Biosecurity and Biosafety—A Growing Concern

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Albuquerque, NM USA
12 May 2008

SAND No. 2008-XXX C
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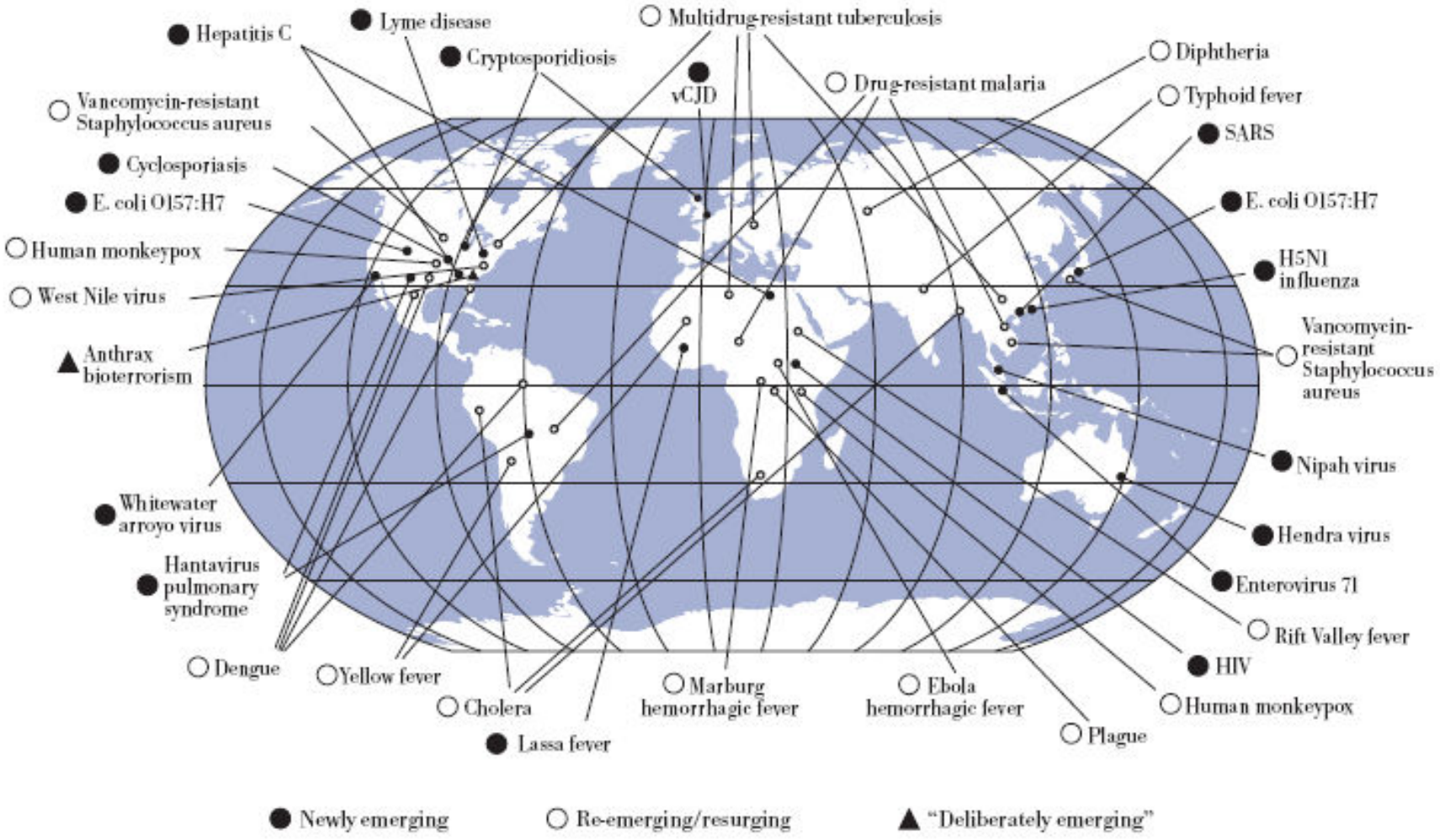
Examples of Emerging and Re-Emerging Diseases



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

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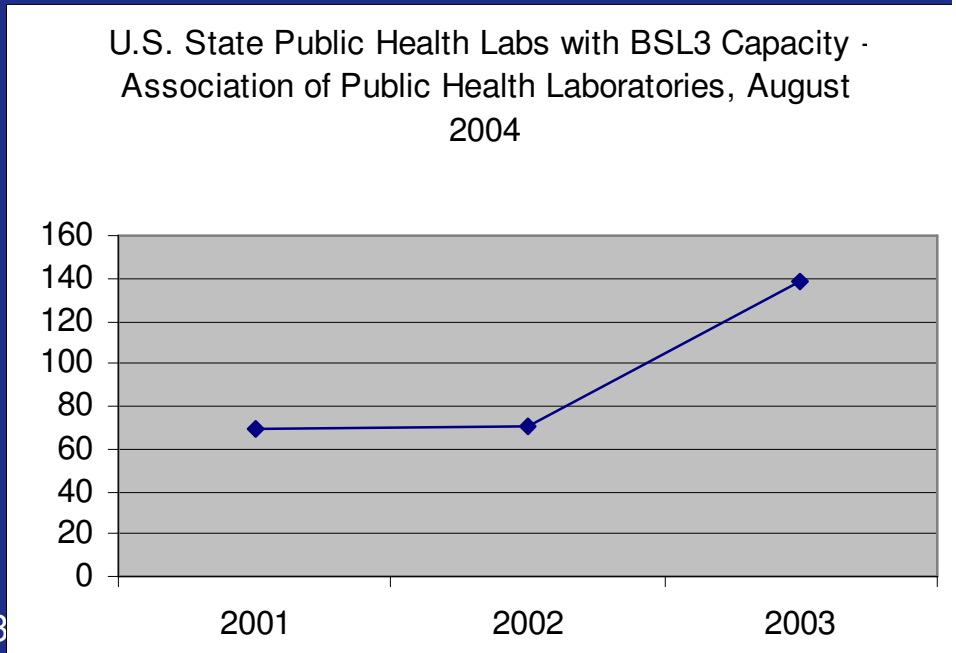
Examples of Expansion of Containment Laboratories Inside the U.S.

- **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

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**

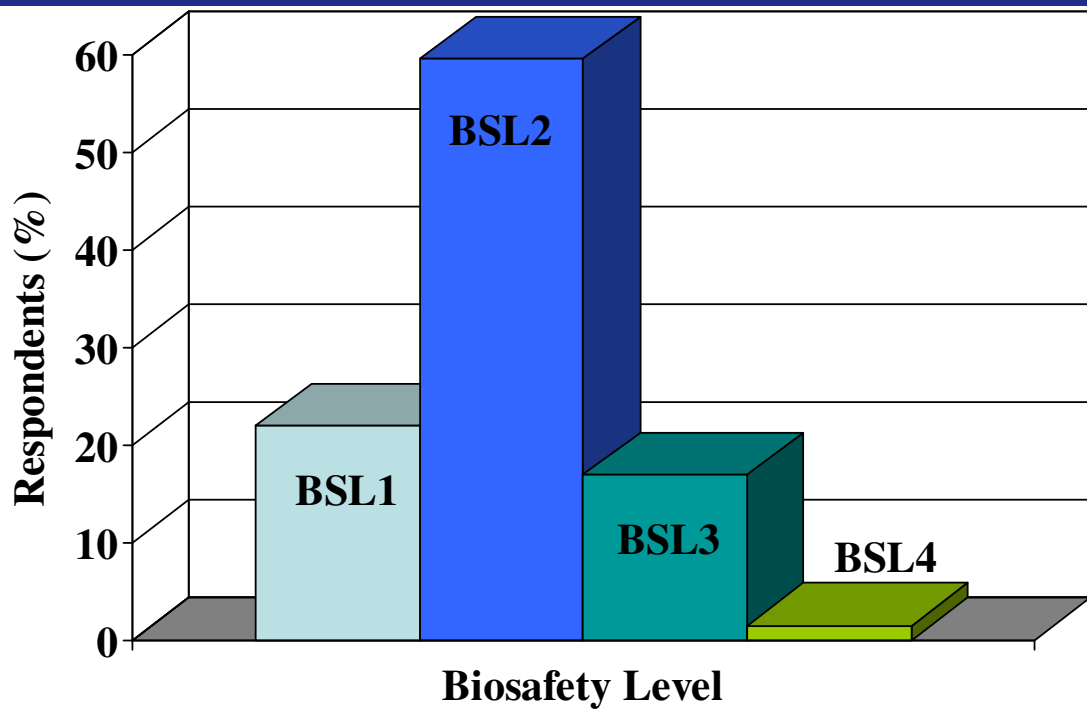
References:

- 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

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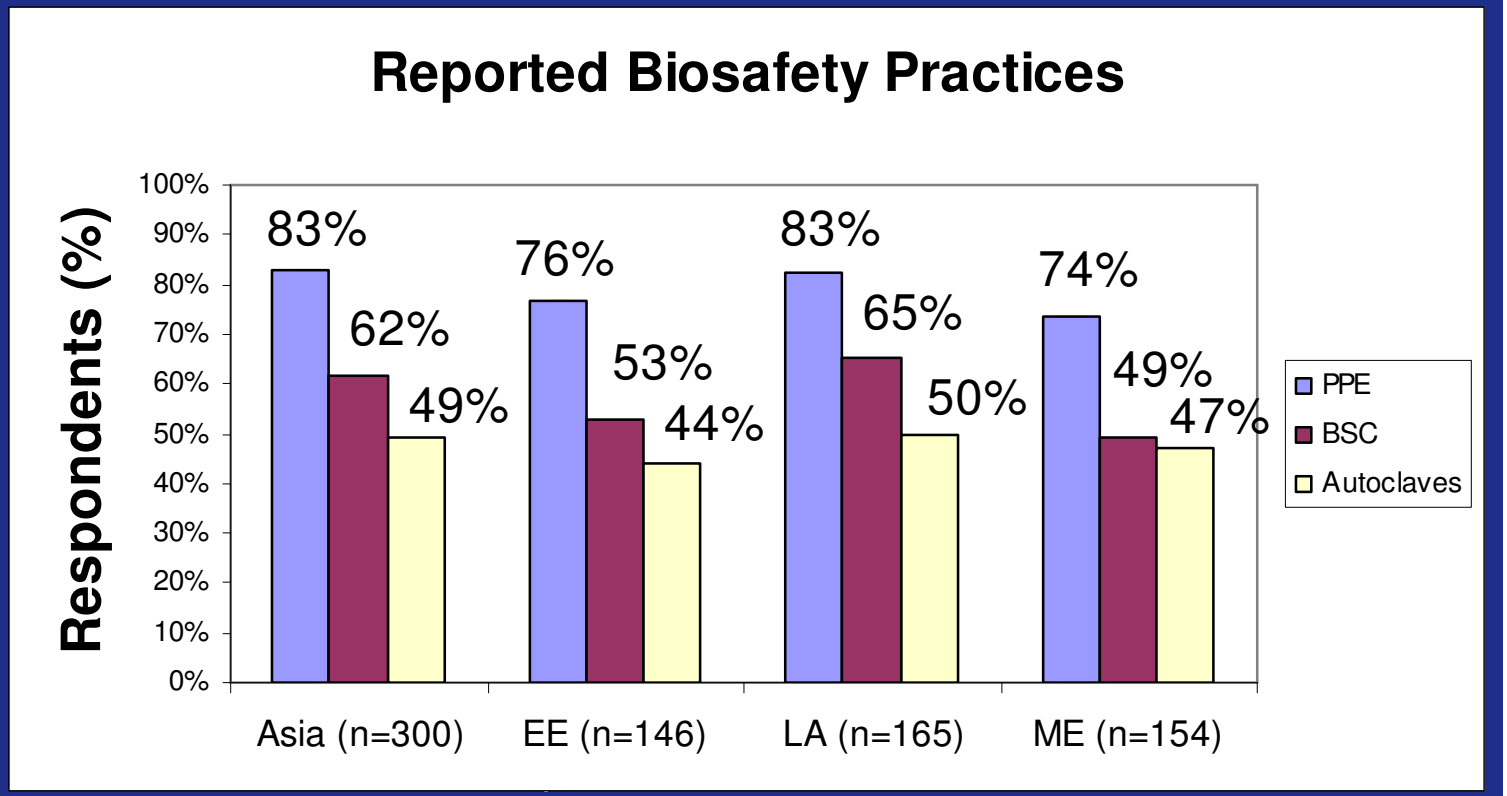
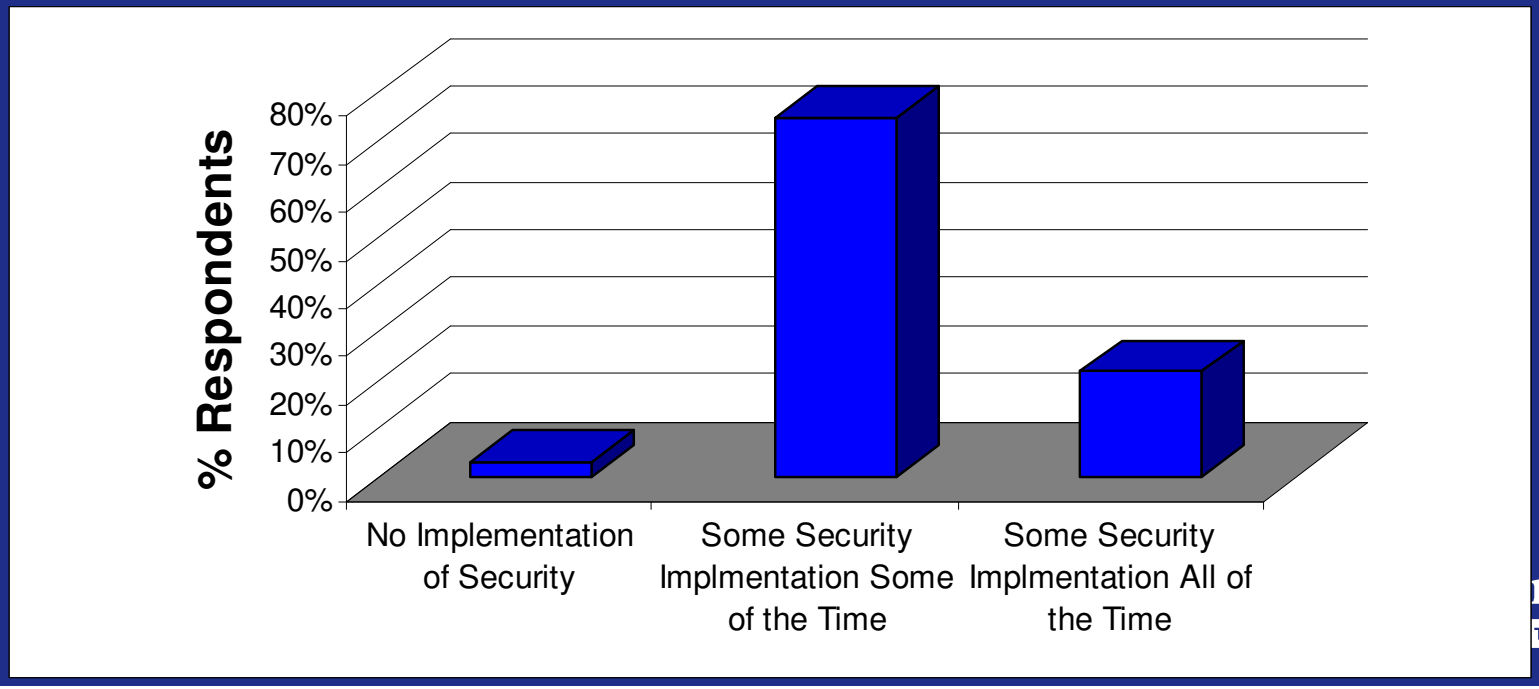
Biosafety Practices Reported in Surveys

- **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



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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%

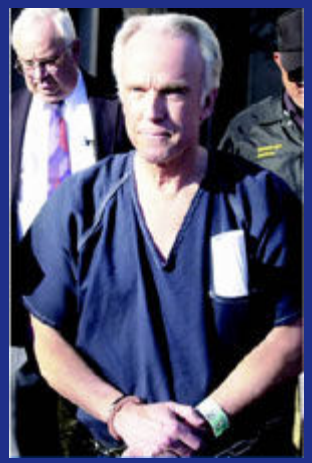
Examples of Growing Attention to Laboratory Biosecurity and Biosafety Internationally

- **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 *Yesinia 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

TAMU Select Agent researcher – Dallas Morning News



Thomas Butler

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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!!

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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

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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

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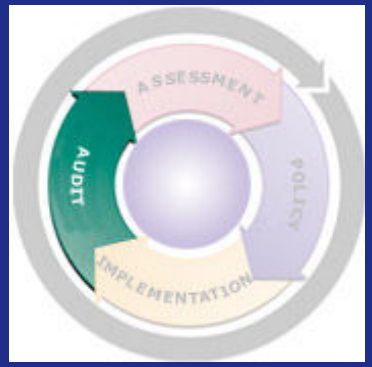
Oversight to Ensure Continual Improvement

- **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

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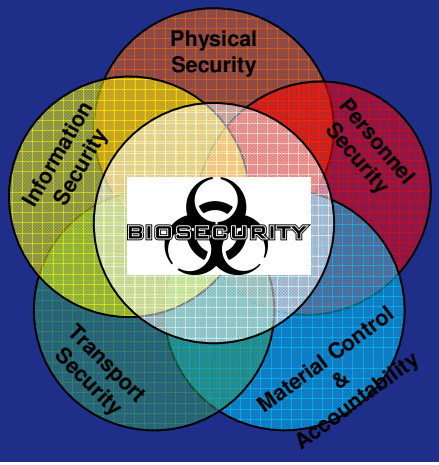
Biorisk Management Systems Approach

- **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**



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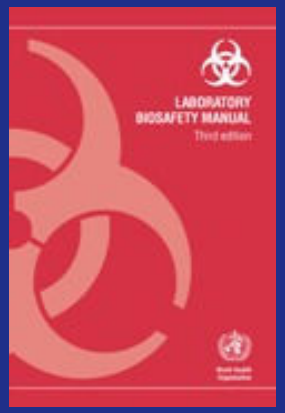
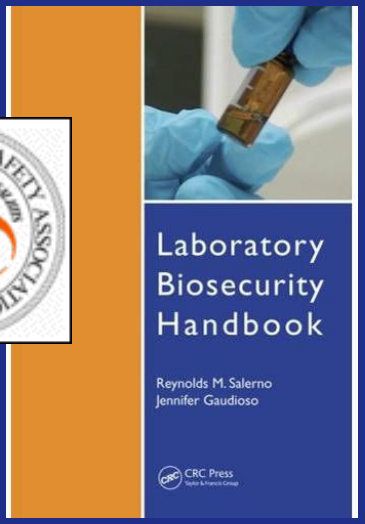
Biorisk Management Resources

- **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





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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**

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