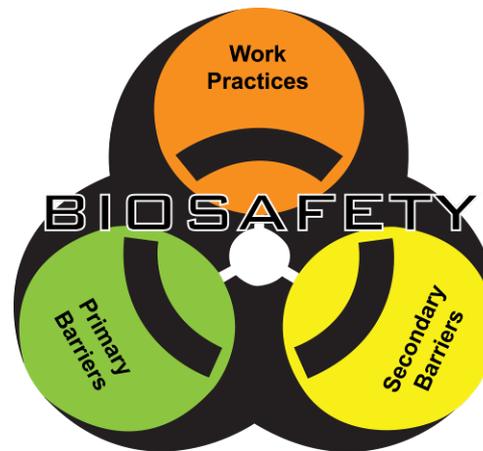
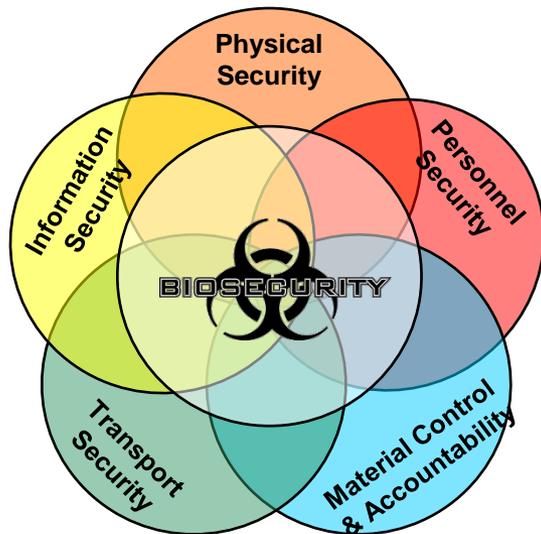




Program Management



Controlling Laboratory Biorisks Training Course

International Biological Threat Reduction Program

Global Security Programs

Sandia National Laboratories

Albuquerque, NM USA



SAND No. 2008-0480P

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.



What is Program Management?

- **A laboratory program which seeks to effectively and efficiently manage an institution's laboratory biorisks**
- **Effective program management is central to the success of implementing biosafety and biosecurity in any laboratory!**
- **Laboratory biorisk management programs need:**
 - Resources
 - Institutional guidelines and operating procedures
 - Training
 - Oversight





Class Objectives

- **Stress the importance of Program Management in a laboratory**
- **Describe specific laboratory roles and responsibilities**
- **Describe the “Plan-Do-Check-Act” approach**



Common Concerns with Implementing Program Management

- How do you allocate scarce resources?
- What do you address in operating procedures?
- Which training is required and for whom?
- What level of oversight is appropriate?

It Depends on the Risk Assessment!!

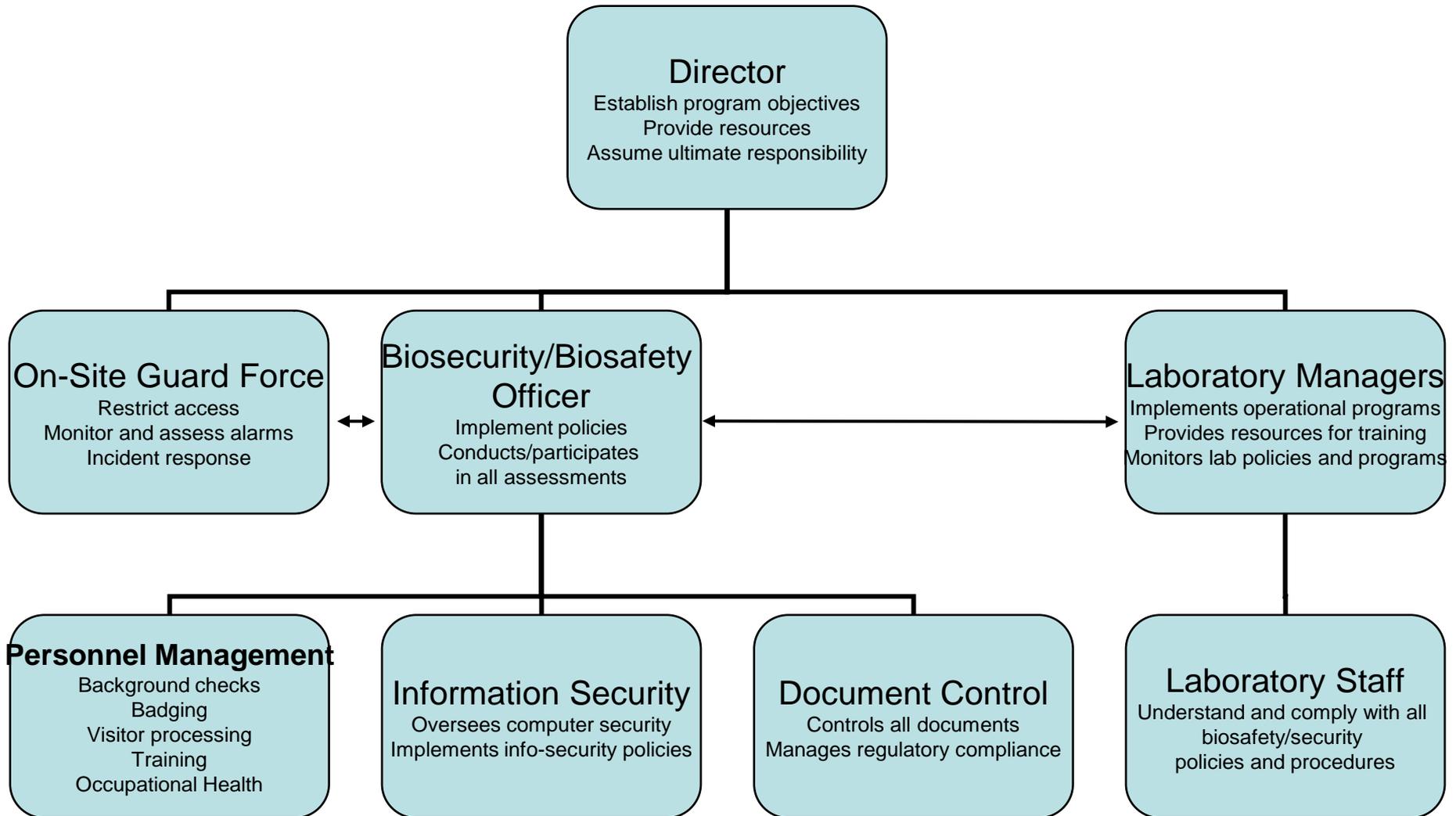


Program Management Roles and Responsibilities

- **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



Program Management Roles and Responsibilities





Class Discussion

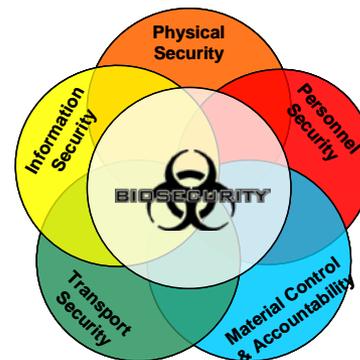
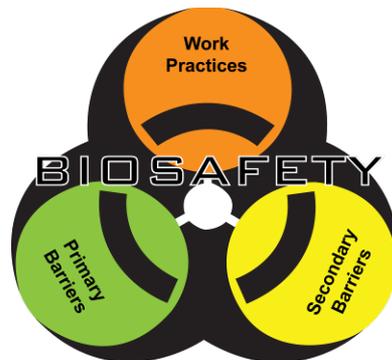
- **What is the most important factor/s hindering successful implementation of program management in your country? In your laboratory?**

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



Biorisk Management Systems Approach

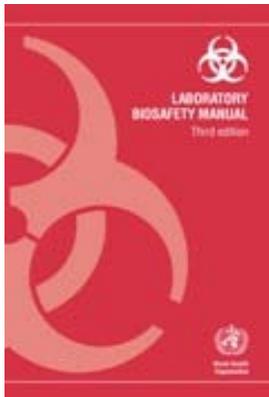
- **Need a cohesive framework for implementing a program to control biorisks**
- **Example management systems commonly used in labs**
 - ISO 9001:2000 – a quality management system
 - ISO 14001:2004 – an environmental management system
 - OHSAS 18001:2007 – an occupational health & safety management system
 - CWA 15793:2008 – laboratory biorisk management system





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





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

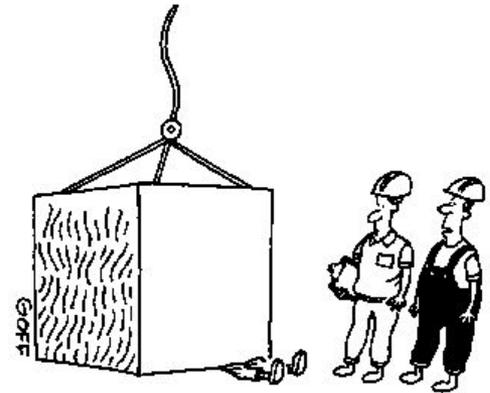
- **Define specific Biorisk Program objectives**
- **Ensure compliance with all national and international requirements**
- **Effectively allocate limited resources to address highest risks first**
- **Perform a risk assessment**
- **Make risk mitigation decisions**





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

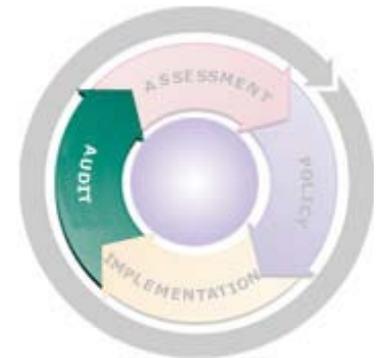
- **Provide standard training**
 - Although this is NOT sufficient
- **Provide personnel knowledge and skills**
- **Implement training initiatives**
- **Implement risk mitigation measures**
- **Perform Facility maintenance**





Check

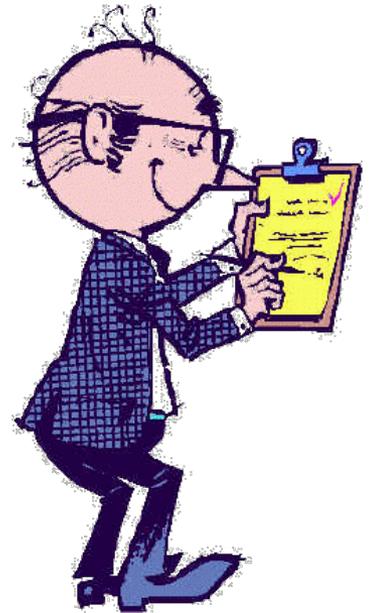
- **Biorisk management program must be documented**
- **Documents need to be reviewed and updated at regular intervals, and after any incidents**
- **Regular audits are vital tools to assess program effectiveness, and evaluate opportunities for improvement**





Act

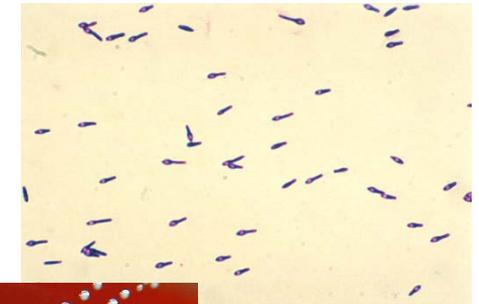
- **Biorisk management program should be regularly reviewed and updated**
- **Review information should include**
 - Audit results
 - Work activities
 - Status of risk assessment activities
 - Status of preventative and corrective actions
 - Follow-up actions from previous management reviews
 - Results of incident investigations
 - Changes that could impact program
- **Review should lead to decisions and actions to improve**





Summary

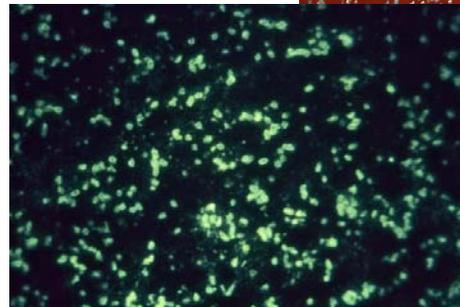
- **Program management is an overarching component of both biosafety and biosecurity programs!**
- **Ensures success of the programs by**
 - Planning
 - Staffing
 - Funding
 - Training
- **Should address every element of the biorisk program**



Clostridium botulinum



Brucella melitensis



Yersinia Pestis