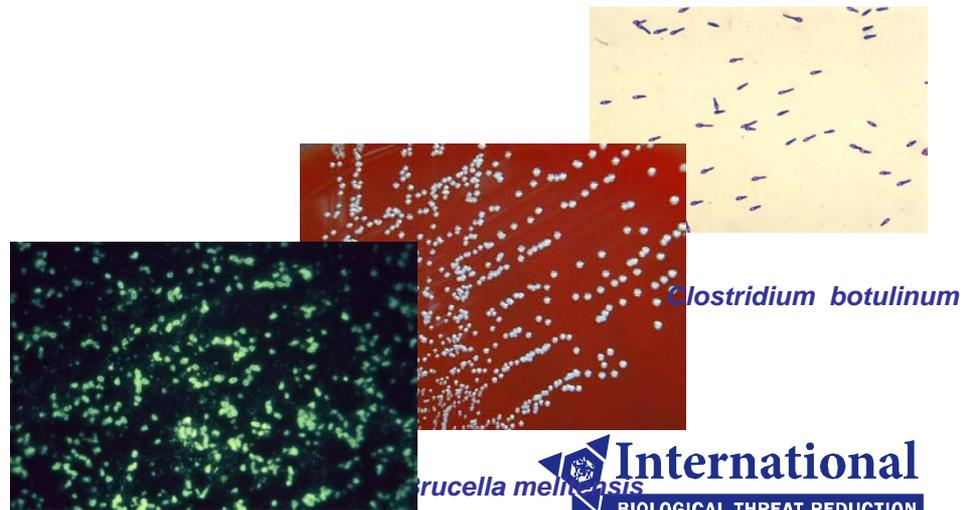


# Conclusions

- **Need to integrate biosafety and biosecurity considerations into decisions about laboratory operations**
- **Risk assessment is the fundamental resource allocation tool**
  - For making decisions about which risks need to be protected against
  - Graded protection
- **Biosecurity is a key part of laboratory operations**
- **Program management is an overarching component of both biosafety and biosecurity programs**
  - Should address every element of the biosafety and biosecurity program

**“Security precautions should become a routine part of laboratory work, just as have aseptic techniques and other safe microbiological practices.”**

**(WHO LBM 3rd edition)**



*Clostridium botulinum*

*Yersinia Pestis*

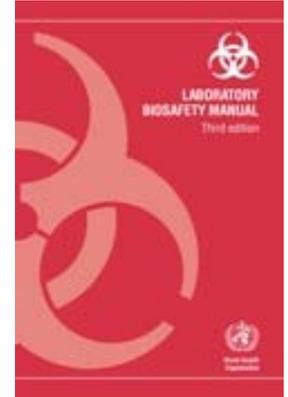
*Brucella melitensis*



# 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

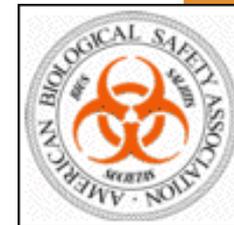


- **Transport of Infectious Substances**

- IATA guidance
- WHO guidance

- **On the Web**

- Biosecurity Engagement Program: [www.BEPstate.net](http://www.BEPstate.net)
- Brazilian Biosafety Association: [www.anbio.org.br](http://www.anbio.org.br)
- American Biological Safety Association: [www.absa.org](http://www.absa.org)
- Sandia National Laboratories: [www.biosecurity.sandia.gov](http://www.biosecurity.sandia.gov)
- European Biosafety Association: [www.ebsa.be](http://www.ebsa.be)
- Asia-Pacific Biosafety Association: [www.a-pba.org](http://www.a-pba.org)



Laboratory  
Biosecurity  
Handbook

Reynolds M. Salerno  
Jennifer Gaudioso

CRC Press  
Taylor & Francis Group





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