



# *Principles of Biorisk Management Programs*

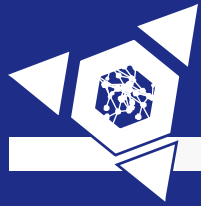
**First Joint Project Meeting**  
**Capacity Building at Pakistan National Accreditation Council for  
Laboratory Biorisk Management Systems**

**May 17 - 19, 2011**

**International Biological Threat Reduction  
Sandia National Laboratories**

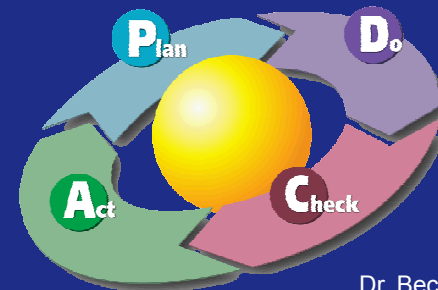
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,  
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under contract DE-AC04-94AL85000.



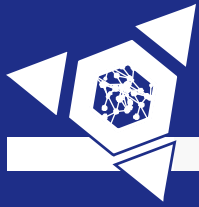


# Outline of Presentation

1. Introduction to Sandia's *International Biological Threat Reduction*
2. Biorisk management: The “AMP” Model
  1. Maximize protection of valuable biological materials
  2. Foster a culture of awareness and compliance
3. Biorisk management system implementation
  1. Plan, Do Check, Act (PDCA)
  2. CWA 15793



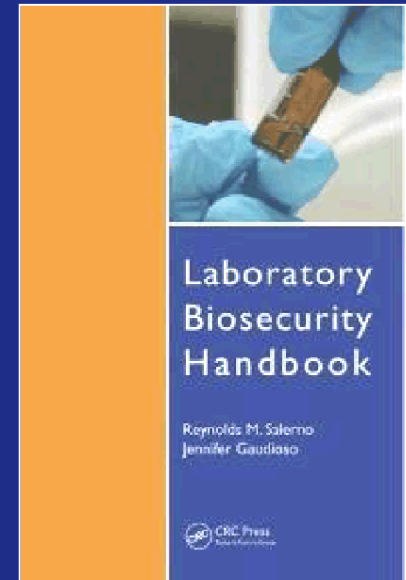
Dr. Becky Hammonds



# Sandia IBTR Mission and Goals

***IBTR works across the globe to protect against the accidental or intentional misuse of the life sciences to harm people, agriculture, or other critical resources***

- **IBTR's highest goals**
  - **Promote** the responsible use of biological agents, equipment, and expertise at bioscience facilities
  - **Strengthen** capacities to detect and control dangerous biological agents
  - **Improve** understanding and mitigation of accidental and deliberate biological risks





# Laboratory Biosafety and Biosecurity

- **Laboratory Biosafety**

- A set of preventive measures designed to ***reduce the risk of accidental exposure to or release of a biological agent***

- **Laboratory Biosecurity**

- A set of preventive measures designed to ***reduce the risk of intentional removal (theft) and misuse of a biological agent*** – intent to cause harm



***“Laboratory biosafety and biosecurity mitigate different risks, but they share a common goal: keeping VBM (Valuable Biological Materials) safely and securely inside the areas where they are stored and used.”***

- World Health Organization, *Biorisk Management: Laboratory Biosecurity Guidance*



# IBTR Program and Unique Technical Capabilities

**Laboratory Biosafety, Biosecurity,  
and Biocontainment**

**Policy, Regulatory, & Guidelines Support**

**Training and Workshops**

**Assessments and Analysis**

**Infectious Disease Diagnostics and Control**

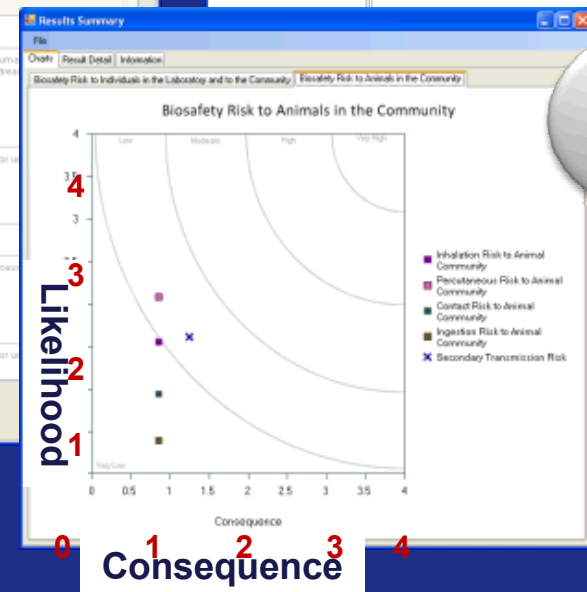
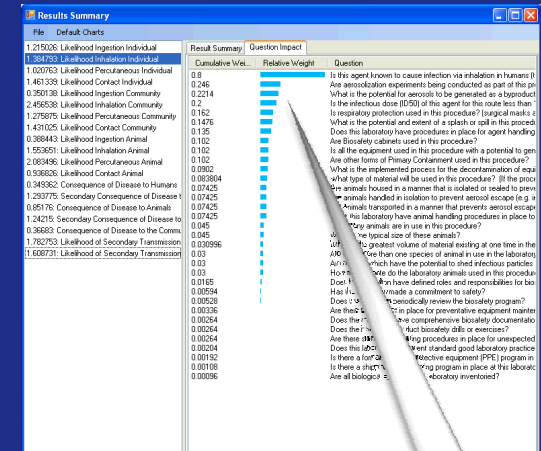




## Risks based on routes of exposure

# Agents

# Procedures



## Risk drivers

# Strengthening Biological Risk Management

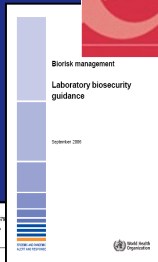


## *Vision for Integrated BioRisk Management:*

- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs and establish accountability through development of Country "report cards"

# International Laboratory Biorisk Management Documents

- **Technical: World Health Organization**  
Laboratory Biosafety Manual (2004)  
  
Biorisk Management: Laboratory Biosecurity Guidance (2006)
- **Management: CEN Workshop Agreements**  
CWA 15793 Laboratory Biorisk Management Standard  
  
CEN WS 55 – CWA 15793 Guidance Document (under development)  
  
CEN WS 53 – Biosafety Professional Competence



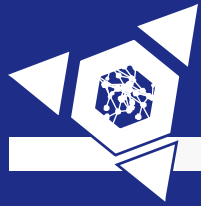




# How To Avoid Biorisk Management Problems?

- **Laboratory biorisk management programs need:**
  - Appropriate resources
  - Institutional guidelines and operating procedures
  - Training
  - Oversight
- **But... How do you:**
  - - decide to allocate your scarce resources?
  - - determine what needs to be addressed in operating procedures?
  - - determine which training is required for whom?
  - - determine what level of oversight is appropriate?





# Biorisk Management = Assessment Mitigation Performance



Hazard ID  
Risk Assessment



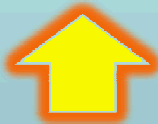
Biorisk Control Measures  
Risk Management



Processes  
QA/QC  
Objectives



# Biorisk Management = Assessment Mitigation Performance



Hazard ID  
Risk Assessment



Biorisk Control Measures  
Risk Management



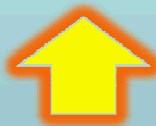
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Biorisk Management =  
**A**ssessment **M**itigation **P**erformance



Hazard ID  
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Hazard ID  
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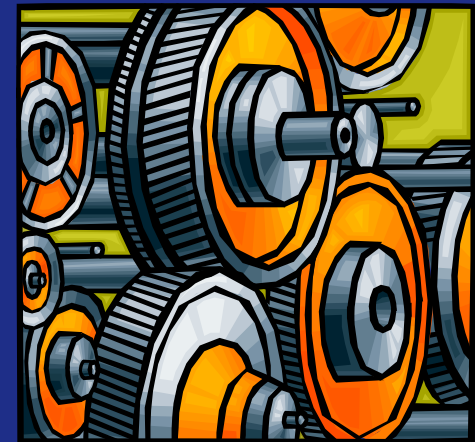
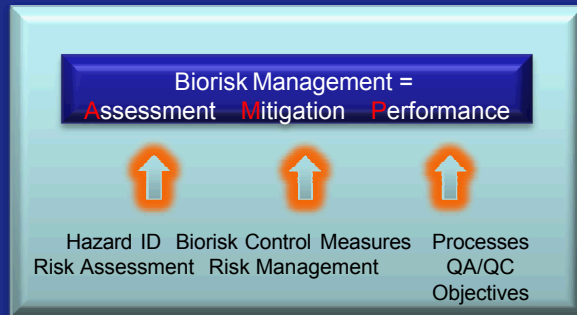
Biorisk Control Measures  
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# How Do We Convert the AMP Concept Into a Management System?



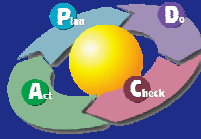
# Biorisk Program Management!

- 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
- Numerous stakeholders in program management





# Biorisk Management Systems Approach



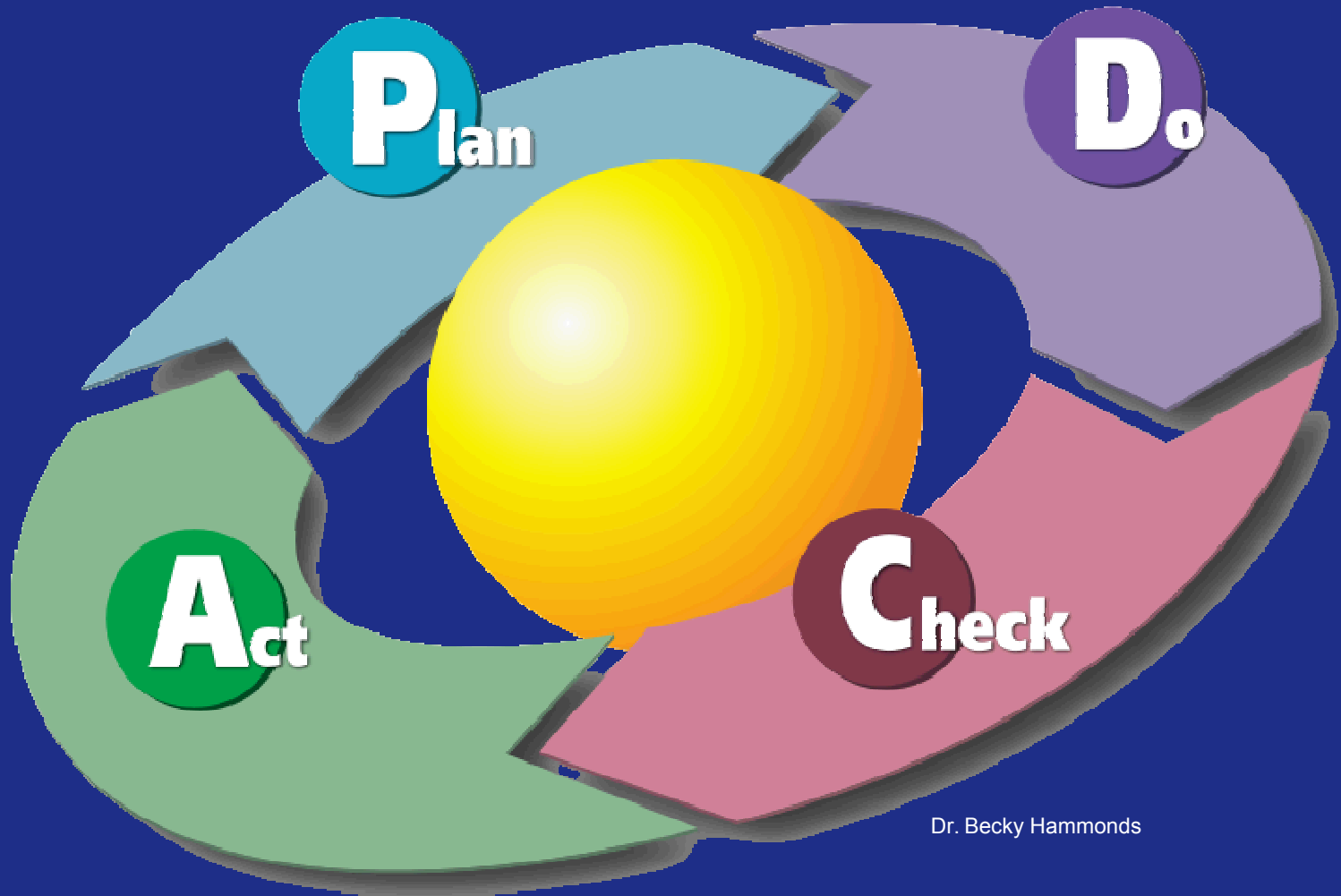
- “Plan-Do-Check-Act” approach: a goal of *continuous improvement*
- **Plan**
  - *Planning*, including identification of hazards and risks and establishing program goals
- **Do**
  - *Implementing*, including training and operational issues
- **Check**
  - *Checking*, including monitoring and corrective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



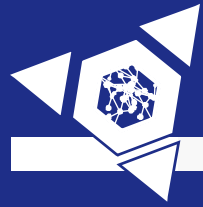




# Systematic Approach



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# Plan, Do , Check Act Within the AMP Model

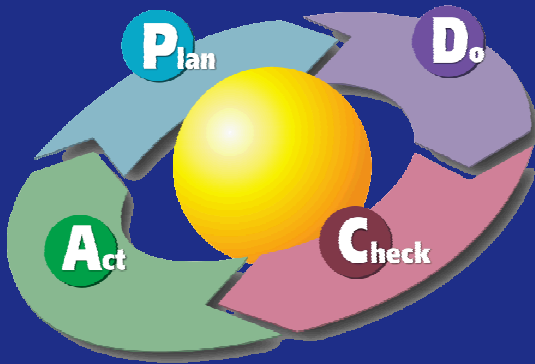
- **A**ssessment = Plan, Do, Check, Act
- **M**itigation = Plan, Do, Check, Act
- **P**erformance = Plan, Do, Check, Act
- Mitigation is improved and sustained when performance measures are included





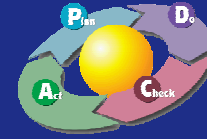
# Requirements of a Management System

- In a management system, all aspects of a **PDCA cycle** have to be addressed:
  - Structured approach for achieving objectives and goals
  - Based on identified tasks and controls
  - Defined roles and responsibilities
  - Documented for reference and change control
  - Competence requirements, including on-going development
  - Records of controls, competence and performance

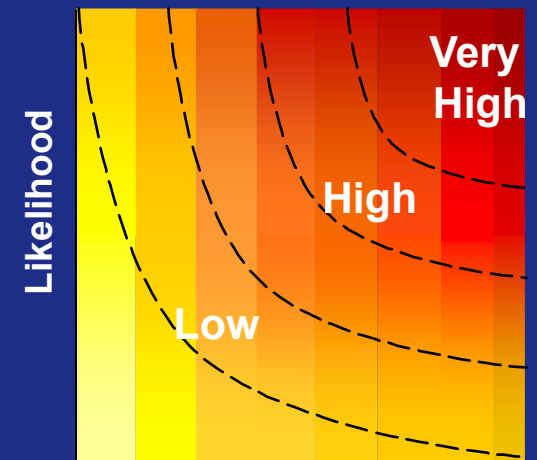




# Plan

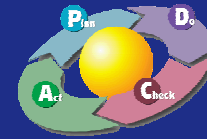


- Define specific Biorisk Program objectives
- Ensure compliance with all national and international requirements
- Effectively allocate limited resources to address highest risks first
- Perform a risk assessment
- Make risk mitigation decisions

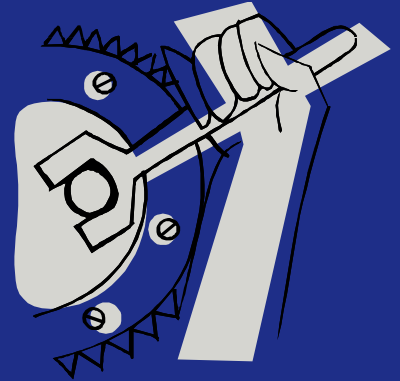




# Do



- **Determine roles and responsibilities**
- **Provide standard training**
  - Although this is NOT sufficient, it is only a start
- **Provide personnel knowledge and skills**
- **Implement risk mitigation measures**
- **Perform Facility maintenance**

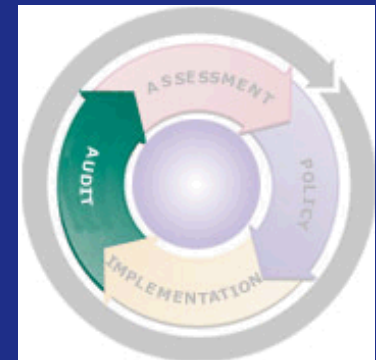




# Check



- 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 and external inspections





# Act

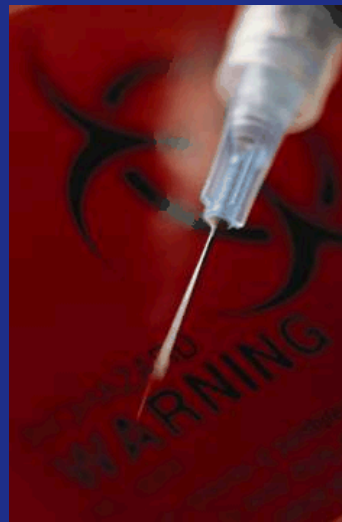


- **Biorisk management program should be regularly reviewed and updated**
- **Review information should include**
  - Audit results
  - Work activities
  - Status of risk assessment activities
  - Status of preventative and corrective actions
  - Follow-up actions from previous management reviews
  -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





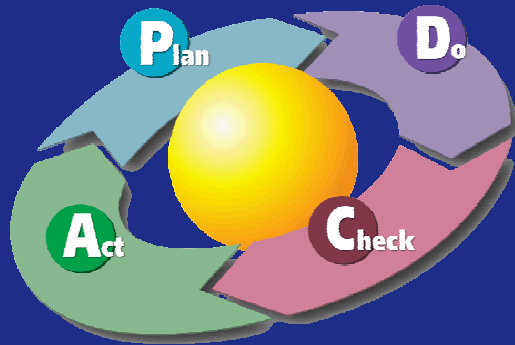
**What program management systems and resources are available for biorisk?**







# Laboratory Biorisk Management Standard CWA 15793:2008



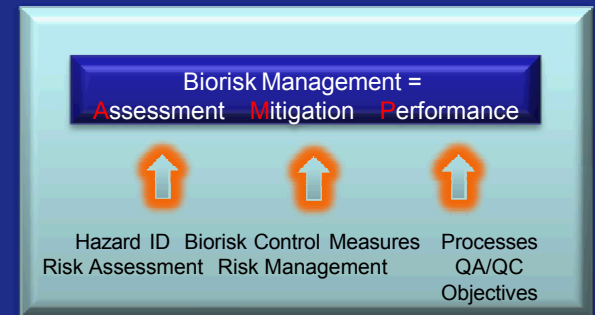
- International standard based on PDCA management model
- Accreditation/Certification is a possibility, but not mandatory





# Conclusions

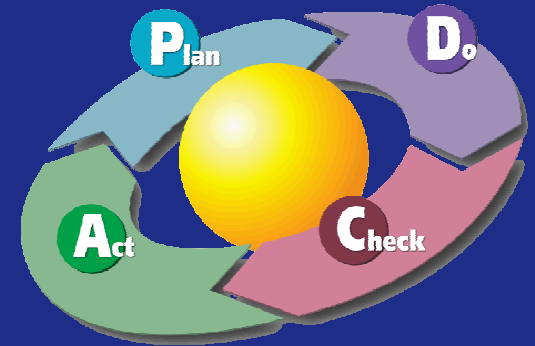
- **Biorisk management is essential for biosafety *and* biosecurity**
- **Consideration should be given to the AMP approach to help ensure that biorisk management systems are:**
  - Well-designed based on risk assessment
  - Implemented effectively and efficiently, saving time and money
  - Sustainable





# Conclusions

- **Implementation of continual improvement and corrective action (PDCA) programs:**
  - Lead to biorisk management programs performing above standard requirements
  - Encourage active participation by all stakeholders in biorisk management
  - Facilitates the implementation of the AMP biorisk management model
- **Adoption and implementation of the CWA 15793:2008**
  - Promotes a common standard for biorisk management





# Discussion and Questions

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# BACKUP SLIDES