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Biosecurity Risk Assessment

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NNSA National Nuclear Security Administration

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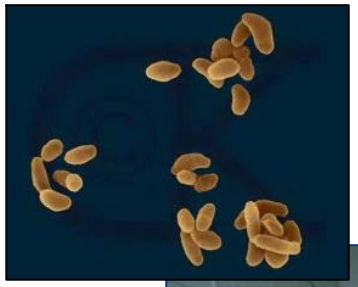
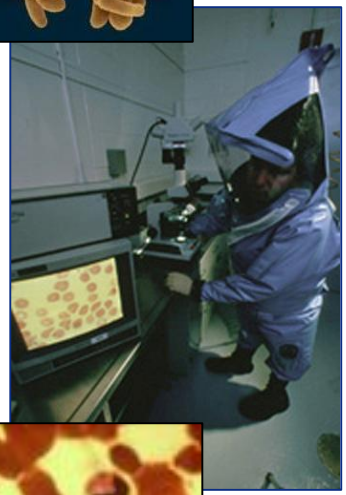
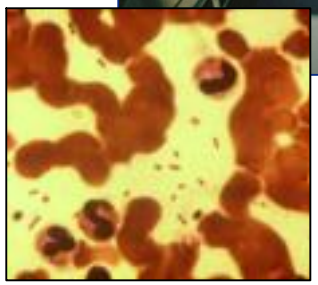
Biosafety and Biosecurity

- **Biosafety**
  - Objective: reduce or eliminate accidental exposure to or release of potentially hazardous agents
- **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**
  - Biosecurity and biosafety should be integrated systems that avoid compromising necessary infectious disease research and diagnostics



Francisella tularensis





Yersinia pestis

Biosecurity Based on Risk Management

- **Biosecurity risk management considerations**
  - Critical not to unduly compromise legitimate bioscience operations
  - Security resources are not infinite. Existing resources should be used efficiently
  - Security systems should be designed to address unique situations
  - Security systems should be based on the asset or material that requires protection
  - Most biological materials can be isolated from nature

- **"The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin"**
  - 42 CFR 73.11 (b)
  - 7 CFR 331.11 (b)
  - 9 CFR 121.11 (b)

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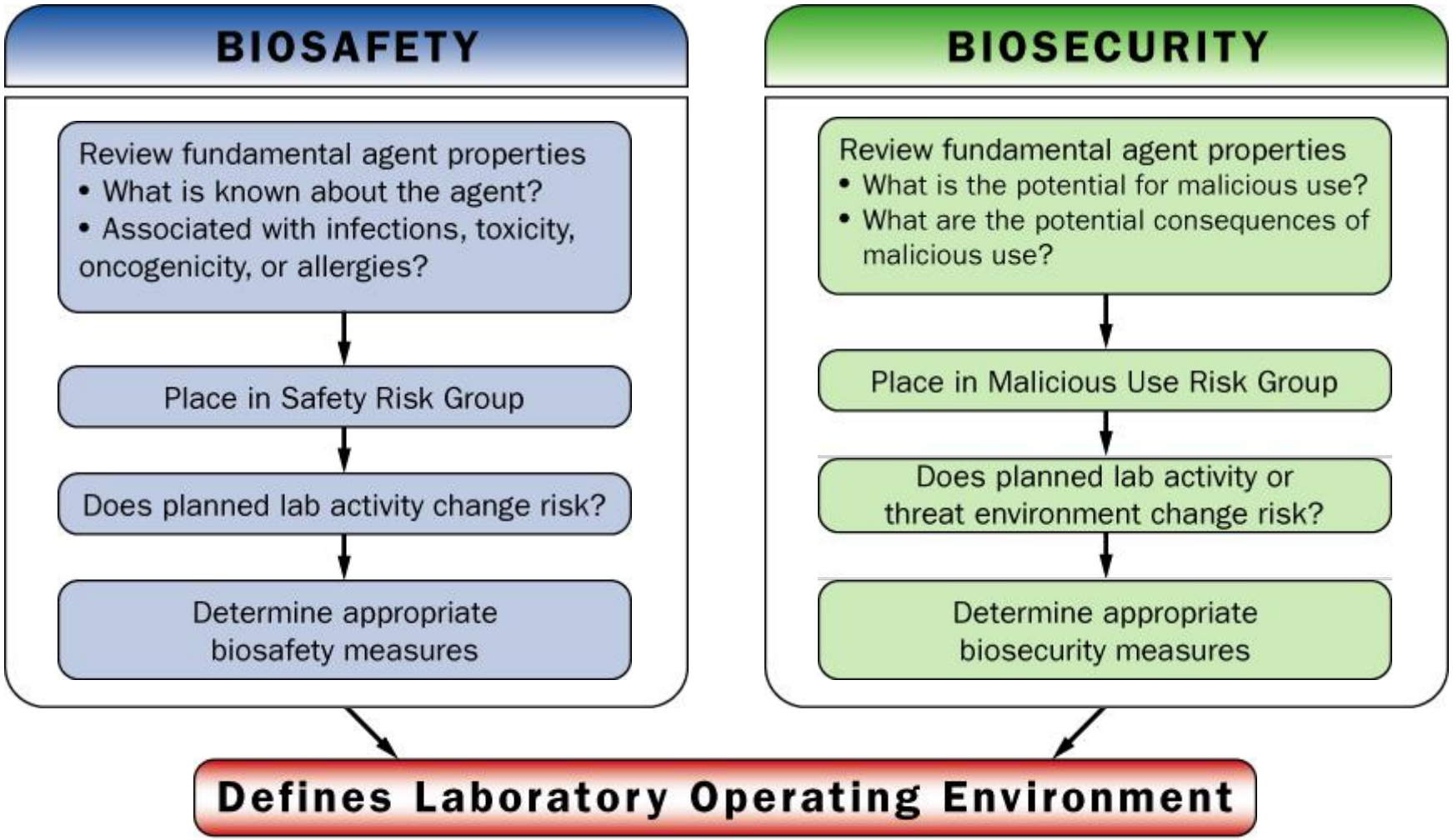
Risk Management

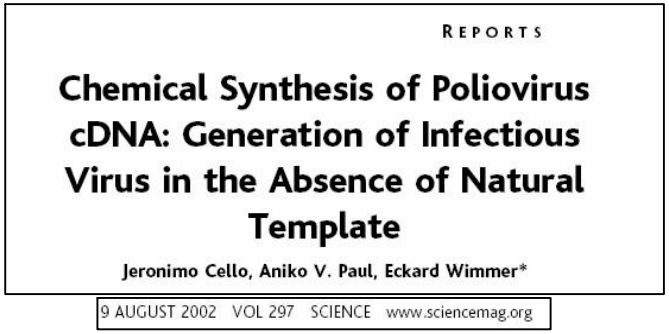
- Establishes which assets should be protected against which threats
  - Assets include items that are:
    - Dangerous
    - Hard to replace
    - Rare
    - Critical to operations
- Ensures that the amount of protection provided to a specific asset, and the cost for that protection, is proportional to the risk of the theft or destruction of that asset
- Begins with a risk assessment
- Proceeds with risk mitigation
- Continuously improves with monitoring and adjustment

Integrated Biosafety and Biosecurity



Malicious Use Risk Group Evaluation

- **Assess value of the agents from an adversary's perspective**
  - **Consequences**
    - Contagiousness
    - Medical effects (morbidity and mortality)
    - Psychological impact
    - Economic impact
  - **Weaponization potential**
    - Acquisition
    - Production
      - Ease of growth
      - Ease of processing
      - Ease of storage
    - Dissemination
      - Modes (e.g. Aerosol, Oral)
      - Environmental hardiness

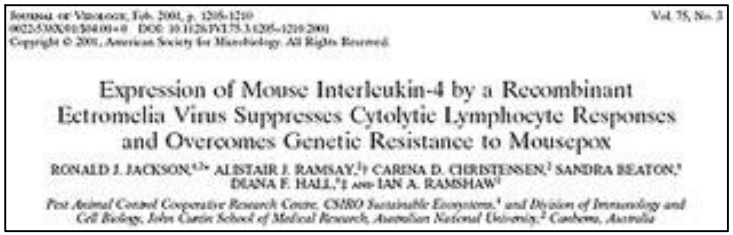


REPORTS

Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template

Jeronimo Cello, Aniko V. Paul, Eckard Wimmer*

9 AUGUST 2002 VOL 297 SCIENCE www.sciencemag.org



Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox

Malicious Use Risk Groups

- **Nonpathogenic**
  - Malicious use would have insignificant or no consequences
- **Low Malicious Use Risk (LMUR)**
  - Difficult to deploy, and/or
  - Malicious use would have few consequences
- **Moderate Malicious Use Risk (MMUR)**
  - Relatively difficult to deploy, and
  - Malicious use would have localized consequences with low to moderate casualties and/or economic damage
- **High Malicious Use Risk (HMUR)**
  - Not particularly difficult to deploy, and
  - Malicious use could have national or international consequences, causing moderate to high casualties and/or economic damage
- **Extreme Malicious Use Risk (EMUR)**
  - Would normally be classified as HMUR, except that they are not found in nature (eradicated)
  - Could include genetically engineered agents, if they were suspected of being a HMUR

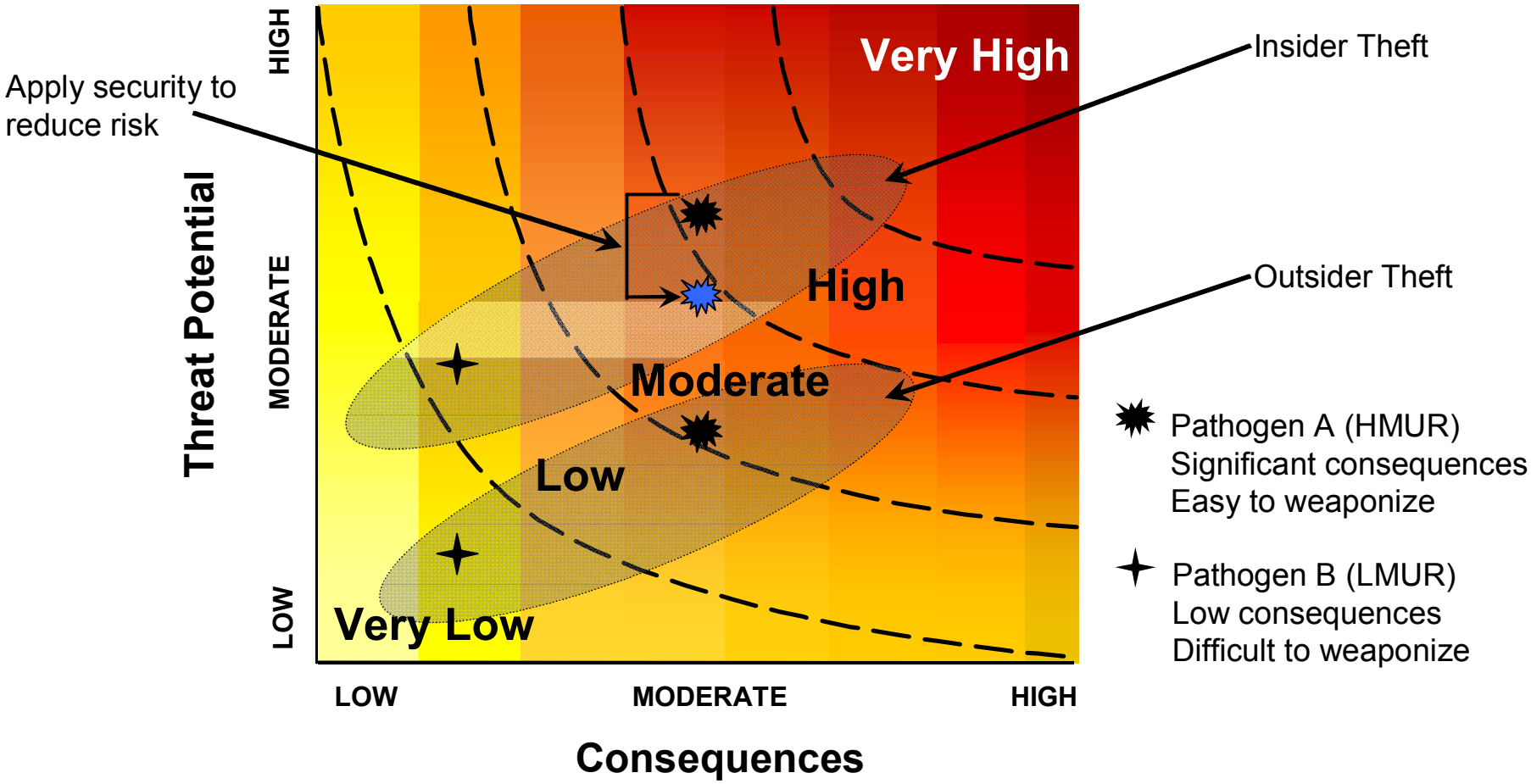
Elements That May Modify Risk

- **Consider lab experiment**
  - **Does planned experiment produce an agent with higher weaponization potential or higher potential consequences?**
    - **For example: Increased stability, GMOs, large quantities, aerosol challenges**

Threat Environment

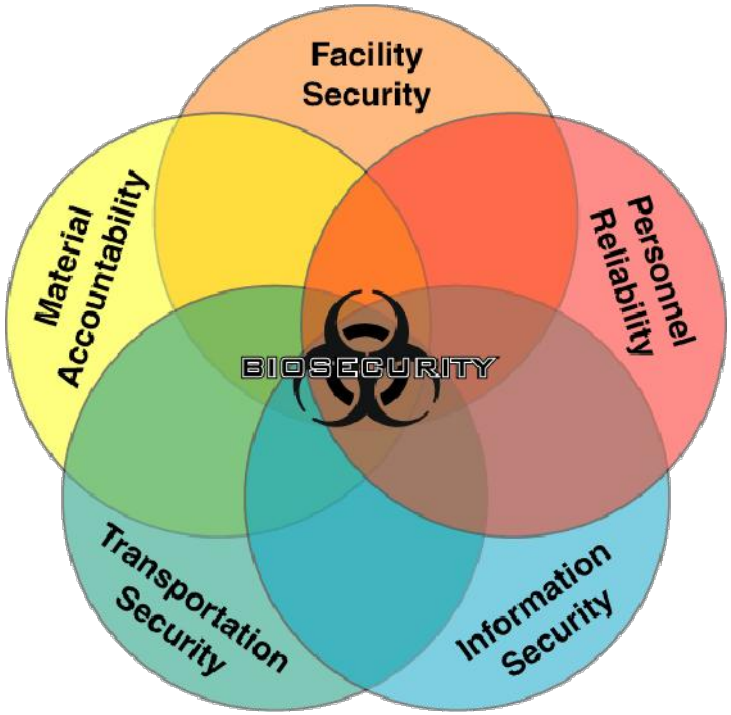
- **Adversary Classes**
  - Terrorist
  - Extremist
  - Criminal
- **Insiders**
  - Authorized access to the facility, dangerous pathogens, and/or restricted information
  - Distinguish Insiders by level of authorized access
    - Site
    - Building
    - Asset
  - Facility management, site security, and local law enforcement interviews
- **Outsiders**
  - No authorized access
  - Local law enforcement, site security, and intelligence community interviews

Biosecurity Risk: Insider vs. Outsider Threat



Biosecurity System

- **Biosecurity system components**
  - **Physical security**
  - **Personnel security**
  - **Material handling and control measures**
  - **Transport security**
  - **Information security**
  - **Program management practices**



- **Each component tailored for the risk**

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Conclusions

- Need to integrate biosafety and biosecurity considerations into decisions about laboratory operations
- 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

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Where To Go for Further 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) has expressed interest in establishing biosecurity guidelines
- Laboratory Biosecurity Handbook – CRC Press, forthcoming
- www.biosecurity.sandia.gov

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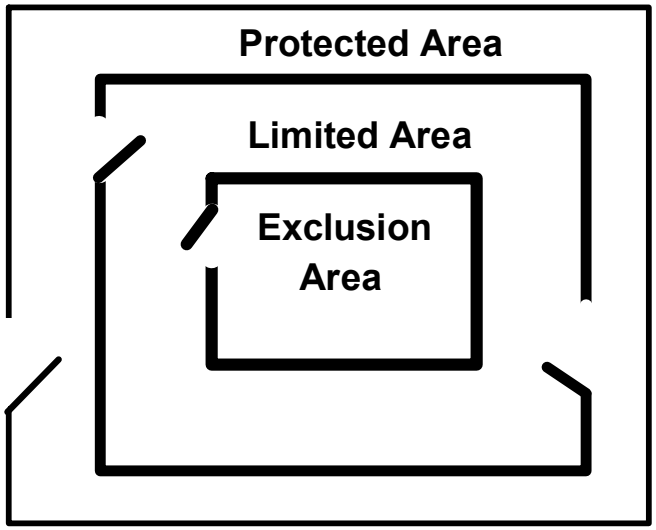
Backup slides

Physical Security

- **Moderate**
  - Store and use pathogens (and infected animals) within Limited Areas
  - Restrict access using controlled keys and secured windows
  - Control visitors

- **High**
  - Store and use pathogens (and infected animals) within Exclusion Areas
  - Electronic Intrusion Detection System and/or guards
  - Controlled and authenticated key
    - Something you *have* (key) plus something you *know* (PIN)
  - Restrict and control visitors
  - Maintain records of entry/exit



Personnel Security

- **Moderate**
  - **Background investigation**
    - **Criminal history**
    - **Verifiable compliance with rules and regulations**
  - **Drug test**

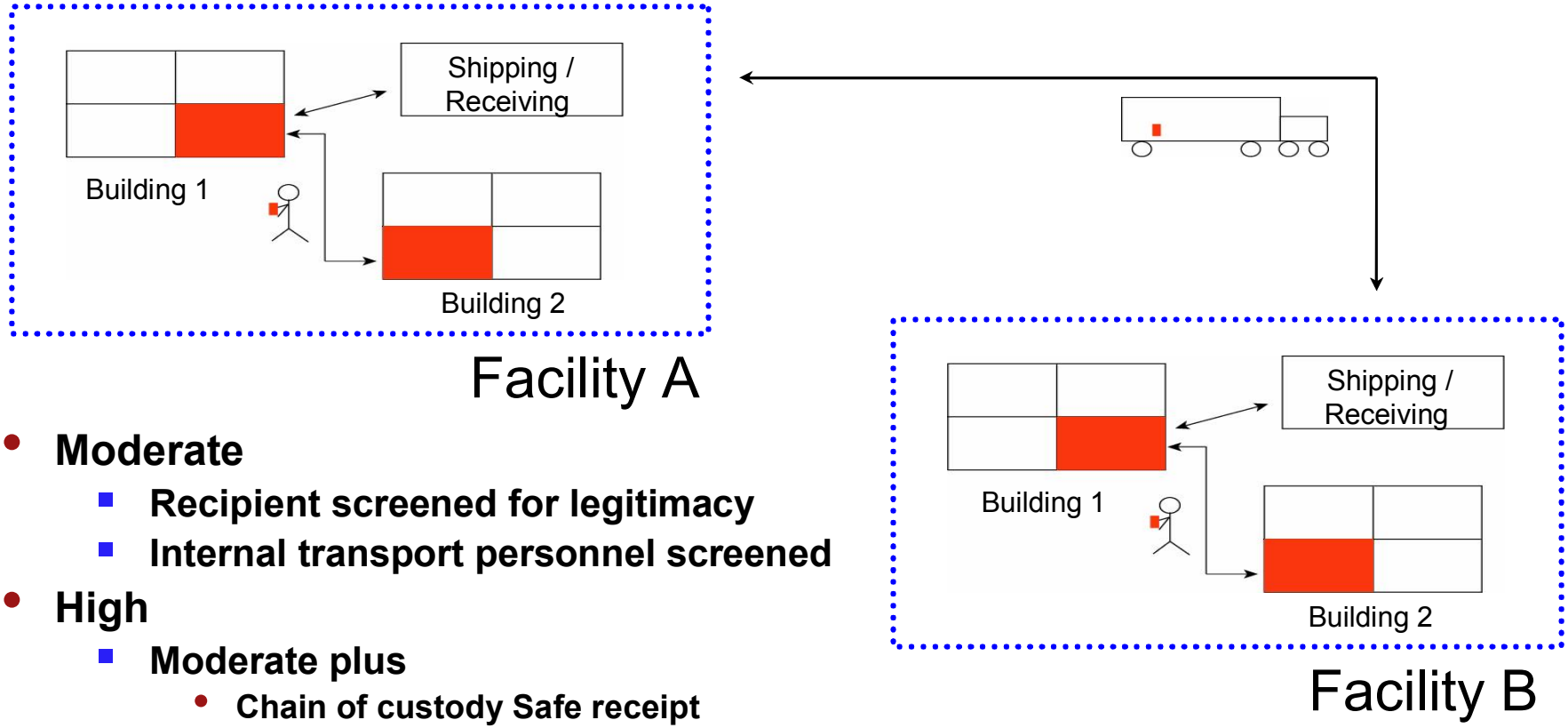
- **High**
  - **Moderate plus**
    - **Personal and associate interviews**
    - **Credit history**
    - **Terrorist/extremist/criminal affiliation**
    - **Periodically reinvestigate**

Material Control & Accountability

- **Moderate**
  - **Seed stocks cataloged and records stored securely**
    - **Transfers in and out**
    - **Source**
    - **Strain**
    - **Form**
    - **Responsible individual**
  - **Working stocks, including infected animal status, tracked through laboratory notebooks**

- **High**
  - **Moderate plus**
    - **Increased control over working stocks**

Transport Security

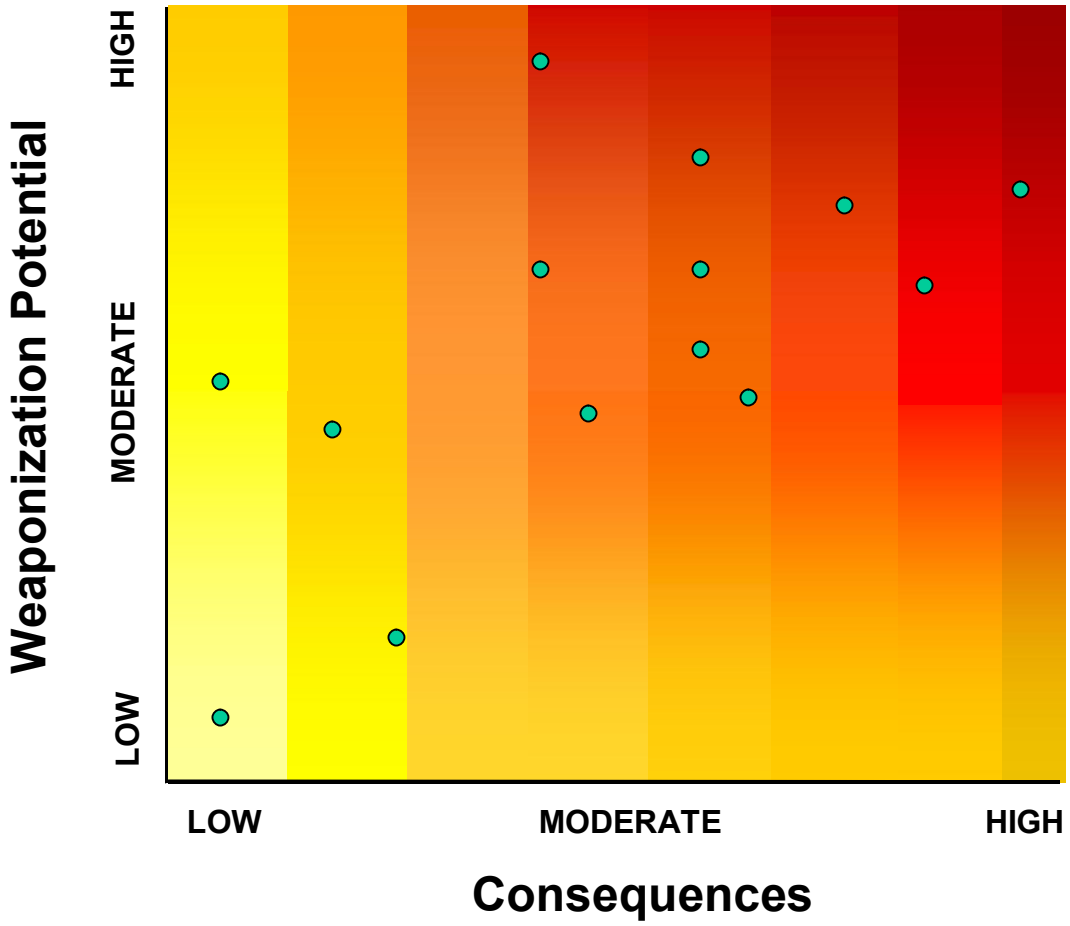


- **Moderate**
  - **Recipient screened for legitimacy**
  - **Internal transport personnel screened**
- **High**
  - **Moderate plus**
    - **Chain of custody Safe receipt notification**
    - **Physical controls on storage containers**

Information and Program Management

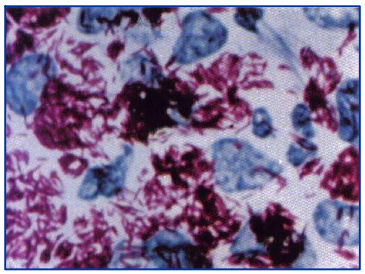
- Protect information that is too sensitive for public distribution
  - Label information and limit distribution
  - Implement network and desktop security
- Types of sensitive information
  - Risk assessments
  - Security system design
  - Access authorizations
- Program management
  - Management commitment of resources
  - Personnel training
  - System testing and maintenance

Results of Malicious Use Risk Group Evaluation



LMUR Agent Example: *Mycobacterium leprae*

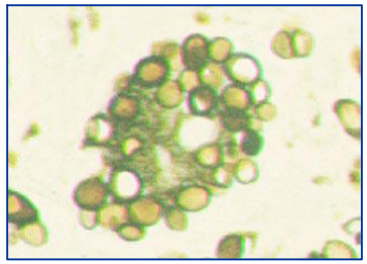
- **Consequences**
  - **Leprosy**
    - **Not highly virulent, most exposed people do not develop leprosy**
    - **Not highly contagious**
    - **Completely curable – majority recover without treatment**
- **Weaponization potential**
  - **Production is a significant challenge**
  - **Not environmentally hardy**
- **Assessment: low consequences and low weaponization potential**



Mycobacterium leprae

MMUR Agent Example: *Coccidioides immitis*

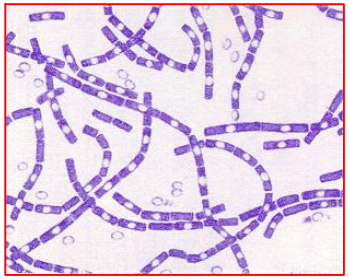
- **Consequences**
  - **Coccidioidomycosis (Valley fever)**
    - **Usually asymptomatic, 30-40% of infected become ill**
    - **Not contagious**
    - **5-10 out of every 1000 infected develop life-threatening infection**
- **Weaponization potential**
  - **Requires technical skills to handle**
  - **Easy to procure virulent strain (wide endemic area)**
  - **Easy to grow colonies and produce spores**
- **Assessment: low to moderate consequences and moderate weaponization potential**



Coccidioides immitis

HMUR Agent Example: *Bacillus anthracis*

- **Consequences**
  - **Pulmonary anthrax (via aerosolized anthrax)**
    - **High fatality rate**
    - **Not contagious, relatively high infectious dose required**
    - **Early diagnosis is difficult**
- **Weaponization potential**
  - **History of weaponization and terrorist use**
  - **Wide endemic area but many less virulent strains**
  - **Easy to grow colonies and produce spores**
  - **Very stable in environment and storage**
- **Assessment: moderate to high consequences and relatively high weaponization potential**



Bacillus anthracis

EMUR Agent Example: Variola major virus

- Consequences
  - Smallpox
    - High fatality rate
    - Contagious
    - Very few people vaccinated
- Weaponization potential
  - History of weaponization
  - Very stable in aerosol
  - Extremely difficult to obtain
- Assessment: high consequences and moderate weaponization potential

Variola major

Patient's leg covered in smallpox