



Integrated Biosecurity System Design: Current Principles, Practices, and Requirements

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US Policy Response to the Bioterrorist Threat

- Emerging US security regime has two sets of objectives
 - Enhance ability to respond to public and agricultural health emergencies
 - Reduce the risk that bioscience and biotechnology could be used maliciously
- Realization that bioscience facilities are potential sources of biological weapons material (viable and virulent pathogens)
- USA PATRIOT Act of 2001 – US Public Law 107-55
 - Restricted Persons
- Bioterrorism Preparedness Act of 2002 – US Public Law 107-188
 - 42 CFR 73 (Human and Overlap)
 - 9 CFR 121 (Animal and Overlap)
 - 7 CFR 331 (Plant)





US Select Agent Rule (2005)

- Facility registration if it possesses one of 80 Select Agents
- Facility must designate a Responsible Official
- Background checks for individuals with access to Select Agents
- Access controls for areas and/or containers that contain Select Agents
- Detailed inventory requirements for Select Agents
- Security, safety, and emergency response plans
- Safety and security training
- Regulation of transfers of Select Agents
- Extensive documentation and recordkeeping
- Safety and security inspections





Security System Considerations

- **Cannot protect every asset against every conceivable threat**
- **Detection of theft extremely difficult**
 - **Microscopic**
 - **No detectable signature**
 - **Constantly changing quantities**
- **User input necessary**
 - **Minimize operational impacts**
 - **Integrate with biosafety systems**
- **Resources are limited and must be allocated effectively**
 - **Risk assessment**





Evaluate Value of the Assets from an Adversary's Perspective

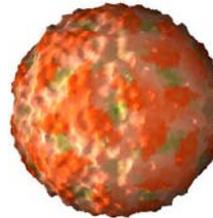
- **Biological agents**

- **Consequences**

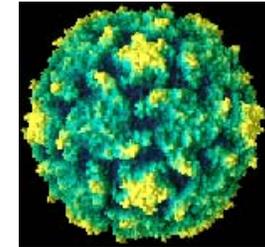
- Lethality
- Morbidity
- Infectivity
- Transmissibility

- **Weaponization potential**

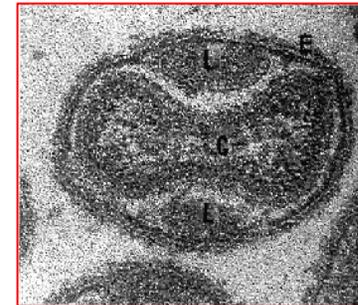
- Environmental hardiness
- Ease of processing
- Ease of distribution
- Ease of growth
- Availability
- Ability to camouflage as a natural outbreak



FMD virus



Polio virus



Variola major

- **Information related to the security of dangerous biological materials could assist an adversary in gaining access**
- **Operational systems may be targeted to facilitate gaining access to dangerous biological materials**



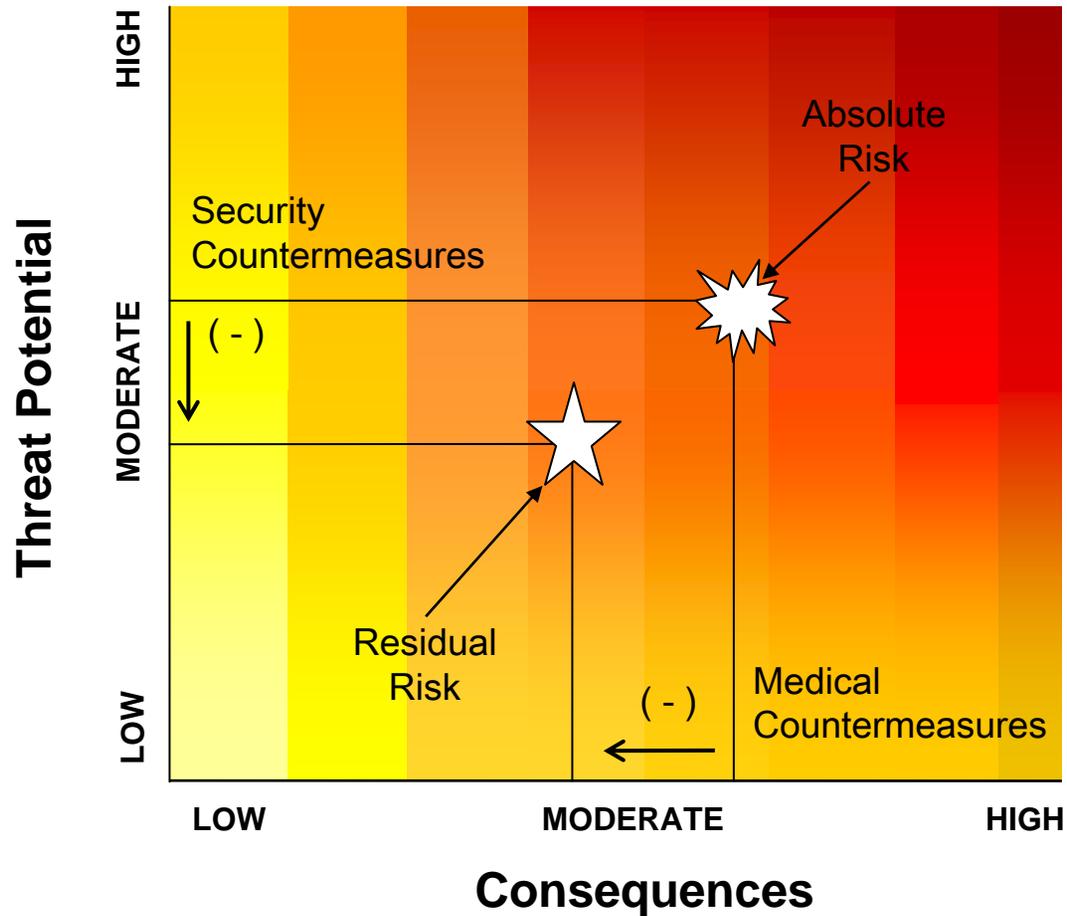
Elements of Risk

- Evaluate adversaries
 - Insiders
 - Outsiders
- Evaluate threat potential
 - Capabilities
 - Tools
 - Motivation
 - Weaponization potential
 - Possibility of being caught
- Evaluate consequences
 - Death and illness
 - Economic
 - Symbolic
 - Social



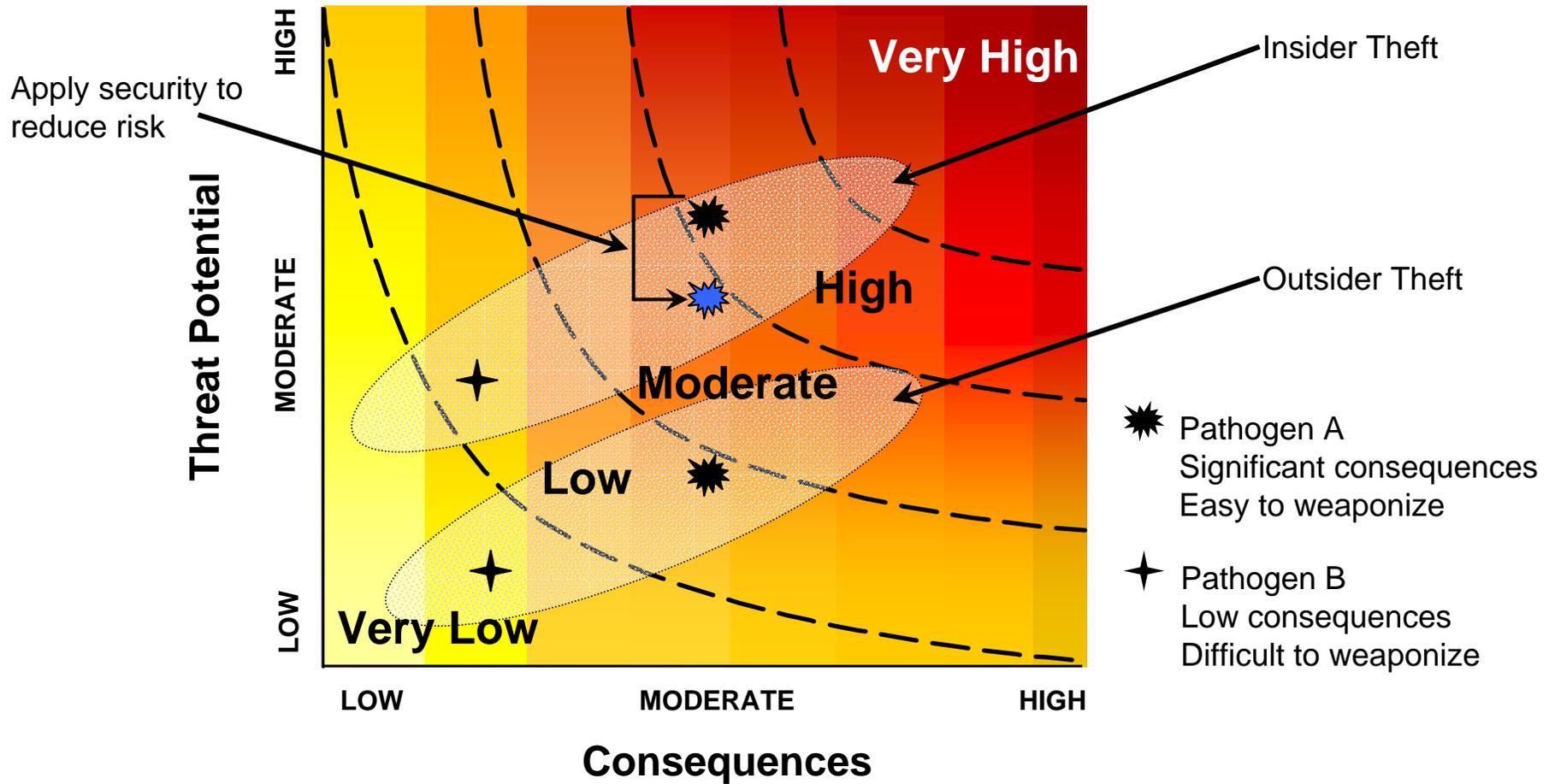


Biosecurity Risk Assessment and Mitigation



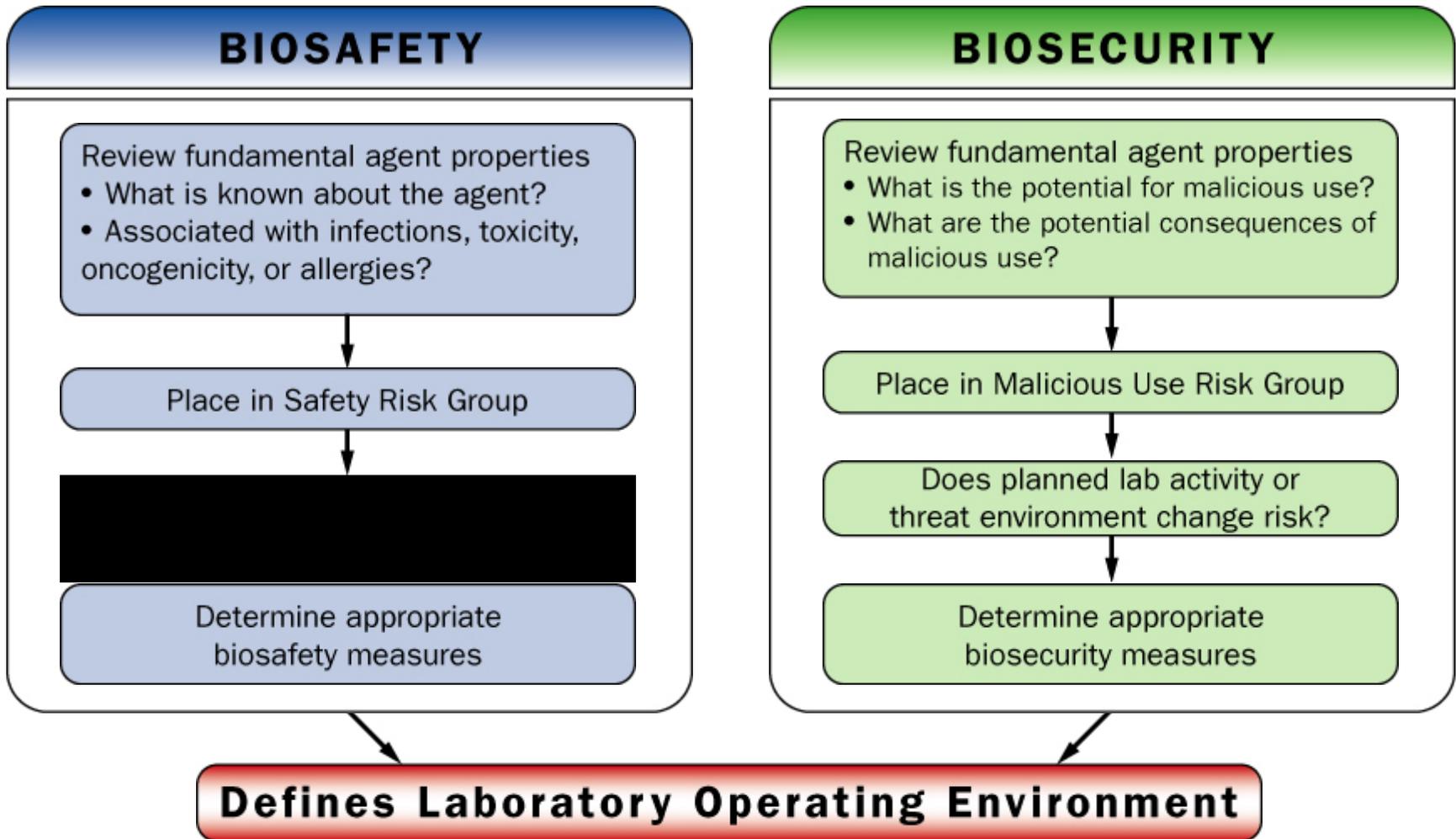


Biosecurity Risk: Insider vs. Outsider Threat





Integrated Biosafety and Biosecurity





Biosecurity Management Responsibilities

- Identify the protection objectives of the biosecurity system
 - Scenarios to protect against
 - Scenarios to be prepared to respond to

- Design the system
 - Physical security
 - Security policies and procedures

- Write security and emergency response plans

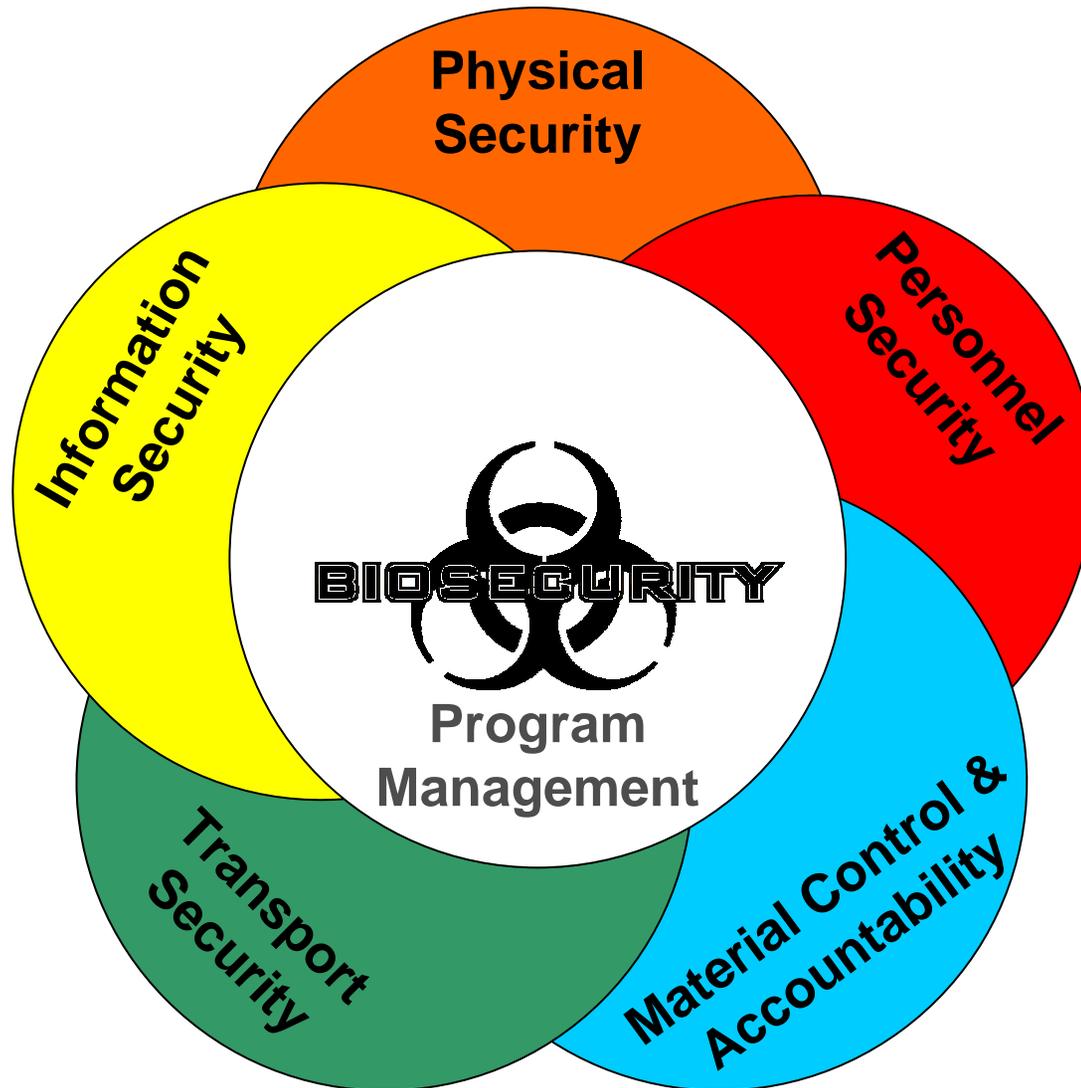
- Conduct regular training and internal reviews

- Allocate resources





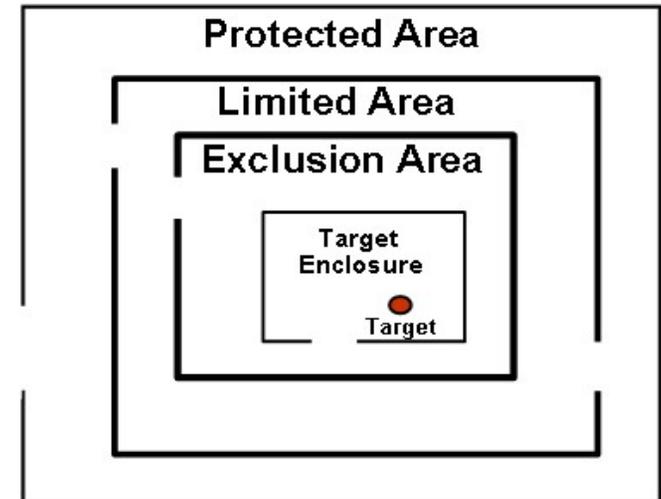
Components of Biosecurity





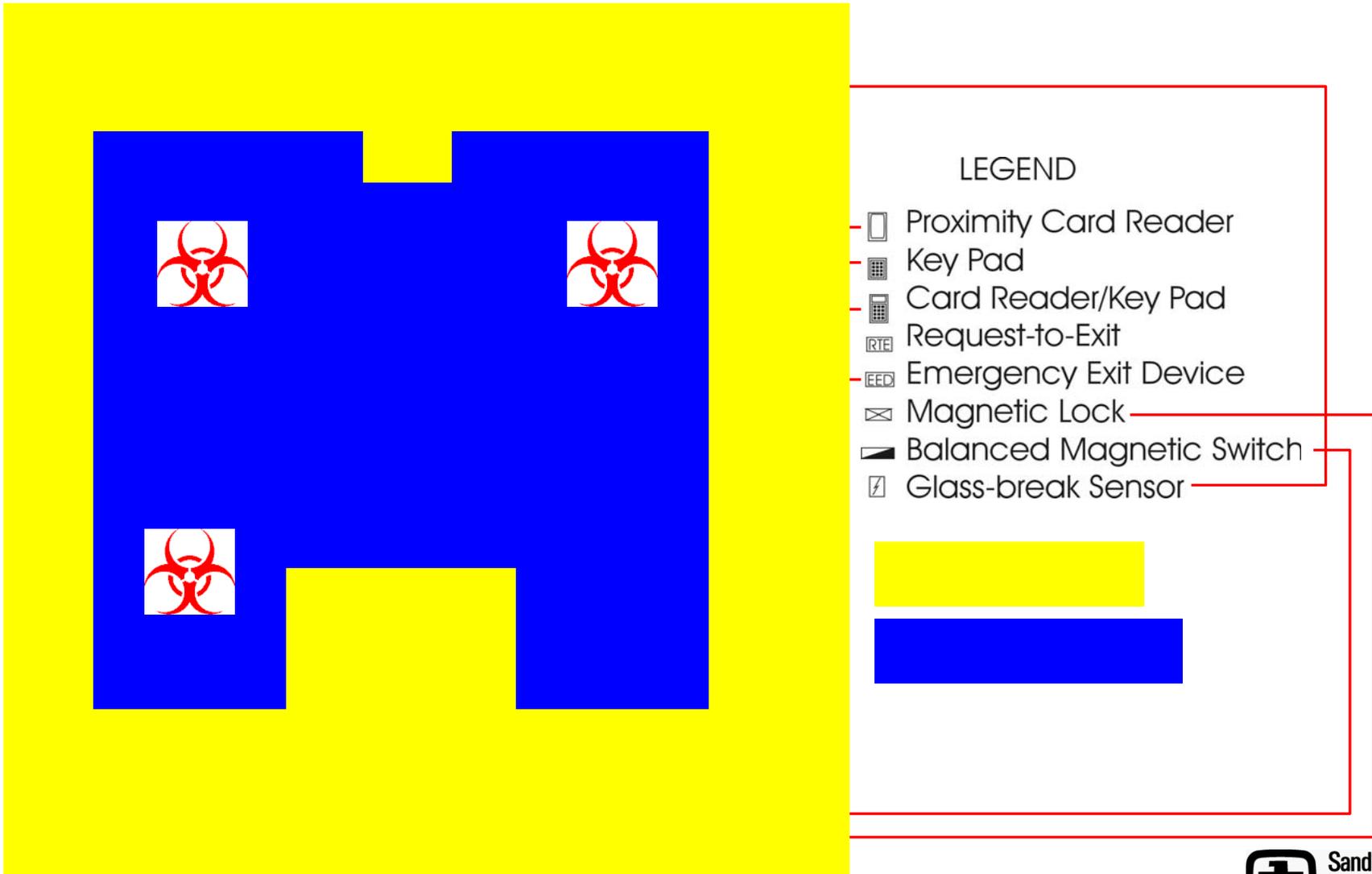
Physical Security

- **Graded protection**
 - Increasingly strict controls from one protection area to another
- **Access control**
 - Ensures only authorized individuals are allowed entry
- **Intrusion detection**
 - Detects unauthorized access





Example Laboratory Building





Personnel Security

- **Personnel Screening**
 - Review and verify personal information
 - Conduct background investigations
 - Increasing level of scrutiny for higher risk positions
- **Badges**
- **Visitor Control**
- **Training**



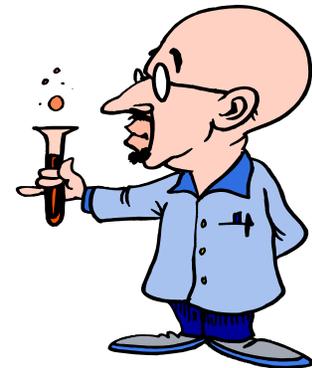


Material Control and Accountability

- **Responsibility**
 - **Accountable individual**

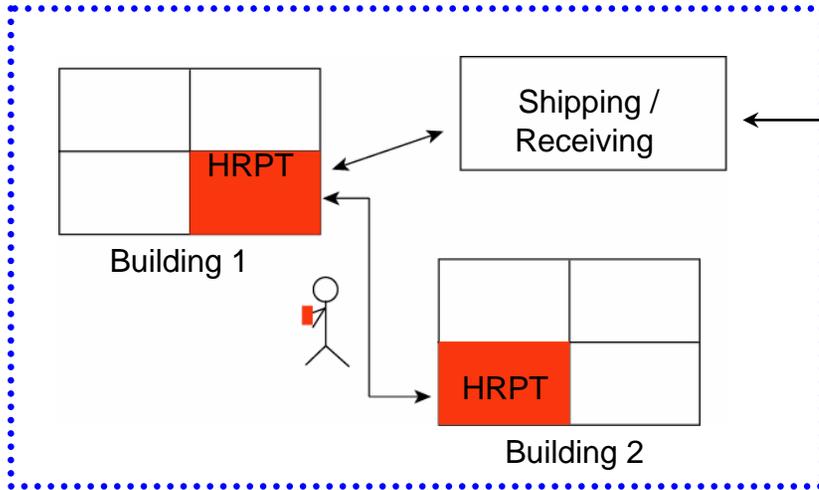
- **Documentation**
 - **Agent name and description**
 - **Quantity**
 - **Based on containers or other “units”**
NOT the number of microbes
 - **Location**

- **Control**
 - **Physical, personnel, information, and transfer security**
 - **Biosafety/Biocontainment**

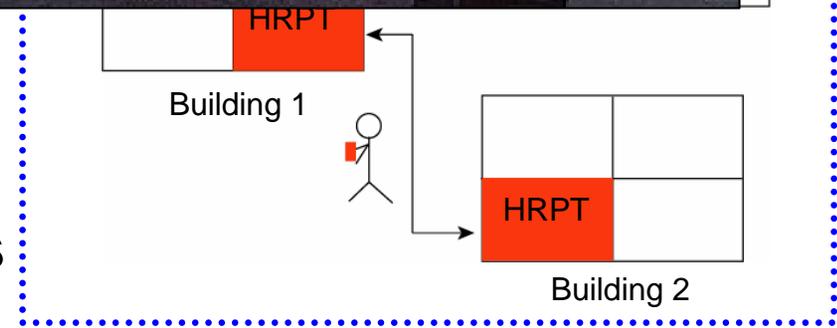




Transport Security



Facility A



Facility B

Transport may occur:

- Across international borders
- Within a country
- Within a facility or building



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**
- **Types of sensitive information**
 - **Security of dangerous pathogens and toxins**
 - **Risk assessments**
 - **Security system design**
 - **Access authorizations**
 - **Personnel records**
 - **Financial records**





Summary

- **Necessary to take steps to reduce the likelihood that dangerous pathogens and toxins could be stolen from a legitimate bioscience facility**
- **Collaboration between architects, engineers, security system designers, and scientific experts necessary for effective risk assessment and security system design**
- **User input is required to avoid operational impacts and conflicts with biosafety**
- **Laboratory biosecurity should integrate physical, personnel, information, material and transfer security systems**

