



Biosecurity and Biosafety—A Growing Concern

Jennifer Gaudio, PhD

International Biological Threat Reduction

Global Security Center

Sandia National Laboratories

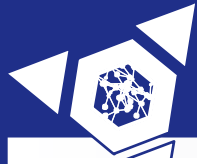
Albuquerque, NM USA

12 May 2008

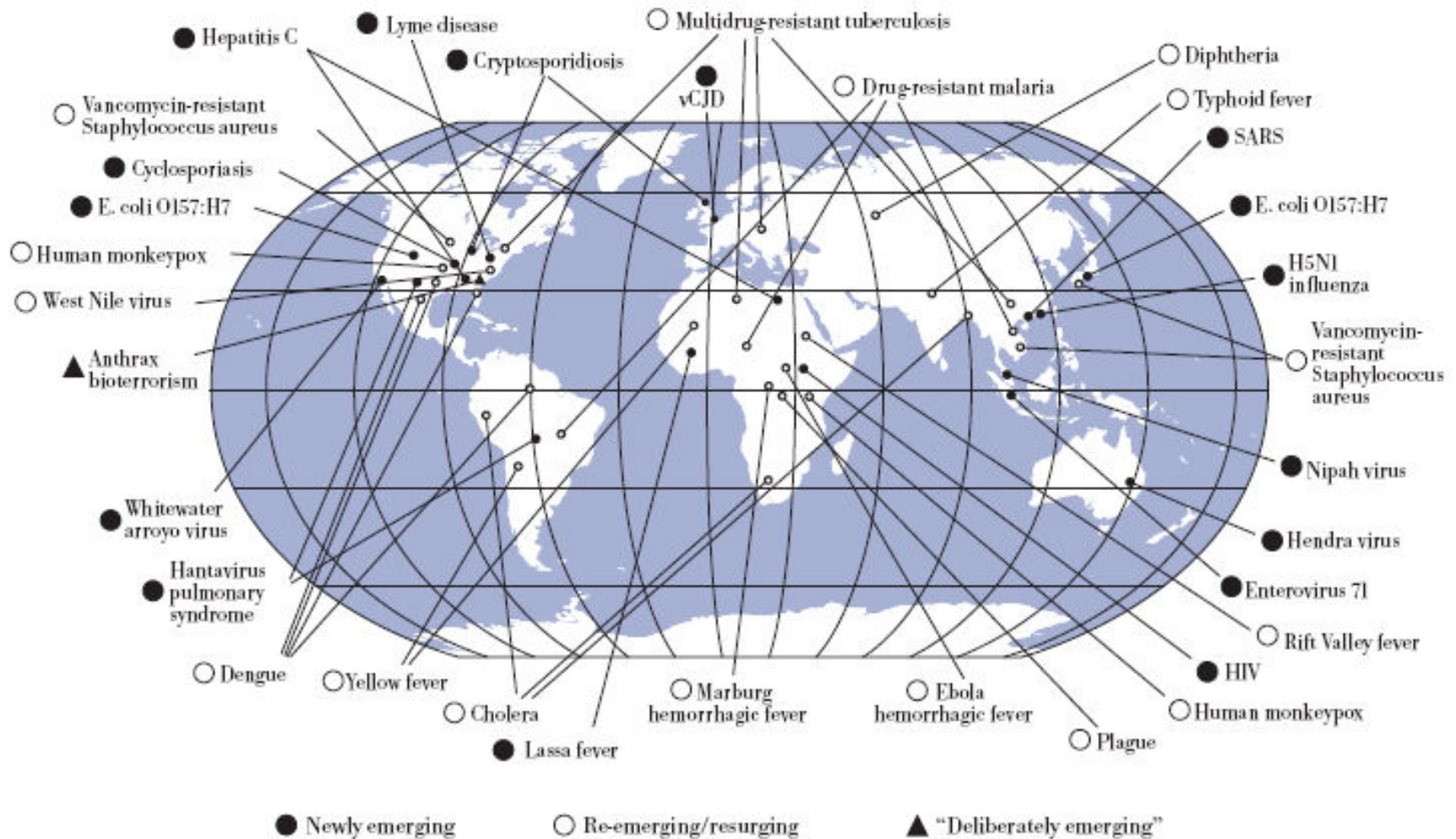
SAND No. 2008-XXX C

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.





Examples of Emerging and Re-Emerging Diseases



Adapted from Morens, D.M., et al. 2004. The Challenge of Emerging and Re-emerging Infectious Diseases. *Nature* 430:242-49.



Infectious Disease

- **Global outbreaks of emerging and reemerging infectious disease present a growing concern to the international community**
- **Infectious diseases now spread across borders as never before**
- **~75% of emerging diseases are zoonotic**
- **Laboratories are a critical tool in the global fight against these diseases**
 - Recent growth in containment laboratories intended to help in the efforts to control these diseases
 - Strengthening national disease surveillance, prevention, control and response systems is a key pillar in the implementation of the International Health Regulations (2005)



SARS virus



FMD outbreak UK





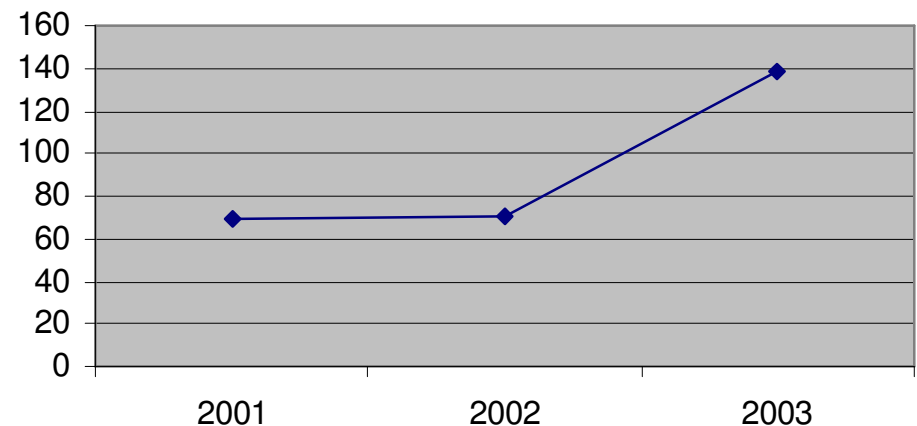
Examples of Expansion of Containment Laboratories Inside the U.S.

- **Hard to count but general consensus that BSL3 and BSL4 space is growing**
- **12 States had public health labs with BSL3 lab space in 1998; this has grown to at least 46 states in 2007**
- **NIAID is funding construction of 13 regional biocontainment laboratories (BSL3) and 2 national biocontainment laboratories (BSL4)**
- **BSL3 labs registered to work with select agents**
 - 1042 with CDC; 314 with USDA; 1356 Total
- **2005 American Society for Microbiology identified 277 distinct facilities in 46 states with BSL3 capable space**

References:

- Keith Rhoades, Congressional Testimony, October 2007, GAO -08-108T
- American Society for Microbiology, Survey of BSL3 Laboratory Capabilities in the United States, September 2005

U.S. State Public Health Labs with BSL3 Capacity - Association of Public Health Laboratories, August 2004





Examples of Expansion of Containment Laboratories Outside the U.S.

- **World Bank is funding construction of BSL3s in many countries**
- **Brazil is currently building a network of 12 BSL3 public health laboratories**
- **New BSL3 labs operational in 2006:**
 - 16 – India
 - 5 – Thailand
 - 2 – Indonesia
 - 1 – Myanmar
 - 1 – Bangladesh
- **Singapore had 3 BSL3 laboratories in 2003 but is building 15**

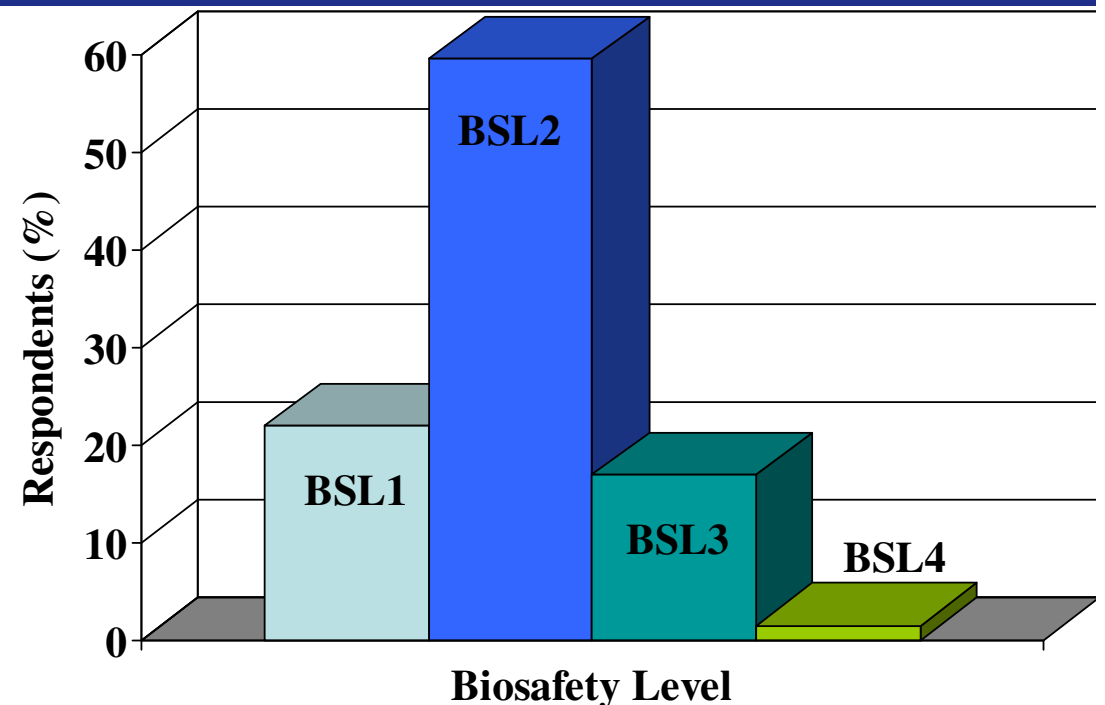
References:

- Singapore Ministry of Health website
- World Bank website
- Gronvall et al, Biosecurity and Bioterrorism, 5(1), 2007, p. 75-85
- Mário Althoff, Coordinator, Brazil Public Health Laboratory Network



Biosafety Levels Reported in Surveys

- 765 survey respondents from Latin America, Asia, Eastern Europe, and the Middle East
- Most respondents work in basic biosafety labs
- Significantly fewer respondents work in containment labs
 - Asia: 41 BSL3, 4 BSL4
 - Eastern Europe: 14 BSL3, 3 BSL4
 - Latin America: 22 BSL3, 0 BSL4
 - Middle East: 13 BSL3, 1 BSL4
- Many do NOT know their biosafety level
 - Asia: 21%
 - Eastern Europe: 35%
 - Latin America: 19%
 - Middle East: 44%





Surveys Indicate Biosafety Often Inadequate by US Standards

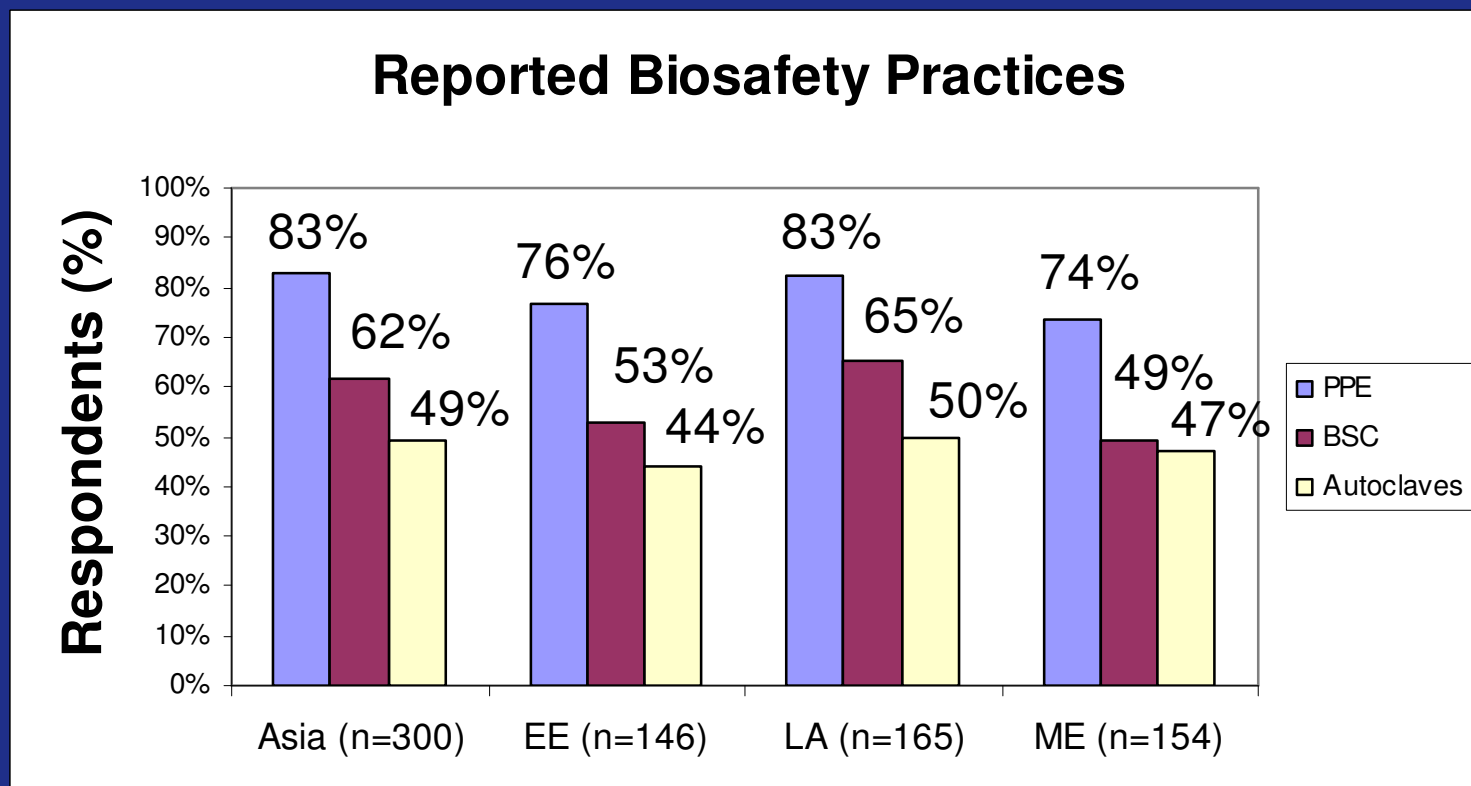
- In Asia: ~2/3 of respondents studying Japanese encephalitis, HPAI, and SARS use BSL 2
- In the Middle East: most respondents studying *Brucella*, HPAI, and *Mycobacterium tuberculosis* use BSL2
- In Latin America: most respondents studying Hanta virus, Yellow fever virus, Dengue, and *Mycobacterium tuberculosis* use BSL2
- In Eastern Europe: *Mycobacterium tuberculosis* is evenly split between BSL2 and BSL3; the majority of HPAI, *Brucella*, and *Coxiella burnetti* work is done at BSL3 or BSL4
- Percentage of respondents who will do the experiment anyway if they do not have a particular item of safety equipment
 - Nearly 50% in Asia
 - ~45% in the Middle East,
 - ~ 30% in Eastern Europe
 - Only 20% in Latin America





Biosafety Practices Reported in Surveys

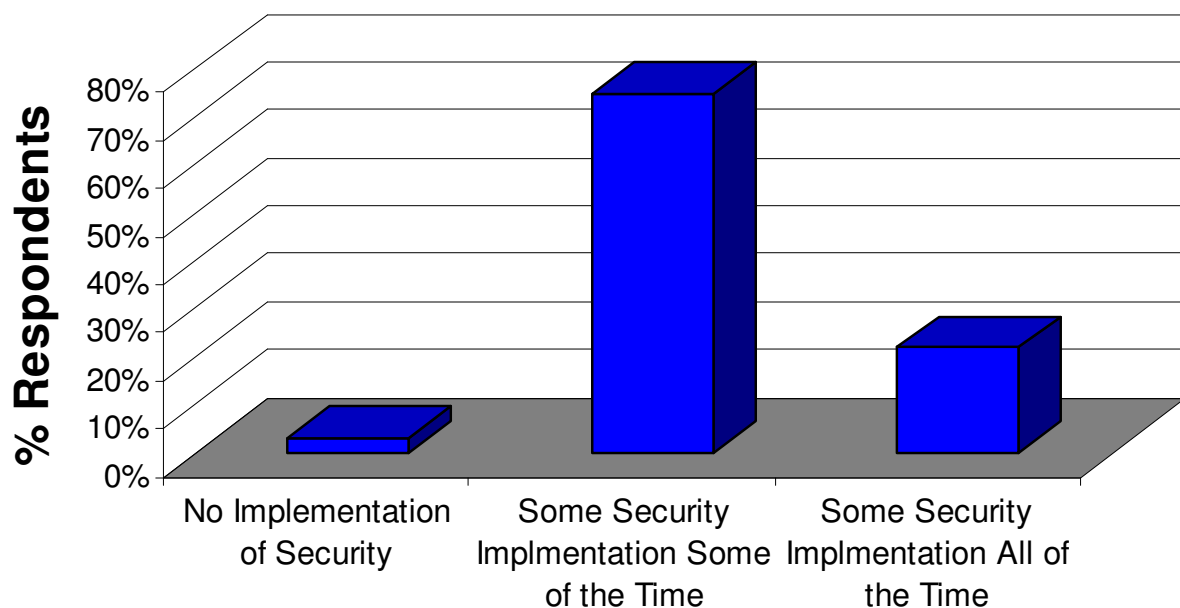
- **Most facilities have some form of PPE**
 - Primarily Gloves and Gowns
- **Only half the facilities have autoclaves within the laboratory or on-site**





Biosecurity Measures Reported in Surveys

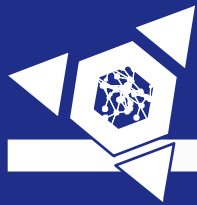
- **Biosecurity implementation was based upon practices of:**
 - Physical Security
 - Personnel Security
 - Material Control and Accountability
- **97% of the total respondents implement some level of biosecurity**
 - 27% implement some biosecurity all of the time
 - 70% implement some security at least some of the time





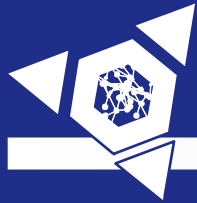
Perceptions of Risk Reported by Survey Respondents

- **Respondents very worried about lab-acquired infections**
 - Asia – 46%
 - Middle East – 46%
 - Latin America – 57%
 - Eastern Europe – 33%
- **Respondents very worried that the biological agent they study could be used to cause harm**
 - Asia – 44%
 - Middle East – 36%
 - Latin America – 42%
 - Eastern Europe – 24%
- But, not from *their* lab....
- **Respondents who think it is likely or very likely that an employee would steal an agent with an intent to cause harm**
 - Asia – 15%
 - Middle East – 17%
 - Latin America – 9%
 - Eastern Europe – 7%
- **Respondents who think it is likely or very likely that an outsider would steal an agent with an intent to cause harm**
 - Asia – 14%
 - Middle East – 15%
 - Latin America – 7.5%
 - Eastern Europe – 8%



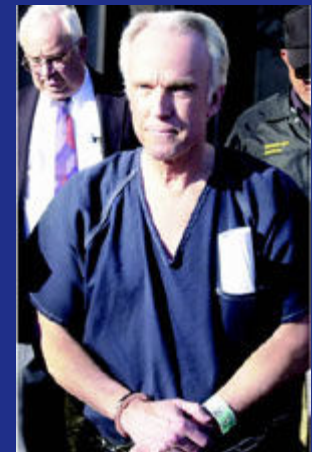
Examples of Growing Attention to Laboratory Biosecurity and Biosafety Internationally

- **World Health Assembly Resolution 58.29 (2005)**
 - Urges Member States to implement an integrated approach to laboratory biosafety, including containment of microbiological agents and toxins
- **European Commission Green Paper on Bio-Preparedness (November 2007) recommends developing European standards on laboratory biosecurity including**
 - Physical protection, access controls, accountability of pathogens, and registration of researchers
- **Organization for Economic Cooperation and Development published “Best Practice Guidelines for Biological Resource Centers” including a section on biosecurity in February 2007**
- **Kampala Compact (October 2005) and the Nairobi Announcement (July 2007) stress importance of implementing laboratory biosafety and biosecurity in Africa**
- **BWC Experts Group meetings in 2003 and 2008 address biosecurity**
- **UNSCR 1540 requires States to establish and enforce legal barriers to acquisition of WMD by terrorists and states, including laboratory biosecurity measures**



Examples of Recent Safety and Security Issues

- **Texas A&M University, United States, 2006 – 2007**
 - U.S. federal officials suspend all Select Agent research due to failures to report two incidents
- **Pirbright Laboratory, Institute of Animal Health, United Kingdom, 2007**
 - Leaks from pipes in the effluent system caused Foot and Mouth Disease outbreak
 - Pipes were known to need maintenance
- **Professor Thomas Butler, United States, 2003**
 - 30 vials of *Yersinia pestis* missing from lab (never recovered); Butler served 19 months in jail
- **Laboratory-acquired outbreaks of SARS, 2003 – 2004**
 - Singapore—September 2003
 - Taiwan (China)—December 2003
 - Beijing and Anhui (China)—March 2004



Thomas Butler



TAMU Select Agent
researcher
– Dallas Morning
News

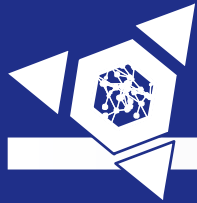


How Do You Avoid Similar Problems at Your Institution?

- **Laboratory biorisk management programs need:**
 - Appropriate resources
 - Institutional guidelines and operating procedures
 - Training
 - Oversight
- **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?

It Depends on the Risk Assessment!!





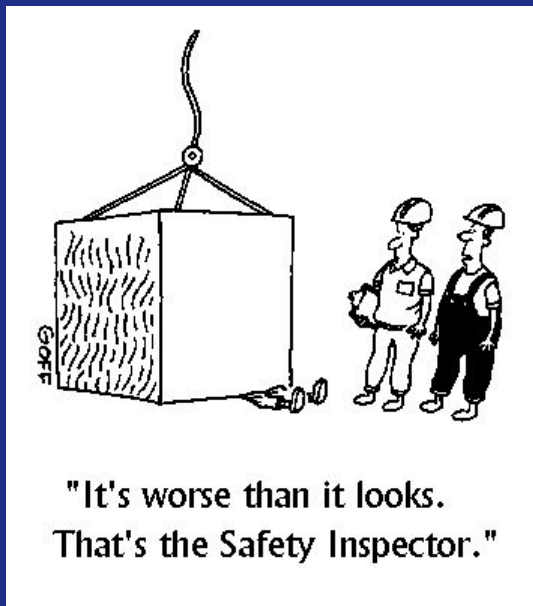
Planning: Risk Assessment as the Foundation

- **Impossible to eliminate risk without eliminating the biohazard**
 - Identify, assess, and manage the risks
- **Need to effectively allocate limited resources to address highest risks first**
- **Risk assessment**
 - Identify and characterize biohazards
 - Evaluate laboratory procedures
 - Evaluate local threat environment
 - Analyze gaps in existing biosafety and biosecurity measures
 - Prioritize gaps based on risks
- **Management uses risk assessment to make risk mitigation decisions**
 - Engineered controls
 - Procedural controls
 - Administrative controls



Implementation: Roles and Responsibilities

- **Biorisk manager** – provides oversight and subject matter expertise
- **Scientific manager** – responsible for implementation
- **Biorisk management committee** – serves as independent review group
- **Top management** – allocates resources and is ultimately responsible for institution's biorisk management program





Implementation: Training

- **Standard training**
 - Combination of lectures and informal mentoring
 - This is NOT sufficient
- **Ladder of knowledge and skills**
 - Basic awareness raising
 - Knowledge of fundamentals
 - Hands-on learning of best practices
 - Advanced training on best practices
 - Facility-specific training
 - Task-specific training
- **New training initiatives are shifting the paradigm**
 - Training needs to give students practice – case studies, interactive discussions, and hands-on training
 - Success of training should be measured against specific learning objectives
 - **Pre and post-training tests, quizzes, and follow-up after end of course**





New Training Initiatives

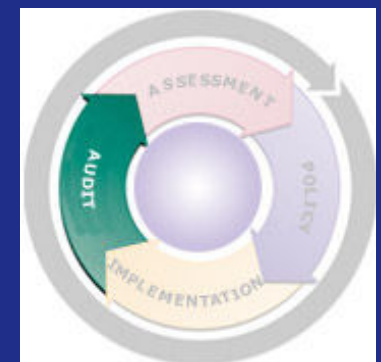
- **American Biological Safety Association: Principles and Practices of Biosafety**
 - Week-long biosafety course, based on case studies and lessons learned
- **World Health Organization and U.S. National Institutes of Health: Laboratory Biosafety Train-the-Trainers**
 - Two-week biosafety course, relying on mix of lecture, case study, and hands-on laboratory exercises
- **Sandia National Laboratories: Controlling Biorisks**
 - Week-long course with an integrated approach to laboratory biosafety and biosecurity, using lecture, case studies, guided discussion, and hands-on laboratory activity
- **Advanced training on best practices**
 - Emory University: Science and Safety Training Program
 - Canadian Science Centre for Human and Animal Health: International High Containment Biosafety Workshop





Oversight to Ensure Continual Improvement

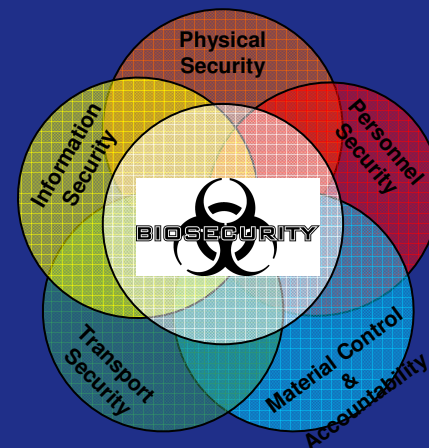
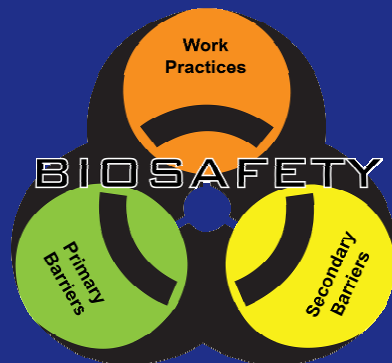
- **Biorisk management program must be documented**
 - Risk assessments, biorisk manuals, standard operating procedures, program objectives, maintenance plans, incident response plans, equipment certifications, inventories, etc.
- **Documents need to be reviewed and updated at regular intervals, and after any incidents**
 - Risk assessments should also be reviewed after any changes to institution's program or threat environment
- **Regular audits are vital tool to assess program effectiveness, and evaluate opportunities for improvement**
 - Frequency determined by risk
 - Internal self assessments
 - External third-party reviews
 - Must develop follow-up plan to address corrective actions
 - Need to verify corrective actions have been completed
- **Need a cohesive framework for implementing a program to control biorisks**
 - Many elements to integrate





Biorisk Management Systems Approach

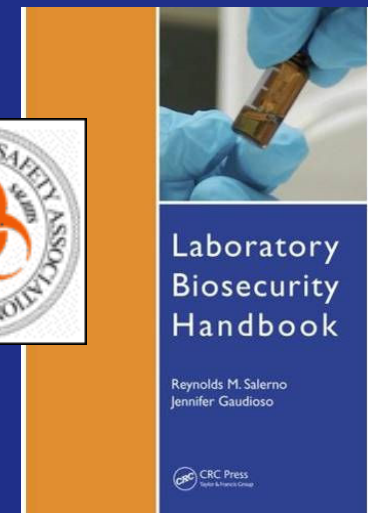
- **Need a cohesive framework for implementing a program to control biorisks**
 - Many elements to integrate
- **Example management systems used in labs**
 - ISO 9001:2000 – a quality management system
 - ISO 14001:2004 – an environmental management system
 - OHSAS 18001:2007 – an occupational health & safety management system
- **CEN Workshop Agreement, 2008 – laboratory biorisk management system**
 - Risk-based approach
- **All rely on a “Plan-Do-Check-Act” approach with the goal of continuous improvement**





Biorisk Management Resources

- **Laboratory Biosafety and Biosecurity Guidance**
 - Laboratory Biosecurity Handbook, CRC Press, 2007
 - WHO Laboratory Biosafety Manual, 3rd edition, 2004
 - **Chapter 9 on Laboratory Biosecurity**
 - WHO/FAO/OIE joint guidance – *Biorisk Management: Laboratory Biosecurity Guidance, 2006*
 - CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories, 5th edition, 2007*
 - **Extensive recommendations on biosecurity**
 - Canada's *Laboratory Biosafety Guidelines, 3rd edition, 2004*
 - Laboratory biorisk management standard
 - **CEN Workshop Agreement 15793, February 2008**
- **Training and Other Key Online Resources**
 - IBWG: internationalbiosafety.org
 - AnBIO: www.anbio.org
 - ABSA: www.absa.org
 - APBA: www.a-pba.org
 - Emory: www.sph.emory.edu/CPHPR/biosafetytraining
 - Canada: www.biosafety.ca/home.html
 - WHO TTT: www.who.int
 - Biosecurity Engagement Program: www.BEPstate.net
 - Sandia: www.biosecurity.sandia.gov





Key Conclusions and Opportunities

- **Growing concern globally about laboratory biosafety, biosecurity, and biocontainment**
- **Many commonalities around the world**
 - Opportunities to learn from each other
- **Cost is a significant factor**
 - Lower cost / lower technology solutions to managing biosafety and biosecurity risks must be made available
 - Risk assessment is the essential planning tool
- **Biorisk management systems can be a good systematic approach to ensuring effective biosafety and biosecurity mitigation measures are in place at the institutional level**





Contact Information

Jennifer Gaudio, Ph.D.
Tel. 505-284-9489
email: jmgaudi@sandia.gov

Sandia National Laboratories
PO Box 5800, MS 1363
Albuquerque, NM 87185
USA

www.biosecurity.sandia.gov