Evolution of Biosecurity

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Why Laboratory Biosecurity?

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People Intentionally Do Bad Things (in laboratories)

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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

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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

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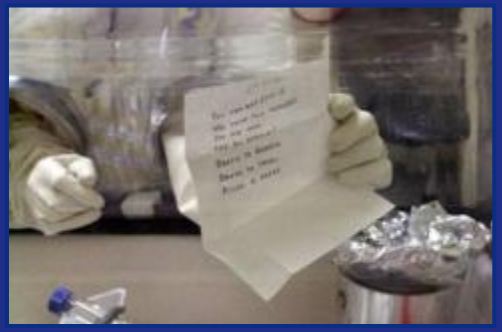
Acquisition from Laboratories that Resulted in Bioterrorism

Aum Shinrikyo – 1990s

Rajneeshees – 1984



Amerithrax– 2001

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"…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

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Evolution of Laboratory Biosecurity

I. Threat reduction

II. Rules and regulations

III. National and international guidance

IV. Biorisk management

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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 ever since
  - US Department of State created a global Biosecurity Engagement Program in 2006

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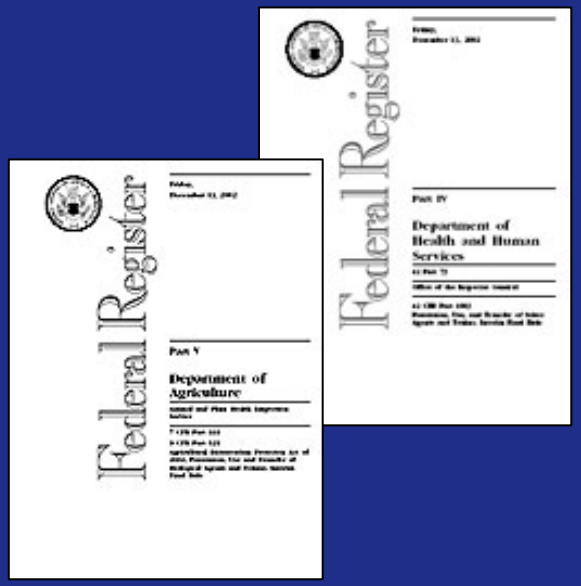
II. When in Doubt, Regulate

- **Select Agent Rule, 1996**
- **"Where is anthrax?"**
- **PATRIOT Act of 2001**
- **Bioterrorism Prevention Act of 2002**
- **Select Agent Rule**
  - Interim Rule, 2003
  - Final Rule, 2005



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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

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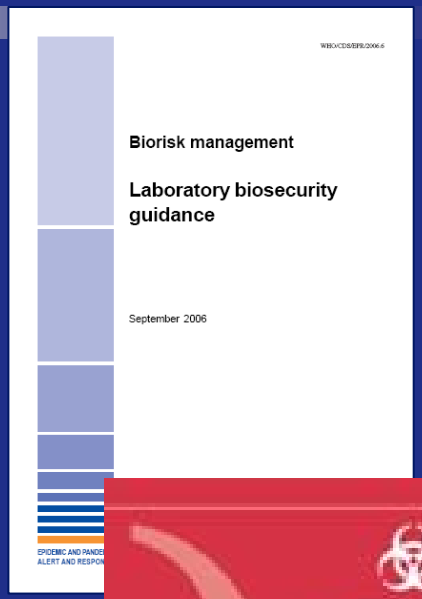
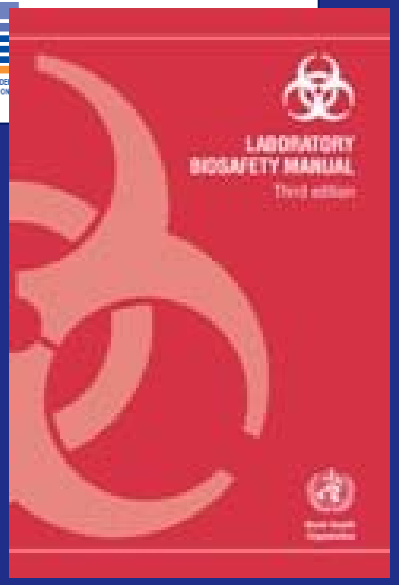
III. Biosecurity Receives International Attention

- **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?

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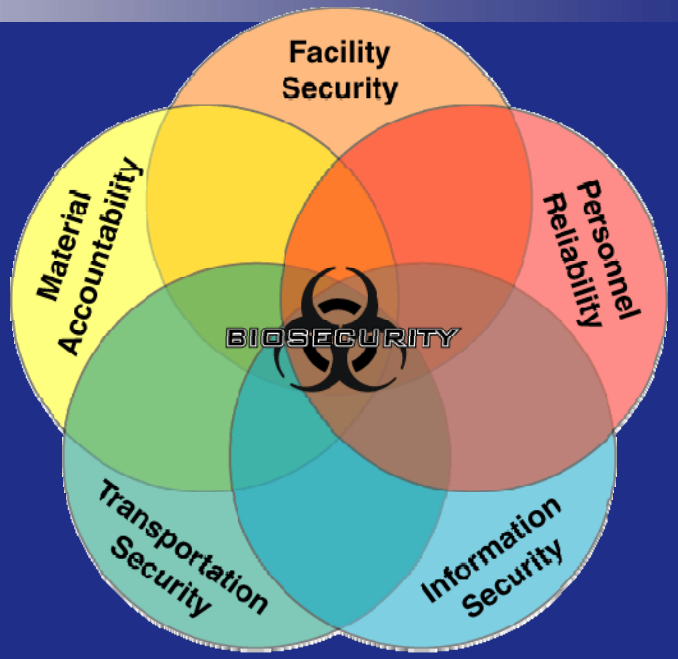
Biosecurity Systems – All at Once

- **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?

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A never-ending question:

What is more important –

Laboratory Biosafety or Laboratory Biosecurity?

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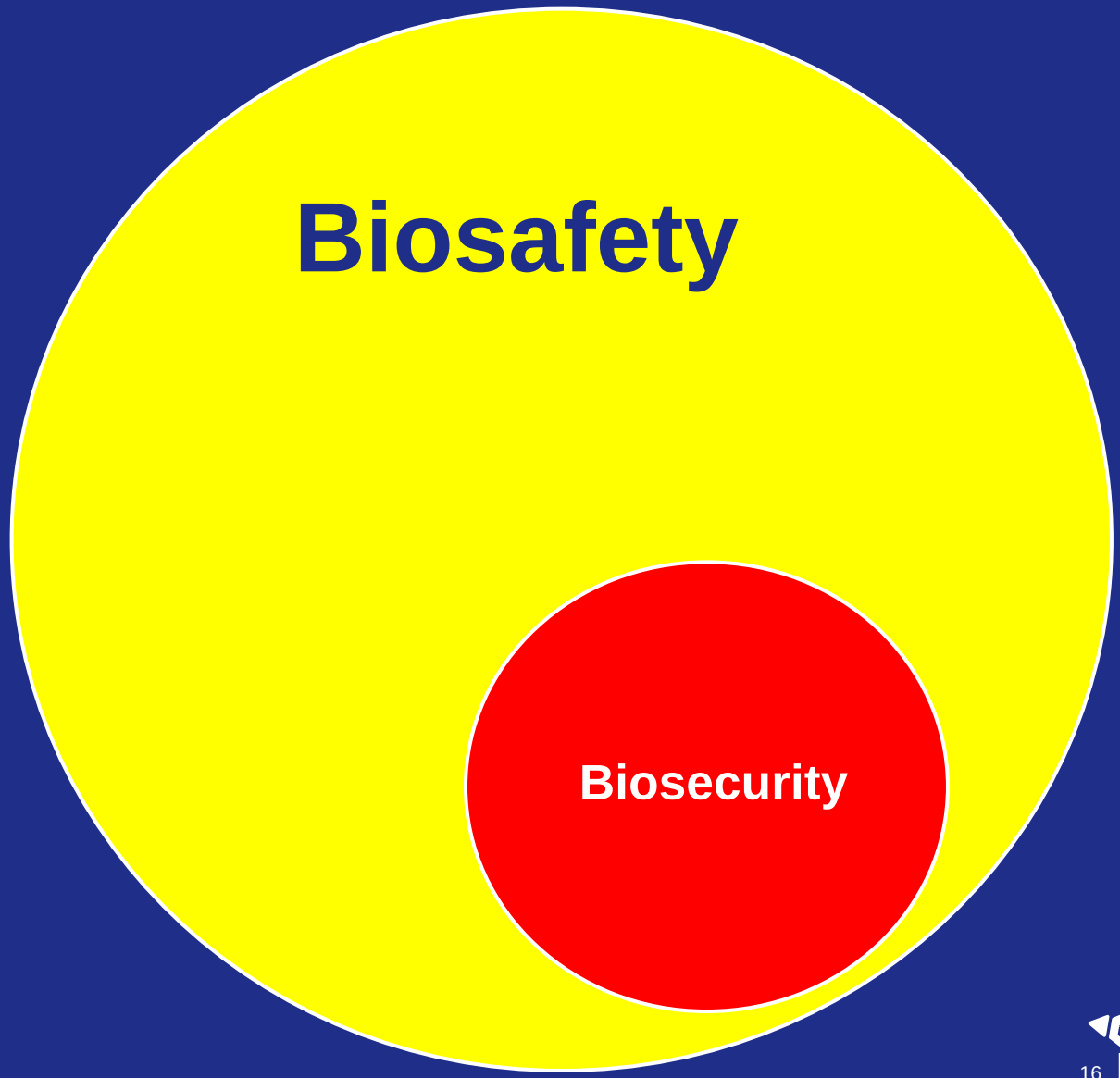

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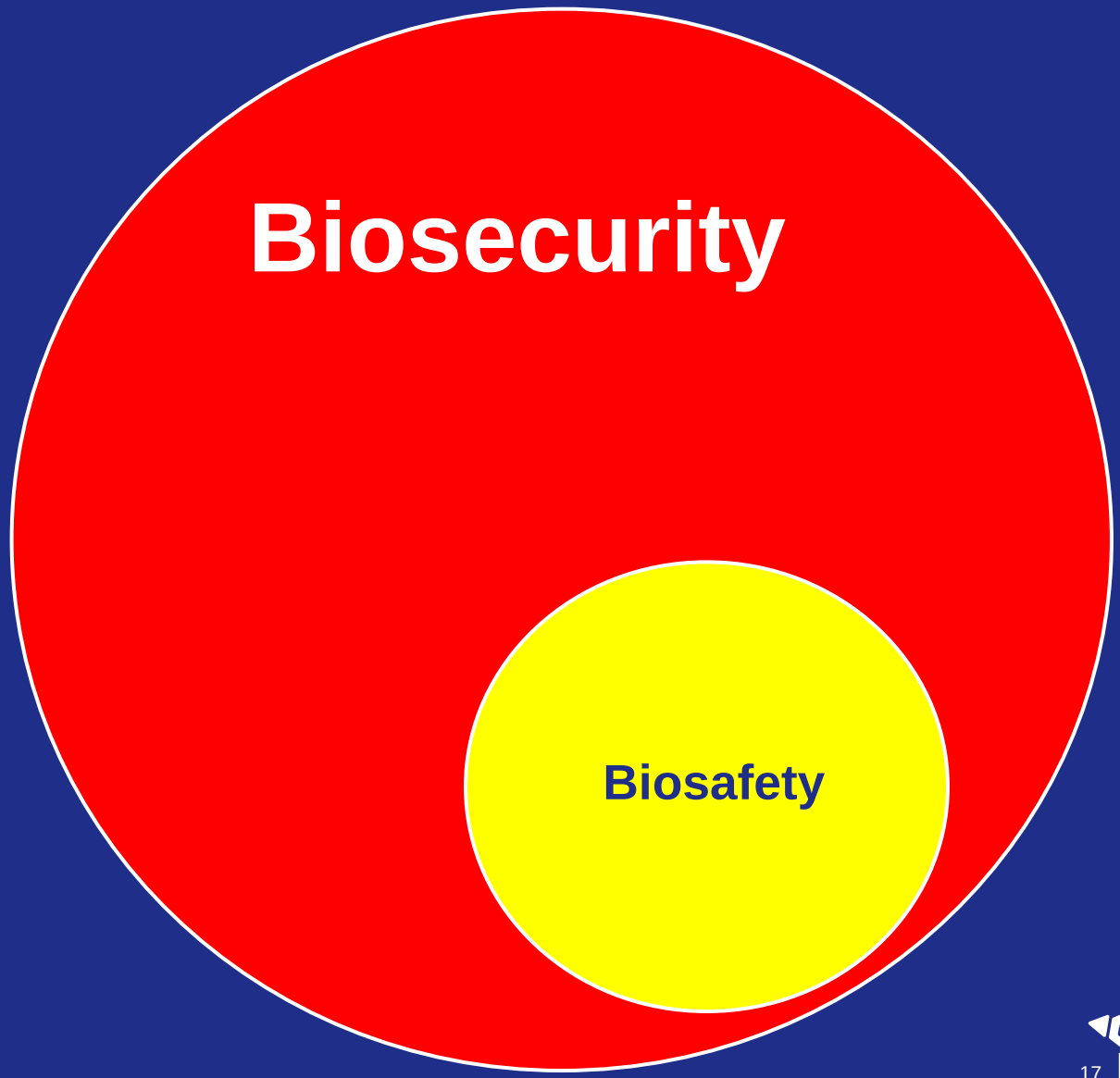

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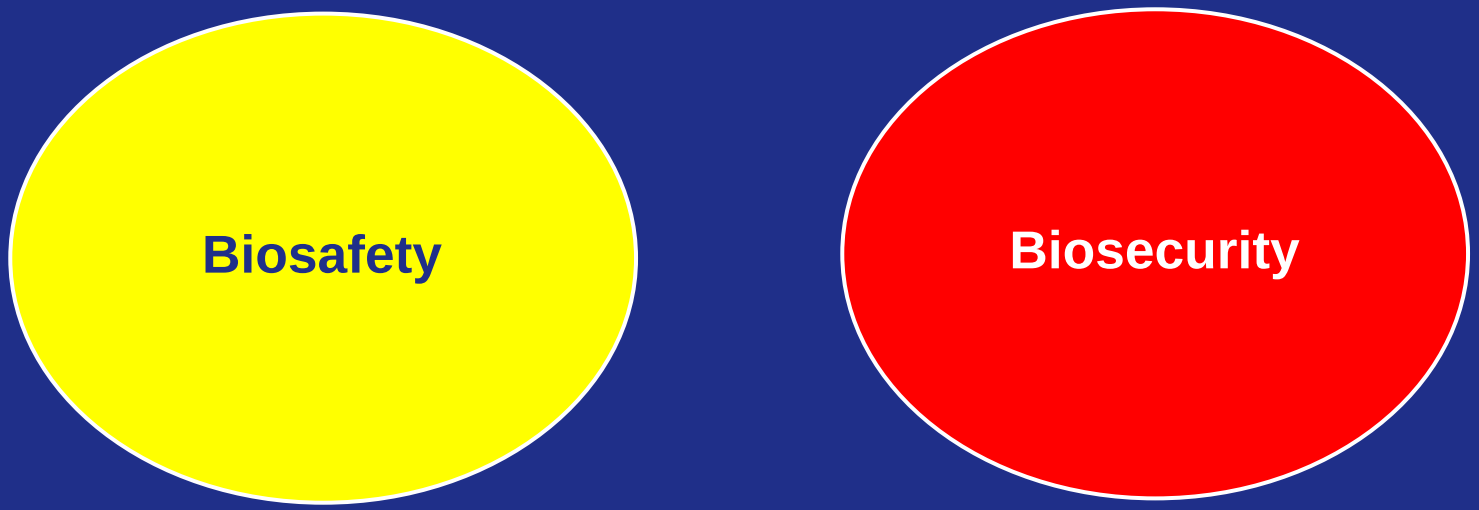
Separate and Unequal Programs?



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IV. The Future

Biorisk Management

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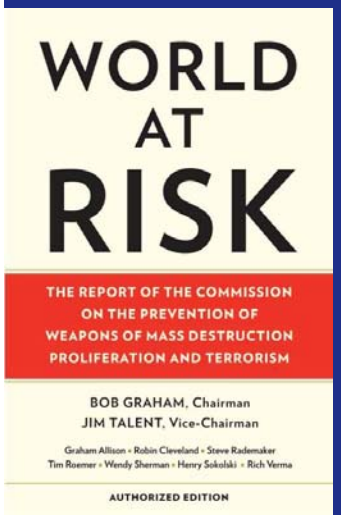
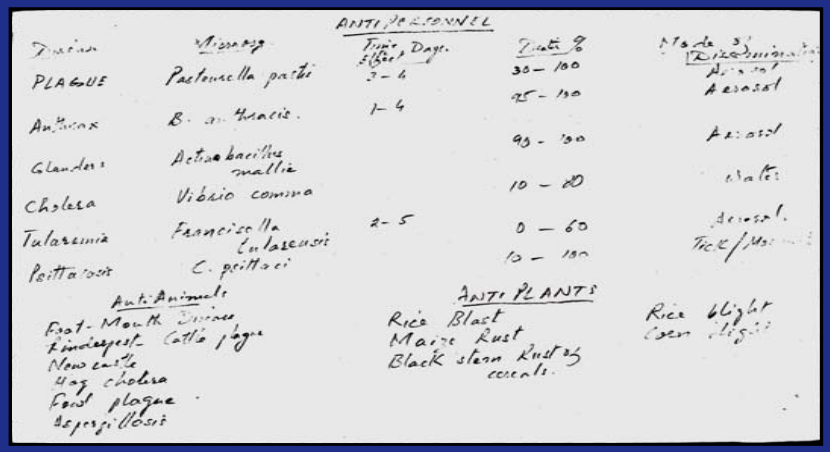
World At Risk, December 2008

- **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

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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

WORLD HEALTH ORGANIZATION

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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!!

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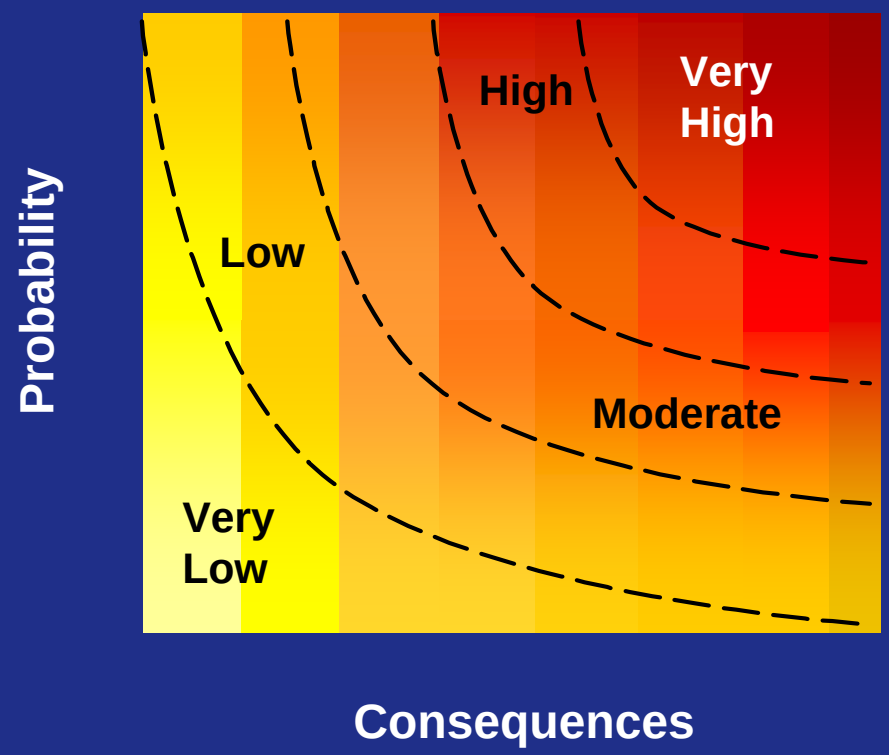
Biorisk Assessment: Many Risks to Evaluate



- 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

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

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Managing Biorisks

- **Many common elements to managing biosafety and biosecurity risks, such as**
  - 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**

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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

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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

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