



Risk Assessment

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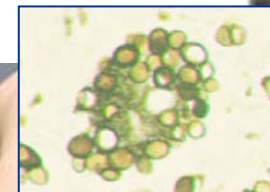
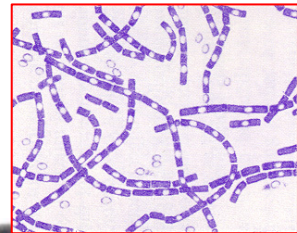
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company, for the United States Department of Energy's National Nuclear Security Administration under contract DE-AC04-94AL85000.





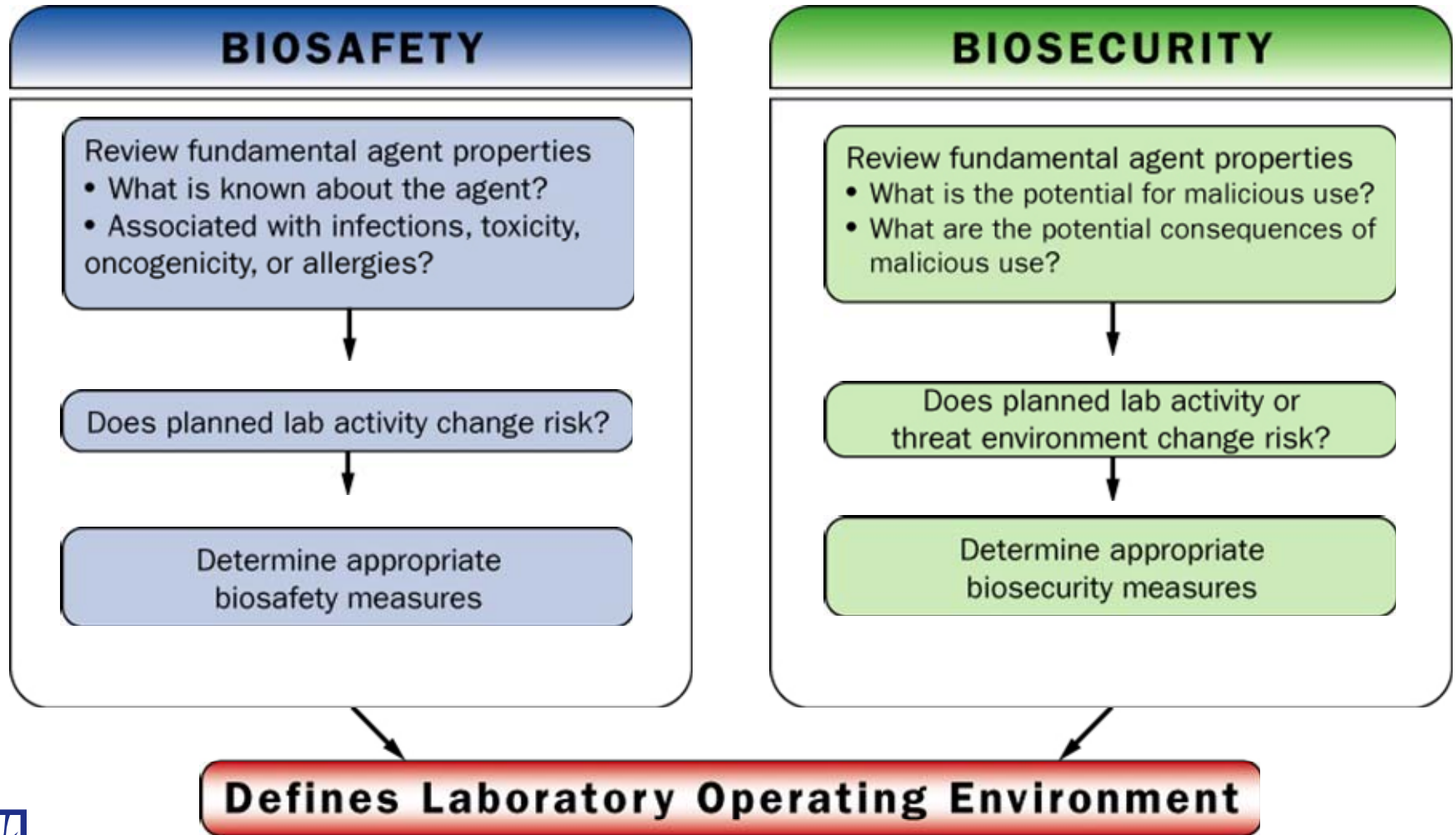
Risk

- **Is a function of the likelihood an adverse event will occur**
 - Risk = Potential * Consequences
- **Laboratory work with pathogens will always involve some level of safety and security risk**
 - Distinguish between “acceptable” and “unacceptable” risks
 - Cannot protect against every conceivable adverse event
- **Resources for risk mitigation are not infinite**
 - Existing resources should be used efficiently





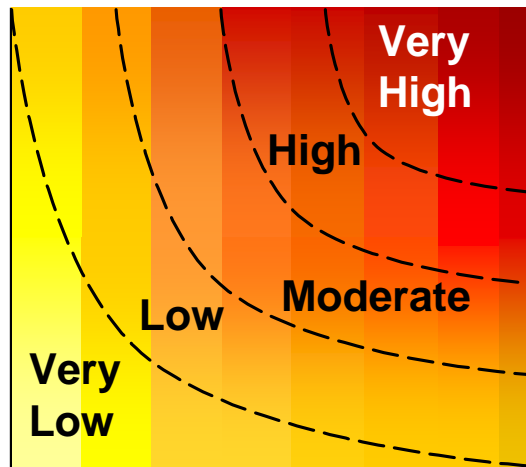
Risk Assessment: Integrated Biosafety and Biosecurity





Risk Assessment

- **Biosafety Risk** is the consequences of infection of a given agent to individuals within the laboratory or the community outside the laboratory, inclusive of humans and animals (domestic, agricultural, and wildlife), and the potential of infection by an infectious route.
- **Biosecurity Risk** is the consequences of a given agent to the community (inclusive of humans and animals) of a malicious release and the potential of the given agent to be acquired from a specific laboratory.



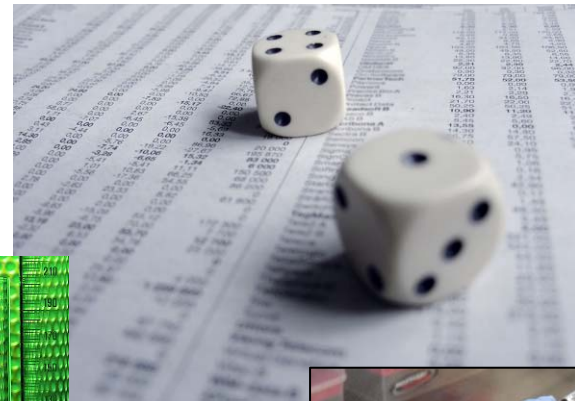
● Protect against unacceptable risk scenarios

● Develop incident response plans for acceptable risk scenarios



Risk Assessment

- **Enables the professional (e.g. biosafety officer, responsible official) to:**
 - Become familiar with the proposed work activities (procedures, equipment, personnel)
 - Be a knowledgeable and credible partner with the investigator to develop a safe and secure environment for the work
- **Review all activities associated with infectious materials**
 - Proposed work activities
 - Personnel
 - Storage
 - Transfer and transport
 - Destruction





Risk Perception in Laboratories

Biosafety risks: laboratory-acquired infections

- **History of lab-acquired infections**
 - Often attributed to carelessness or poor technique
 - Relatively few cases can be attributed to direct accident (mouth pipetting and sharps injuries)
 - Exposure to airborne pathogens generally presumed to be most plausible cause
 - Brucellosis is most common
- **Sporadic infections in community as a result**
 - 1973 and 1978—England had 3 secondary cases of smallpox
 - 1950—2 cases of Q fever in household of scientist
 - 1990—1 documented case of Monkey B virus from animal handler to wife

Biosecurity risks: laboratories as sources of material for malicious use

- **Bioterrorism has emerged as a threat to international security**
 - 1984 Rajneeshee religious cult attacks
 - 1990s Aum Shinrikyo attempts
 - 2001 Anthrax attacks in the US
- **Examples of illicit acquisition**
 - 1990s—Aum Shinrikyo ordered *Clostridium botulinum* from a pharmaceutical company
 - 1995—Larry Wayne Harris, a white-supremacist, ordered 3 vials of *Yersinia pestis* from the ATCC
 - 1995—Laboratory technician Diane Thompson removed *Shigella dysenteriae* Type 2 from hospital's collection and infected co-workers

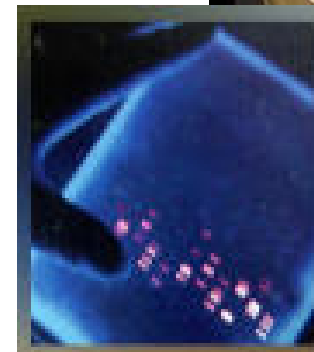
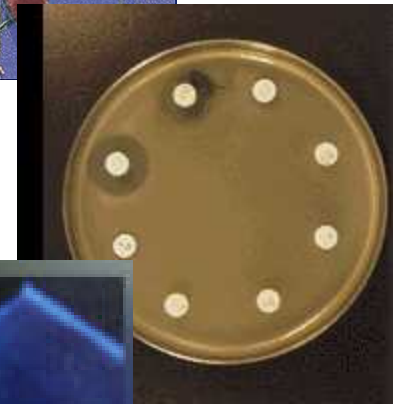


Biosafety Risk Assessment

- 1. Characterize biological agent hazards and laboratory activities**
 - a. Evaluate pathogens and toxins at facility (agent assessment)
 - b. Evaluate laboratory procedure hazards

- 2. Evaluate scenarios (potential problems)**
 - a. Create scenarios consisting of specific agents and specific laboratory procedures
 - b. Determine how the various adverse scenarios could occur (gap assessment)

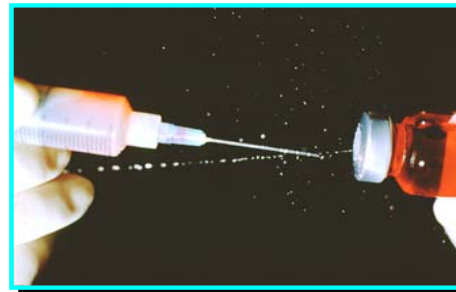
- 3. Characterize the risk**
 - a. Evaluate potential for and consequences of each scenario
 - b. Determine acceptable and unacceptable risks; develop risk statement





Biosafety Risk Assessment

- **Procedure Hazards**
 - Lab vs. field studies
 - Animal studies?
 - Procedures
 - Does planned experiment have the potential to generate aerosols?
 - Equipment
 - Needles, Centrifuges, Homogenizers, Pipettes
- **Other**
 - Deficiencies in host defenses
 - Pre-existing medical conditions
 - Reproductive hazards
 - Pregnancy, teratogens, mutagens
 - Allergies
 - Foreign proteins, vaccine constituents, antimicrobial therapies
 - Immunization status
 - Behavioral elements
 - Education, training, experience, motivation, attentiveness





Biosafety Risk Assessment: Safety Risk Groups



WORLD HEALTH ORGANIZATION

- **Risk Group 1**

- No or low individual and community risk
- Unlikely to cause human or animal disease

- **Risk Group 2**

- Moderate individual risk, low community risk
- Can cause disease but unlikely to be a serious hazard. Lab exposures may cause serious infection, but effective treatment and preventative measures are available and risk of spread of infection is limited



- **Risk Group 3**

- High individual risk, low community risk
- Usually causes serious human or animal disease but does not ordinarily spread. Effective treatment and preventative measures are available.

- **Risk Group 4**

- High individual and community risk
- Usually causes serious human or animal disease and can be readily transmitted. Effective treatment and preventative measures are not usually available





Biosafety Risk Assessment: Elements That May Modify Risk

- **Are their host factors that change the risk?**
 - Deficiencies in host defenses
 - **Pre-existing medical conditions – for example:**
 - Asplenia, eczema
 - Reproductive hazards
 - **Pregnancy, teratogens, mutagens – for example:**
 - Rubella, Toxoplasma, Chlamydia
 - Allergies
 - **Foreign proteins, vaccine constituents, antimicrobial therapies – for example:**
 - Animal dander, egg proteins, latex
 - Immunization status
 - **Immunization against workplace pathogens but ...**
 - Not always the answer (vaccine efficacy, safety issues)
 - Behavioral elements
 - **Education, training, experience, motivation, attentiveness**

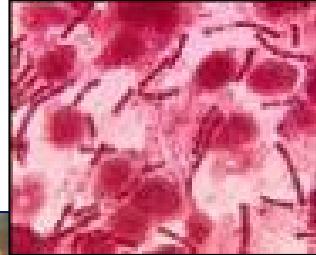


Biosecurity Risk Assessment

- 1. Characterize assets (pathogens and toxins) and threats**
 - a. Evaluate pathogens and toxins at facility (asset assessment)
 - b. Evaluate adversaries who might attempt to steal those pathogens or toxins (threat assessment)

- 2. Evaluate scenarios**
 - a. Create scenarios consisting of “specific adversaries” attempting to steal and misuse a specific biological agent
 - b. Determine how the various scenarios could be perpetrated (vulnerability assessment)

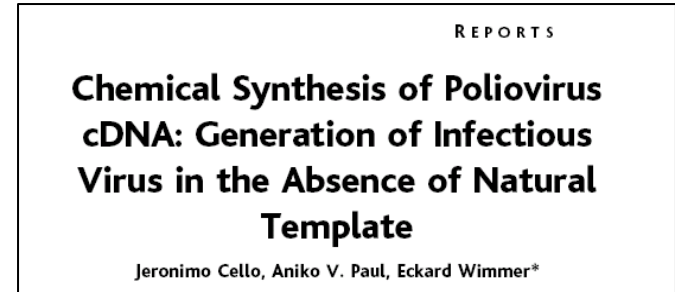
- 3. Characterize the risk**
 - a. Evaluate threat potential and consequences of each scenario
 - b. Determine acceptable and unacceptable risks; develop risk statement



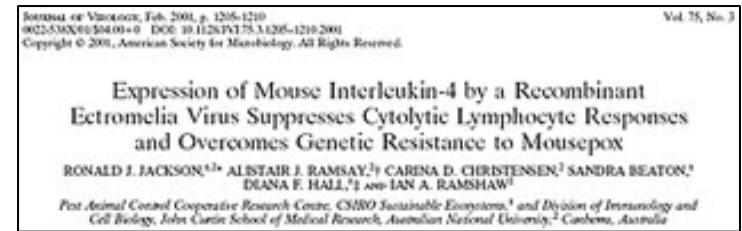


Biosecurity Risk Assessment: Malicious Use Risk Group Evaluation

- **Assess value of the agents from an adversary's perspective**
 - **Consequences**
 - **Population**
 - **Transmissibility**
 - **Mortality**
 - **Morbidity**
 - **Economic**
 - **Psychological**
 - **Potential for malicious use**
 - **Acquisition**
 - **Natural**
 - **Laboratory**
 - **Synthetic biology**
 - **Production**
 - **R&D**
 - **Covert production**
 - **Ease of storage**
 - **Dissemination**
 - **Route of infection (e.g. aerosol, ingestion)**
 - **Environmental hardiness**



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Biosecurity Risk Assessment: Malicious Use Risk Groups

- **Nonpathogenic**
 - Malicious use would have insignificant or no consequences
- **Low**
 - Difficult to disseminate, and/or
 - Malicious use would have few consequences
- **Moderate**
 - Relatively difficult to disseminate, and
 - Malicious use would have localized consequences with low to moderate casualties and/or economic damage, and potentially cause pervasive anxiety
- **High**
 - Not particularly difficult to disseminate, and
 - Malicious use could have national or international consequences, causing moderate to high casualties and/or economic damage, and the potential to cause mass panic and significant social disruption
- **Extreme**
 - Would normally be classified as highly attractive, except that they are not found in nature (eradicated)
 - Could include genetically engineered agents, if they would otherwise be classified as highly attractive





Biosecurity Risk Assessment: Other Assets at Biological Facilities

- **Security Information or Systems**
 - May be targeted to facilitate gaining access to dangerous biological materials
- **Other Facility Assets**
 - May be targeted by political extremists, disgruntled employees, etc.
 - May include:
 - **High containment laboratories**
 - **Animals**



Biosecurity Risk Assessment: Elements That May Modify Risk

- **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

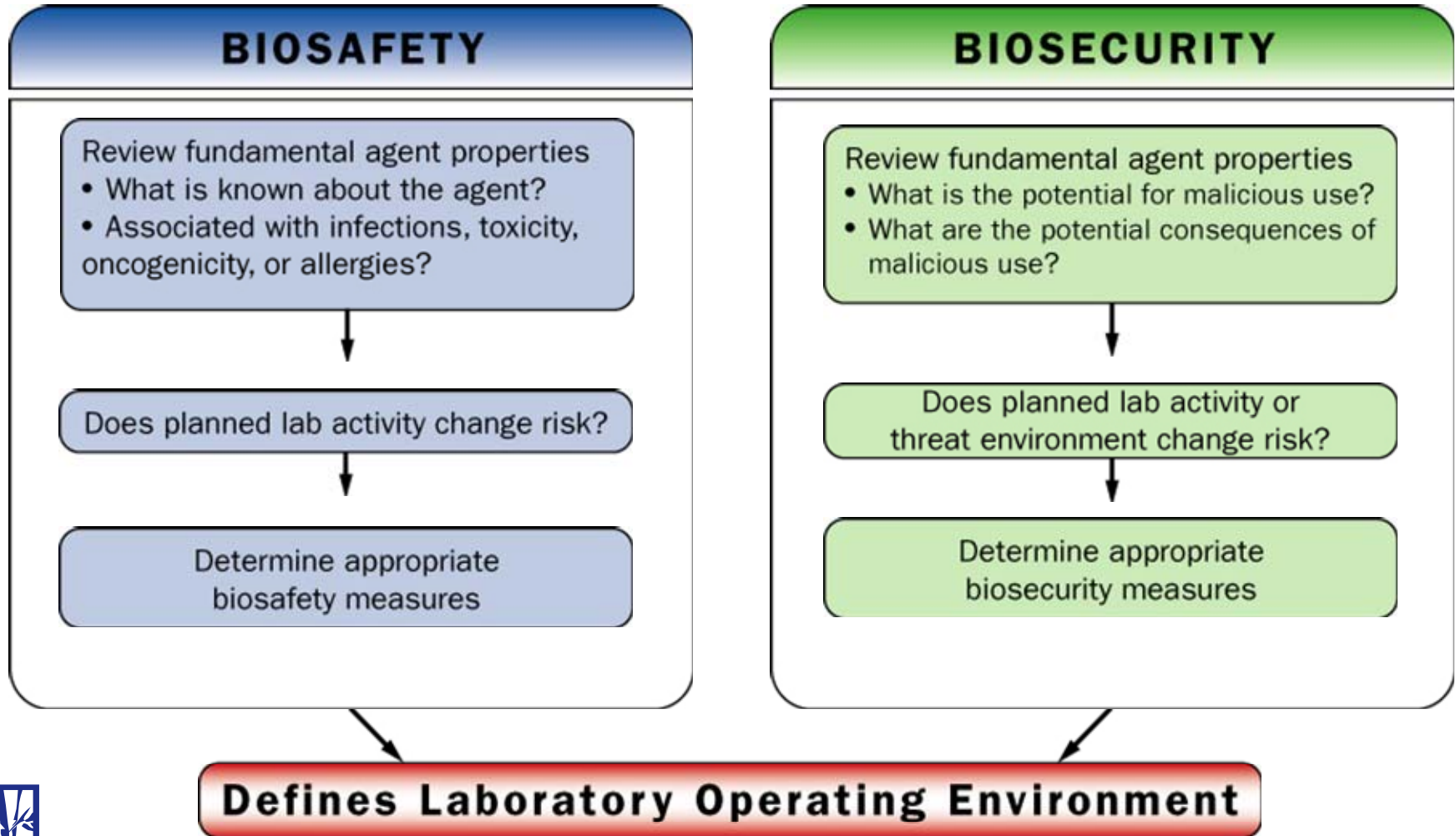
- **Outsiders**

- No authorized access
- Local law enforcement, site security, and intelligence community interviews





Integrated Biosafety and Biosecurity





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
 - Risk assessment is a fundamental resource allocation tool for making decisions about which risks need to be protected against
- **Parallels exist between safety and security risk assessment processes**
- **Risk assessment and risk decision are the critical foundations for the design of a laboratory biosafety and biosecurity program**

