



Building a Solid Foundation for Laboratory Biosafety and Biosecurity

Jennifer Gaudioso, PhD

International Biological Threat Reduction

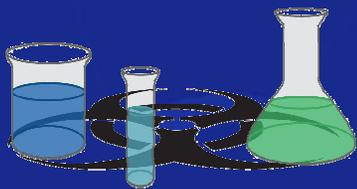
Global Security Center

Sandia National Laboratories

Albuquerque, NM USA

11 March 2008

www.biosecurity.sandia.gov



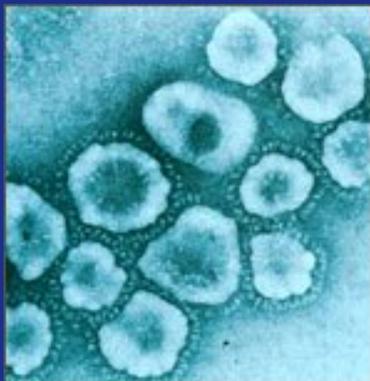
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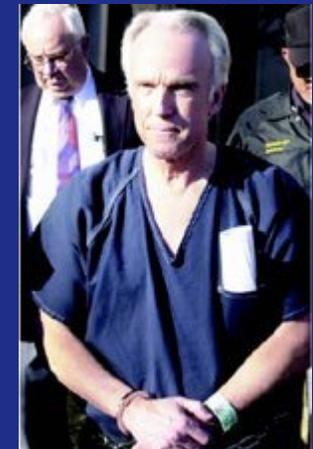


Examples of Safety and Security Issues Arising from Problems in Biorisk Management

- **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



TAMU Select Agent researcher
– Dallas Morning News



Thomas Butler



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!!





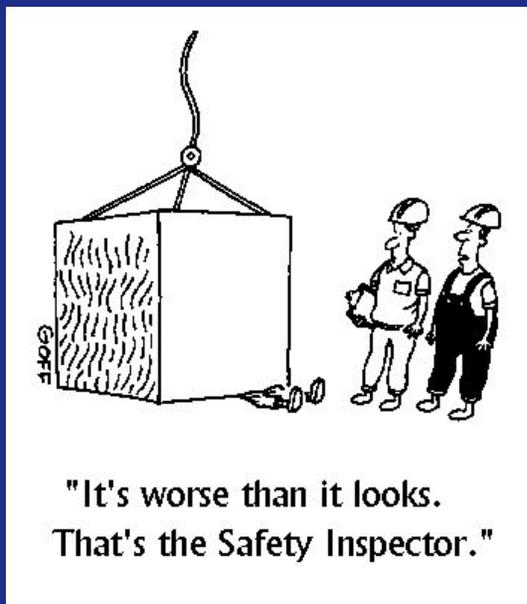
Planning: Risk Assessment as the Foundation

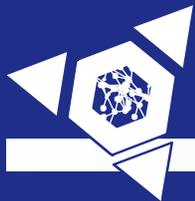
- **Impossible to eliminate risk without eliminating the biohazard**
 - Identify, assess, and manage the risks
- **Need to effectively allocate limited resources to address highest risks first**
- **Risk assessment**
 - Identify and characterize biohazards
 - Evaluate laboratory procedures
 - Evaluate 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

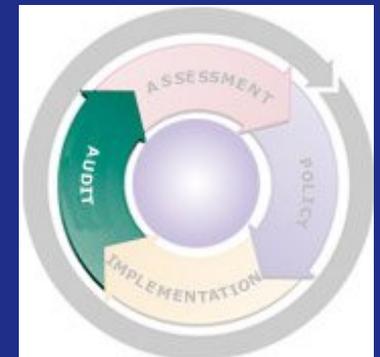
- **American Biological Safety Association: Principles and Practices of Biosafety**
 - Week-long biosafety course, based on case studies and lessons learned
- **World Health Organization and U.S. National Institutes of Health: Laboratory Biosafety Train-the-Trainers**
 - Two-week biosafety course, relying 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

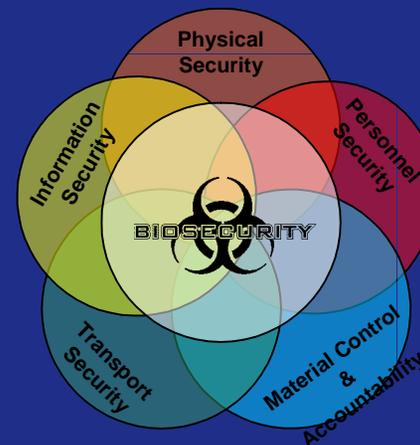
- **Biorisk management program must be documented**
 - Risk assessments, biorisk manuals, standard operating procedures, program objectives, maintenance plans, incident response plans, equipment certifications, inventories, etc.
- **Documents need to be reviewed and updated at regular intervals, and 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





Biorisk Management Systems Approach

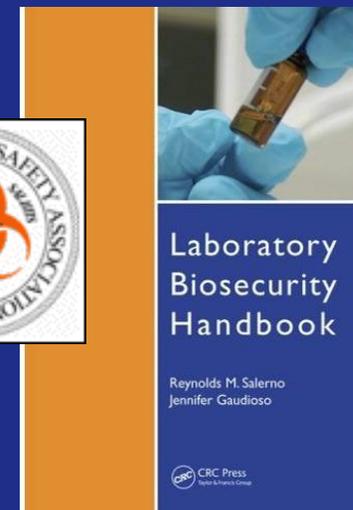
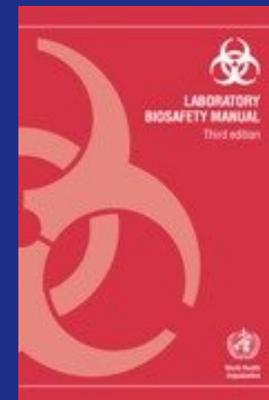
- **Need a cohesive framework for implementing a program to control biorisks**
 - Many elements to integrate
- **Example management systems used in labs**
 - ISO 9001:2000 – a quality management system
 - ISO 14001:2004 – an environmental management system
 - OHSAS 18001:2007 – an occupational health & 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 Resources**
 - ABSA PPB: www.absa.org
 - Emory: www.sph.emory.edu/CPHPR/biosafetytraining
 - Canada: www.biosafety.ca/home.html
 - Sandia: www.biosecurity.sandia.gov
 - WHO TTT: www.who.int





DOS/ISN/CTR Biosecurity Engagement Program



Why

- Combat Terrorist Threat
- Deter Proliferation

Where

- South Asia, Southeast Asia
- Global

What

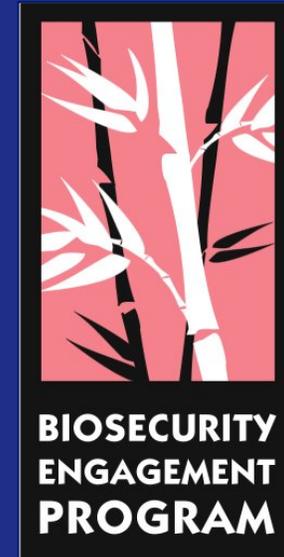
- Scientist Engagement
- Biosafety and Biosecurity
- Global Biological Threat Reduction

How

- Strengthen Scientific Collaboration
- Safe, Secure, Sustainable S&T Development

Programmatic Effort:

- Threat Driven
- Annual NADR appropriation
- New \$26M for BEP in FY08





DOS/ISN/CTR

Biosecurity Engagement Program



Assistance

- Biosecurity and Biosafety Support
- Training
- Surveillance and Diagnostics
- Grants Assistance Program
- Global Collaboration

Benefits

- Transparency
- Unique Insights on Infectious Disease
- Meaningful Relationships
- Diplomacy
- Long-Term Impact on Global Security
- Enhance other Assistance Efforts
- Promote Biosecurity Standards



www.BEPstate.net



Contact Information

Jennifer Gaudioso, 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