Principles of Managing Biological Risks: Laboratory Biosafety and Laboratory Biosecurity

Sandia National Laboratories

Laboratory Biosecurity and Biosafety Workshop

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www.biosecurity.sandia.gov

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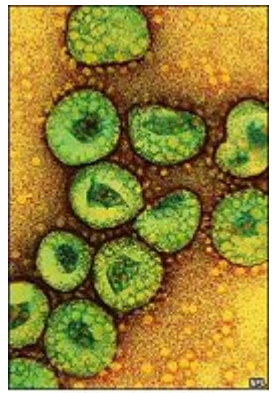
The Infectious Disease Threat

- **Recent outbreaks of emerging infectious disease awakened the international community to threats to public and agricultural health**
- **Most threat mitigation strategies have focused on outbreak management**
- **Measures must also be developed to *prevent* outbreaks of highly infectious disease**
- **Laboratory biosafety and biosecurity are two such methodologies that can help prevent infectious disease outbreaks**
  - ***Biosafety***
    - **Protect laboratory personnel and the environment from <u>accidental</u> exposure to or release of potentially hazardous agents**
  - ***Biosecurity***
    - **Protect biological agents against theft by those who intend to cause <u>deliberate</u> exposure through malicious use**



SARS virus

Today, the infectious disease threat is a global problem that requires global solutions

Severe Acute Respiratory Syndrome (SARS)

- In 2003, SARS infected over 8,000 people and killed almost 800
- The disease ravaged economies in the Pacific Rim and Canada and struck fear across the globe
- Laboratory acquired SARS outbreaks occurred in Singapore, Taiwan, and mainland China
  - Singapore—September 2003
  - Taiwan (China)—December 2003
  - Beijing and Anhui (China)—March 2004

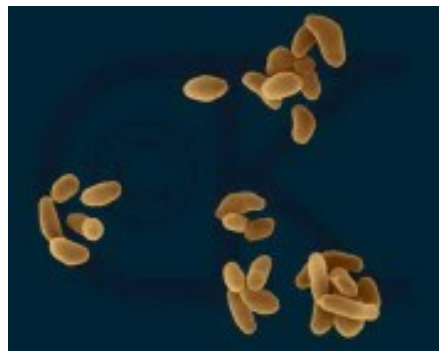
Laboratory-Acquired Case of SARS

- ***Singapore – September 2003***
  - A graduate student acquired SARS in a BSL-3 laboratory in the Environmental Health Institute
  - Inappropriate laboratory procedures and a cross-contamination of West Nile virus samples with SARS-CoV in the laboratory led to the infection
    - No secondary transmission
- ***Taiwan (China), December 2003***
  - Scientist was working on SARS-CoV in a BSL-4 facility at the Institute of Preventative Medicine, National Defence Center (IPM-NDMC)
  - Disinfected spillage of material in the transportation chamber with 70% ethanol and manual cleaning
  - SARS-CoV was collected from the handle of an alcohol spray bottle from the transportation chamber and the switch panel of the cabinet
    - No secondary transmission
- ***China, March-April 2004***
  - Beijing and Anhui Province linked to the National Institute of Virology, China CDC
  - The source of the outbreak was incomplete inactivation of SARS-CoV by cold inactivation
  - Involved two verified chains of SARS-CoV transmission
    - Three generations, resulting in 9 cases
    - Three additional cases documented by seroconversion

Laboratory-Acquired Cases of Ebola and Tularemia

- **Ebola**
  - **1994 Outbreak in Cote d'Ivoire**
  - **Swiss zoologist performs autopsy on wild chimpanzee**
  - **Accidental infection occurs; zoologist contracts Ebola**

- **Tularemia**
  - **In 2004, three laboratory workers at Boston University contracted tularemia**
  - **Concern that lax illness reporting practices could lead to outbreaks of infectious disease among the local community**



Examples of Illicit Acquisition

- Rajneeshees acquired *Salmonella typhimurium* from a medical supply company (1984)
- Larry Wayne Harris, a white-supremacist, ordered 3 vials of *Yersinia pestis* from the ATTC (1995)
- J.A. Krantz stole *Ascaris suum* eggs and used against roommates (1970)
- Laboratory technician Diane Thompson removed *Shigella dysenteriae* Type 2 from hospital's collection and infected co-workers (1995)
- Weathermen group attempted to get an employee at Ft. Detrick to obtain pathogens (1970)
- Dr. Suzuki stole *Salmonella typhi* cultures from the Japanese National Institute of Health (1964)

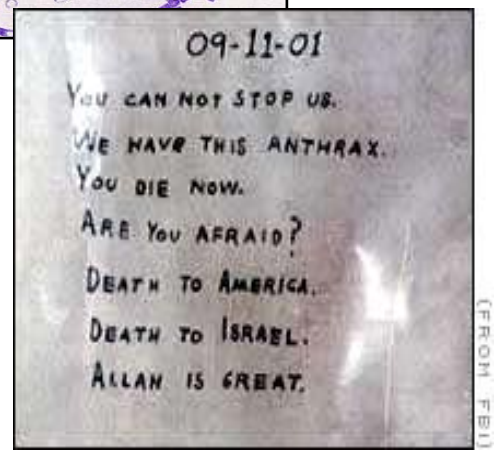
Bhagwan Shree Rajneesh

Larry Wayne Harris

The Anthrax Attacks of 2001

- **In 2001 *Bacillus anthracis* spores were maliciously released through the United States postal system in 2001**
  - **5 deaths and 22 additional illnesses resulted**
- **The attack has increased U.S. awareness of the biological weapons and bioterrorist threat**
  - **As result, the U.S. has imposed new rules that are designed to improve the security and agent accountability of legitimate bioscience research laboratories**
- **Suspicion that the material was obtained from a bioscience laboratory**

Bacillus anthracis



Strengthening Biological Risk Management

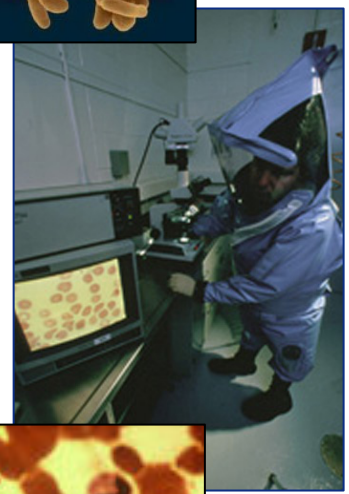
Vision for Integrated BioRisk Management:

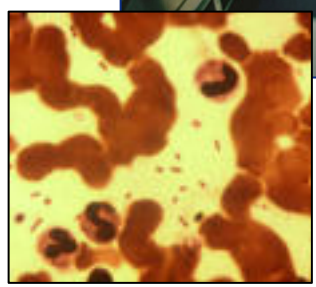
- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs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

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

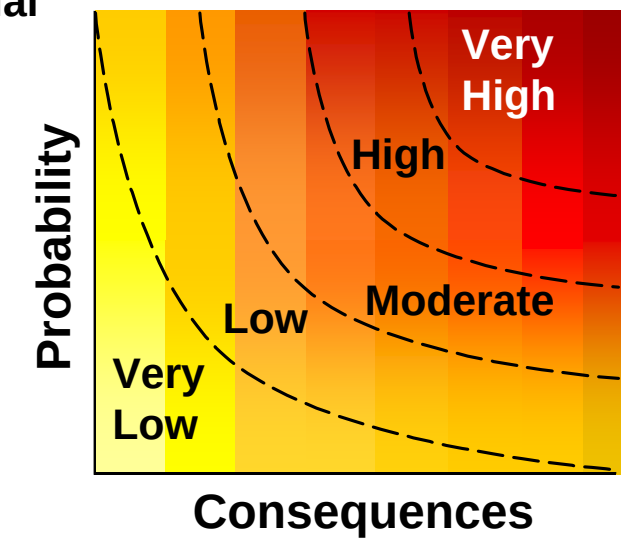




Yersinia pestis

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

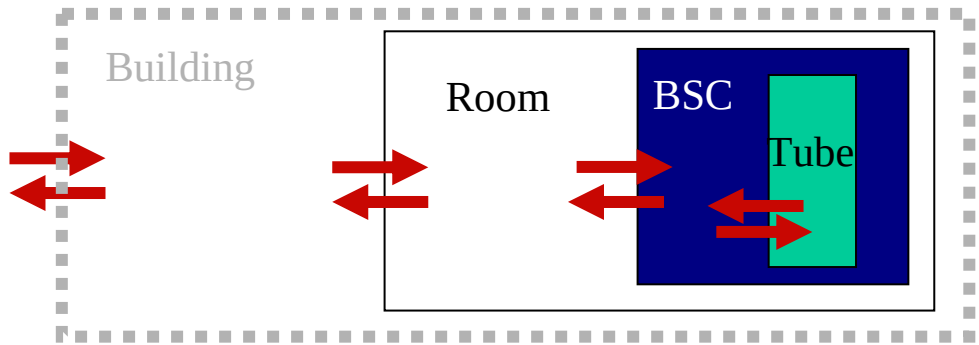
- Develop incident response plans for acceptable risk scenarios

Components of Laboratory Biosafety

Biosafety: Engineering Controls

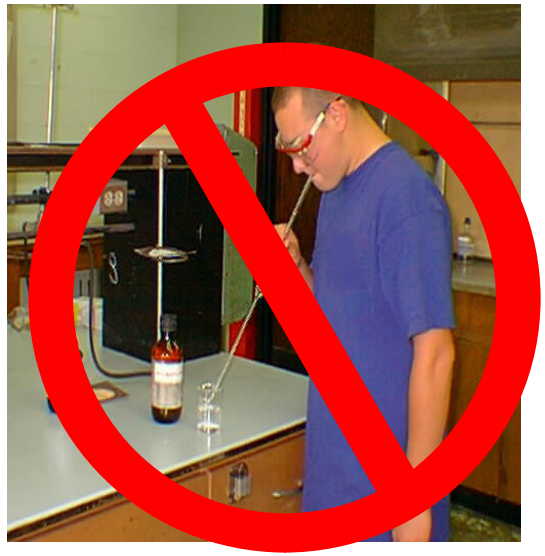
- Primary barriers – contain the agent at the source
  - **Biological safety cabinet**
  - **Animal caging**
  - **Specialized lab equipment (centrifuges, fermenters, etc.)**

- 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**



Biosafety: Work Practices

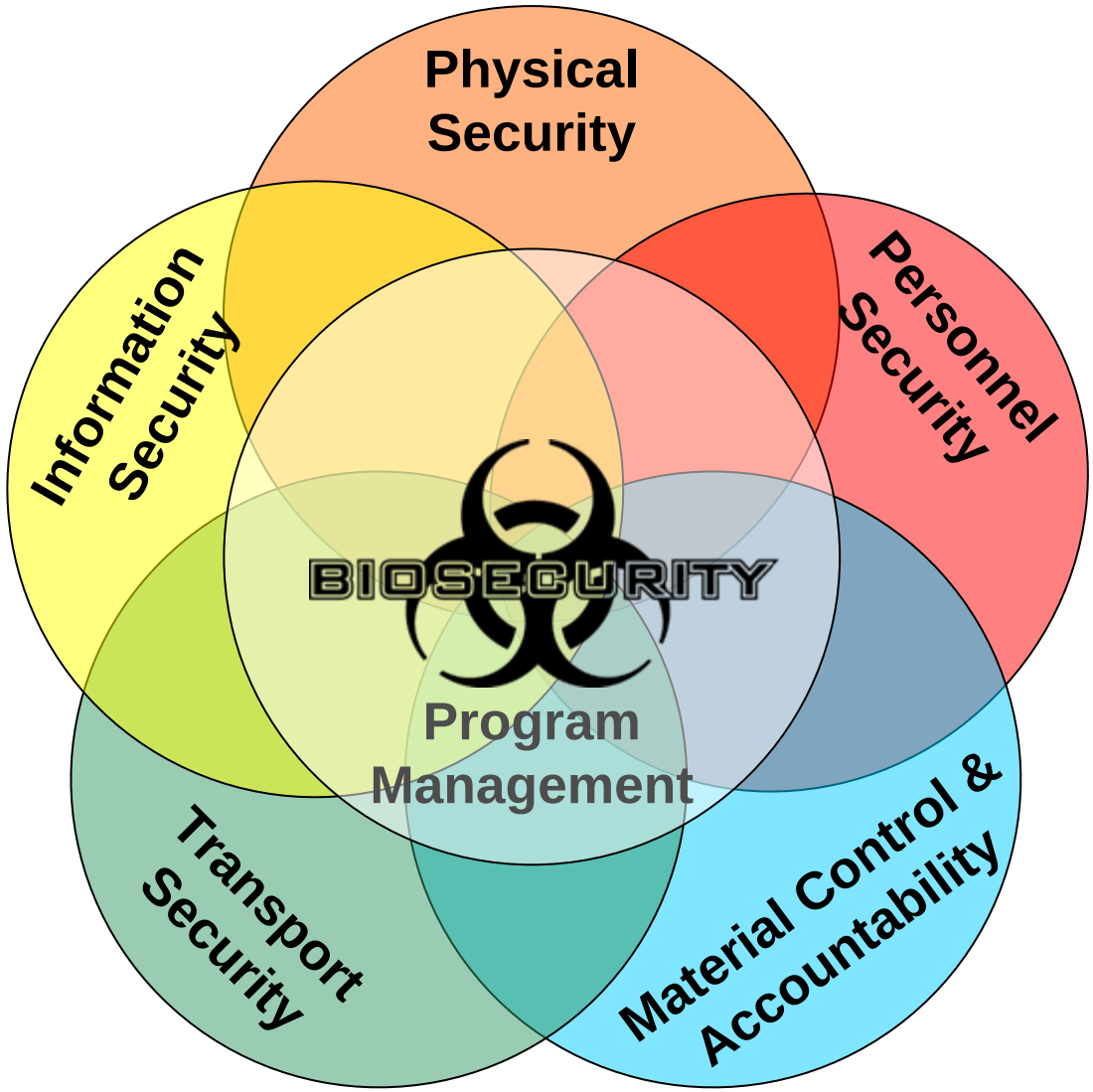
- Good microbiological technique
- Wash hands often
- No mouth pipetting
- No eating or drinking in lab
- Minimize aerosol generation
- Careful pipetting technique
- Decontaminate work surfaces
- Safe sharps handling
- Training
- Written procedures



Biosafety: Personal Protective Equipment

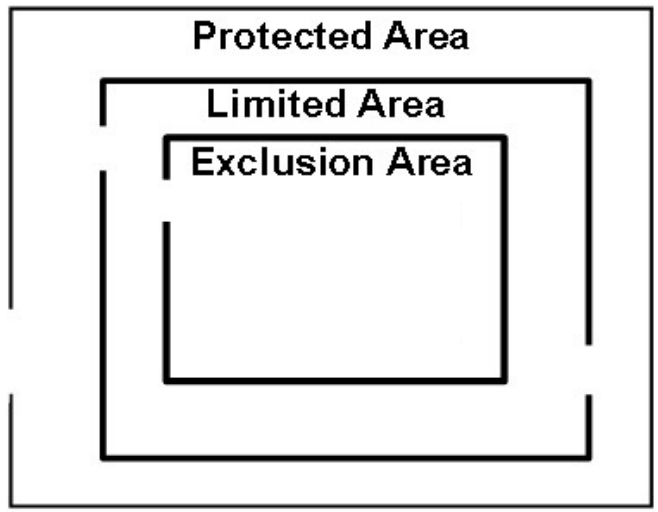
- Types of PPE
  - Gloves
  - Appropriate footwear
  - Lab coats
  - Eye and face protection
  - Respirator
- Purpose
  - Provides a barrier against skin, mucous membrane or respiratory exposure to infectious agents
  - To prevent spread of contamination
- Limitations
  - Does not eliminate the hazard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

Components of Biosecurity



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



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**

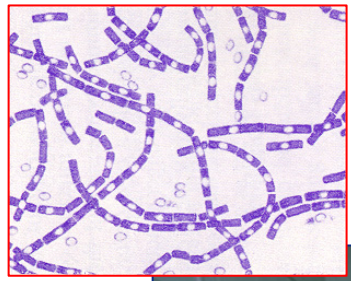
Laboratory Biosecurity Supports Laboratory Biosafety

- Laboratory biosecurity supports the laboratory biosafety agenda of preventing disease in people, animals, and plants and minimizing the risk of worker injury

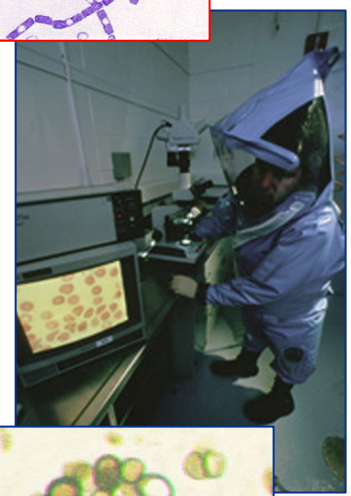
- Safe and secure laboratories help
  - Ensure the containment of hazardous infectious substances in laboratories
  - Maintain citizens' confidence in the activities of the bioscience research community
  - Increase transparency to investors in the biomedical and biotechnology industries
  - Protect valuable research and commercial assets
  - Reduce the risks of crime and bioterrorism

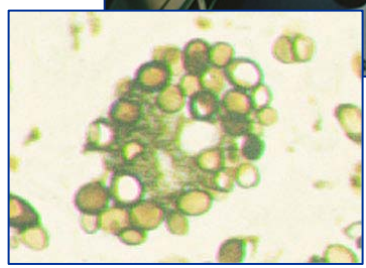
Conclusions

- **Infectious disease threaten the international community**
  - **"Pathogens need no visas"**
- **The international community must strengthen its ability to *respond* to outbreaks of infectious disease wherever and however they occur**
- **The international community must also strengthen its ability to *prevent* outbreaks of infectious disease**
- **Laboratory biosafety and biosecurity are critical *prevention* measures for mitigating the risk of infectious agents escaping from the facilities where they are stored, used, and transported**



Bacillus anthracis





Coccidioides immitis