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Evolution of Biosecurity

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www.biosecurity.sandia.gov

International
BIOLOGICAL THREAT REDUCTION

Why Laboratory Biosecurity?

People Intentionally Do Bad Things (in laboratories)

Dr. Mitsuru Suzuki, Dec 1964 – Mar 1966

- **Location: Japan**
- **Perpetrator**
  - 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*
  - Stolen from the Japan's National Institute of Health
- **Dissemination**
  - Sponge cake, other food sources
  - Later implicated in 200 – 400 illnesses
    - 4 deaths
- **Outcome**
  - Official investigation started after anonymous tip to Ministry of Health and Welfare
  - Charged with infecting people, but not with any deaths

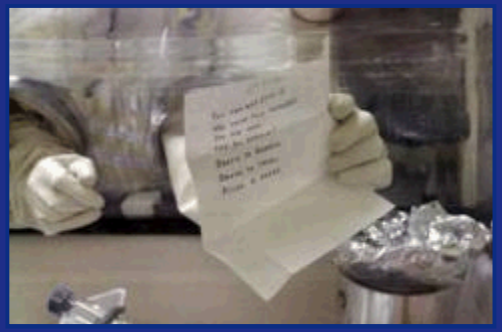
Diane Thompson, October 1996

- **Location: Hospital in Dallas, TX**
- **Perpetrator**
  - 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 of the St. Paul Medical Center where she worked
- **Dissemination**
  - Contaminated pastries in the office break room
  - Infected 12 of her coworkers
- **Outcome**
  - Arrested, convicted, 20 year sentence

Illegal Acquisition from Laboratories that Resulted in Bioterrorism

Aum Shinrikyo – 1990s

Rajneeshees – 1984



Amerithrax – 2001

"…given the high level of know-how needed to use disease as a weapon to cause mass casualties, the United States should be less concerned that terrorists will become biologists and far more concerned that biologists will become terrorists."

-World At Risk,
The report of the commission on the prevention of weapons of mass destruction proliferation and terrorism, December 2008

Evolution of Laboratory Biosecurity

I. Threat reduction

II. Regulations, regulations

III. National and international guidance

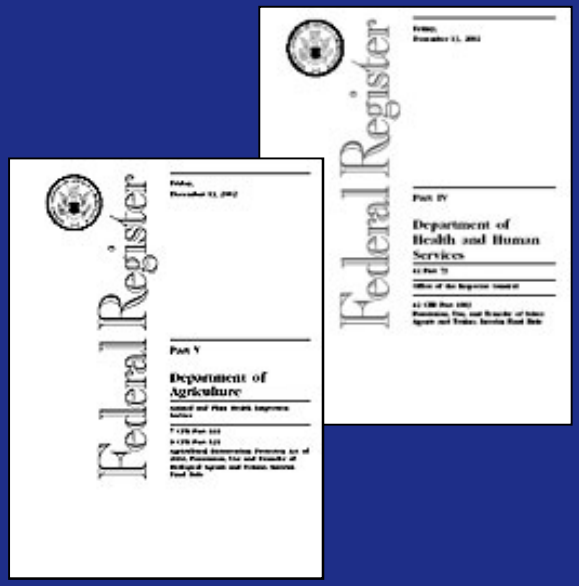
IV. Biorisk management

I. Reducing the Threat

- **"Biosecurity" originated with the Nunn-Lugar Cooperative Threat Reduction program**
  - Addressed materials, equipment, and expertise, with continued emphasis on materials
  - DOD meeting of FSU lab directors on laboratory biosecurity in Albuquerque in 2000
  - DTRA's Biological Threat Reduction Program has strengthened laboratory biosecurity in the FSU since
  - US Department of State created a global Biosecurity Engagement Program in 2006

II. When in Doubt, Regulate

- **Select Agent Rule, 1996**
- **“Where is anthrax?”**
- **PATRIOT Act of 2001**
- **Bioterrorism Prevention Act of 2002**
- **Select Agent Rule**
  - Interim Rule, 2002
  - Final Rule, 2003



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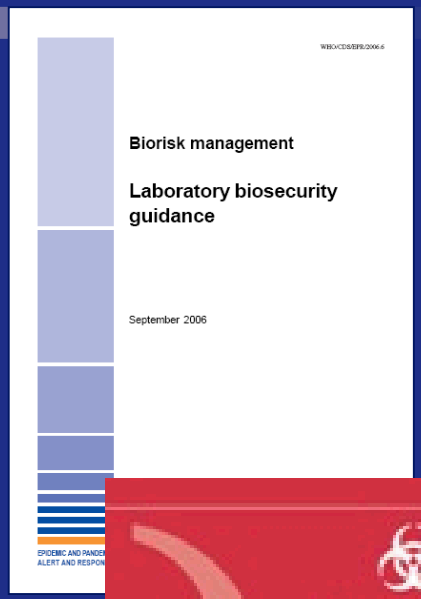
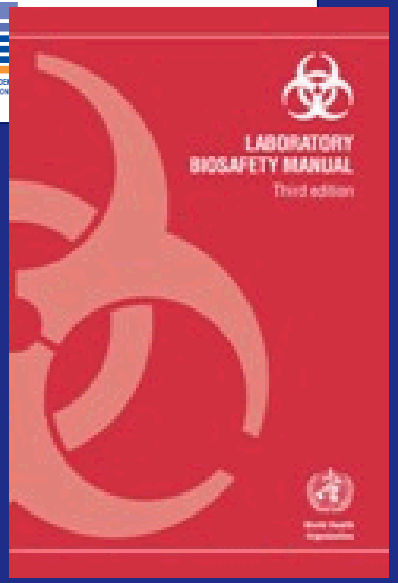
Guns, guards, gates …
Lights, cameras, and overreaction

- Biosecurity as a police operation
- Reliance on “security professionals” with no biology or biocontainment experience
- Fundamentals of security ignored: What to protect? Against what?
- Wasteful spending and disillusioned scientists
- Tarnished reputation for laboratory biosecurity

III. Biosecurity Receives International Attention

- **2003: BWC technical experts meeting**
- **2004: United Nations Security Council Resolution 1540**
- **Other nations address biosecurity, e.g.**
  - Australia, Canada, Denmark
  - France, Japan, Singapore
  - South Korea, United Kingdom
- **Guidance documents**
  - 2006: WHO “Laboratory Biosecurity Guidance”
  - 2007: OECD “Guidelines on Biosecurity for BRCs”
  - 2007: 5th edition of CDC/NIH *Biosafety for Microbiological and Biomedical Laboratories*
  - 2007: *Laboratory Biosecurity Handbook*





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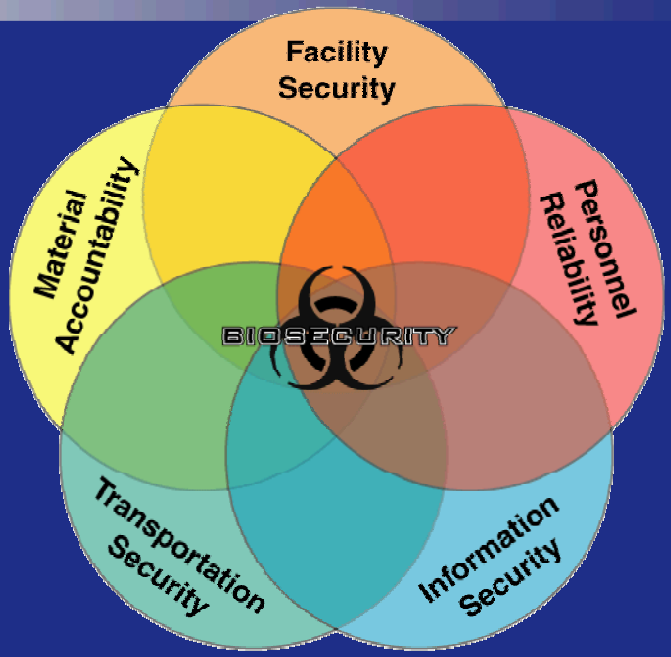
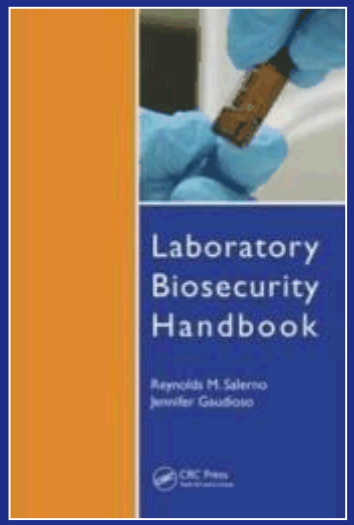
How to implement laboratory biosecurity?

Biosecurity Systems – All at Once

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



- **Each component implemented based on results of risk assessment**



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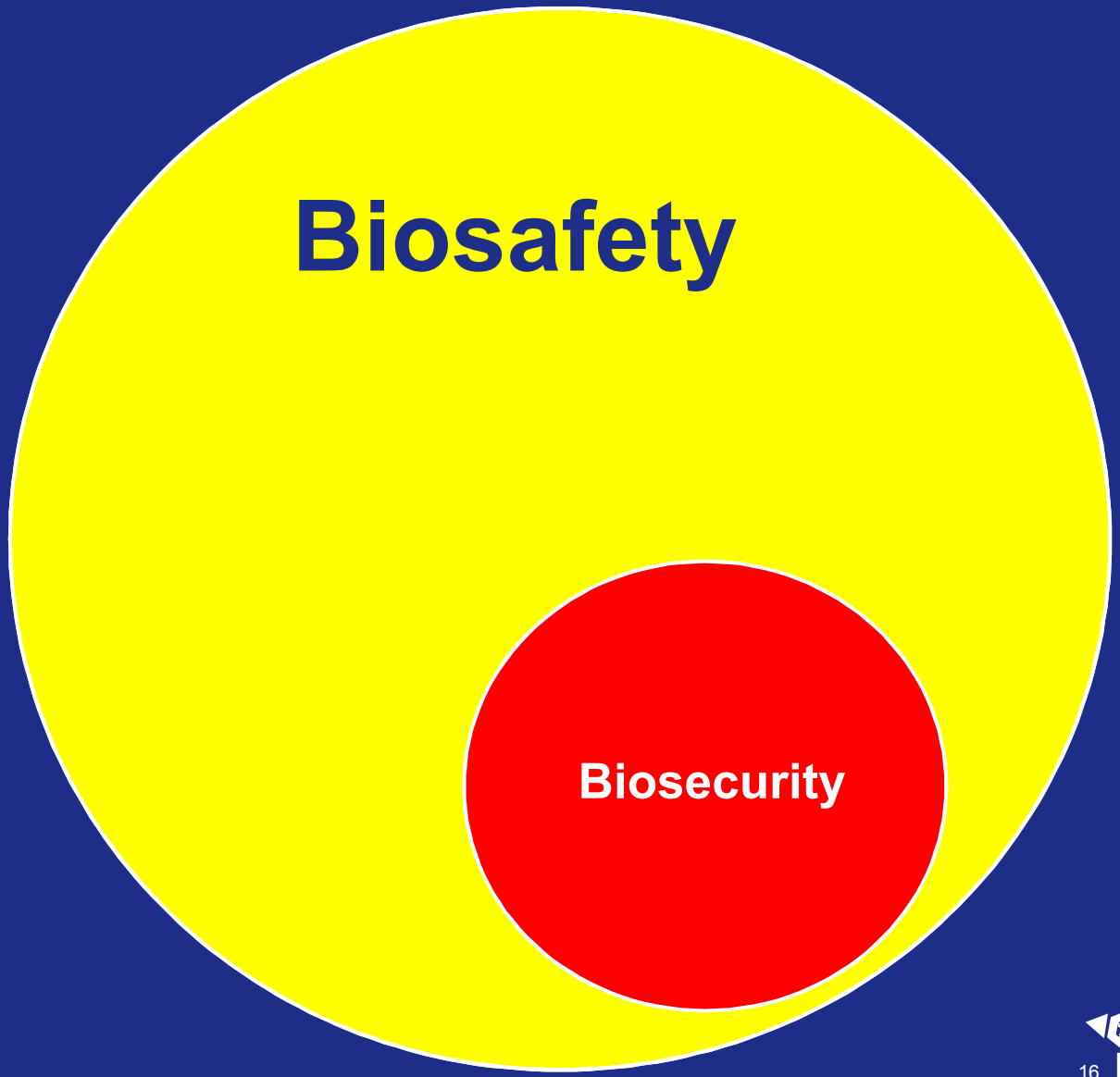
Biosecurity Leveraging the Foundations of Biosafety

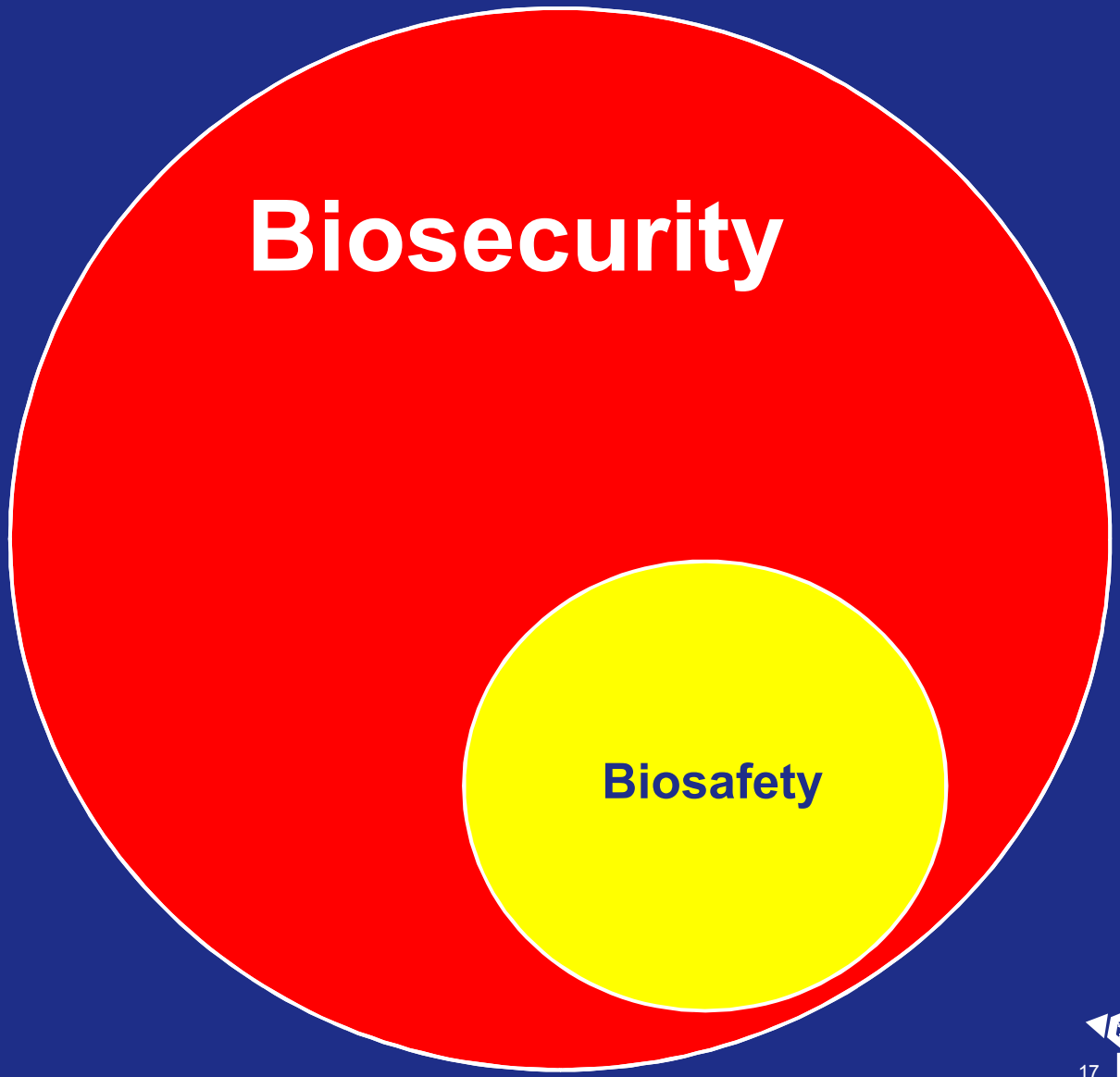
- Do you limit who may enter your laboratories?
- Do you know who works in your laboratories with dangerous pathogens?
- Do you trust those persons to conduct their jobs well and responsibly?
- Have they been appropriately trained to protect themselves, the environment, and the pathogens?
- Do you maintain and control your collections of dangerous pathogens, inside and outside the laboratories?

A never-ending question:

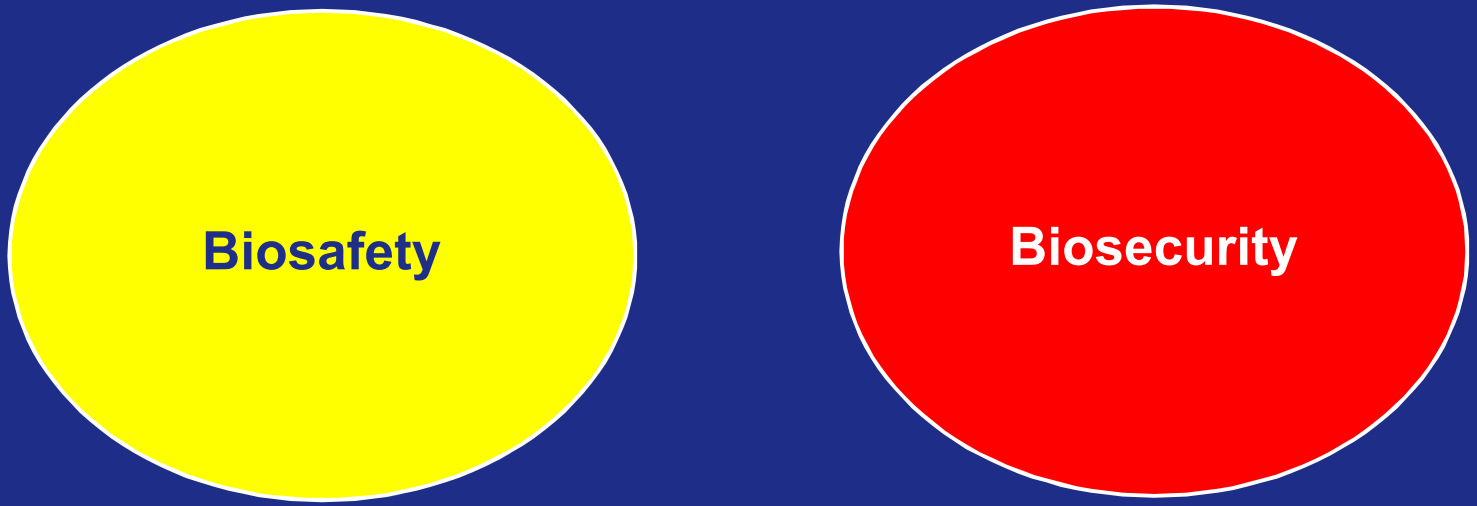
What is more important –

Laboratory Biosafety or Laboratory Biosecurity?




Biosecurity
Biosafety

Separate and Unequal Programs?

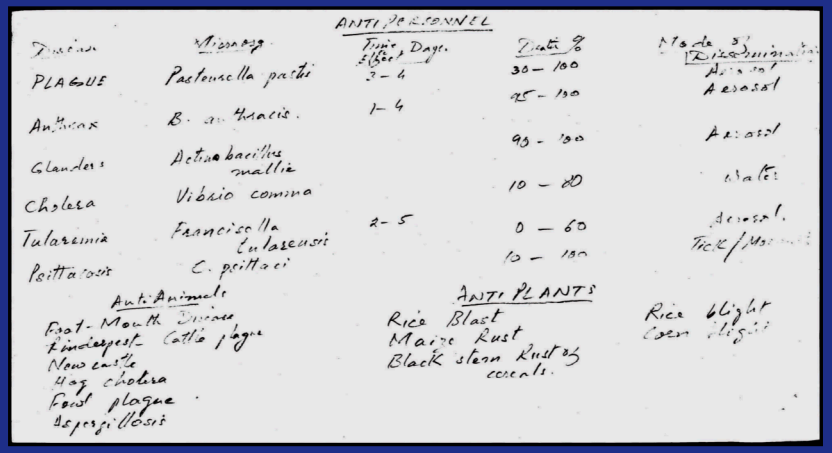


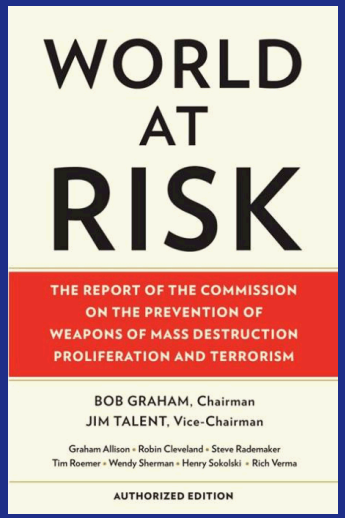
IV. The Future

Biorisk Management

World At Risk, December 2008

- **The Report of the Commission on the Prevention of WMD Proliferation and Terrorism**
  - "The Commission believes that terrorists are more likely to be able to obtain and use a biological weapon than a nuclear weapon."
  - "The currently separate concepts of biosafety and biosecurity should be combined into a unified conceptual framework of *laboratory risk management,* and this program should be integrated into a program of mandatory education and training for scientists and technicians in the life sciences."





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International Calls for Biorisk Management Approach

- **Laboratory Biorisk Management Standard**
  - Risk-based approach
  - CWA 15793:2008

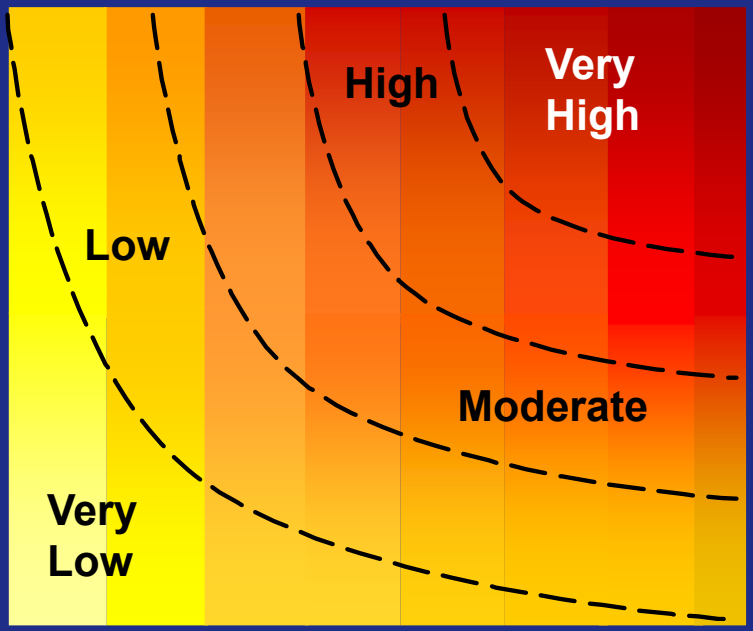
- **World Health Organization Biorisk Reduction Program**
  - Addresses laboratory biosafety and biosecurity and infection control
  - For example, recently released laboratory handling guidance for H1N1

Laboratory Biorisk Program Management

- **Seeks to effectively and efficiently manage an institution's laboratory biorisks**
- **Laboratory biorisk management programs need**
  - Appropriate resources
  - Institutional plans and operating procedures
  - Training (leading to new or changed behaviors)
  - Oversight (ensuring that desired behaviors are maintained)
- **But**
  - How do you decide to allocate your scarce resources?
  - How do you determine what needs to be addressed in operating procedures?
  - How do you determine which training is required for whom?
  - How do you determine what level of oversight is appropriate?
  - How do you determine which behaviors you expect your staff to display?

It Depends on the Risk Assessment!!

Biorisk Assessment: Many Risks to Evaluate



- Risk of accidental infection to laboratory worker
- Risk of accidental infection to others at the institution
- Risk of accidental infection to outside community
- Risk of accidental infection in animal community
- Risk of theft and malicious use against humans
- Risk of theft and malicious use against animals

The probability of a laboratory security incident may be lower than a laboratory safety incident, but the consequences could be significantly greater.

Managing Biorisks

- **Many common elements to managing biosafety and biosecurity risks**
  - Training
  - Manuals, documentation
  - Limiting access
  - Inventories
  - Knowledge of end user prior to shipping materials
  - Determining suitability of persons for job before granting access to the lab

- **Many bioscience laboratories have always protected their materials, protocols, and research**

Laboratory Biorisk Management Systems

- Provide for the health and safety of laboratory workers and the environment
- Ensure the containment of hazardous infectious substances in laboratories
- Maintain citizens' confidence in the activities of the bioscience research community
- Increase transparency to investors in the biomedical and biotechnology industries
- Protect valuable research and commercial assets
- Reduce the risks of crime and terrorism

Conclusions

- United States should learn from the international community
- Protecting against risks of working with pathogens and toxins – including theft and misuse – should be a critical element of every modern bioscience laboratory
- Laboratory biosecurity should be based on intellectually substantive and scientifically credible methodologies – just like biosafety
- Arguing about the relative importance of biosafety and biosecurity is worthless
- Setting a new biorisk management paradigm is essential