Balancing Security and Research at Biomedical and Bioscience Laboratories: The Security Risk and Threat Assessment

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Sandia National Laboratories

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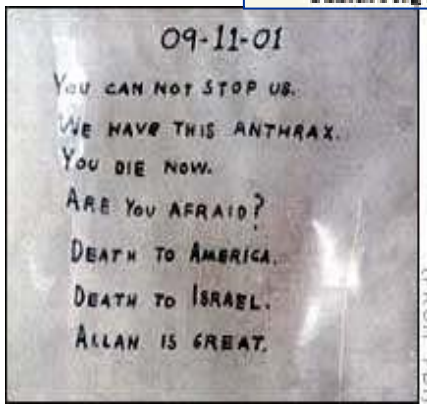
Need to Secure Select Agents

- **Biosecurity aims to mitigate the BW threat at the source**
  - **Prevent terrorists or proliferant states from acquiring select agents from government, commercial, or academic facilities**
- **Biosecurity systems should specifically protect against theft and diversion of select agents by applying a set of well-established security strategies**
  - **Define risk by evaluating probabilities and consequences**
  - **Protect defined assets against defined threats**
  - **Apply a graded protection approach**
  - **Integrate security technologies and procedures**
  - **Impact operations only to the level required**
- **Securing select agents is an important element of comprehensive BW nonproliferation programs**
  - **Cannot prevent BW terrorism or proliferation**
  - **Must be augmented by other national mechanisms**

Patient's leg covered in smallpox



Challenges to Securing Select 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
- **Laboratory culture**
  - Biological research communities not accustomed to operating in a security conscious environment

Biosecurity Cost-Benefit Considerations

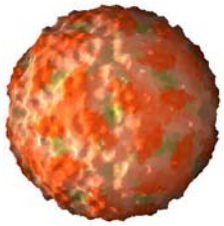
- **Bioscience facilities are not unique repositories**
  - **Most agents can be isolated from nature**
  - **Many similar collections of agents exist worldwide**
- **Relatively few agents can be easily grown, processed, weaponized, and successfully deployed while maintaining virulence/toxicity**
  - **Very few agents used as a weapon could cause mass human, animal, or plant casualties**
  - **Not all agents equally attractive to adversaries**
- **Need a methodology to make informed decisions about how to design an effective and efficient biosecurity system**

Biosecurity Methodology

- **Qualitative risk and threat assessment is the essential first step**
  - **Process should include scientists, technicians, managers, security professionals, and law enforcement (counter-terrorism) experts**
- **Asset identification and prioritization**
  - **What are their attractiveness to an adversary and their consequences of diversion?**
- **Threat identification**
  - **Who are the adversaries, what are their capabilities?**
- **Risk prioritization of asset/threat scenarios**
  - **Evaluation of probabilities and consequences**
- **Management decision**
  - **Risks to protect against: security system design parameters**
  - **Risks to accept: incident response planning parameters**

Asset Identification and Prioritization

- **Primary consequence**
  - Loss could lead to national security event (bioterrorism)
  - Certain biological agents
- **Secondary consequence**
  - Loss could assist in achieving a primary consequence or access to a primary asset
  - Certain information related to select agents
- **Tertiary consequence**
  - Loss could affect operations
  - Certain facilities, equipment, etc.



FMD virus

Yersinia pestis

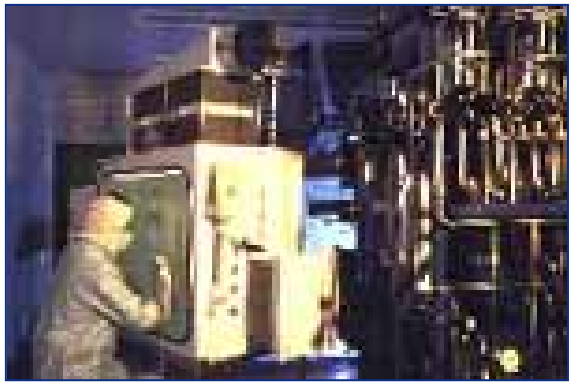
Bacillus anthracis

Fermentation vessel

Threat Identification

- Adversary categories
  - Insider with authorized access
  - Invited outsider(s) – visitor
  - Outsider(s) with limited access and system knowledge
  - Outsider(s) with no access but has general knowledge
  - Outsider(s) with no access and no general knowledge
  - Collusion between an insider and an outsider

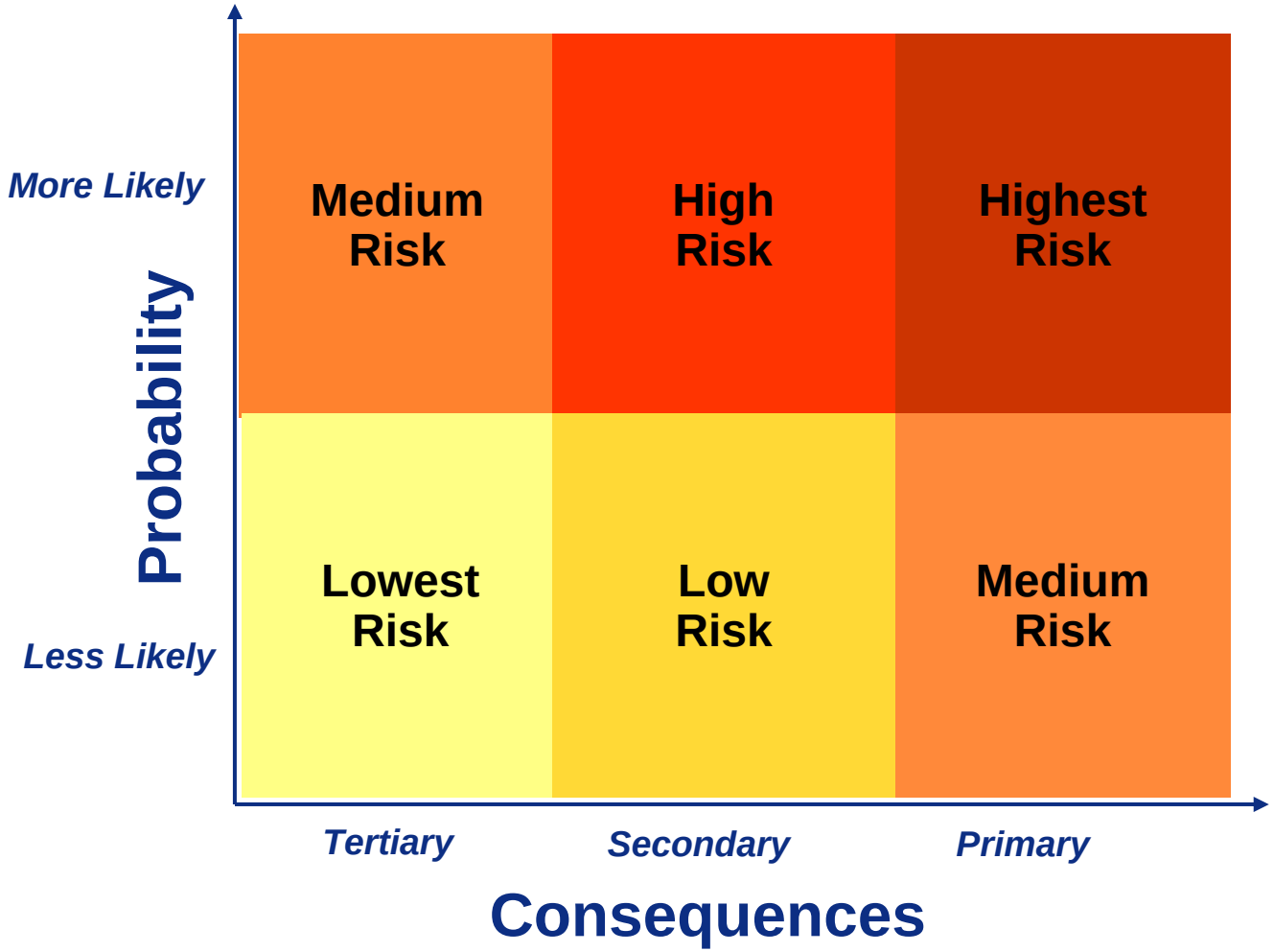
- How will the adversaries perpetrate the event?
  - Alone or in a group?
  - Armed or unarmed?
  - Covert or overt?



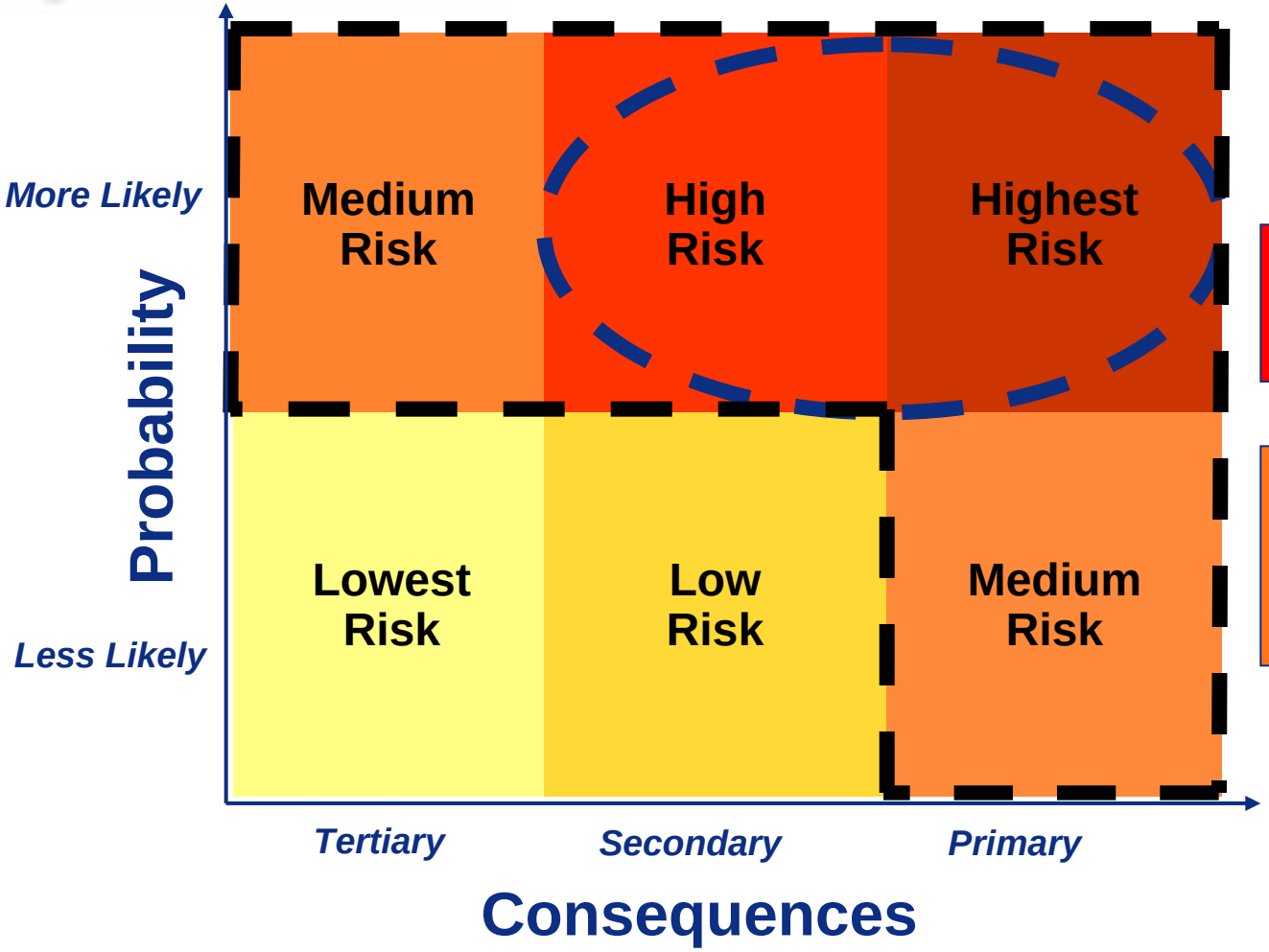
Asset/Threat Scenario Development

- **What will the adversaries aim to do?**
  - **Steal, destroy, disperse agents**
  - **Steal, destroy information**
  - **Steal, destroy equipment**
  - **Destroy operational systems**
  - **Destroy/deface facility**
  - **Injure, kill people**
  - **Etc.**
- **Develop reasonable scenarios based on defined assets and threats**

Risk Prioritization



Management Risk Decision



- Protect against high risk scenarios
- Develop incident response plans for medium and low risk scenarios

Generic Biosecurity Design Parameters

- **Highest risk scenarios**
  - **Insider, visitor, or outsider with limited access attempting to steal select agents covertly**
- **High risk scenarios**
  - **Insider, visitor, or outsider with limited access attempting to steal select agent-related information covertly**
- **Medium risk scenarios**
  - **Small outsider groups that would aim to destroy or deface the facility**
- **Terrorist commando assault unlikely**
  - **Agents available elsewhere**
  - **Overt attack using force would signal authorities to take medical countermeasures**

Generic Biosecurity Protection Principles

- Personnel Reliability
- Physical Security
- Information Technology Security
- Material Control and Accountability
- Material Transfer Security
- Program Management

Typically excludes substantial perimeter systems and armed guard forces

Personnel Reliability

- Allow access only to those individuals who have
  - Legitimate need to handle select agents
  - Appropriate training in biosafety, containment, and security procedures
  - Been registered with CDC/APHIS
- Conduct background investigations on individuals who handle, use, or transfer select agents
- Establish visitor interaction procedures
  - Screening, badging, and escorting
- Report suspicious activity

Physical Security

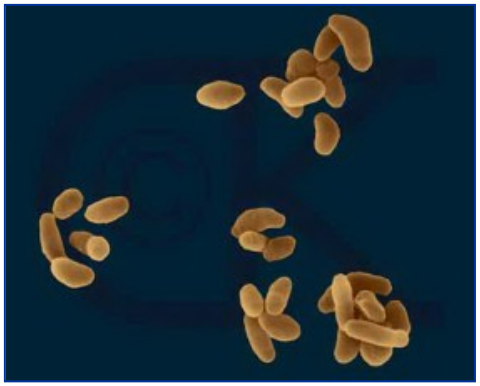
- Implement systems to deter, detect, and respond to unauthorized attempts to gain access to select agents
- Establish graded protection areas with
  - Intrusion detection
  - Access controls and transaction recording
  - Alarm assessment capabilities
  - Physical barriers and delay systems
  - Law enforcement response capabilities

Material Control and Accountability

- Develop systems to document
  - What materials exist in a certain facility
  - Where they are located
  - Who is responsible for them
  - Who has access to them
- Avoid trying to apply quantitative material-balance inventory accounting principles

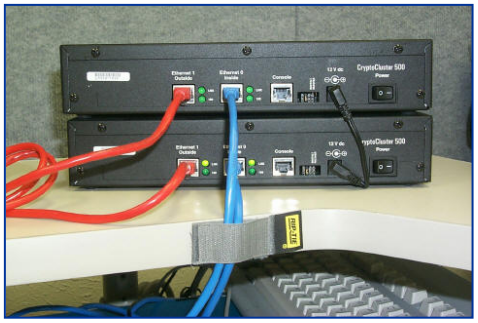
Material Transfer Security

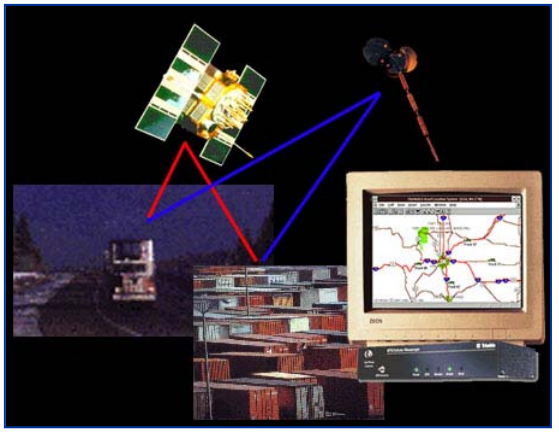
- Document, account for, and control select agents when they are moving between protected areas within a facility
- Receive authorization and monitor external transfers between registered facilities before, during, and after transport



Information Technology Security

- Control access to sensitive information related to select agents
- Establish policies and implement technologies for handling, using, and storing paper-based, telephonic, photographic, and electronic media





Program Management

- Provide policy oversight and implementation of the biosecurity program
- Maintain documentation of
  - Security plan
  - Incident response plan
  - Security training program
  - Self-assessment and auditing program

Summary

- Necessary to take steps to reduce the likelihood that select 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

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