



# Building a Solid Foundation for Laboratory Biosafety and Biosecurity

SAND2008-1138C

*Jennifer Gaudioso, PhD*

**International Biological Threat Reduction Program**

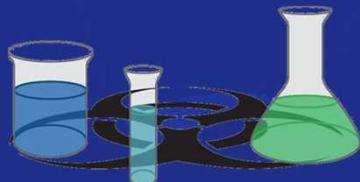
**Global Security Programs**

**Sandia National Laboratories**

**Albuquerque, NM USA**

**11 March 2008**

**[www.biosecurity.sandia.gov](http://www.biosecurity.sandia.gov)**



SAND No.

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.



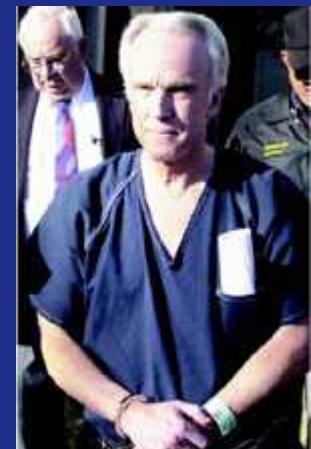


# Examples of Safety and Security Issues Arising from Problems in Biorisk Management

- **Texas A&M, 2006 – 2007**
  - U.S. federal officials suspend all select agent research due to failures to report two incidents
- **Pirbright, 2007**
  - Leaks from pipes in the effluent system caused Foot and Mouth Disease outbreak
  - Pipes were known to need maintenance
- **Thomas Butler, 2003**
  - 30 vials of *Yersinia pestis* missing from lab (never recovered); Butler served 19 months in jail



TAMU select agent researcher  
– Dallas Morning News



Thomas Butler



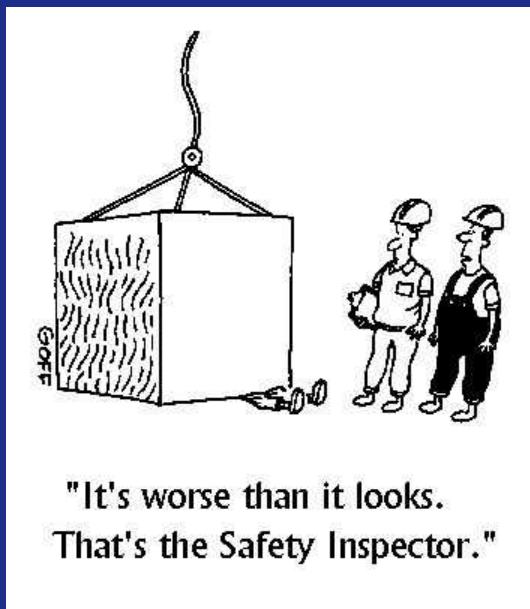
# Planning: Risk Assessment as the Foundation

- **Resource allocation**
- **Impossible to eliminate risk without eliminating the biohazard**
  - Identify, assess, and manage the risks
- **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 allocate program resources**
  - 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

- **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
- **Standard training**
  - Combination of PowerPoint lectures and mentoring
- **New training initiatives shifting paradigm**





# New Training Initiatives



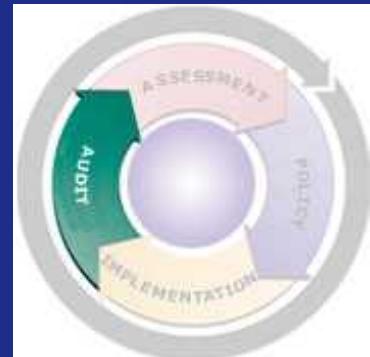
- **American Biological Safety Association: Principles and Practices of Biosafety**
  - Week long biosafety course, based on case studies and lessons learned
- **World Health Organization and U.S. National Institutes of Health: Laboratory Biosafety Train-the-Trainers**
  - Two week biosafety course relying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

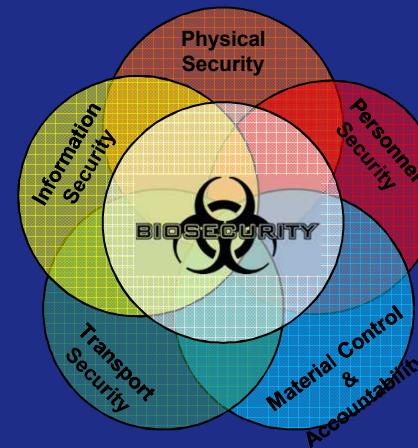
- **Biorisk management program must be documented**
  - Risk assessments, biorisk manuals, standard operating procedures, program objectives, maintenance plans, incident response plans, equipment certifications, inventories, etc
- **Documents need to be reviewed and updated at regular intervals and after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





# 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 – a laboratory biorisk management system
- All rely on a “Plan-Do-Check-Act” approach with the goal of continual improvement



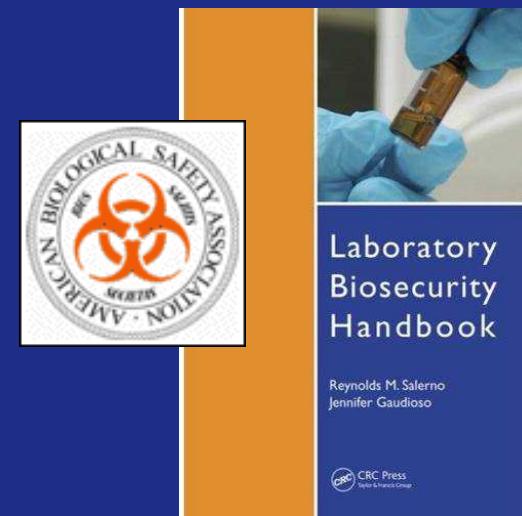


# Resources

- **Laboratory Biosafety and Biosecurity Guidance**
  - Laboratory Biosecurity Handbook, 2007, CRC Press
  - WHO Laboratory Biosafety Manual, 3rd edition
    - **Ch 9 is Laboratory Biosecurity**
  - WHO/FAO/OIE joint guidance – *Biorisk Management: Laboratory Biosecurity Guidance, 2006*
  - CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*
    - **5th edition, 2006, extensive recommendations on biosecurity**
  - Canada's *Laboratory Biosafety Guidelines*, 3rd edition
  - Laboratory biorisk management standard
    - **CEN Workshop Agreement 15793, February 2008**



- **Training Resources**
  - ABSA PPB: [www.absa.org](http://www.absa.org)
  - Emory: [www.sph.emory.edu/CPHPR/biosafetytraining](http://www.sph.emory.edu/CPHPR/biosafetytraining)
  - Canada: [www.biosafety.ca/home.html](http://www.biosafety.ca/home.html)
  - Sandia: [www.biosecurity.sandia.gov](http://www.biosecurity.sandia.gov)
  - WHO TTT: [www.who.int](http://www.who.int)





# Contact Information

**Jennifer Gaudioso, Ph.D.**  
**Tel. 505-284-9489**  
**email: [jmgaudi@sandia.gov](mailto:jmgaudi@sandia.gov)**

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

**[www.biosecurity.sandia.gov](http://www.biosecurity.sandia.gov)**