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PREVENTION: BIOSAFETY AND BIOSECURITY



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Laboratory Biosafety and Biosecurity

■ Biosafety

- A set of preventive measures designed to reduce the risk of accidental exposure to or release of a biological hazard
- Goal: reduce risk of accidental exposure to or release of potentially hazardous agents

■ Biosecurity

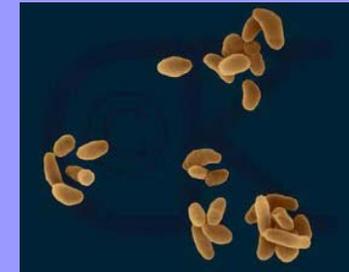
- A set of preventive measures designed to reduce the risk of theft of a biological material
- Goal: protect biological agents against theft and malicious use

■ Common strategy

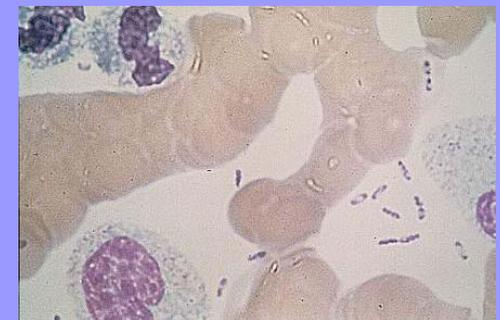
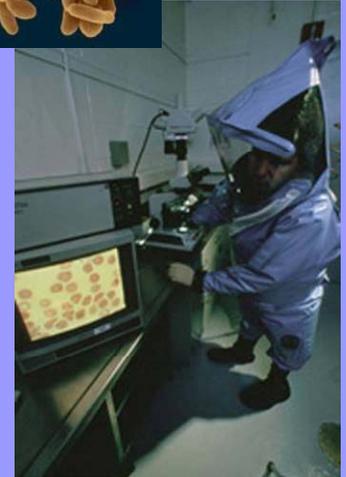
- Implement graded levels of protection based on a risk assessment

■ Methods of implementation 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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Risk

- Is a function of the likelihood an adverse event will occur
- Laboratory work with pathogens will always involve some level of safety and security risk
 - Distinguish between “acceptable” and “unacceptable” risks
 - Cannot protect against every conceivable accident or adverse event
- Resources for risk mitigation are not infinite
 - Existing resources should be used efficiently



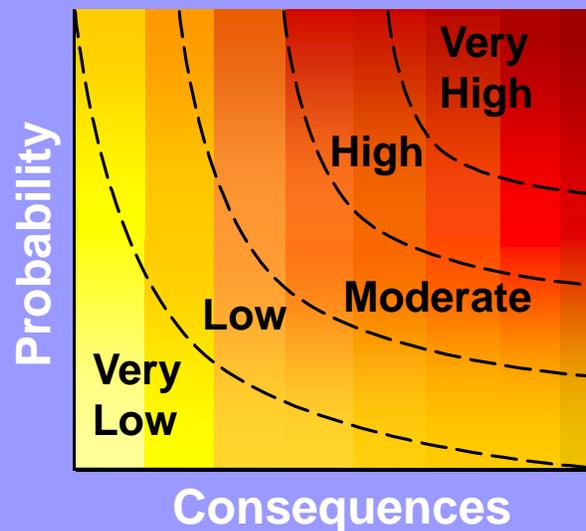
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Laboratory Biosafety and Biosecurity Based on Risk Assessment

- Safety and security in a biological environment will never be perfect
- Most biological agents can be 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/exp 2009 theft and misuse of that material

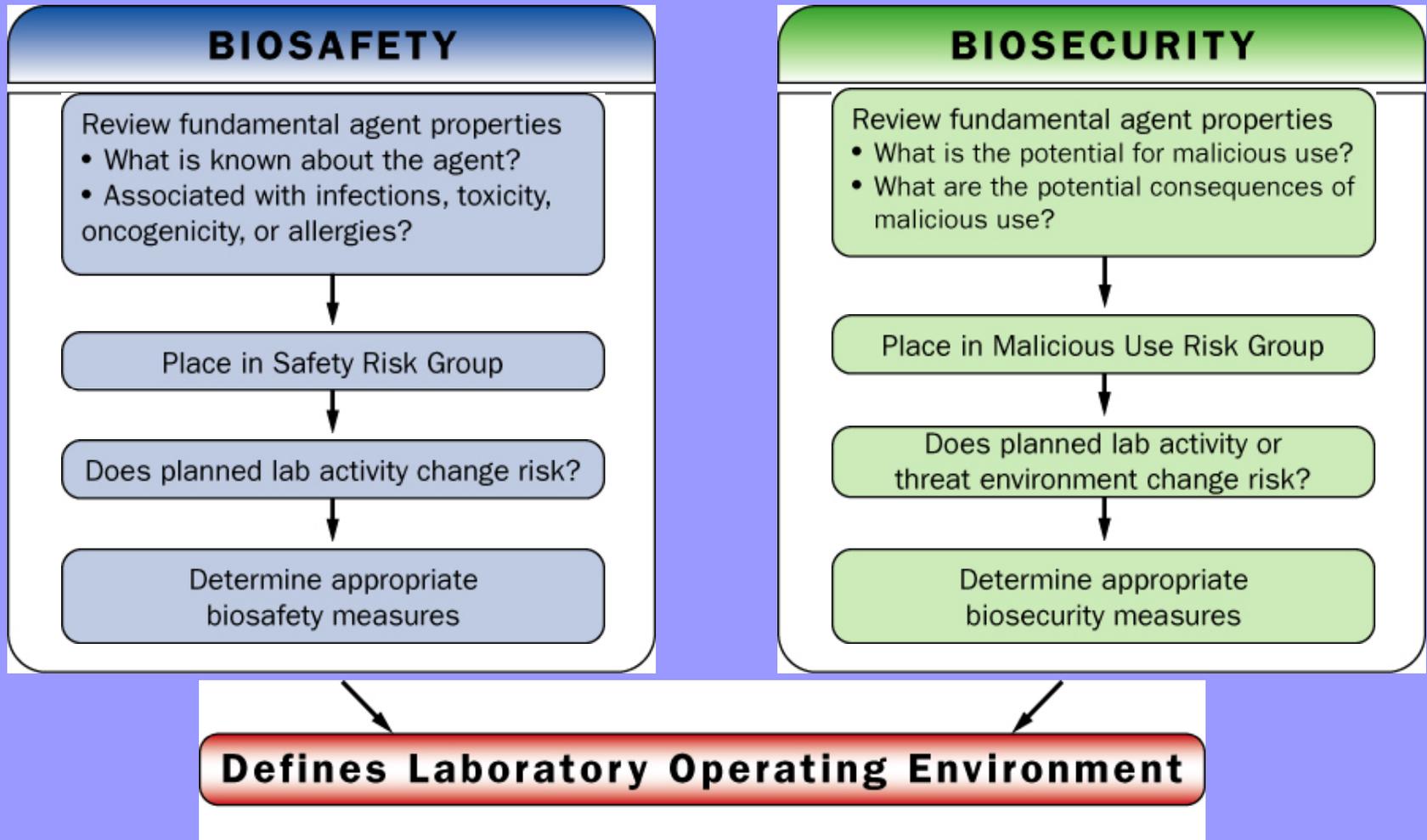


- Protect against unacceptable risk scenarios

- Develop incident response plans for acceptable risk scenarios



Risk Assessment: Integrated Biosafety and Biosecurity





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Biosafety Risk Assessment

- Assess the biological material
 - Contagious
 - Routes of exposure
 - Host range
 - Affects multiple species
 - Type of material
 - Environmental or diagnostic specimen
 - Pure culture
- Assess what is being done with the material in the laboratory
 - Diagnostics
 - Procedures that may generate an aerosol
- Consider personal protection
 - Respirators
 - Gloves
- Law Enforcement should understand similar concepts when handling potentially contaminated crime scenes
 - Contaminated evidence
 - Collection procedures that generate aerosols
 - Personnel protective equipment





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Biosafety: Personal Protective Equipment (PPE)

- **Purpose**
 - Provides a barrier to prevent exposure to infectious agents
- **Types**
 - Gloves
 - Footwear
 - Lab coats
 - Eye and face protection
 - Respirator
- **Limitations**
 - Does not eliminate the hazard
 - Integrity decreases with use
 - Not all protective equipment is created equal
 - Select the right equipment for the task at hand





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Biosecurity Risk Assessment

- Evaluate assets
 - Biological agents
 - Information
- Evaluate lab activity
 - Increasing environmental stability
- Evaluate threat environment
 - Criminal activity
 - Extremist activity
 - Terrorist activity



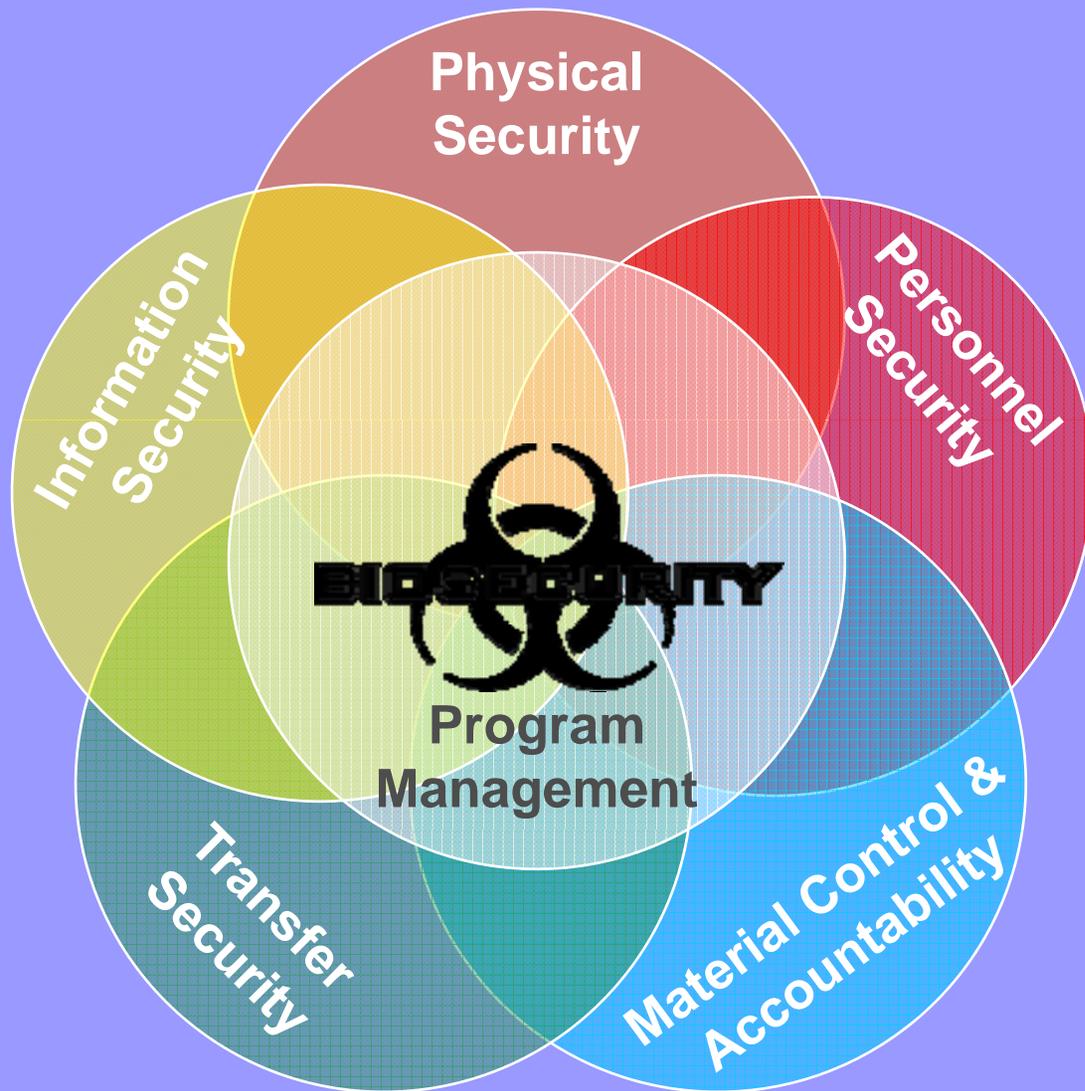


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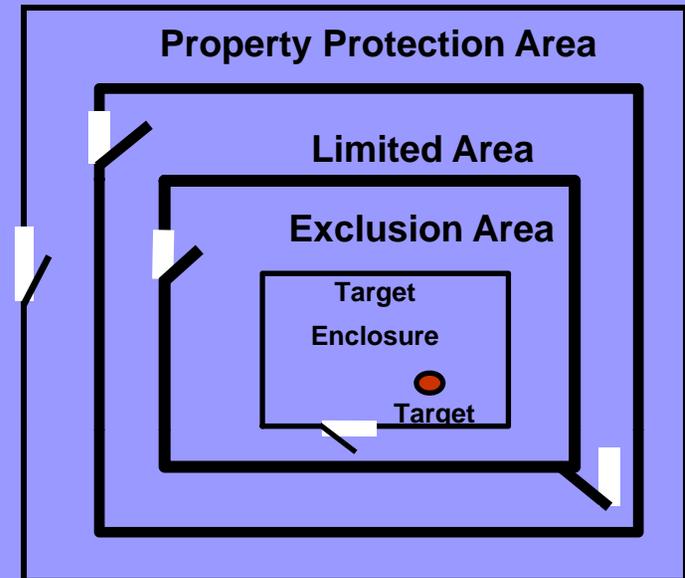
Components of Biosecurity





Physical Security

- Physical Structure
 - Property Protection Areas
 - Low risk assets
 - Limited Areas
 - Medium risk assets
 - Offices containing sensitive information
 - Hallways surrounding Exclusion Areas
 - Exclusion Areas
 - High or Extreme Risk assets
 - Computer network hubs
 - Electronic security system hubs
- Access Control
 - Only authorized individuals are allowed access
 - Implement stricter controls as you approach highest risk assets





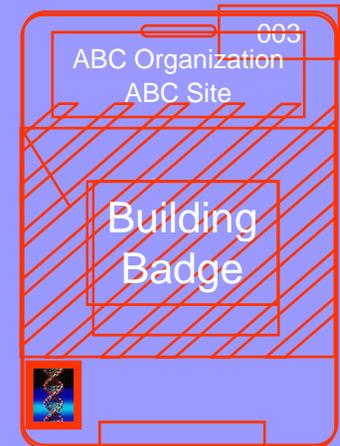
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Personnel Security

- Personnel Screening
 - Pre-employment
 - Review and verify personal information
 - Work ethic
 - Comprehensive background investigations
 - Criminal history
- Badges
 - Access can be limited to specific areas
- Visitor Control
 - Equipment repair/maintenance personnel
 - Employee families
- Training





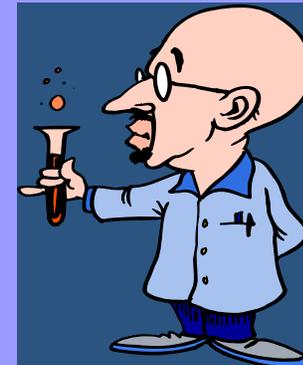
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Material Control and Accountability

- Maintain control of biological material
 - During experimentation
 - During shipment
- Documentation
 - Biological agent name and description
 - Quantity
 - Based on containers NOT the number of organisms
 - Location of use and storage
- Control:
 - Physical
 - Lock and key
 - Administrative
 - Personnel, information, and transfer security
 - Recordkeeping
 - Tracking during shipment





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Information Security

- Protect information that is too sensitive for public distribution
 - Label information as appropriate
 - Limit distribution to individuals with the "need to know"
 - Restrict methods of communication
 - Implement network and computer security
- Types of sensitive information:
 - Biological agent information
 - Experimental procedures and data
 - Security access information
 - Security system design
 - Personnel records





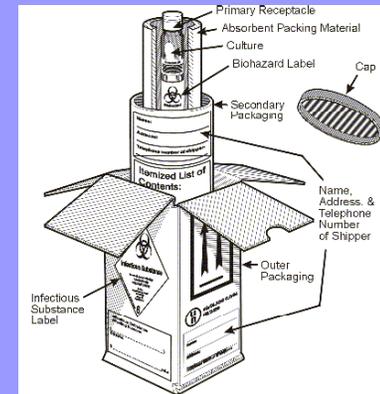
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Transportation Security

- Control of biological material during transportation
 - Within a facility
 - Between facilities
 - Domestically
 - Internationally
- Packaging is important
 - International shipments of certain materials require specific packaging
- Independent carriers may be involved
 - Reputable carriers should be used
- Verify receipt of shipment
- International shipments of infectious materials (dangerous goods) must follow international regulations



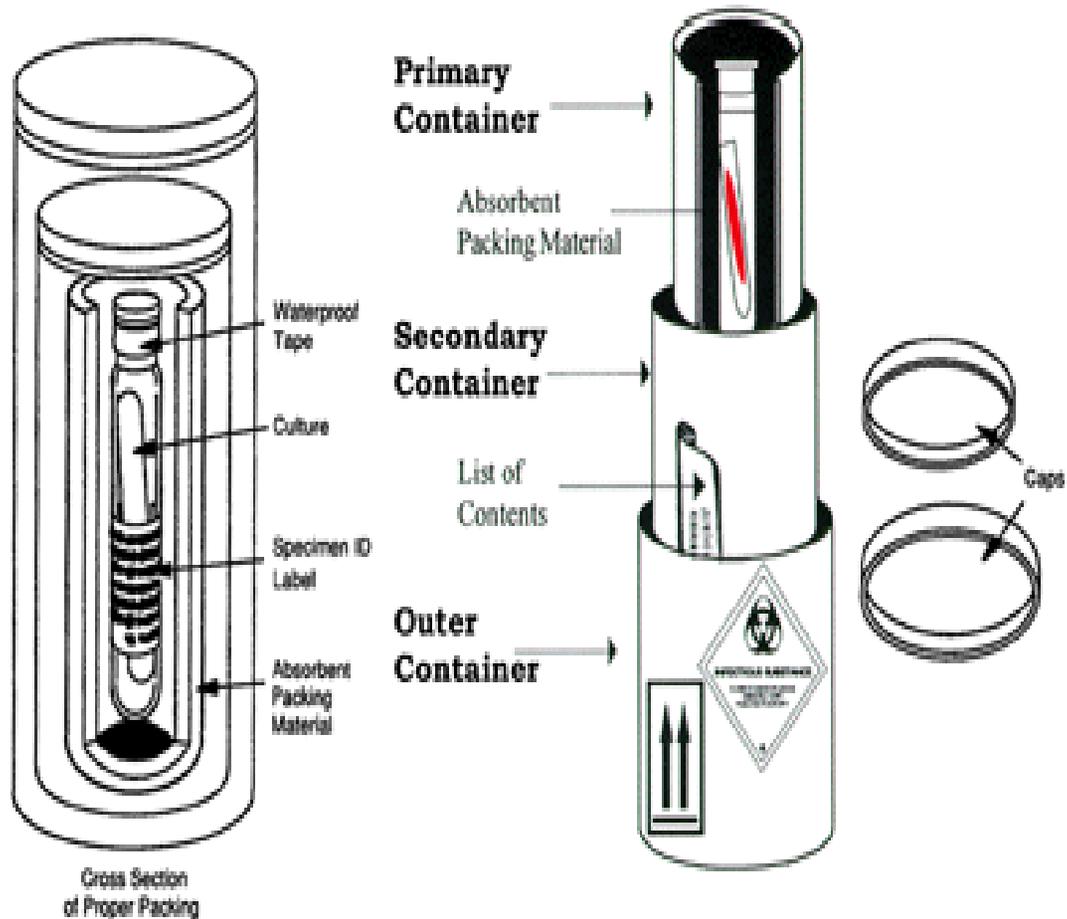


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INFECTIOUS SUBSTANCE PACKAGING



48 CFR Part 6.2/94
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Shipment Tracking

- “Paper trail” of bacterial agent transport and delivery
- Keep a running record of each individual who has possession of the biological agent during shipment
- Confirm receipt at destination
- Documentation should include:
 - Description of biological agent being shipped
 - Contact information for a responsible person
 - Record of any individual who assumes custody on behalf of someone else



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Potential Role of Law Enforcement

- Physical Security and Access Control
 - Attempted unauthorized access
 - Suspicious person
 - Theft of keys
 - Attempted subversion of the security system
 - Security breach
- Personnel Security
 - Background investigation
 - Fraudulent application information or credentials
- Transportation Security
 - Package theft
 - Theft of carrier vehicle
- Information Security
 - Theft or loss of information
 - Laboratory notebook
 - Experimental procedures or data
 - Security access codes



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Potential Role of Law Enforcement (continued)

■ Material Control and Accountability

- Investigate theft or loss
 - biological agents, equipment, information
- Investigate potential compromise of security system

■ Information Security

- Compromise of information
- Theft
- Suspicious requests for information

■ Additional

- Assess the threat environment
 - Local and regional criminal activity
 - Local and regional terrorist activity