



Program Management

Biorisk Management Training Course
International Biological Threat Reduction Program
National Institutes of Virology
October 2009

SAND No.

Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,
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Program Management Roles and Responsibilities

- **Numerous stakeholders in program management**
- **All should:**
 - Ensure each component of biosafety and biosecurity are implemented and function optimally
 - Thoroughly understand and implement the risk assessment process
 - Decide which risks should be mitigated, and allocate resources accordingly
 - Clearly delineate the roles and responsibilities of laboratory personnel



Class Discussion

- **What is the most important factor/s hindering successful implementation of program management in your laboratory?**

- **How does management in your laboratory implement operational training and education?**



Biorisk Management Systems Approach

- All rely on a “Plan-Do-Check-Act” approach with the goal of continuous improvement
- **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

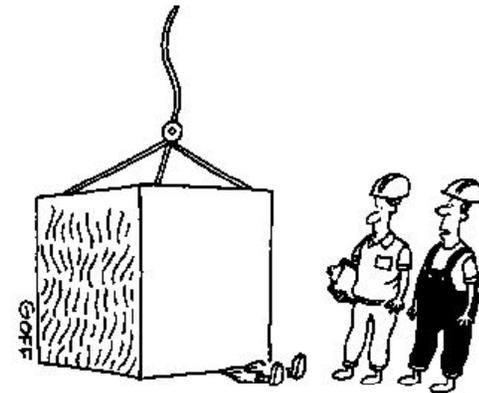
- **Define specific Biorisk Program objectives**
- **Ensure compliance with all national and international requirements**
- **Effectively allocate limited resources to address highest risks first**
- **Perform a risk assessment**
- **Make risk mitigation decisions**





Do

- **Determine roles and responsibilities**
 - Biorisk manager
 - Scientific manager
 - Biorisk management committee
 - Top management



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



Do

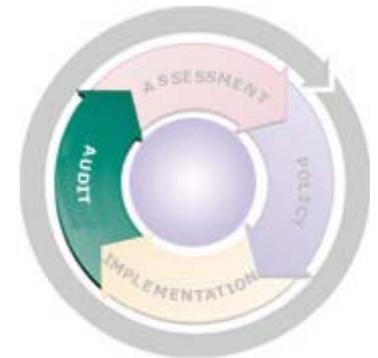
- **Provide standard training**
 - Although this is NOT sufficient
- **Provide personnel knowledge and skills**
- **Implement training initiatives**
- **Implement risk mitigation measures**
- **Perform Facility maintenance**





Check

- **Biorisk management program must be documented**
- **Documents need to be reviewed and updated at regular intervals, and after any incidents**
- **Regular audits are vital tools to assess program effectiveness, and evaluate opportunities for improvement**





Internal Inspections: Discussion

- What are the objectives of an internal inspection?
- What should an internal inspection focus on?
- Who should carry out an internal inspection?
- With what frequency?
- How should the results of internal inspections be communicated, documented, and followed up?



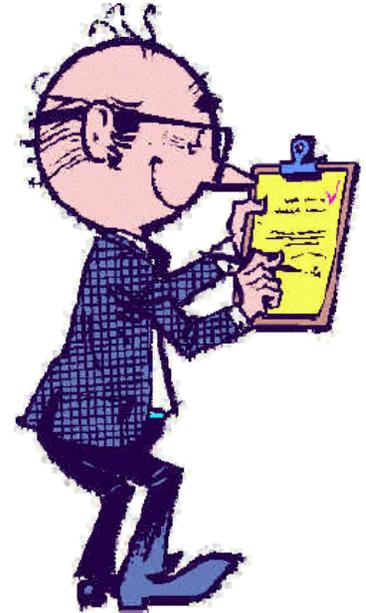
External Inspections: Discussion

- What are the objectives of an external inspection?
- What should an external inspection focus on?
- Who should conduct external inspections?
- What triggers an external inspection? With what frequency are they carried out?
- How should the results of external inspections be communicated, documented, and followed up?



Act

- **Biorisk management program should be regularly reviewed and updated**
- **Review information should include**
 - Audit results
 - 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**





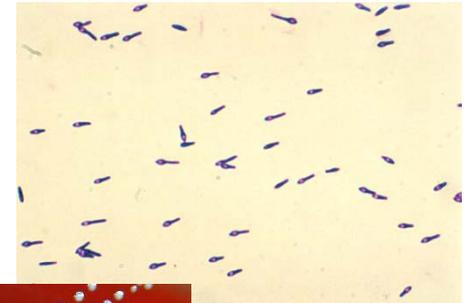
System Effectiveness: Discussion

- **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?**



Summary

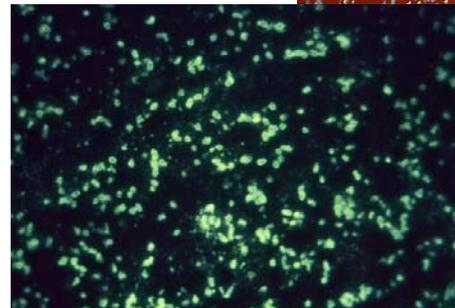
- **Program management is an overarching component of both biosafety and biosecurity programs!**
- **Ensures success of the programs by**
 - Planning
 - Staffing
 - Funding
 - Training
- **Should address every element of the biorisk program**



Clostridium botulinum



Brucella melitensis



Yersinia Pestis