



Biosecurity Methodology

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**US-Taiwan Nonproliferation and Confidence Building Measures
Workshop**

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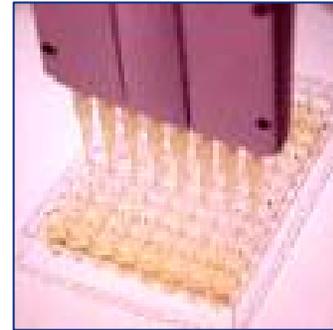


Challenges to Securing Biological Agents

- **Dual-use characteristics**
 - Valuable for many legitimate, defensive, and peaceful commercial, medical, and research applications

- **Nature of the material**
 - Living and self-replicating organisms
 - Used in very small quantities
 - Cannot be reliably quantified
 - Exist in many different process streams in facilities
 - Contained biological samples are virtually undetectable using standoff technologies

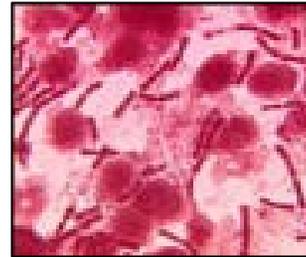
- **Laboratory “culture”**
 - Biological research communities not accustomed to operating in a security conscious environment





Biosecurity Risk Assessment

1. Evaluate assets
2. Evaluate threat
3. Evaluate risk



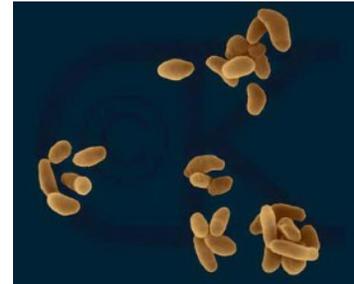


Evaluate Value of the Assets from an Adversary's Perspective

- **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



- **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**

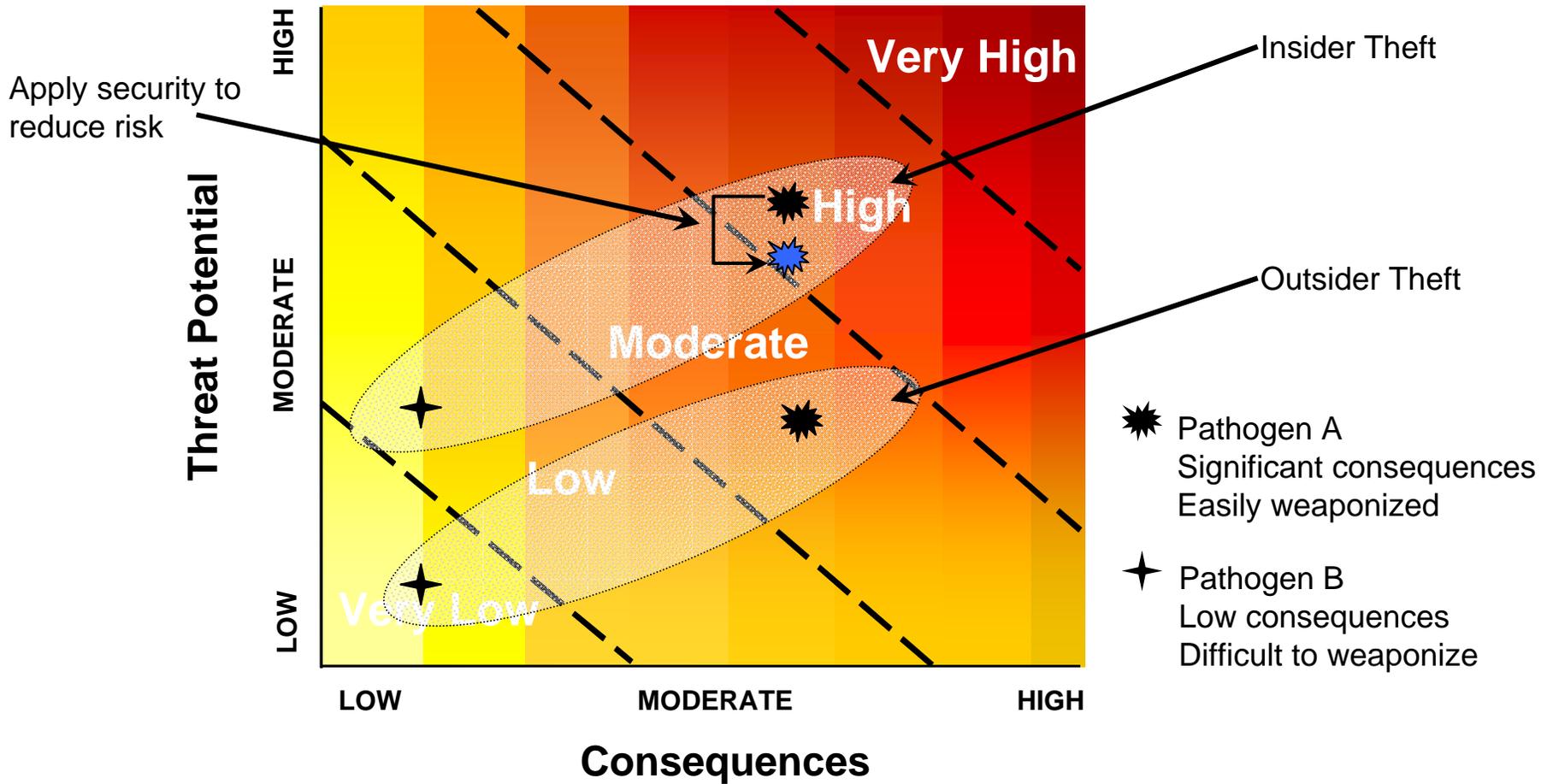
- **Evaluate threat potential**
 - **Capabilities**
 - **Tools**
 - **Motivation**
 - **Weaponization potential**
 - **Possibility of being caught**

- **Evaluate consequences**
 - **Death and illness**
 - **Economic**
 - **Symbolic**
 - **Social**





Risk





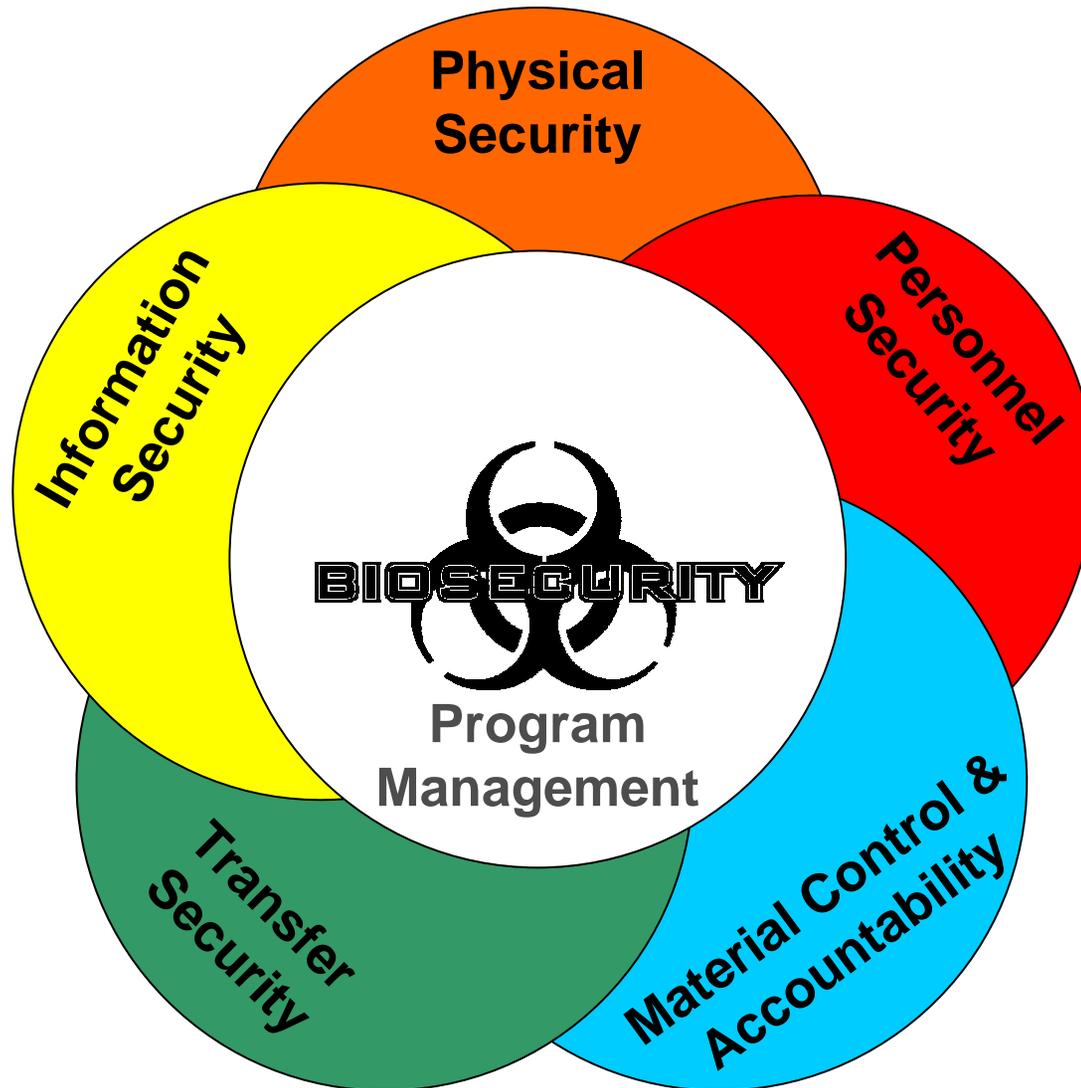
Management Responsibilities

- Identify which possible but unlikely scenarios the security system should not be required to protect against
- Establish a protection strategy
- Determine the physical security system design
- Develop security policies and procedures
- Allocate resources





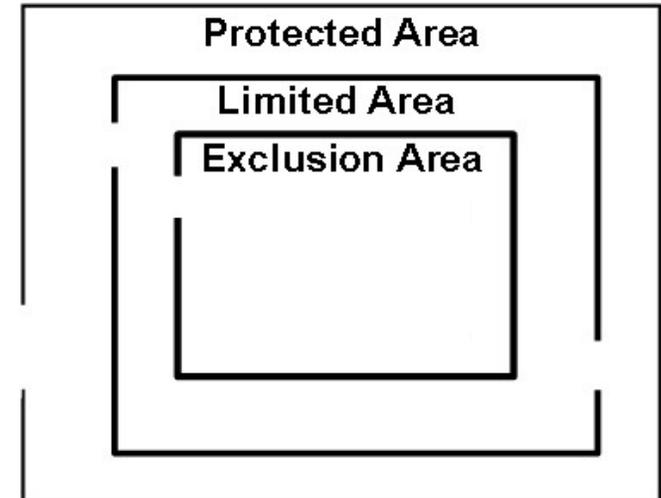
Components of Biosecurity





Physical Security

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





Personnel Security

- **Personnel Screening**
 - **Conduct screening for authorized individuals**
 - **Increasing level of scrutiny for high risk positions**
- **Badges**
- **Visitor Control**
- **Training**



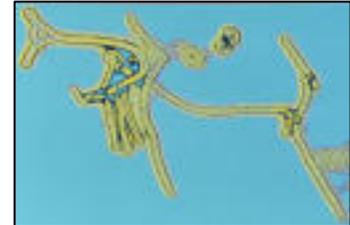


Material Control and Accountability

- **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

- **Transport may occur:**
 - **Across international borders**
 - **Within a country**
 - **Within a facility or building**



- **Chain of Custody**
 - **Keep a running record of each individual who has possession of the biological material en route**
 - **Confirm receipt of biological material at destination**



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 the *high risk agents* could be stolen from bioscience facilities**
- **Critical that these steps are designed specifically for biological materials and research so that the resulting system will balance science and security concerns**

