



Evolution of Biosecurity

Biosecurity Inspector Training

Staten Serums Institut

31 August – 2 September 2009

www.biosecurity.sandia.gov

SAND No. 2009-5485C

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.





Why Laboratory Biosecurity?

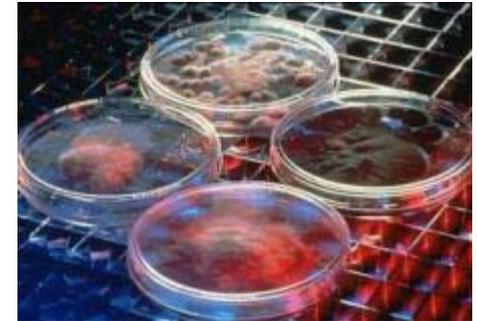


People Intentionally Do Bad Things
(in laboratories)



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

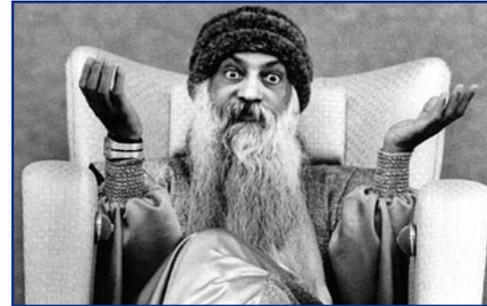




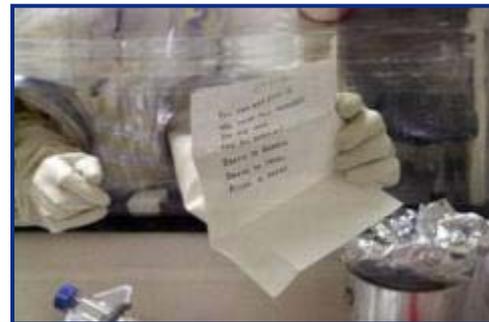
Acquisition from Legitimate Facilities that Resulted in Bioterrorism



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. Rules and regulations
- III. National and international guidance
- IV. Biorisk management



I. Reducing the Threat

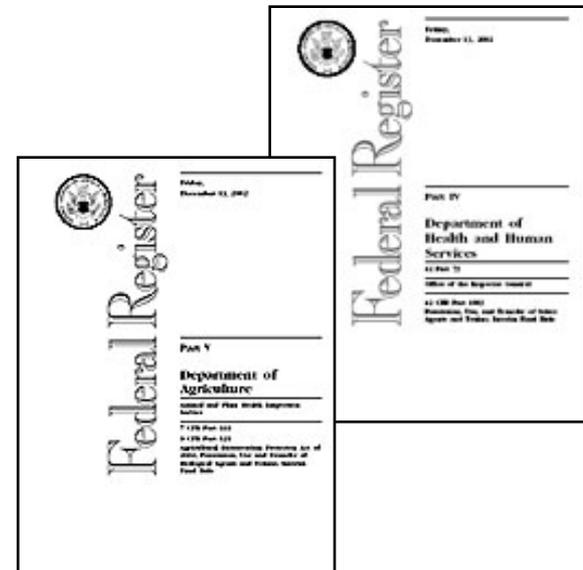
- “Biosecurity” originated with the Nunn-Lugar Cooperative Threat Reduction program
 - Addressed materials, equipment, and expertise, with continued emphasis on materials
 - DOD meeting of FSU lab directors on laboratory biosecurity in Albuquerque in 2000
 - DTRA’s Biological Threat Reduction Program has strengthened laboratory biosecurity in the FSU ever 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, 2003
 - Final Rule, 2005





Guns, guards, gates ...

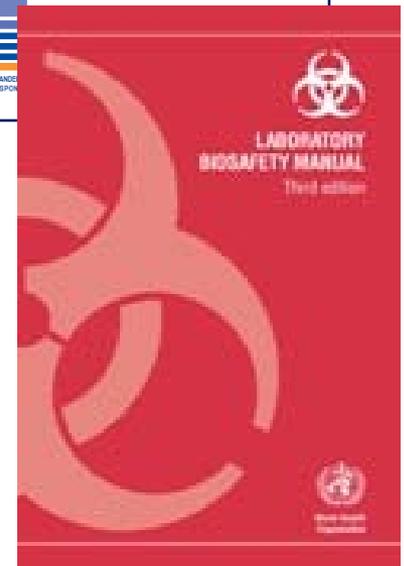
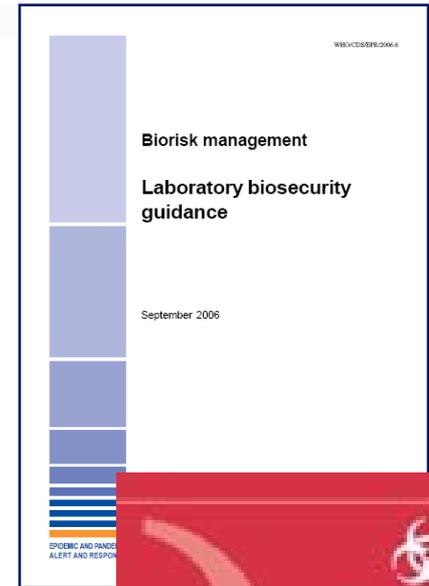
Lights, cameras, and overreaction

- 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*



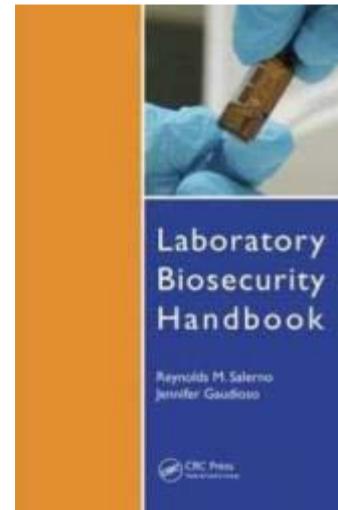
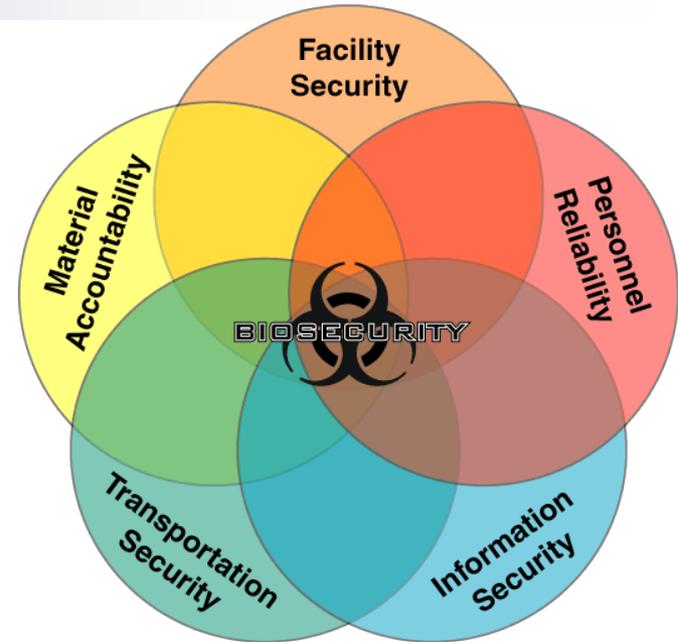


How to implement laboratory biosecurity?



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





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?



Biosafety

Biosecurity

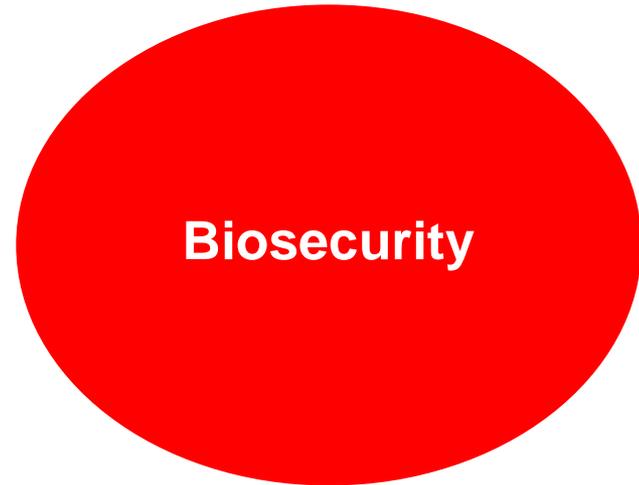
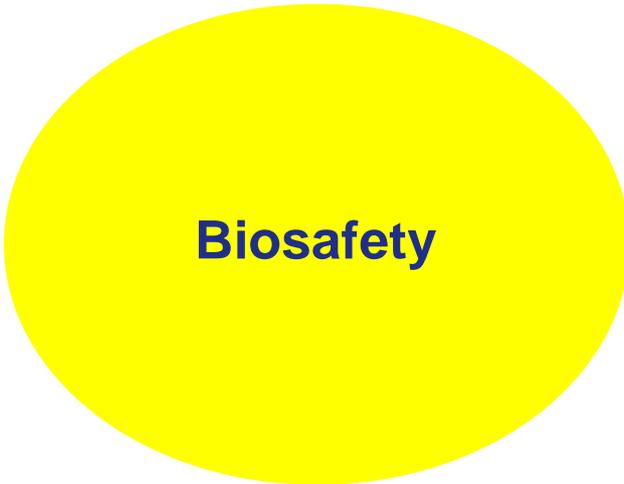


Biosecurity

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.”

WORLD AT RISK

THE REPORT OF THE COMMISSION ON THE PREVENTION OF WEAPONS OF MASS DESTRUCTION PROLIFERATION AND TERRORISM

BOB GRAHAM, Chairman
JIM TALENT, Vice-Chairman

Graham Allison • Robin Cleveland • Steve Rademaker
Tim Roemer • Wendy Sherman • Henry Sokolaki • Rich Verma

AUTHORIZED EDITION

Disease	Microbe	Time, Days	Deaths	Mode of Transmission
PLAGUE	<i>Pasteurella pestis</i>	3-4	30-100	Aerosol
Anthrax	<i>B. anthracis</i>	1-4	25-100	Aerosol
Glanders	<i>Actinobacillus mallei</i>		95-100	Aerosol
Cholera	<i>Vibrio comma</i>		10-20	Water
Tularemia	<i>Francisella tularensis</i>	2-5	0-60	Aerosol
Botulism	<i>C. botulinum</i>		10-100	Food/Insect
Anti-Animals		ANTI PLANTS		
Foot-Mouth Disease		Rice Blast		Rice blight
Hand-foot-and-mouth disease		Maize Rust		Corn blight
Newcastle		Black stem rust of wheat		
4 day cholera				
Food plague				
Aspergillus				



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





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