A Conceptual Framework for Biosecurity Levels

Unified Science & Technology for Reducing Biological Threats & Countering Terrorism

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NNSA National Nuclear Security Administration

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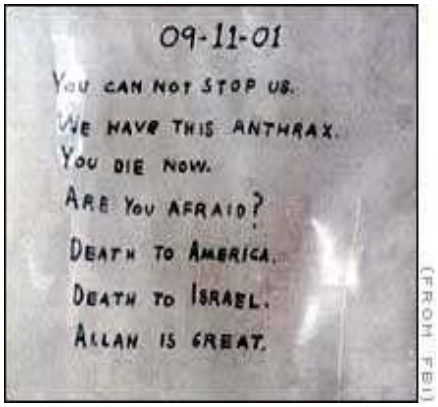
Need to Secure Biological Agents

- **Aim of biosecurity is to mitigate biological weapons (BW) threat at the source**
  - **Prevent terrorists or proliferant states from acquiring biological agents from government, commercial, or academic facilities**
- **Biosecurity only addresses a small part of the BW threat**
  - **Biosecurity cannot prevent BW terrorism or proliferation, or even diversion**
- **Biosecurity is an important element of comprehensive BW nonproliferation program**
  - **Biosecurity must be augmented by other strategies**



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Two Security Strategies

- **List-based**
  - **On list = regulated**
  - **Off list = unregulated**
  - **Examples include:**
    - **Biological agents**
    - **Export controlled materials**
- **Risk-based**
  - **Risk assessment used to determine appropriate levels of control**
  - **Examples include:**
    - **Categories of sensitive and classified information**
    - **Graded physical protection of nuclear materials**

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Current US Regulations are Problematic

- USA PATRIOT Act – US Public Law 107-55
  - Restricted Persons
- Bioterrorism Preparedness Act – US Public Law 10
  - 42 CFR 73 (Human)
  - 9 CFR 121 (Animal)
  - 7 CFR 331 (Plant)
- If a facility has one or more of 82 "Select Agents," then it is subject to the regulations (list-based regulations)
- Facilities choosing not to pursue research with Select Agents

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Existing Lists are not Adequate

- Select Agent lists
  - Based on threats to public and agricultural health (infectious disease risk)
- CDC Category A, B, and C agents
  - Excluded those agents that represent a threat to animal and plant health
  - Does not adequately reflect an evaluation of ease or difficulty of deploying agents as weapons
- Biosafety levels
  - Some agents used in BSL-2 facilities arguably are more attractive to adversaries, and should be better protected, than some BSL-3 agents

Lists apply an all or nothing approach to security but not all agents are equally attractive to an adversary.

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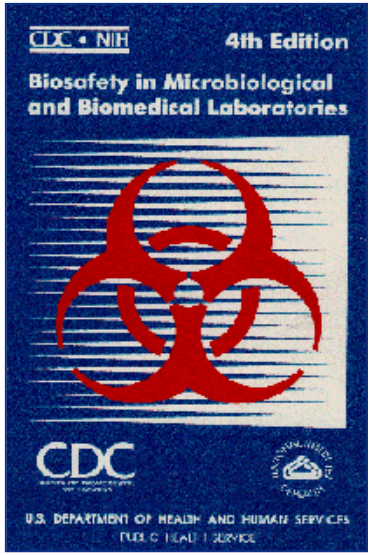
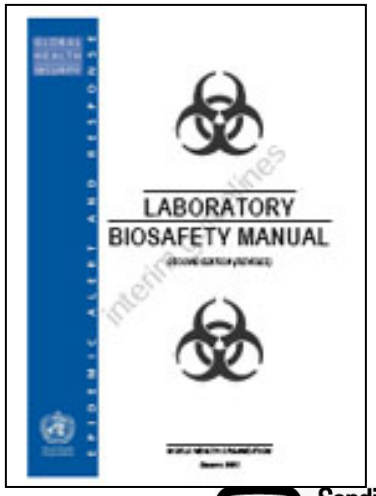
Biosafety as a Model

- Objective of biosafety is to reduce or eliminate accidental exposure to or release of potentially hazardous agents
- CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories” (BMBL) and WHO “Laboratory Biosafety Manual”
- Four Biosafety Levels that represent a graded application of practices and techniques, laboratory equipment, and facility design (“containment”) – based on agent safety risk assessments
- Biosafety now considered standard microbiological practice around the world





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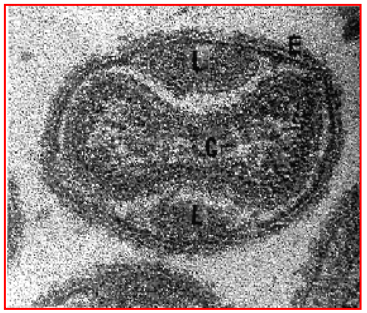
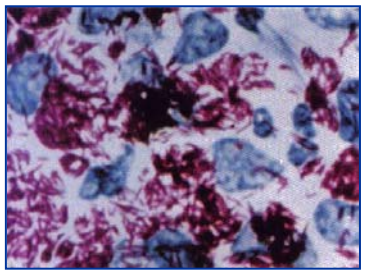
Biological Agent Security Risk Assessment

- All biological agents do not need same level of protection
- Agents should be placed in a Biosecurity Level based upon their risk of theft and malicious use as a biological weapon
  - Risk is a function of both probability and consequences
- Probability of use associated with the ease or difficulty involved in deploying the agent as a weapon
- Consequences of use associated with infectious disease risk

Bacillus anthracis



Variola major



Mycobacterium leprae

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Biological Agent Security Risk Levels

- **Low Risk Pathogens and Toxins (LRPT)**
  - Relatively difficult to deploy as a weapon, and/or
  - Use as a weapon would have few consequences
- **Moderate Risk Pathogens and Toxins (MRPT)**
  - Relatively difficult to deploy as a weapon, and
  - Use as a weapon would have localized consequences with low to moderate casualties and/or economic damage
- **High Risk Pathogens and Toxins (HRPT)**
  - Not particularly difficult to deploy as a weapon, and
  - Use as a weapon could have national or international consequences, causing moderate to high casualties and/or economic damage
- **Extreme Risk Pathogens and Toxins (ERPT)**
  - Would normally be classified as HRPT, except that they are not found in nature
  - Eradicated HRPT pathogens
  - Could include genetically engineered agents, if they were suspected of representing a HRPT candidate

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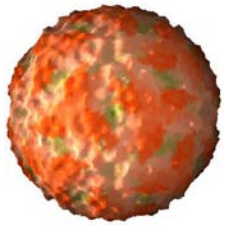
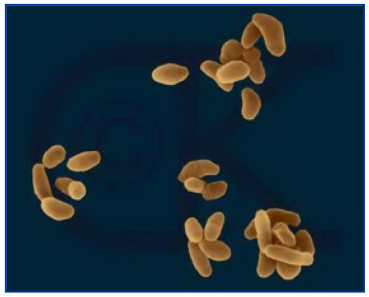
Impact of Biosecurity Levels

- Most biological agents would likely be LRPT
- Most current select agents would likely be MRPT
- Very few agents would be HRPT or ERPT

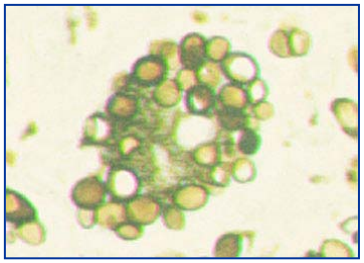


FMD virus

- Security associated with LRPT and MRPT would be achievable and cost-effective for the broad biological research community
- Limited numbers of facilities would work at HRPT or ERPT security levels, needing more costly security measures



Francisella tularensis



Coccidioides immitis

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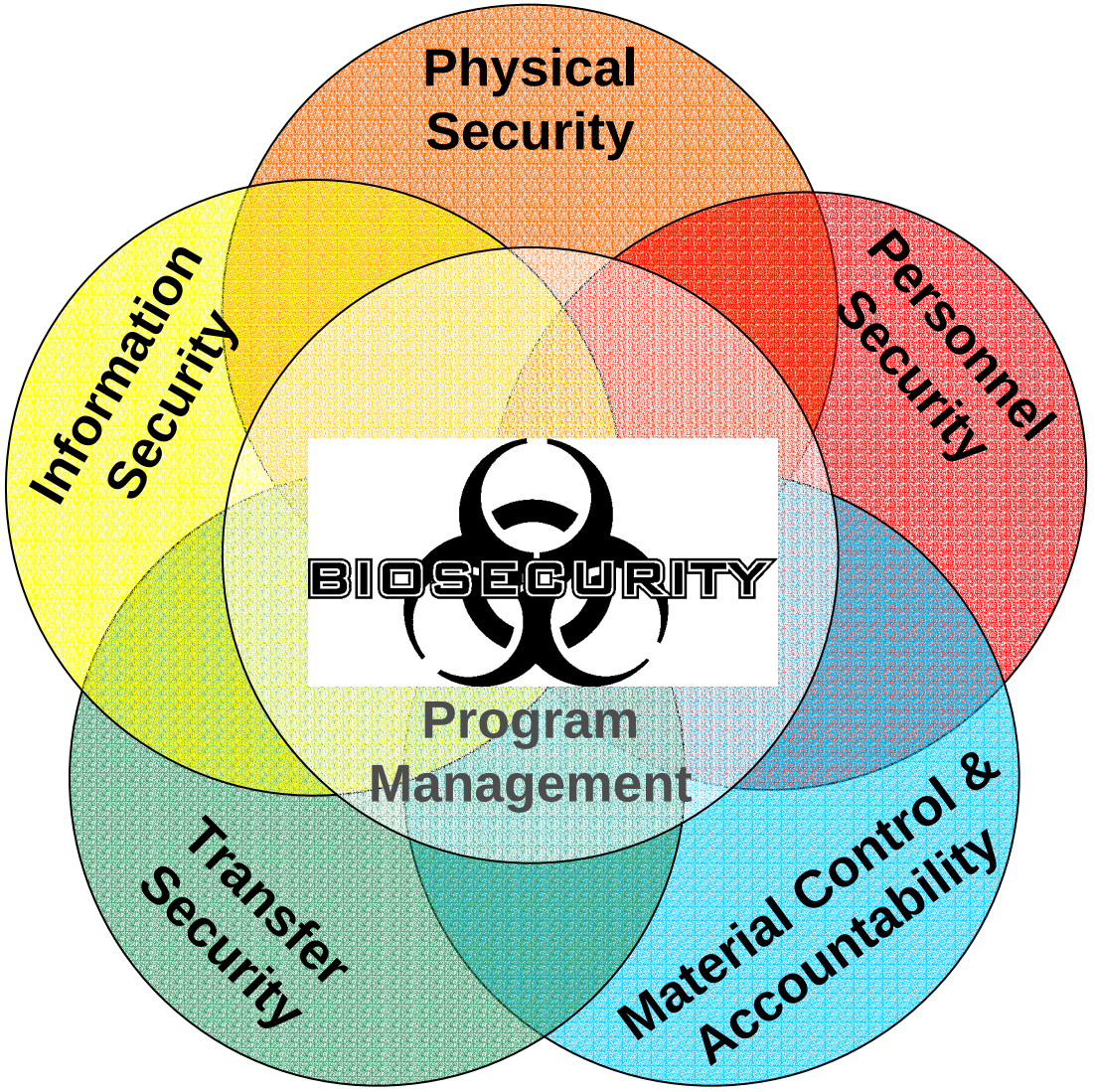
Components of Biosecurity



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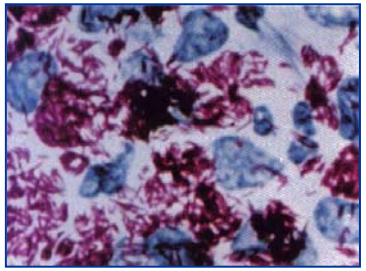
LRPT Agent Example: *Mycobacterium leprae*

- **Consequences:**
  - **Leprosy**
    - **Not highly virulent, most exposed people do not develop leprosy**
    - **Not highly contagious**
    - **Completely curable – majority recover without treatment**

- **Probability:**
  - **Production is a significant challenge**
  - **Not environmentally hardy**



Mycobacterium leprae

- **Conclusion: low consequence & low probability**

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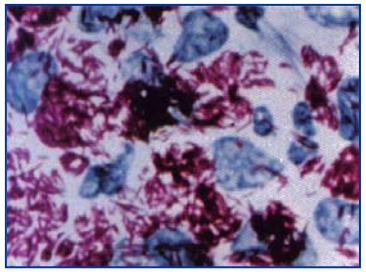
Low Risk Security Level

- Doors on unattended laboratories should be locked
- Principal Investigator should be aware of work and individuals in his/her lab
- Laboratory notebooks should document the stocks and use of agents



Mycobacterium leprae

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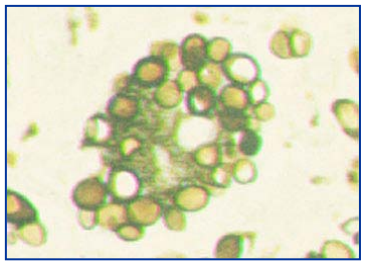
MRPT Agent Example: *Coccidioides immitis*

- **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**



Coccidioides immitis

- **Probability:**
  - **Requires technical skills to handle**
  - **Easy to procure (wide endemic area)**
  - **Easy to grow colonies and produce spores**

- **Conclusion: low to moderate consequence & moderate probability**

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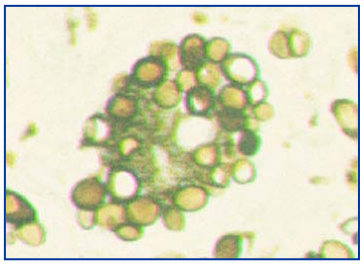
Moderate Risk Security Level

- Basic access controls (e.g. controlled keys) for areas where agents are used and stored
- Basic personnel suitability check should be completed for all those who enter the controlled area
- Materials should be accounted for and inventoried in databases



Coccidioides immitis

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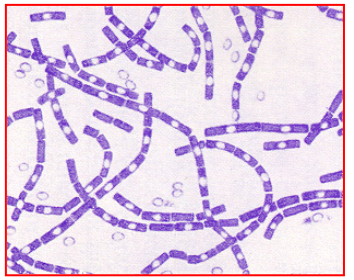
HRPT Agent Example: *Bacillus anthracis*

- **Consequences:**
  - **Pulmonary anthrax (via aerosolized anthrax)**
    - **High fatality rate**
    - **Not contagious, relatively high infectious dose required**
    - **Early diagnosis is difficult**



Bacillus anthracis

- **Probability:**
  - **History of weaponization and terrorist use**
  - **Wide endemic area but many less virulent strains**
  - **Easy to grow colonies and produce spores**

- **Conclusion: moderate to high consequence & relatively high probability**

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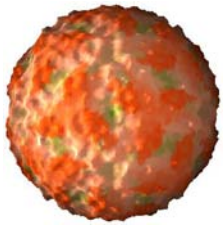
High Risk Security Levels

- Electronic access controls
- Personnel screening should include more comprehensive background investigations
- Accountability records should be maintained
- Material transfers should be pre-approved and require a continuous chain of custody
- Information about the security of these agents should be protected
- Biosecurity Officer should oversee the implementation of appropriate biosecurity measures



FMD virus

Yersinia pestis

Bacillus anthracis

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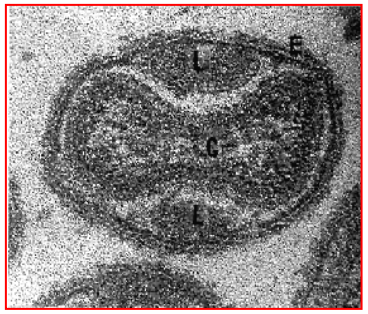
ERPT Agent Example: Variola major virus

- **Consequences:**
  - **Smallpox**
    - **High fatality rate**
    - **Contagious**
    - **Very few people vaccinated**



Variola major

- **Probability:**
  - **History of weaponization**
  - **Very stable in aerosol**
  - **Extremely difficult to obtain**

Patient's leg covered in smallpox

- **Conclusion: high consequence & moderate probability**

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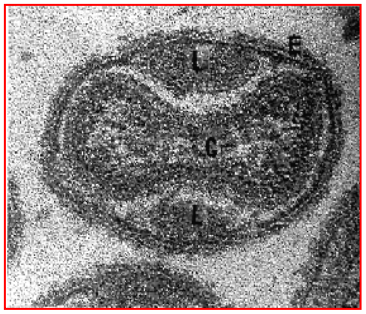
Extreme Risk Security Level

- Two- or three-level electronic access controls
- In-depth personnel suitability background checks
- Accountability records should be maintained
- Two authorized individuals should be required for access to stocks
- Material transfers should be pre-approved and require a continuous chain of custody
- Information about the security of these agents should be protected
- Local guard force should be able to respond to intrusions
- Biosecurity Officer should oversee the implementation of appropriate biosecurity measures



Variola major

Patient's leg covered in smallpox

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Summary

- **Control of certain biological materials is necessary, but *how* that is achieved must be carefully considered and implemented**

- **Graded risk-based approach helps direct scarce security resources to those agents that present a true weapons risk**

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