International
BIOLOGICAL THREAT REDUCTION

BIOSECURITY ENGAGEMENT PROGRAM

Introduction to Biosecurity and Biosecurity Risk Assessment

International Biological Threat Reduction Department
Sandia National Laboratories
September 19, 2007

Overview of the Principles of Laboratory Biosecurity
V Congresso Brasileiro de Biossegurança

www.biosecurity.sandia.gov

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NNSA National Nuclear Security Administration

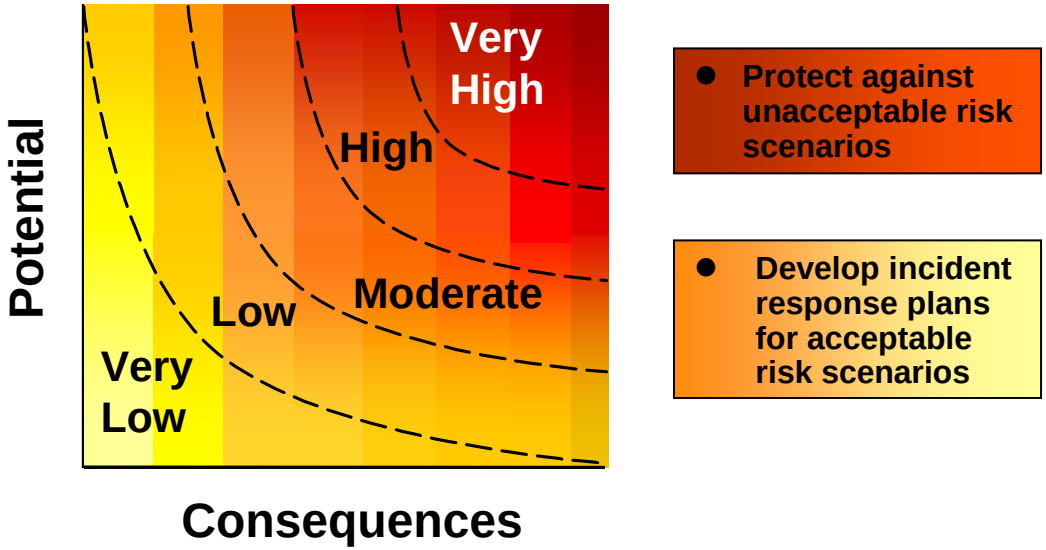
Sandia National Laboratories

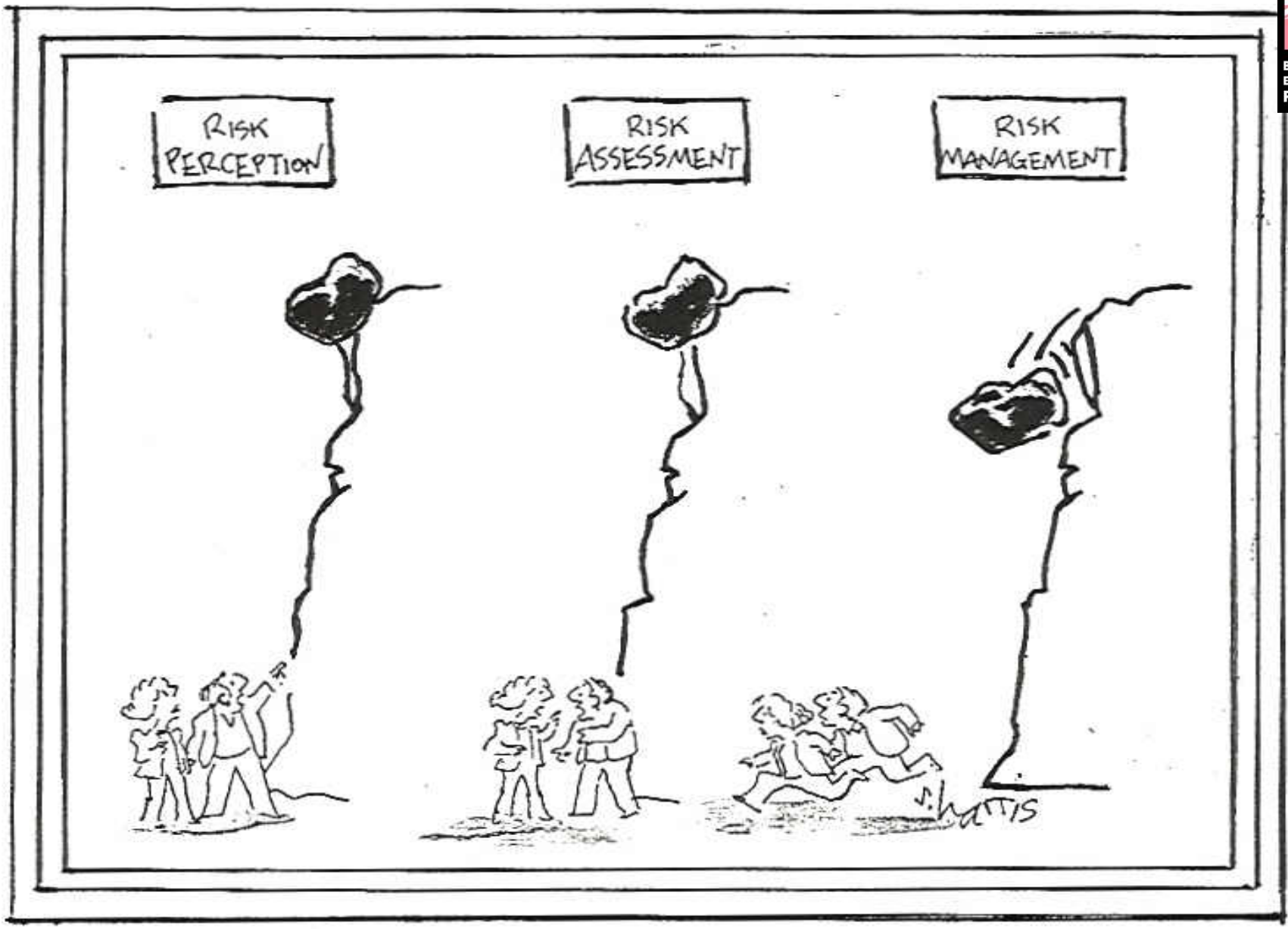
Risk

- Is a function of the likelihood an adverse event will occur
- 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

Biosecurity Based on Risk Management

- Is a function of the likelihood an adverse event will occur
  - Risk = Potential * Consequences
- Cannot eliminate risk
  - Management must determine which risks are unacceptable (risk decision)
- Risk assessment is key to resource allocation
  - Graded protection
  - Existing resources should be used efficiently
  - Ensure that protection and the cost is proportional to the risk




RISK PERCEPTION
RISK ASSESSMENT
RISK MANAGEMENT
V. HATTIS

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
  - SARS—including 3 generations (9 cases)

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

Bioterrorism, Biocrimes and the Medical Profession

- **Tubocurarine: 1966**
  - **Dr. Mario Jascalevich, New Jersey doctor, accused of poisoning 5 patients with this plant-derived toxin**
- **Curacit: May 1977 – November 1980**
  - **Arnfinn Nesset, nursing home operator in Norway, killed 27 residents at a nursing home with curacit**
- **HIV: 1987 – 1990**
  - **Dr. David Acer, Florida dentist, infects 6 patients with HIV,**
  - **Unclear if deliberate act**
- **Ricin: August 1995**
  - **Dr. Ray W. Mettetal, Jr., a neurologist in Virginia, was found in possession of ricin after arrest on another issue**
  - **Debora Green, a physician, convicted of trying to murder her estranged husband with ricin**

Illustrative Case: Dr. Mitsuru Suzuki, Dec 1964 – Mar 1966

- Location: Japan
- Perpetrator: Dr. Mitsuru Suzuki
  - Physician
  - Training in bacteriology
- Objective: Revenge due to deep antagonism to what he perceived as a prevailing seniority system
- Organisms:
  - *Shigella dysenteriae* and *Salmonella typhi*:
- Dissemination:
  - Sponge cake, other food sources
  - Later implicated in 200 – 400 illnesses
    - 4 deaths
- Official investigation started after anonymous tip to Ministry of Health and Welfare
- Outcome:
  - Charged, but was not convicted of any deaths

Illustrative Case: Diane Thompson, October 1996

- **Location: Hospital in Dallas, TX**
- **Perpetrator: Diane Thompson**
  - **Clinical laboratory technician**
- **Objective: Unclear, possibly revenge against former boyfriend and cover-up by infecting co-workers**
- **Organism: *Shigella dysenteriae* Type 2**
  - **Acquired from clinical laboratory**
- **Dissemination**
  - **Contaminated pastries in the office break room**
  - **Infected 12 of her coworkers**
- **Outcome**
  - **Arrested, convicted, 20 year sentence**

LTC Kay D Burkman
Officer Basic Course: Veterinary Corps Track
Food Security Risks
http://www-nehc.med.navy.mil/downloads/06Conference/EH/Food_Security_Risks_OBC_Sep05.ppt

Bioterrorism, Biocrimes and the Medical Profession (continued)

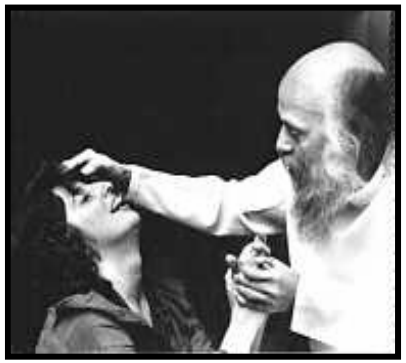
- **HIV: October 1998**
  - **Richard Schmidt, a gastroenterologist in Louisiana, convicted of attempted second degree murder for infecting nurse Janice Allen, with HIV by injecting her with blood from an AIDS patient**
- **HIV: January 1999**
  - **Brian T. Stewart, a phlebotomist, sentenced to life in prison for deliberately infecting his 11-month-old baby with HIV-infected blood to avoid child support payments**
- ***Mycobacterium tuberculosis*: June 1999**
  - **Physician reports theft of a vial**

References: Carus WS. 1998. Bioterrorism and Biocrimes: The Illicit Use of Biological Agents in the 20th Century. Washington (DC): Center for Counterproliferation Research, National Defense University; Mohtadi, H. and Murshid, A. 2006. A Global Chronology of Incidents of Chemical, Biological,Radioactive and Nuclear Attacks: 1950-2005, National Center for Food Protection and Defense.

Bioterrorism: Rajneeshees – August 1984

- Location: The Dalles, Oregon
- Perpetrator: Rajneesh Cult
- Objective: Gain control of the Wasco County Court by affecting the election
- Organism: *Salmonella typhimurium*
  - Purchased from commercial supplier
- Dissemination
  - Restaurant salad bars
  - 751 illnesses
- Early investigation by CDC suggested the event was a naturally occurring outbreak
- Cult member arrested on unrelated charge confessed involvement with the event

Bhagwan Shree Rajneesh



Bioterrorism: Aum Shinrikyo – 1990s

Aerosolization of Bacillus anthracis and botulinum toxin by Aum Shinrikyo

- Location: Tokyo, Japan
- Perpetrator: Aum Shinrikyo Cult
- Objective: Fulfill apocalyptic prophecy
- Organisms:
  - *Bacillus anthracis*
    - Vaccine strain
  - *Clostridium botulinum*
    - Environmental isolate
    - Avirulent strain
  - Ebola virus
    - Attempted to acquire from Zaire outbreak under guise of an "Humanitarian mission"
- Dissemination
  - Aerosolization in Tokyo
    - *B. anthracis*
    - Botulinum toxin
- Outcome:
  - Leader Asahara was convicted of criminal activity

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)

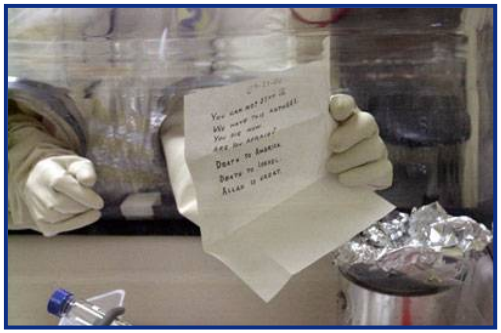
2. **Evaluate scenarios**
   a. Create scenarios consisting of specific adversary attempting to steal and misuse a specific biological agent
   b. Determine how the various scenarios could be perpetrated (vulnerability assessment)

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

Bioterrorism: Anthrax, October 2001

- Location: More than 60 sites in the US
- Perpetrator: Unknown
- Objective: Unknown
- Organism:
  - *Bacillus anthracis*
- Dissemination
  - 4-7 letters sent through postal system
  - 22 confirmed cases of anthrax
    - 11 Cutaneous
    - 11 Inhalational (5 Deaths)
- Outcome: Perpetrator not yet identified

"Amerithrax"



Foot and Mouth Disease (FMD), UK

- FMD outbreak confirmed August 3, 2007
- Preliminary analysis indicates that a nearby laboratory is the likely source
- Investigation into laboratory biosafety and biosecurity practices
  - Engineering controls
  - Management systems
  - Working practices
- Investigation into possible release points
  - Airborne
  - Waterborne
  - Human movement
    - Accidental or intentional release

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

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**

Asset Assessment

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

Biosecurity Risk Assessment: Malicious Use Risk Groups

- **Nonpathogenic**
  - Malicious use would have insignificant or no consequences
- **Low**
  - Difficult to deploy, and/or
  - Malicious use would have few consequences
- **Moderate**
  - Relatively difficult to deploy, 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 deploy, 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

Threat Assessment

- **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

Evaluate Scenarios

- Scenarios of specific adversaries attempting to steal and misuse specific pathogens or toxins
  - Can screen assets that do not present sufficient risk
    - Nonpathogenic and LMUR
  - Can screen adversaries for certain scenarios because they have no interest in biological agents or have insufficient means

Asset	Adversary	Action
EMUR	Insider	Theft of biological agent
EMUR	Terrorist group	Theft of biological agent
EMUR	Colluding terrorist group	Theft of biological agent
HMUR	Insider	Theft of biological agent
HMUR	Terrorist group	Theft of biological agent
HMUR	Colluding terrorist group	Theft of biological agent
HMUR	Single terrorist	Theft of biological agent
MMUR	Insider	Theft of biological agent
MMUR	Single terrorist	Theft of biological agent

Vulnerability Assessment

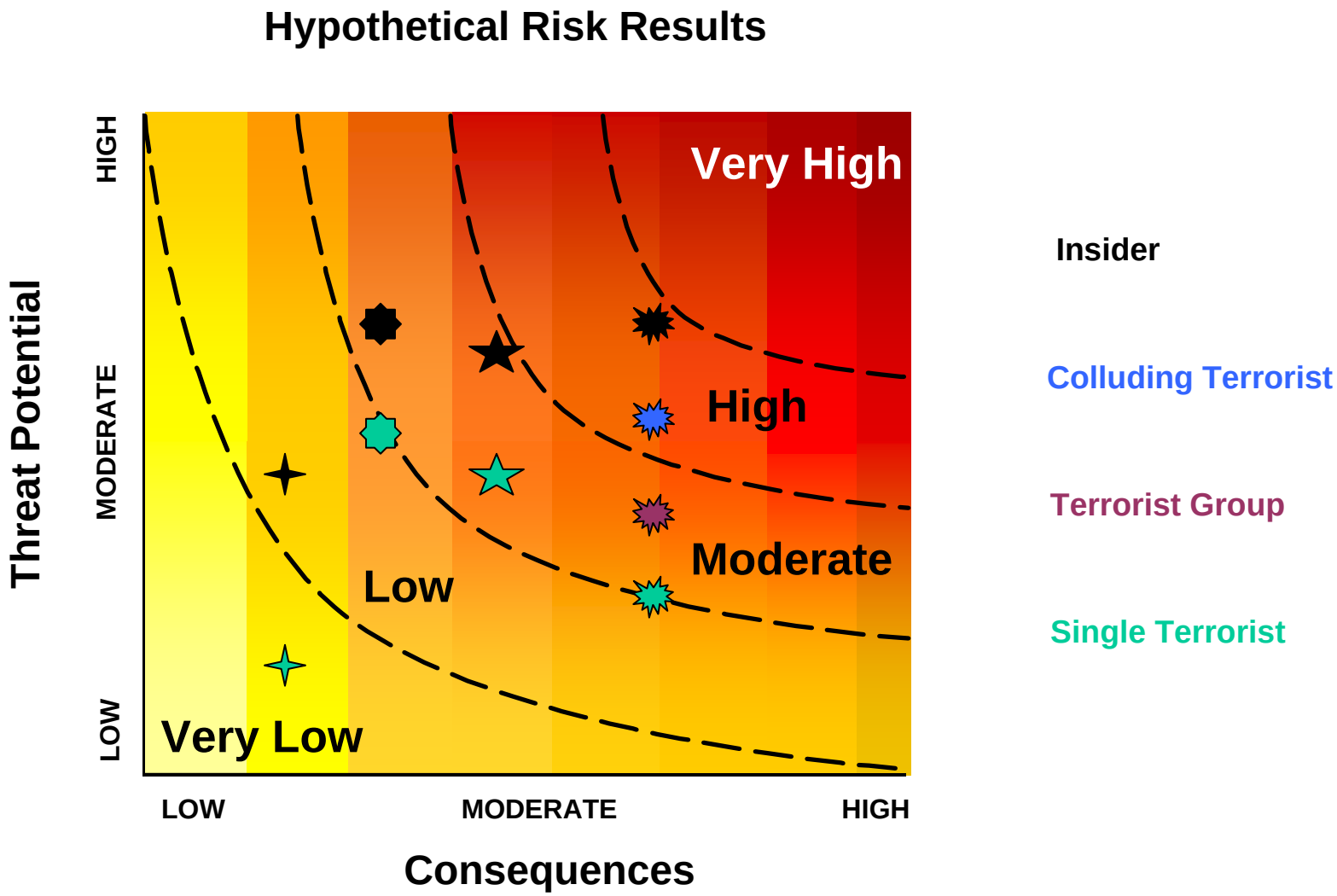
- Do vulnerabilities exist that allow defined scenarios to occur?
- For biosecurity risk assessment, evaluate existing laboratory biosecurity system
  - Physical security, Personnel security, Material control & accountability, Transport security, Information security, Program Management

- Physical security vulnerability assessment
  - Are access controls in place to buildings and laboratories where the biological agents in the scenarios are stored and used?
  - For scenarios with outsiders, evaluate
    - Intrusion detection systems
    - Site perimeter
    - Response force

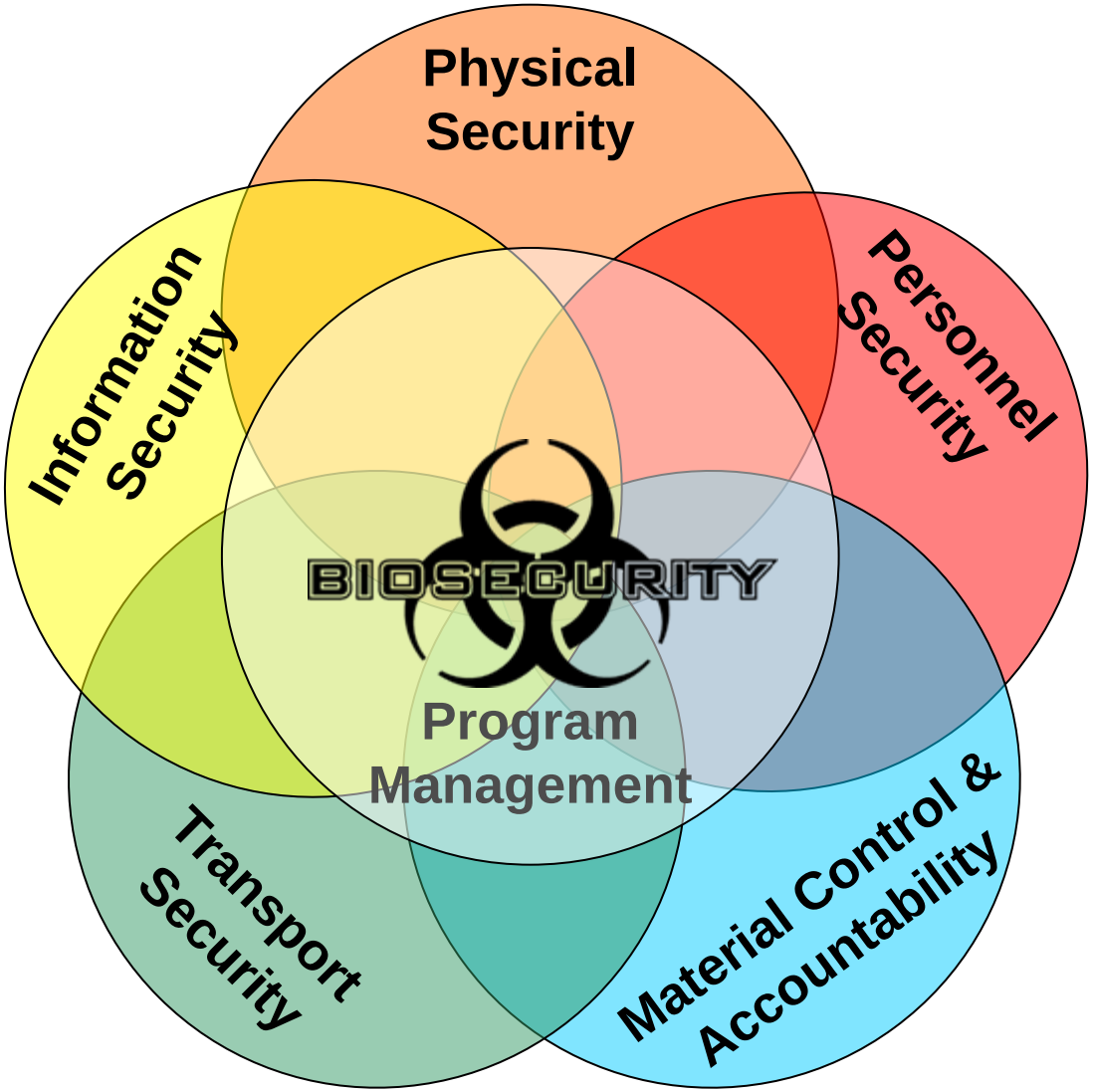
Characterize the Biosecurity Risk

- Evaluate the threat potential and consequences of each scenario
  - Agent task complexity
  - Adversary attributes
  - Site vulnerability
  - Consequences: population, economic, psychological
- Determine which scenarios represent acceptable risks and which represent unacceptable risks
  - Plot scenarios on biosecurity risk graph
  - *Relative risks*
- Develop a risk statement or definition to articulate the objectives of the biosecurity system
  - Define which biosecurity scenarios represent unacceptable risks that must be mitigated
    - Deny, Contain, Deter

Characterize the Biosecurity Risk

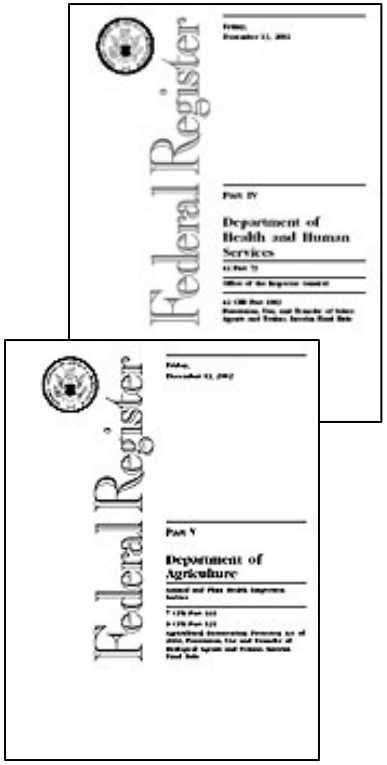


Risk Management: Implementation of Biosecurity



US Select Agent Rule (2005)

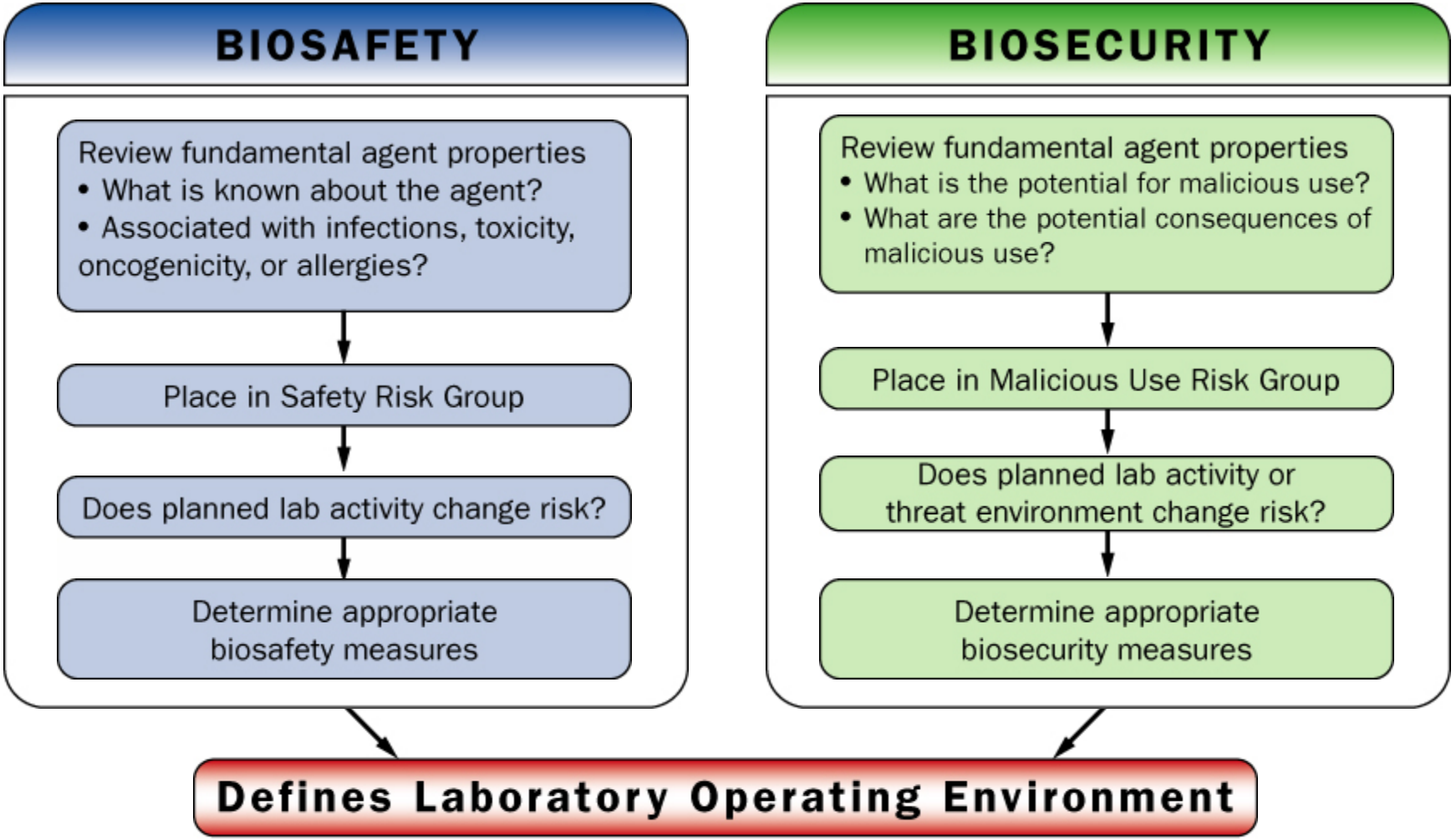
- Facility registration if it possesses one of 81 Select Agents
- Facility must designate a Responsible Official
- Background checks for individuals with access to Select Agents
- Access controls for areas and containers that contain Select Agents
- Detailed inventory requirements for Select Agents
- Security, safety, and emergency response plans
- Safety and security training
- Regulation of transfers of Select Agents
- Extensive documentation and recordkeeping
- Safety and security inspections



International Obligations

- Bacteriological (Biological) and Toxin Weapons Convention (BWC) addresses three relevant issues.
  - National Implementing Legislation
  - National Pathogen Security (biosecurity)
  - International Cooperation
  - States Parties agree to pursue national implementation of laboratory and transportation biosecurity (2003)
- UNSCR 1540 urges States to take preventative measures to mitigate the threat of WMD proliferation by non-state actors
  - "Take and enforce effective measures to establish domestic controls to prevent the proliferation of . . . biological weapons . . .; including by establishing appropriate controls over related materials"

Risk Assessment and Risk Management: 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
  - Not all pathogens and toxins warrant the same level of laboratory biosecurity
  - Tiered system of protection based on risk assessment and risk management methodologies
- Risk assessment is the fundamental resource allocation tool
  - For making decisions about which risks need to be protected against