Biorisk Management

Biosecurity Inspector Training

Staten Serums Institut

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www.biosecurity.sandia.gov

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Examples of Safety, Security, and Sustainability Issues

- **Laboratories have had to halt operations due to regulatory infractions**
  - Texas A&M University, United States, 2006 – 2007
    - **U.S. federal officials suspend all Select Agent research due to failures to report two incidents**
  - Professor Thomas Butler, United States, 2003
    - **30 vials of *Yesinia pestis* missing from lab (never recovered); Butler served 19 months in jail**

- **Laboratories have been constructed but unable to operate as intended long term**
  - BSL-4 laboratory in Etobicoke, Ontario, Canada – operating as a BSL-3
  - BSL-3 laboratory at Los Alamos National Laboratory – operating as a BSL-2
  - Several BSL-3 laboratories in Southeast Asia that are no longer operating at all due to problems maintaining the facilities
- **Laboratories have had operations impacted from LAIs and releases**
  - Pirbright Laboratory, Institute of Animal Health, UK, 2007
    - **Leaks from pipes in the effluent system caused FMD outbreak**
  - Laboratory-acquired outbreaks of SARS, 2003 – 2004

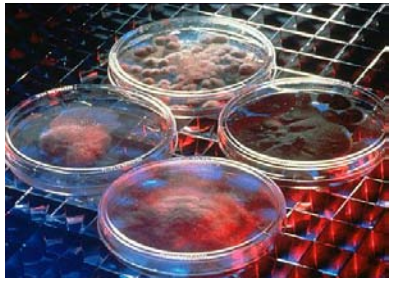
Biosafety vs. Biosecurity Discussion

- **List 3 ways biosecurity can reinforce biosafety objectives:**
  - 1.
  - 2.
  - 3.

- **List 3 potential conflicts between biosafety and biosecurity:**
  - 1.
  - 2.
  - 3.

Laboratory Biorisk Program Management

- **Seeks to effectively and efficiently manage an institution's laboratory biorisks**
- **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?

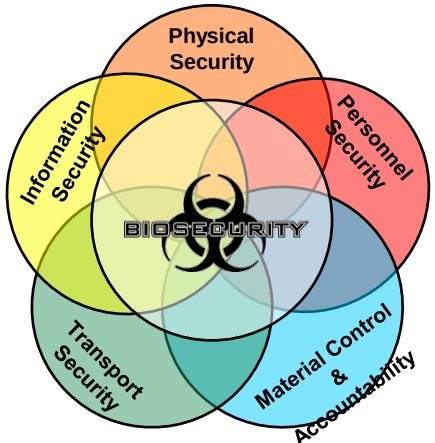
It Depends on the Risk Assessment!!

Risk Assessment Usually Not the Only Input for Risk Management

- **Mitigation strategies for risk are based on several factors:**
  - Science (the risk assessment)
  - Technical limitations
  - Economic constraints
  - Politics
  - Legal implications
  - Health
  - Social

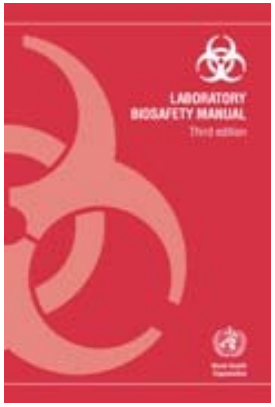
Biorisk Management Systems Approach

- **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
  - CWA 15793:2008
- **All rely on a "Plan-Do-Check-Act" approach with the goal of continuous improvement**



Laboratory Biorisk Management Standard

- **Based on international best practices**
  - World Health Organization – *Laboratory Biosafety Manual, 3rd edition*
  - WHO/FAO/OIE joint guidance – *Biorisk Management: Laboratory Biosecurity Guidance, 2006*
- **Developed by consensus, initiated by leading professional organizations**
  - European Biological Safety Association
  - American Biological Safety Association
  - Asia Pacific Biosafety Association



European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Plan – Do – Check - Act

- **Plan**
  - Planning, including identification of hazards and risks and establishing program goals
- **Do**
  - Implementing, including training and operational issues
- **Check**
  - Checking, including monitoring and corrective action
- **Act**
  - Reviewing, including process innovation and acting to make needed changes to the management system.

Plan

- **Define Biorisk Program objectives**

- **Ensure compliance with all national and international requirements**
  - Biosafety and biosecurity regulations, Biological Weapons Convention, etc

- **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 – a fundamental planning tool**
  - 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

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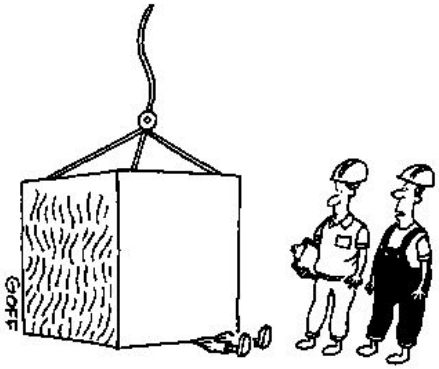
Do

- **Determine 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

- **Are there other key roles and responsibilities ?**



"It's worse than it looks.
That's the Safety Inspector."

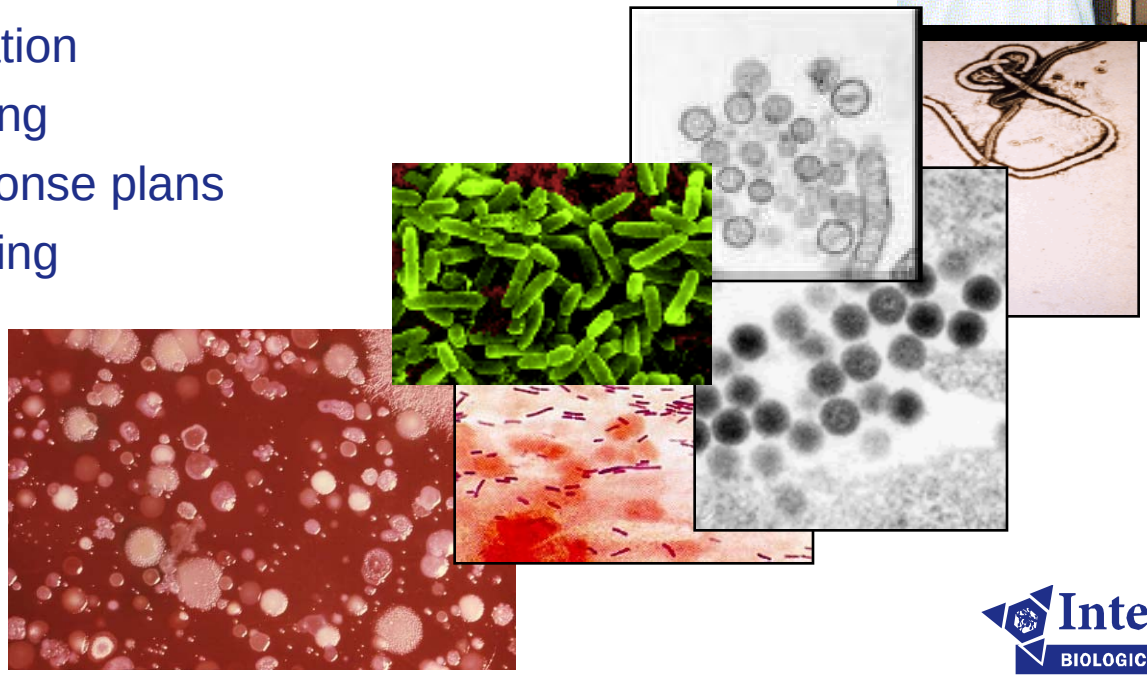
Do

- **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**

Do

- **Risk mitigation**
  - Occupational health program
  - Facility maintenance
  - Access controls
  - Personnel screening
  - Good laboratory practices
  - PPE
  - Decontamination
  - Waste handling
  - Incident response plans
  - Animal handling
  - Etc



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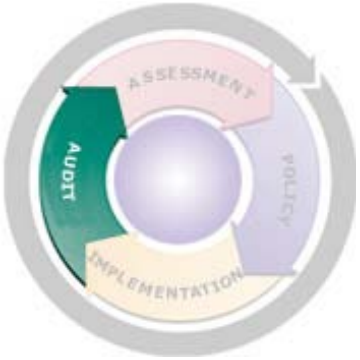
Check

- **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



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Act

- **Biorisk management program should be regularly reviewed and updated**
  - Is it effective?
- **Review information should include**
  - Results of audits
  - Work activities
  - Status of risk assessment activities
  - Status of preventative and corrective actions
  - Follow-up actions from previous management reviews
  - Results of incident investigations
  - Changes that could impact program
- **Review should lead to decisions and actions to improve**
  - Effectiveness of biorisk management program
  - Requirements and risk assessments
  - Resource needs

System Effectiveness: Discussion

- **What metrics might be used to measure the effectiveness of a facility's risk management system?**
  - Management performance indicators?
  - Operational performance indicators?
  - Biorisk status indicators?
- **Can the same metrics be used for biosafety and biosecurity?**

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Considerations in the Development of Laboratory Standards

- **Standards are technical documents, detailing a repeatable way to do something**
  - Technical standards can be international or local
  - Can be prescriptive or performance-based
  - Standards can be voluntary or incorporated into regulations

- **Every laboratory is unique**
  - Standards must be flexible to be broadly applicable and sustainable
  - Trade-off between level of detail and applicability

- **Success requires that standards are:**
  - Cost-effective, consistent, clear, sensible,
  - Developed in an open, transparent, fair process

- **Commitment by top management, focus on continual improvement are also key to successful implementation of standards**

Certificating Laboratories to Standards

- **Certification ensures that a facility, process, or piece of equipment is functioning in accordance with published standards published and administered by a regulatory entity.**
  - Example: Biological Safety Cabinet certification - ANSI/NSF 49.

- **There are currently no international laboratory certification standards for laboratories (only management standards) and, thus, no accrediting or certification entity.**

- **High containment design and operation is driven by the risk assessment (RA). Since the RA is developed specifically for each lab, developing criteria for certification becomes problematic.**

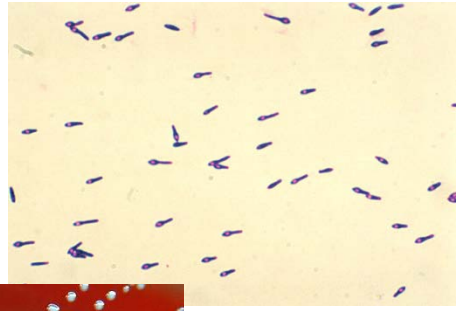
- **Certifying a lab without published certification standards can introduce significant liability issues.**

Summary

- **Program management is an overarching component of both biosafety and biosecurity programs**

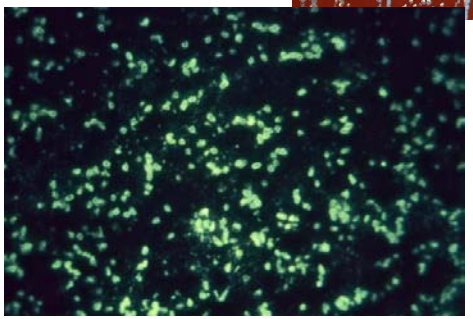
- **Ensures success of the programs by**
  - Planning
  - Staffing
  - Funding
  - Training

- **Should address every element of the biorisk program**



Clostridium botulinum

Brucella melitensis



Yersinia Pestis

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