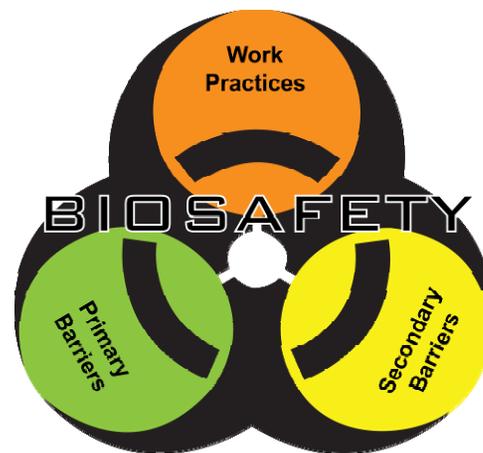
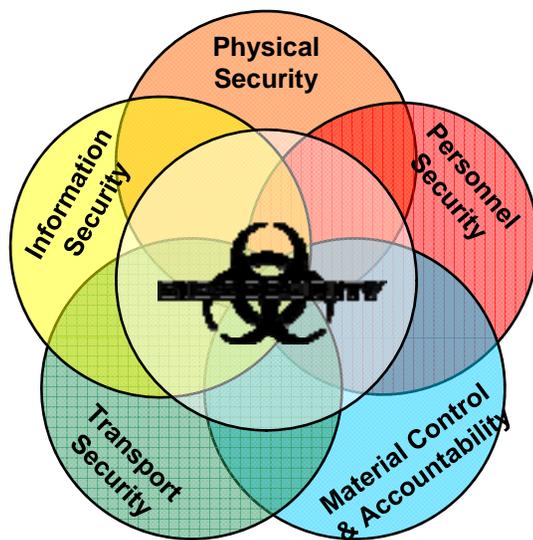




Biosecurity Concepts



African Biological Safety Association (AfBSA)

“WORKING SAFELY AND SECURELY WITHIN BSL-2 LABORATORIES”

Reynolds Salerno

International Biological Threat Reduction Program

Global Security Programs

Sandia National Laboratories

Albuquerque, NM USA

SAND No. 2008-0480P

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.



Strengthening Biological Risk Management

Vision for Integrated BioRisk Management:



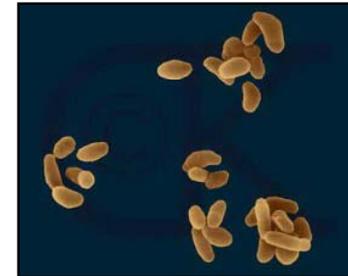
- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs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



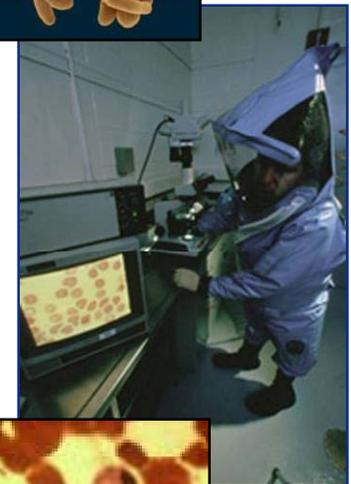


Laboratory Biosafety and Biosecurity

- **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**
 - Biosafety and biosafety should be integrated systems that avoid compromising necessary infectious disease research and diagnostics



Francisella tularensis



Yersinia pestis



Laboratory Biosecurity Supports Laboratory Biosafety

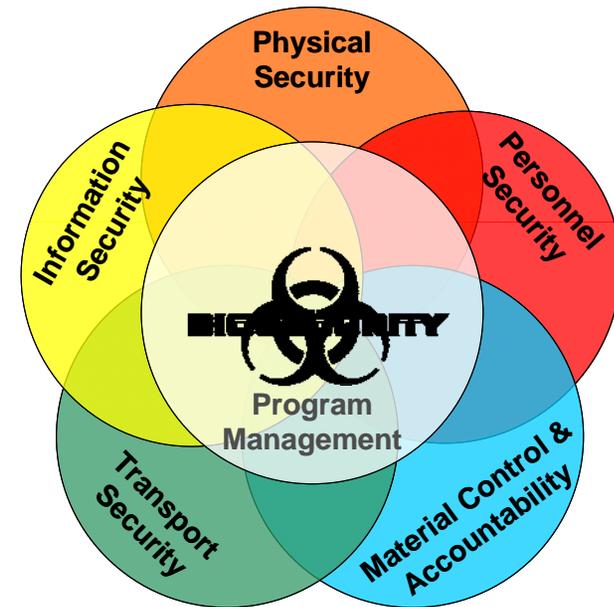
- **Laboratory biosecurity supports the laboratory biosafety agenda of preventing disease in people, animals, and plants and minimizing the risk of worker injury**
- **Safe and secure laboratories help**
 - Ensure the containment of hazardous infectious substances in laboratories
 - Maintain citizens' 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





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





Elements of a Physical Security System

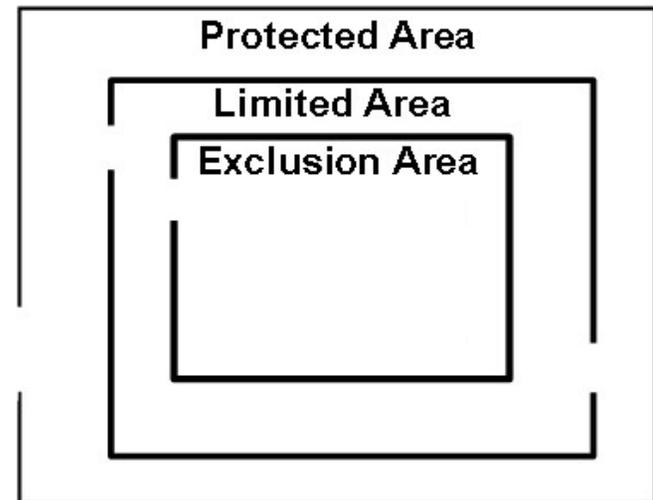
- Graded protection
- Access control
- Intrusion detection
- Response force





Physical Security: Concentric Layers of Security

- **Property Protection Areas**
 - Low risk assets
 - Grounds
 - Public access offices
 - Warehouses
- **Limited Areas**
 - Moderate risk assets
 - Laboratories
 - Sensitive or administration offices
 - Hallways surrounding Exclusion Areas
- **Exclusion Areas**
 - High risk assets
 - High containment laboratories
 - Computer network hubs





Physical Security

- **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





Elements of a Personnel Security Program

- **Personnel Screening**
- **Badges**
- **Visitor Control**
- **Training**





Personnel Security: Visitor Controls

- **Types**

- Personal Visitors
 - **Family members**
- Casual Visitors
 - **Tours, seminars**
 - **Equipment repair technicians**
- Working Visitors
 - **Visiting researchers**
 - **Facility maintenance personnel**

- **Controls**

- All visitors should have a host at the facility
- Visitors should be escorted in restricted areas





Personnel Security: Badges

- **Badges should be issued to those individuals authorized to be in restricted areas**
- **Badge return**
 - Upon employee termination
 - Daily or at the conclusion of a limited term for visitors
- **Report lost or stolen badges**





Personnel Security

- **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: Objective

- **Ensure the complete and timely knowledge of:**
 - What materials exist
 - Where the materials are
 - Who is accountable for them
- **NOT: to detect whether something is missing**





Material Control & Accountability: Key Issues

- **What materials are subject to MC&A measures**
- **The operating procedures associated with the materials**
 - where they can be stored and used
 - how they are identified
 - how inventory is maintained
- **What records need to be kept for those materials and the timeliness requirements for those records**
- **What does accountability means**
- **Documentation and reporting requirements**





Internal Transport Security

- **Movement of materials to and from restricted areas within a facility**
- **May involve personnel from**
 - Labs
 - Shipping areas
 - Receiving areas
 - Disposal areas (e.g. autoclave and incinerator rooms)
- **Move materials safely and securely**
 - SOPs
 - Leak-proof containers
 - Pre-approval?
 - Chain of custody?





External Transport Security: Facility Responsibilities

- **Personnel security**
 - For people who have access to dangerous pathogens and toxins or information during transfers
- **Establish chain of custody (CoC)**
 - Record all individuals who have contact with the dangerous pathogens and toxins
- **Provide physical security**
 - For packages that need temporary storage
- **Protect transport documentation**
- **Determine who is able to authorize, transport, and receive dangerous pathogens and toxins**





Information Security

- **Protect information that is too sensitive for public distribution**
 - Label information as restricted
 - Limit distribution
 - Restrict methods of communication
 - Implement network and desktop security
- **Biosecurity-related sensitive information**
 - Security of dangerous pathogens and toxins
 - **Risk assessments**
 - **Security system design**
 - Access authorizations





Program Management

- **Overarching component of laboratory biosecurity and biosafety programs**
- **Guides and provides oversight to both biosecurity and biosafety**
 - Defines program objectives
 - Ensures program has appropriate resources (financial and staffing)
 - Addresses sustainability of program
 - Training program
- **Delineated in a written plan or manual**
 - Comprehensive guidance
 - **Implementation**
 - **Outlines roles and responsibilities**
 - **Outlines security measures**
 - **Policies and procedures**
 - Incident Response Plan
- **Manuals specific for each institution**
 - Should be based on laboratory-specific risk assessment
 - Standard operating procedures (SOPs)





Goals: Biorisk Management

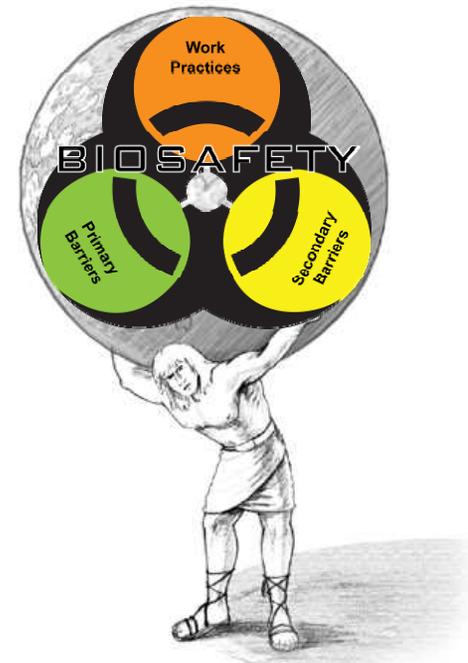
- **Effective laboratory biosafety and laboratory biosecurity working together:**
 - Reduce the risk of injury, infection and death of employees and the public
 - Reduce the risk of environmental contamination
 - Reduce the risk of theft or intentional misuse of biological agents
 - May promote conformation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





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



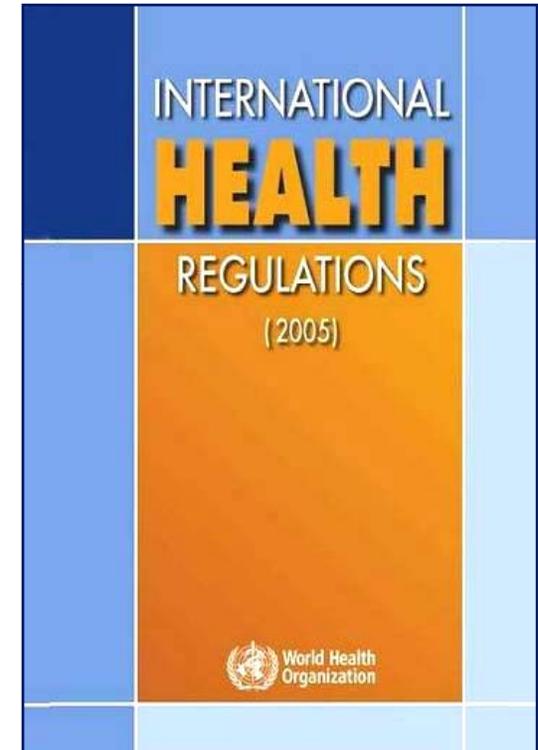
Laboratory Biosecurity





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**



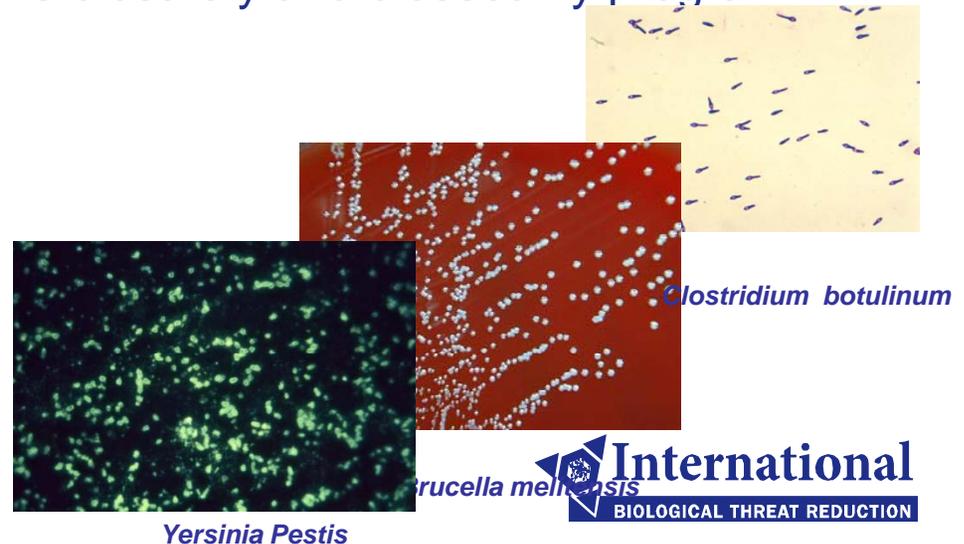


Conclusions

- **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)

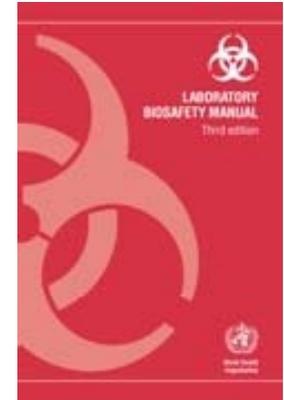




Resources

- **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

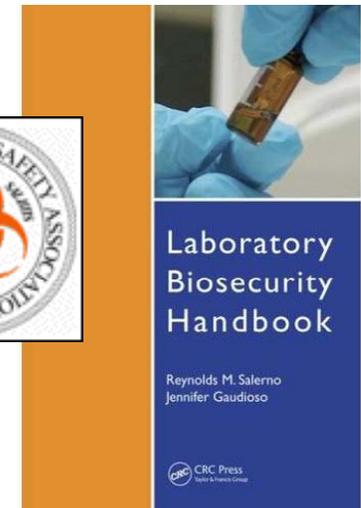
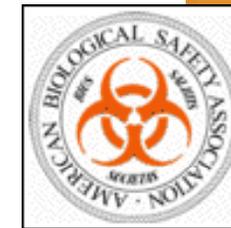


- **Transport of Infectious Substances**

- IATA guidance
- WHO guidance

- **On the Web**

- Biosecurity Engagement Program: www.BEPstate.net
- Brazilian Biosafety Association: www.anbio.org.br
- 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





Obrigada!

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