



Biosafety and Biosecurity in the Laboratory

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Strengthening Biological Risk Management

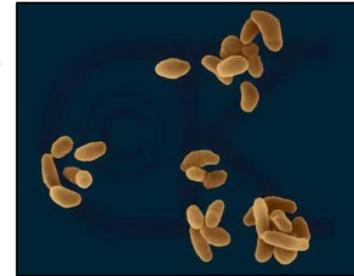


Vision for Integrated BioRisk Management:

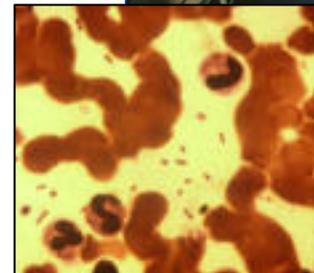
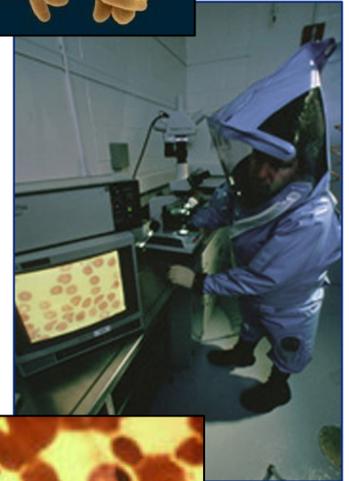
- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs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

Laboratory Biosafety and Biosecurity

- **Laboratory biosafety**
 - Objective: reduce or eliminate accidental exposure to or release of potentially hazardous agents
- **Laboratory biosecurity**
 - Objective: protect biological agents against theft by those who intend to cause harm
- **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**
 - Laboratory biosecurity and biosafety should be integrated systems that avoid compromising necessary infectious disease research and diagnostics



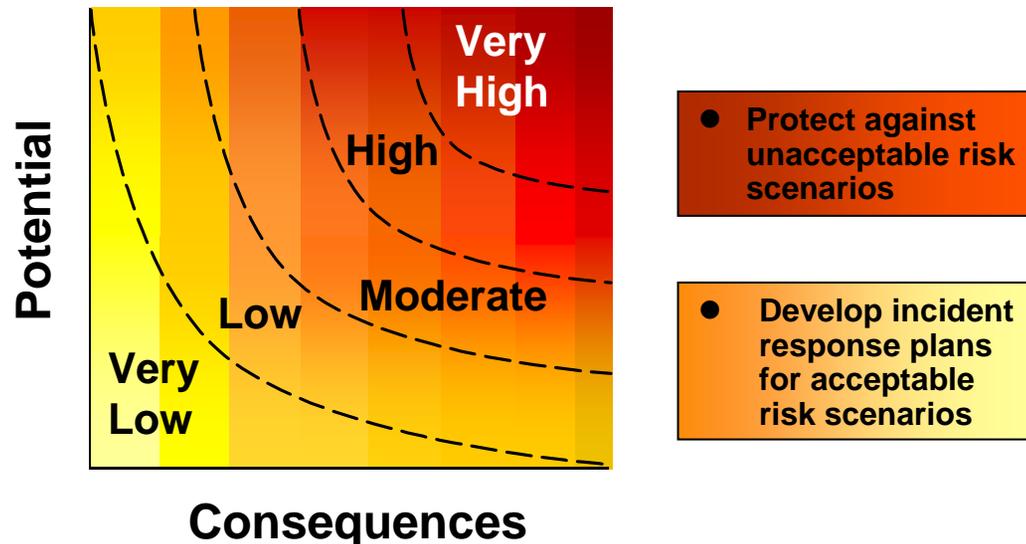
Francisella tularensis

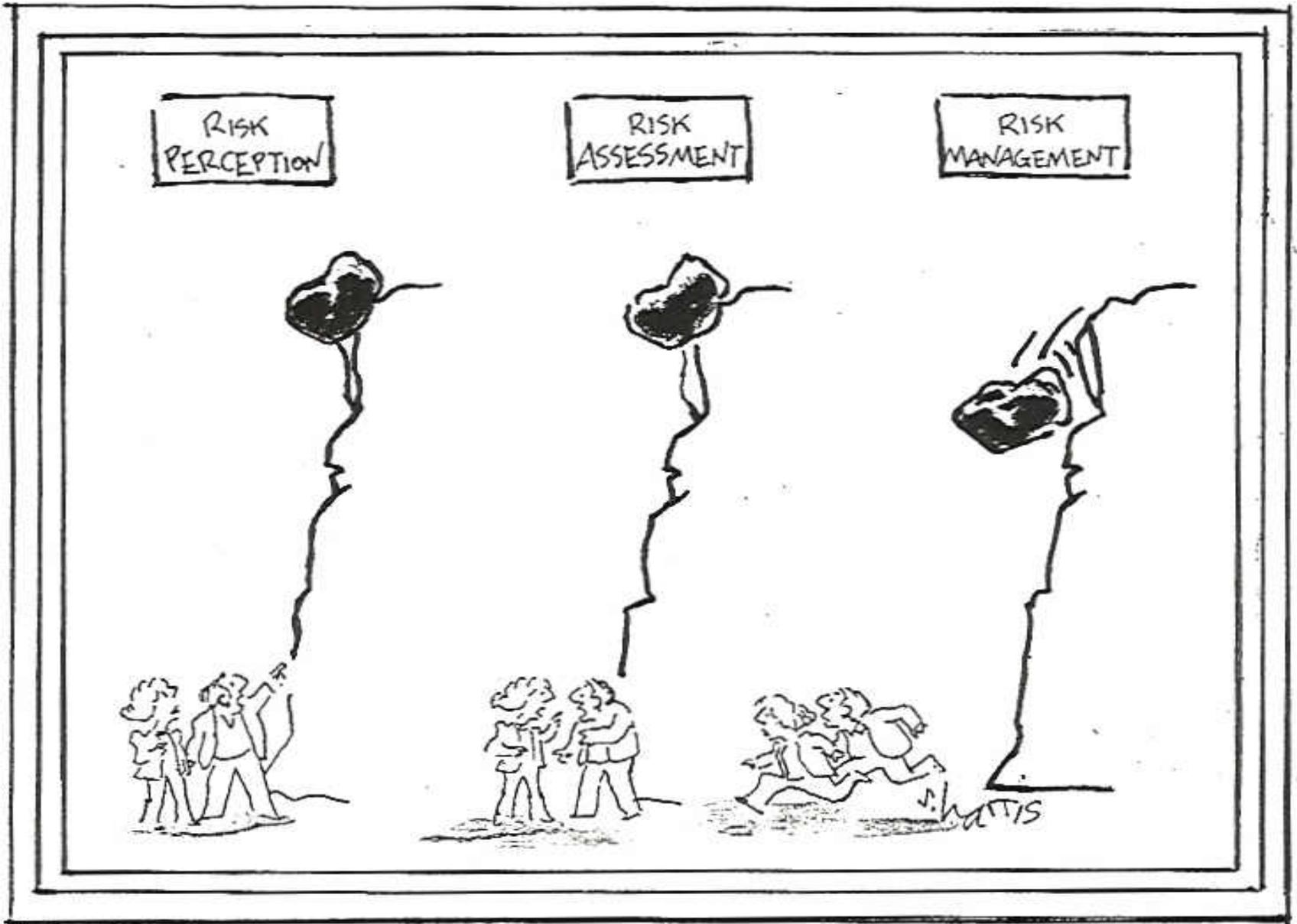


Yersinia pestis

Biosecurity and Biosafety Based on Risk Management

- Laboratory work with pathogens will always involve some level of safety and security risk
- Most biological materials occur in nature and can be isolated from nature
- Critical not to compromise legitimate bioscience operations
 - Systems should be designed to address unique situations
- Resources are not infinite; existing resources should be used efficiently
- Management must distinguish between “acceptable” and “unacceptable” risks
 - Ensure that protection and the cost is proportional to the risk





Risk Perception in Laboratories

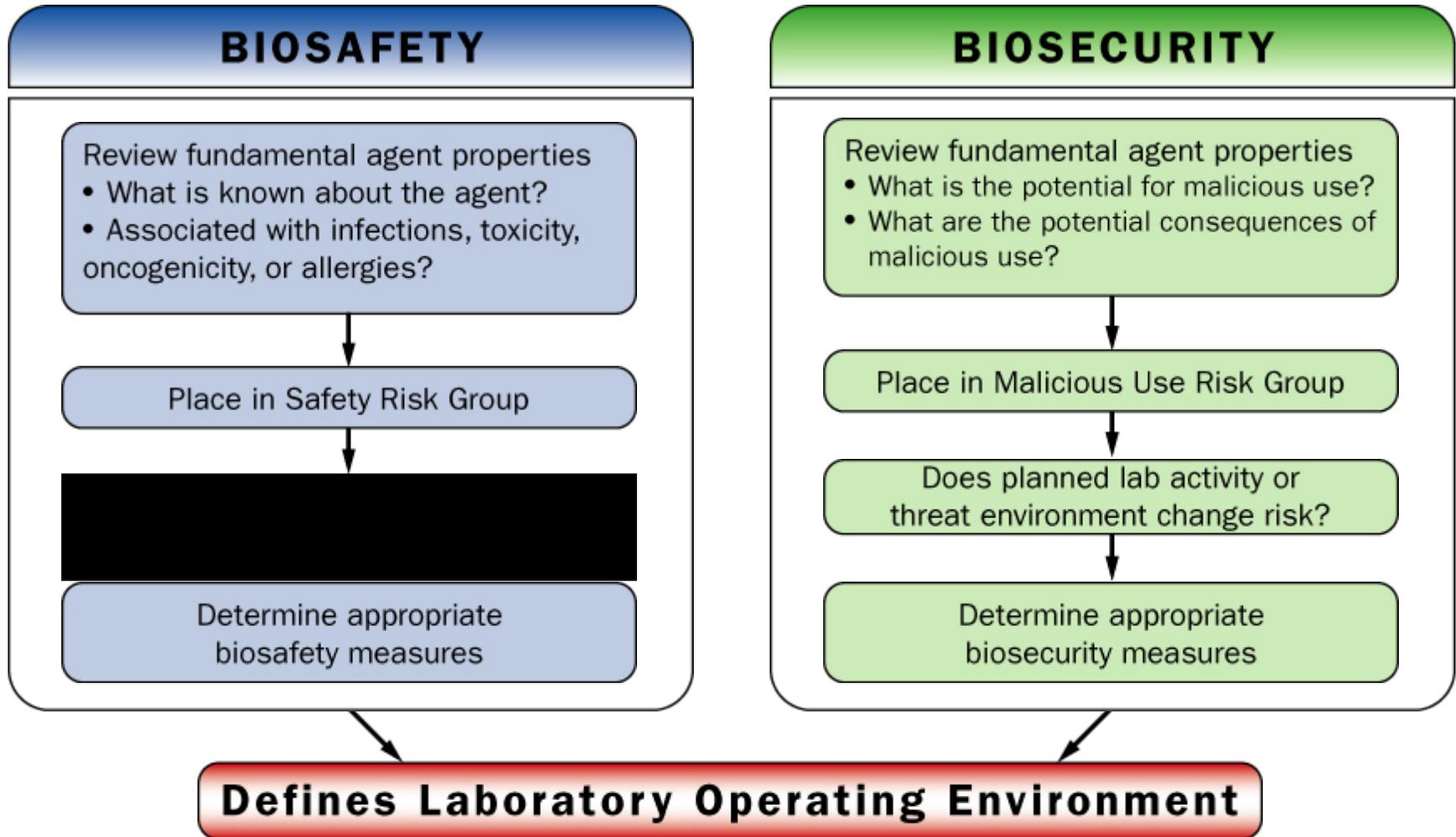
Biosafety risks: laboratory-acquired infections

- 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)

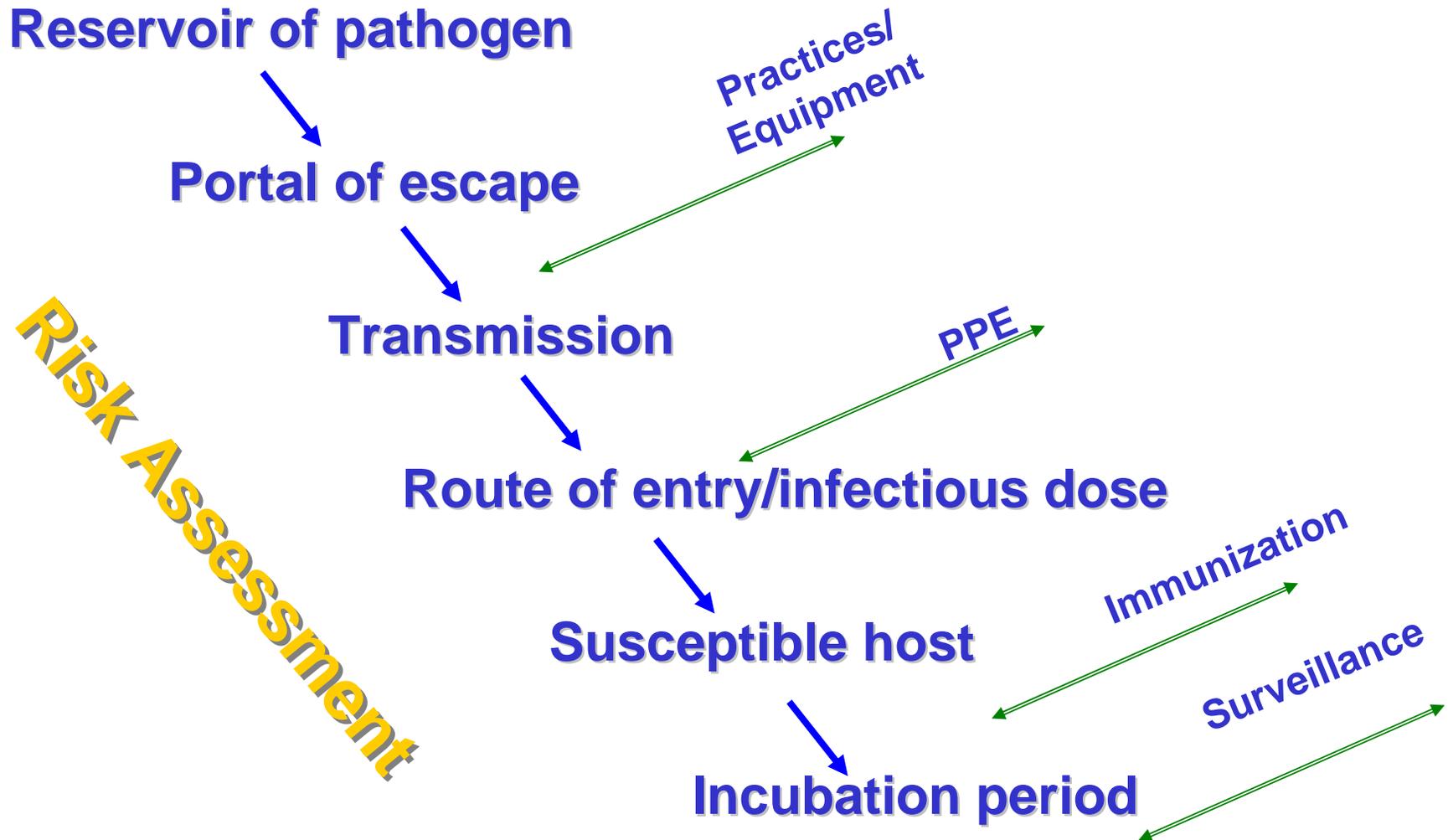
Biosecurity risks: laboratories as sources of material for malicious use

- 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

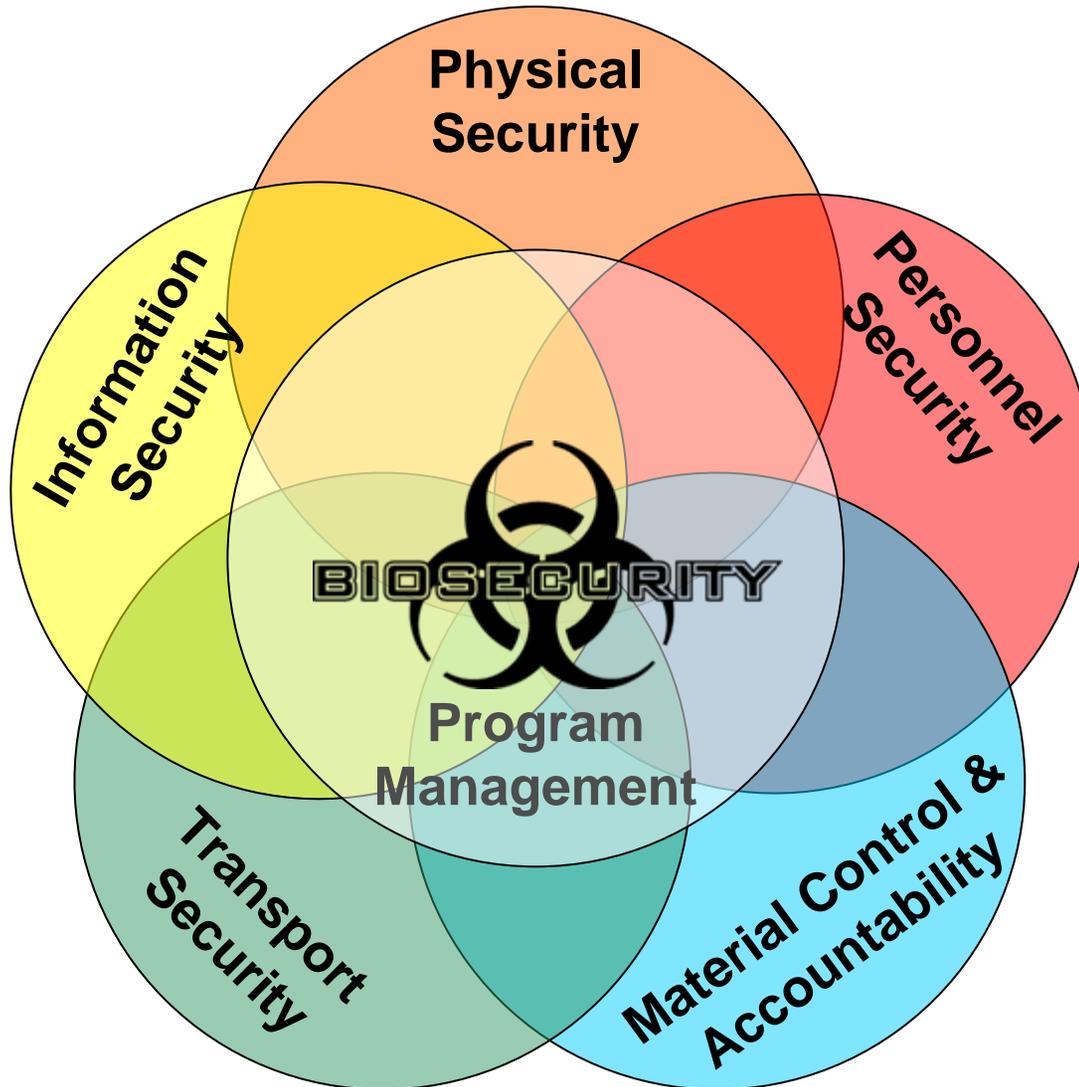
Risk Assessment: Integrated Biosafety and Biosecurity



Risk Management: Implementation of Biosafety



Risk Management: Implementation of Biosecurity



Similar Physical Aspects of Biosafety and Biosecurity

Biosafety

- **Physical protection**
 - **Increasing levels of physical containment to prevent the accidental release of dangerous biological agents**
 - BSL-1
 - BSL-2
 - BSL-3
 - BSL-4
 - **Examples: negative air pressure, cabinets and hoods**

Biosecurity

- **Physical protection**
 - **Graded protection designed to secure dangerous biological agents from adversaries**
 - **Property Protection Area**
 - **Limited Area**
 - **Exclusion Area**
 - **Examples: access controls, delay, intrusion detection**

Similar Procedural Aspects of Biosafety and Biosecurity

Biosafety

- **Material control and accountability**
 - Handling procedures to prevent accidental infection
 - Use of personal protective equipment

- **Personnel reliability**
 - Background checks to ensure proper credentials to handle dangerous organisms
 - Policies to prevent untrained individuals from working with materials that pose a biosafety risk

Biosecurity

- **Material control and accountability**
 - Basic inventory procedures to limit opportunities for illicit acquisition
 - Designation of laboratory workers responsible for specific material

- **Personnel reliability**
 - Background checks to ensure personnel are reliable and trustworthy
 - Procedures to remove unauthorized personnel from secure areas

Similar Procedural Aspects of Biosafety and Biosecurity, cont.

Biosafety

- **Transport**
 - Requirements to ensure the safe transport of materials within a lab
 - Federal and international regulations governing the transport of infectious substances outside the lab

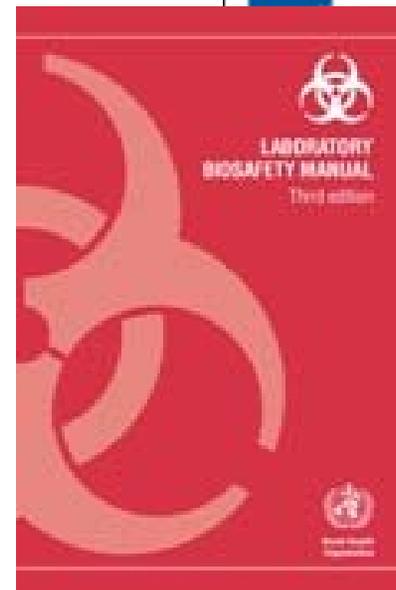
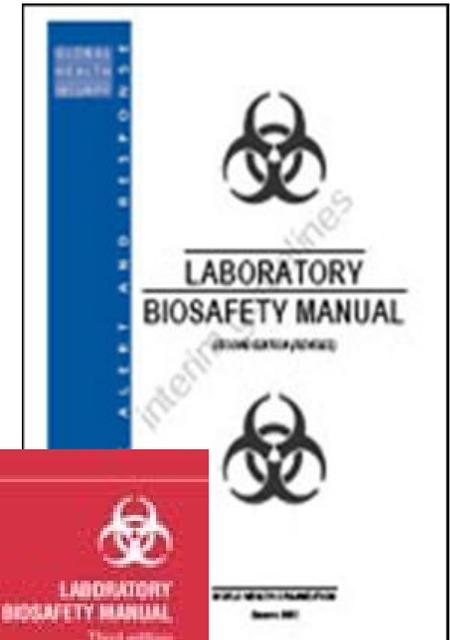
Biosecurity

- **Transport**
 - Best practices to ensure the secure transport of materials both inter-facility and intra-facility
 - Chain of custody where appropriate

Biosafety and Biosecurity share a variety of components

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**



Potential Conflicts between Biosafety and Biosecurity

- **Emergency alarm – electronic locks**
 - Safety – doors fail open
 - Security – doors fail secure
- **Emergency egress**
 - Safety – move people into the safest location as quickly as possible
 - Security – prevent people from moving into or through restricted areas
- **Emergency response**
 - Safety – provide emergency responders with locations of hazards and responsible individuals
 - Security – control distribution of sensitive information only to those with a need to know
- **Signage**
 - Safety – identify hazardous substances and responsible parties
 - Security – avoid identification of target materials or individuals with access
- **Keys required inside laboratory areas**
 - Safety – contamination concern
 - Security – multiple layers of access



Conclusions

- **Biological facility risk assessment provides an opportunity to concentrate resources on the highest risks**
 - **Tiered system of protection based on risk assessment and risk management methodologies**
- **Parallels exist between safety and security risk assessment processes and implementation methodologies**
- **Need to integrate biosafety and biosecurity considerations into decisions about laboratory operations**

Additional Information

- Next edition of CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* will include extensive recommendations on biosecurity
- WHO/FAO/OIE developing joint international biosecurity guidelines
- Organisation for Economic Co-operation and Development (OECD) is establishing biosecurity guidelines
- Laboratory Biosecurity Handbook – CRC Press, forthcoming
- www.biosecurity.sandia.gov

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