International
BIOLOGICAL THREAT REDUCTION

Laboratory Biosecurity Risk Assessment and Management

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www.biosecurity.sandia.gov

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BIOSECURITY ENGAGEMENT PROGRAM

International
BIOLOGICAL THREAT REDUCTION

US Department of State
Biosecurity Engagement Program (BEP)

- **Committed to developing cooperative international programs that promote the safe, secure and responsible use of high-risk pathogens and toxins**

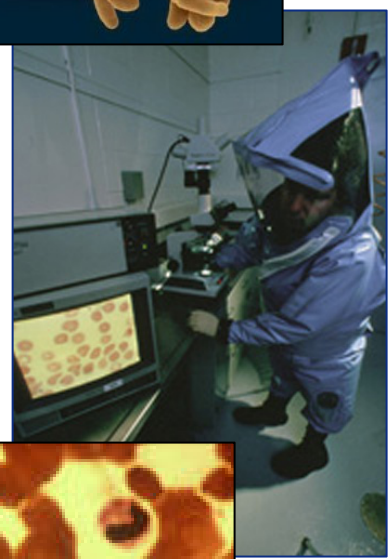
- **BEP working with legitimate bioscientists and law enforcement officials around the world to build relationships, share technical expertise, and promote good practices**
  - **Ensure safe and secure use of dangerous biological agents**
  - **Strengthen capacities to detect and control highly infectious disease**

BIOSECURITY ENGAGEMENT PROGRAM

www.BEPstate.net

Laboratory Biosafety and Biosecurity

- **Laboratory biosafety**
  - **Objective: reduce or eliminate accidental exposure to or release of potentially hazardous agents**
- **Laboratory biosecurity (pathogen security)**
  - **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**
  - **Laboratory biosecurity and biosafety should be integrated systems that avoid compromising necessary infectious disease research and diagnostics**



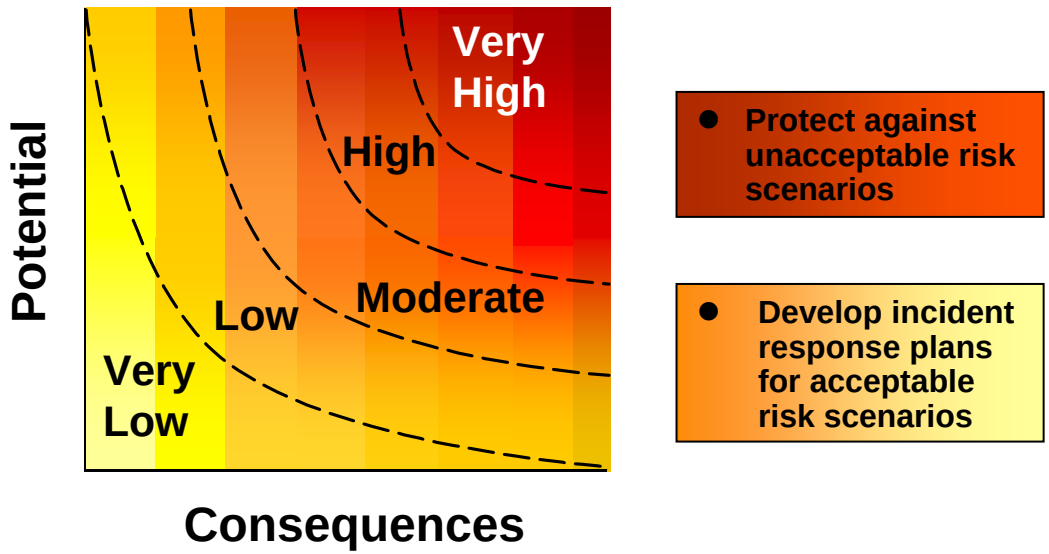
Strengthening Biological Risk Management

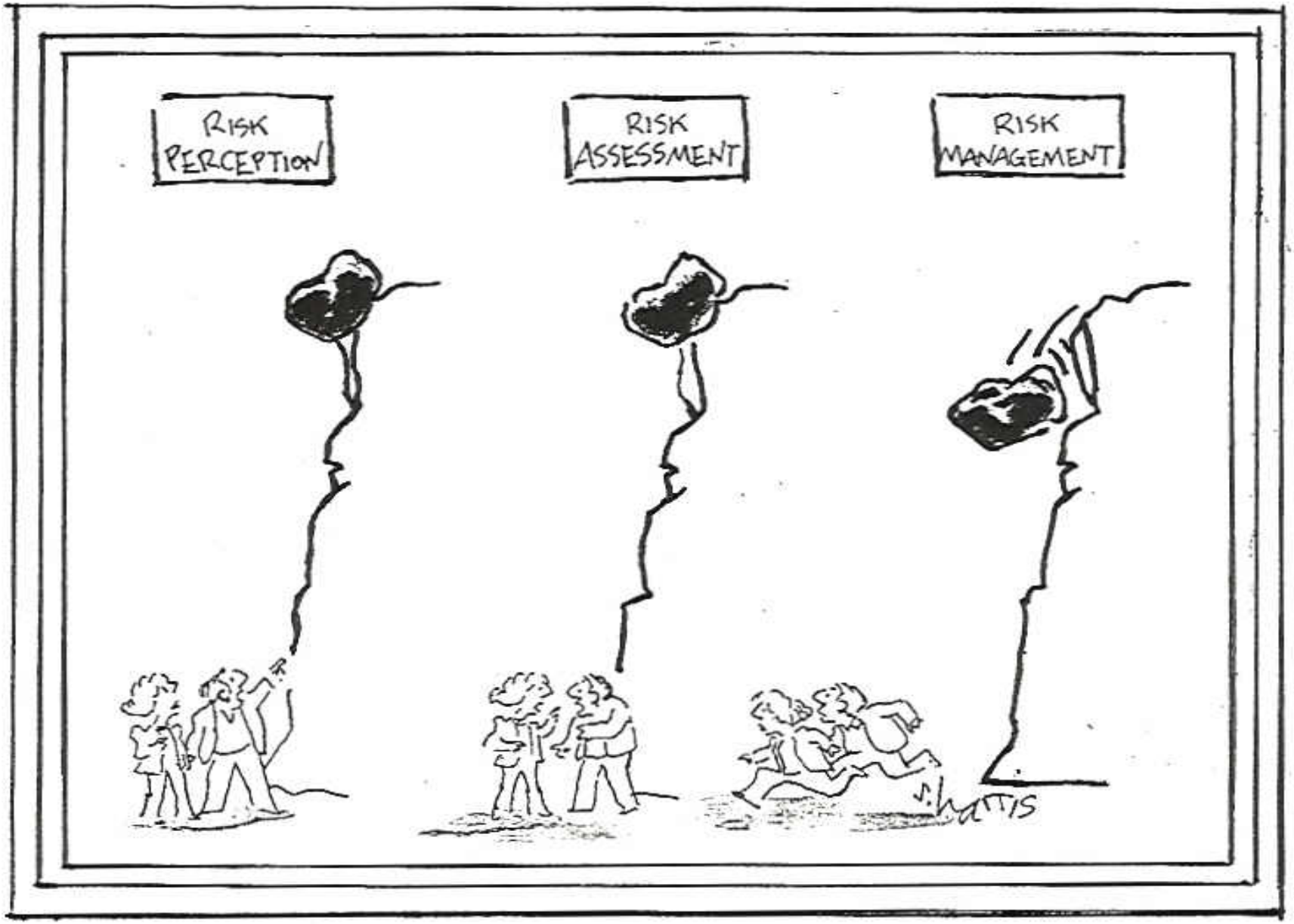
Vision for Integrated BioRisk Management:

- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs and establish accountability through development of Country "report cards"

Biosecurity and Biosafety Based on Risk Management

- Laboratory work with pathogens will always involve some level of safety and security risk
- Most biological materials occur in nature and can be isolated from nature
- Critical not to compromise legitimate bioscience operations
  - Systems should be designed to address unique situations
- Resources are not infinite; existing resources should be used efficiently
- Management must distinguish between “acceptable” and “unacceptable” risks
  - Ensure that protection and the cost is proportional to the risk




RISK PERCEPTION
RISK ASSESSMENT
RISK MANAGEMENT

Risk Perception in Laboratories

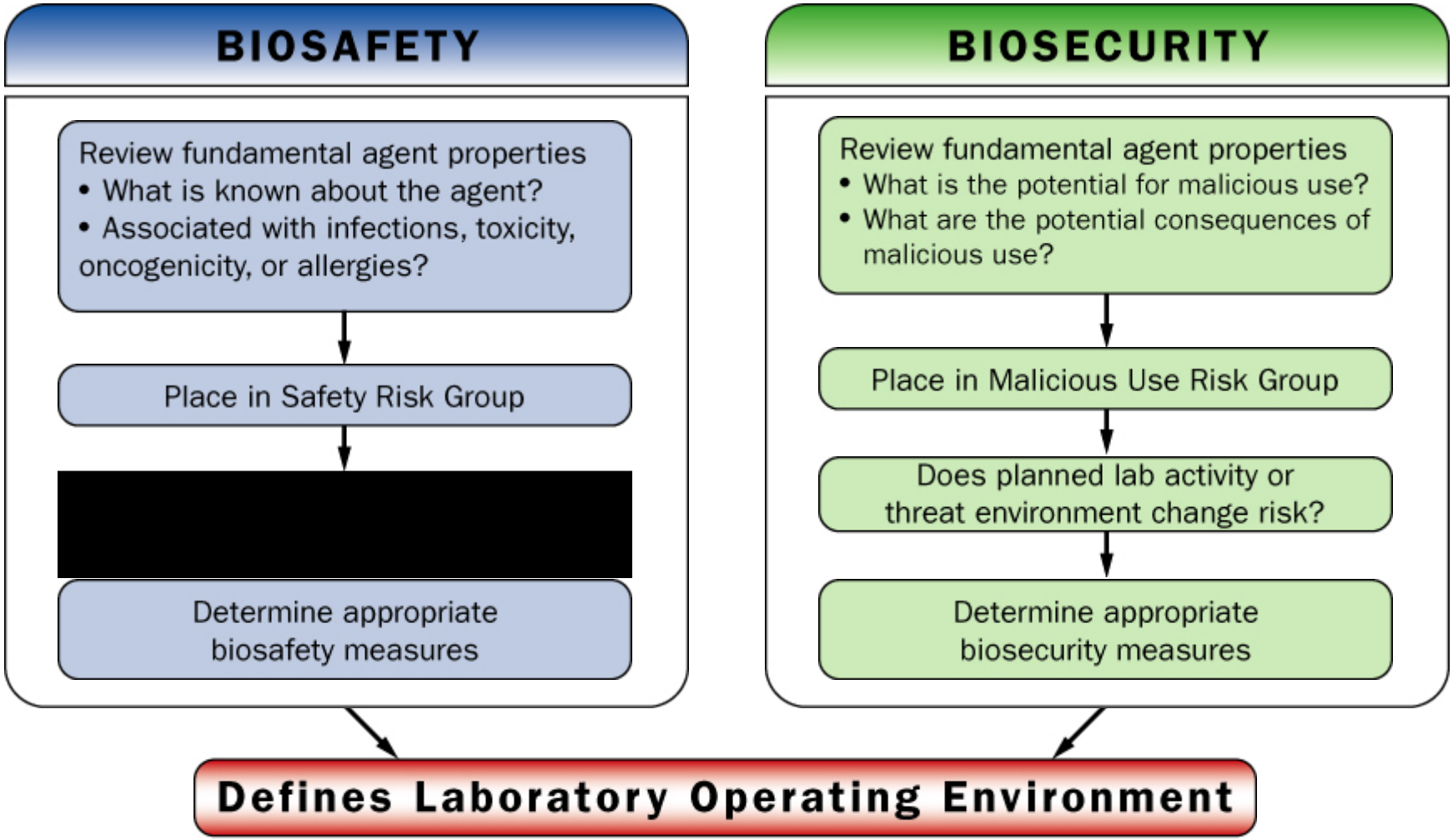
Biosafety risks: laboratories as source of accidental infection

- 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
  - 1950—2 cases of Q fever in household of scientist
  - 1973 and 1978—England had 3 secondary cases of smallpox
  - 1990—1 documented case of Monkey B virus from animal handler to wife
  - 2003—9 cases of SARS, including 3 generations

Biosecurity risks: laboratories as source of material for malicious use

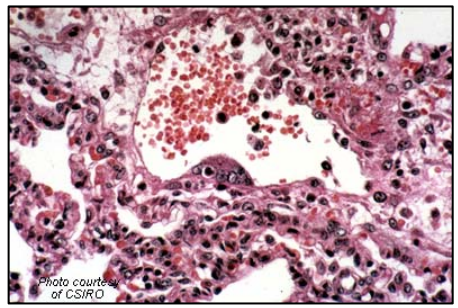
- Bioterrorism has emerged as a threat to international security
  - 1984 Rajneeshee religious cult attacks in the US
  - 1990s Aum Shinrikyo attempts in Japan
  - 2001 Anthrax attacks in the US
- Examples of illicit acquisition
  - 1990s—Aum Shinrikyo ordered *Clostridium botulinum* from a pharmaceutical 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

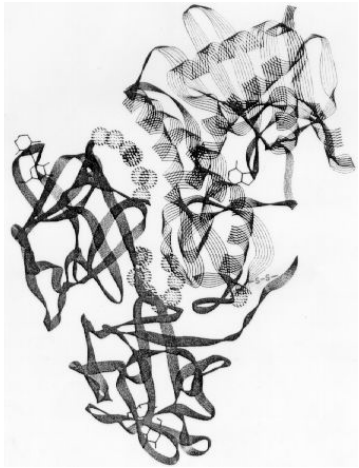
Risk Assessment: Integrated Biosafety and Biosecurity



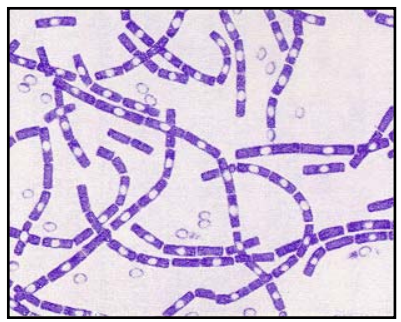
Biosafety Risk Assessment: Safety Risk Group Evaluation

- **What is known about the agent?**
  - **Pathogenicity – ability to cause disease**
  - **Virulence – degree of pathogenicity**
  - **Host range – restricted or broad, human, animals, plants**
  - **Communicability – are there reports of epidemics? Of laboratory infections?**
  - **Transmission – means (e.g. direct contact, vector borne) and routes (e.g. ingestion, inhalation)**
  - **Environmental stability – e.g. resistance to disinfection**





- **Additional agent factors**
  - **Toxicity**
  - **Is the agent associated with cancer (e.g. Hepatitis B virus)?**
  - **Does the agent or by-products induce allergic reactions (e.g. Penicillin)?**



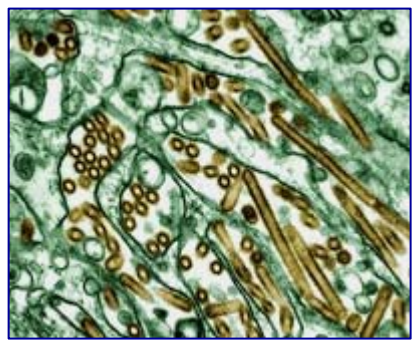
Biosafety Risk Assessment: Safety Risk Groups

- **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. Effective treatment and preventive measures are available.

WORLD HEALTH ORGANIZATION

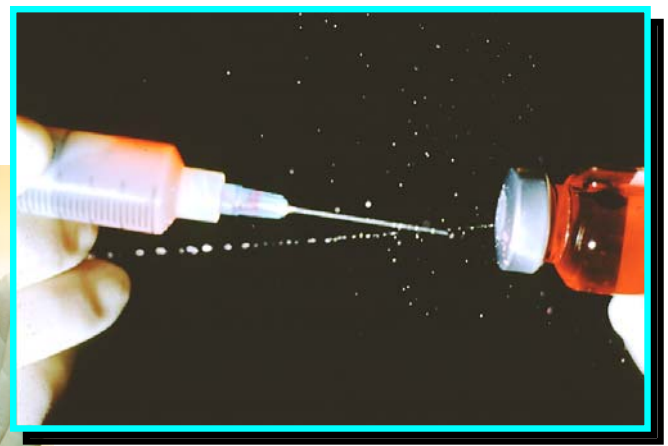
- **Risk Group 3**
  - High individual risk, low community risk
  - Usually causes serious human or animal disease but does not ordinarily spread. Effective treatment and preventive measures are available.



- **Risk Group 4**
  - High individual and community risk
  - Usually causes serious human or animal disease and can be readily transmitted. Effective treatment and preventive measures are not usually available.

Biosafety Risk Assessment: Elements That May Modify Risk

- Risk Group is the starting point of the risk assessment
- Does the environment or activity change the risk?
  - Lab vs. field studies
  - Animal studies?
  - Procedures
    - Does planned experiment have the potential to generate aerosols?
  - Equipment
    - Needles
    - Centrifuges
    - Homogenizers
    - Pipettes



Biosecurity Risk Assessment: 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

JOURNAL OF VIROLOGY, Feb. 2001, p. 1205–1210 Vol. 75, No. 3
0022-538X/01/$04.00+0 DOI: 10.1128/JVI.75.3.1205–1210.2001
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Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox

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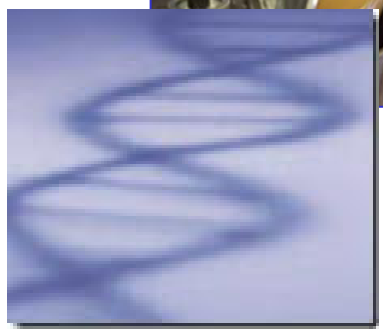
Biosecurity Risk Assessment: Malicious Use Risk Groups

- **Nonpathogenic**
  - Malicious use would have insignificant or no consequences
- **Low Malicious Use Risk (LMUR)**
  - Difficult to disseminate, and/or
  - Malicious use would have few consequences
- **Moderate Malicious Use Risk (MMUR)**
  - 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 Malicious Use Risk (HMUR)**
  - 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 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

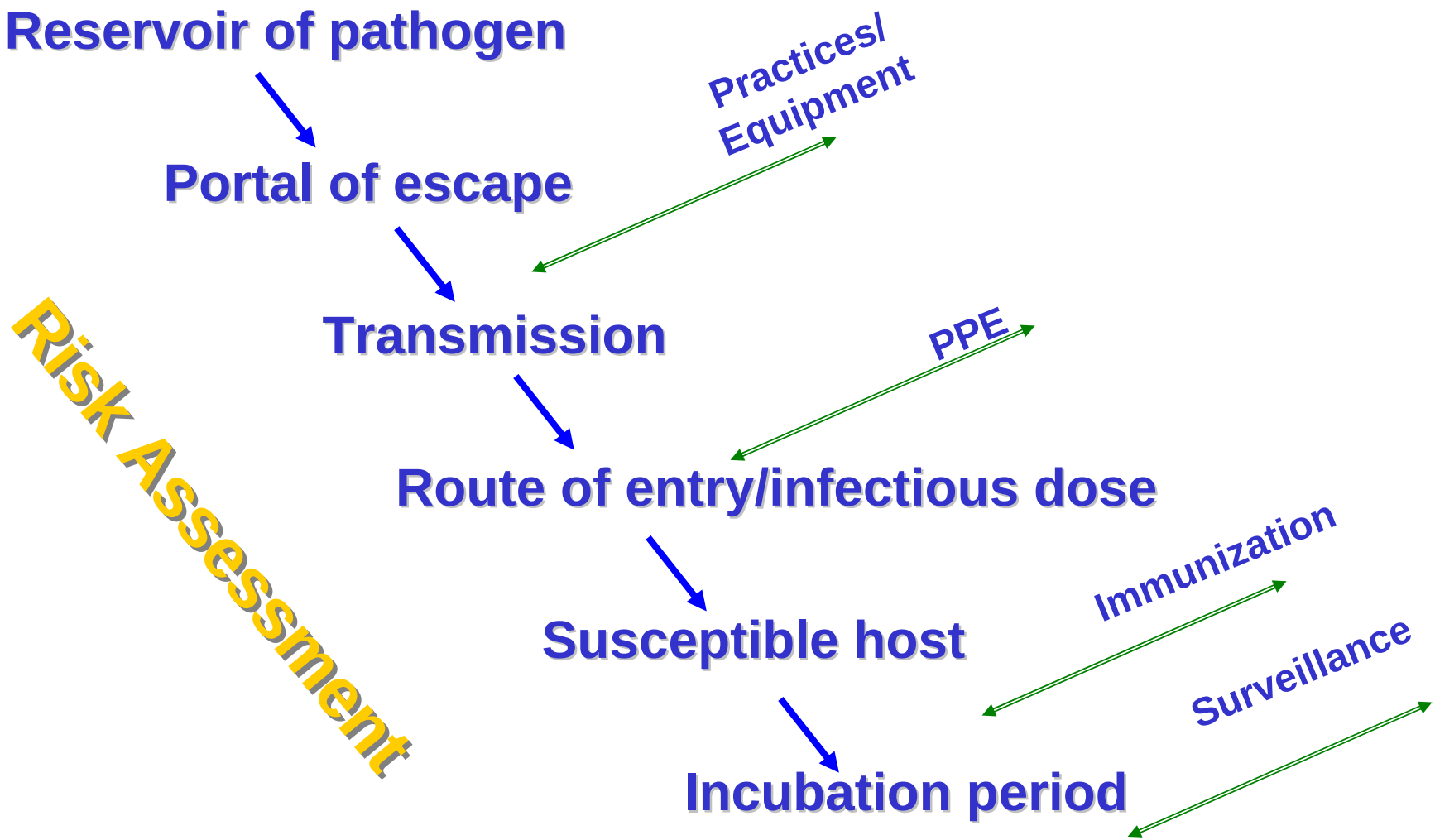
Biosecurity Risk Assessment: Elements That May Modify Risk

- **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**

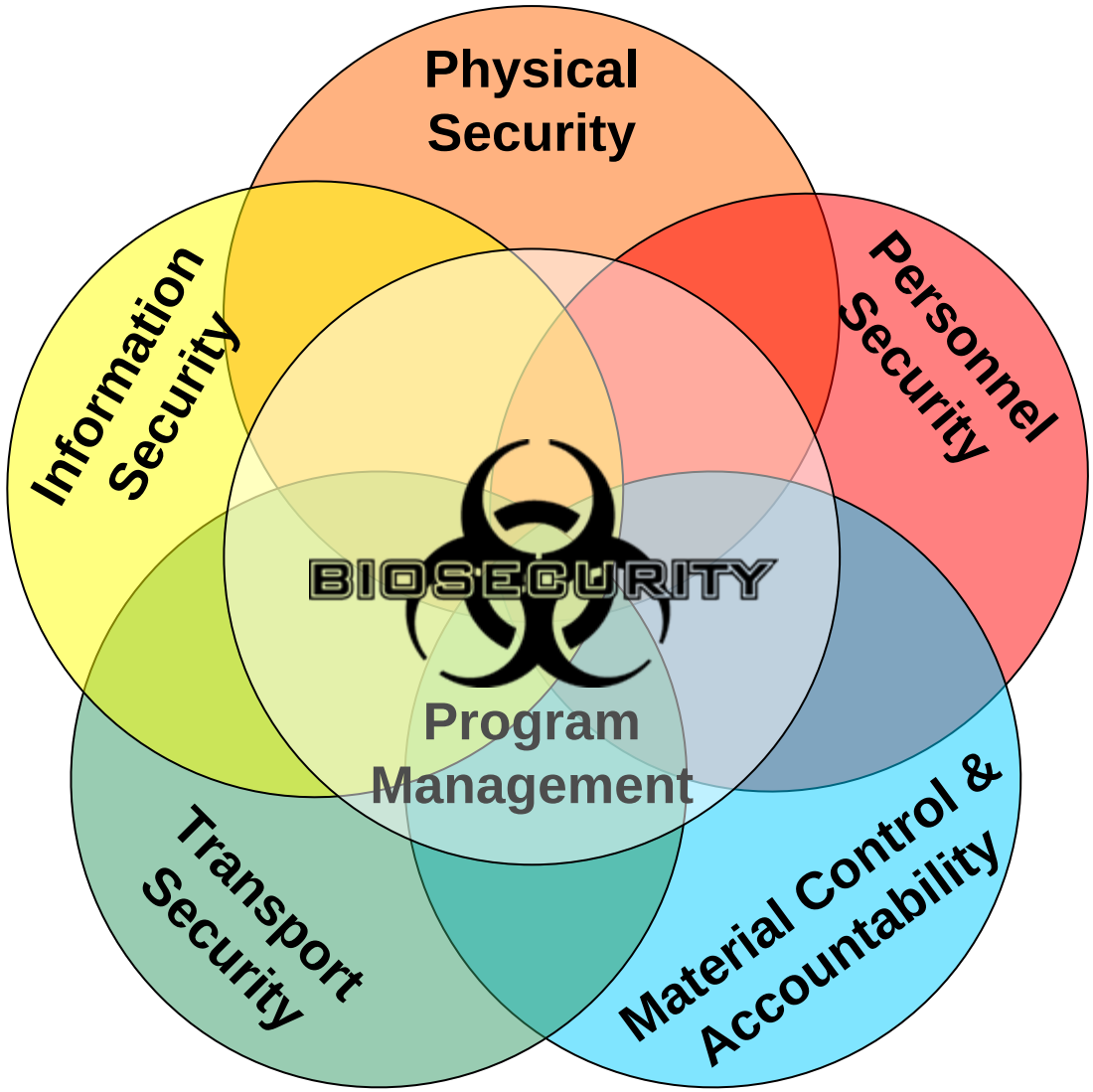


- **Consider threat environment**
  - **Adversary classes:**
    - **Terrorist**
    - **Extremist**
    - **Criminal**
  - **Insiders**
    - **Authorized access to the facility, dangerous pathogens, and/or restricted information**
  - **Outsiders**
    - **No authorized access**

Risk Management: Implementation of Biosafety



Risk Management:
Implementation of Biosecurity (Pathogen Security)



Potential Conflicts between Biosafety and Biosecurity

- Emergency alarm – electronic locks
  - Safety – doors fail open
  - Security – doors fail secure
- Emergency egress
  - Safety – move people into the safest location as quickly as possible
  - Security – prevent people from moving into or through restricted areas
- Emergency response
  - Safety – provide emergency responders with locations of hazards and responsible individuals
  - Security – control distribution of sensitive information only to those with a need to know
- Signage
  - Safety – identify hazardous substances and responsible parties
  - Security – avoid identification of target materials or individuals with access
- Keys required inside laboratory areas
  - Safety – contamination concern
  - Security – multiple layers of access

Conclusions

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