

Principles of Biorisk Management Programs

A faint, semi-transparent world map is visible in the background of the slide.

**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**

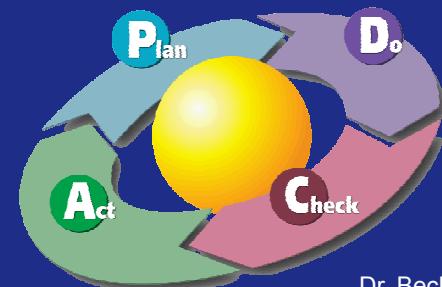
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Outline of Presentation

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



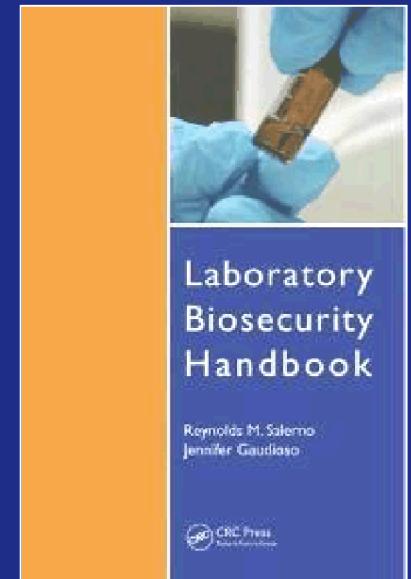
Dr. Becky Hammonds



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

Training and Workshops

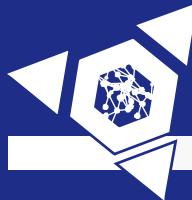
Policy, Regulatory, & Guidelines Support

Assessments and Analysis

Infectious Disease Diagnostics and Control



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Example: Biosafety Risk Assessment Methodology

BioRAM

Risks based on routes of exposure

Inhalation

Ingestion

Contact

Percutaneous

Agents

Procedures

Likelihood of Infection

Transmissibility

Humans

Inhalation

Is this agent known to cause infection via inhalation in humans (to cause infection via droplet or droplet nuclei that have entered the upper or lower respiratory tract) in a laboratory setting?

2

4 = Preferred Route
2 = A possible route
1 = Unknown
0 = Not a route

Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown in humans?

3

4 = Yes
2 = No
0 = If this is not an infectious route

Percutaneous

Is this agent known to cause infection via percutaneous exposure in humans (to cause infection via compromised skin or direct insertion into the blood circulation) in a laboratory setting?

1

4 = Preferred Route
2 = A possible route
1 = Unknown
0 = Not a route

Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown in humans?

2

4 = Yes
2 = No
0 = If this is not an infectious route

Direct Contact

Is this agent known to cause infection via direct contact in humans (to cause infection through the mucous membranes) in a laboratory setting?

3

4 = Preferred Route
2 = A possible route
1 = Unknown
0 = Not a route

Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown in humans?

1

Results Summary

File

Charts Result Detail Information

Generally Risk to Individual

4

3

2

1

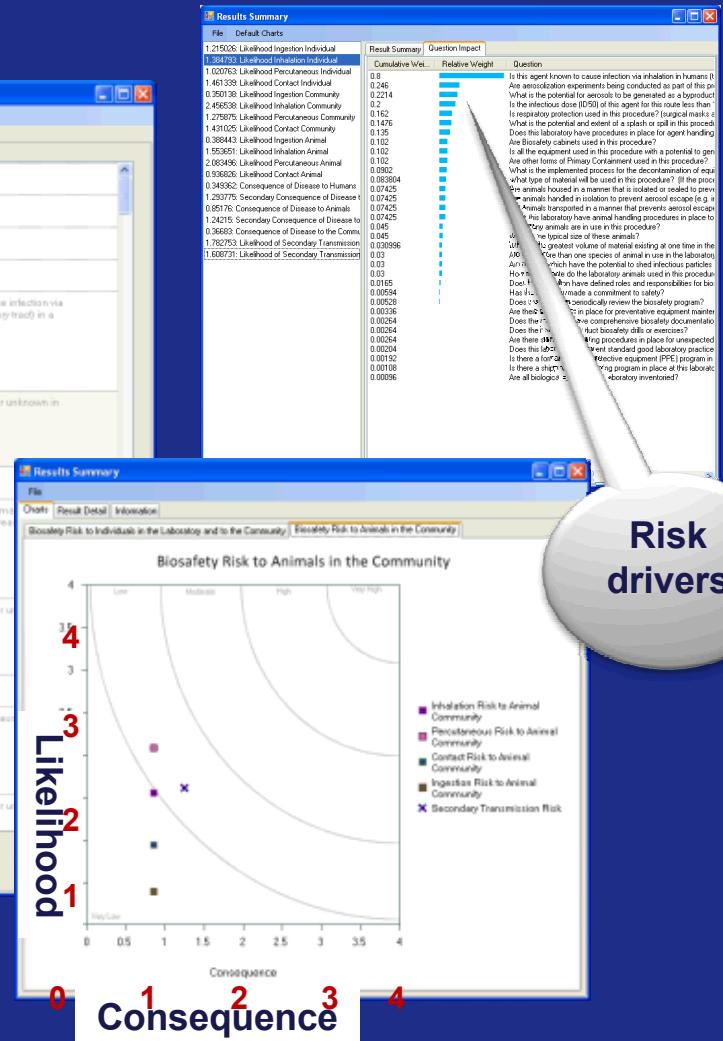
0

Like

Unlikely

Response: Enter

Flag response as an unknown answer



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"

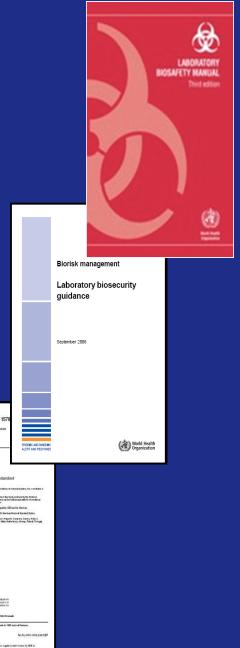




International Laboratory Biorisk Management Documents

- **Technical: World Health Organization**
Laboratory Biosafety Manual (2004)

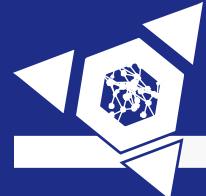
Biorisk Management: Laboratory Biosecurity Guidance (2006)


- **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?



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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



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Biorisk Management = Assessment Mitigation Performance



Hazard ID
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Biorisk Control Measures
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Processes
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Biorisk Management = Assessment Mitigation Performance

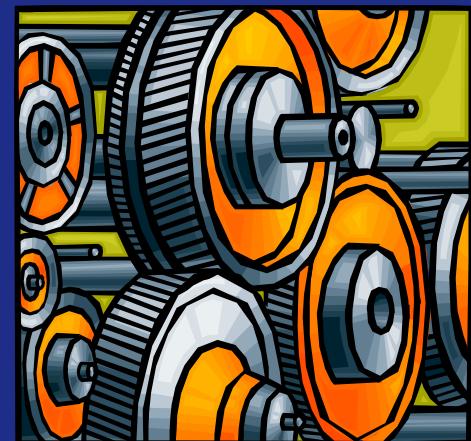

Hazard ID
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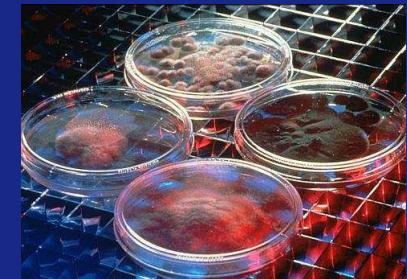
How Do We Convert the AMP Concept Into a Management System?





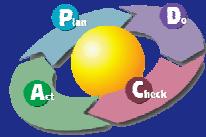
Biorisk Program Management!

- 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



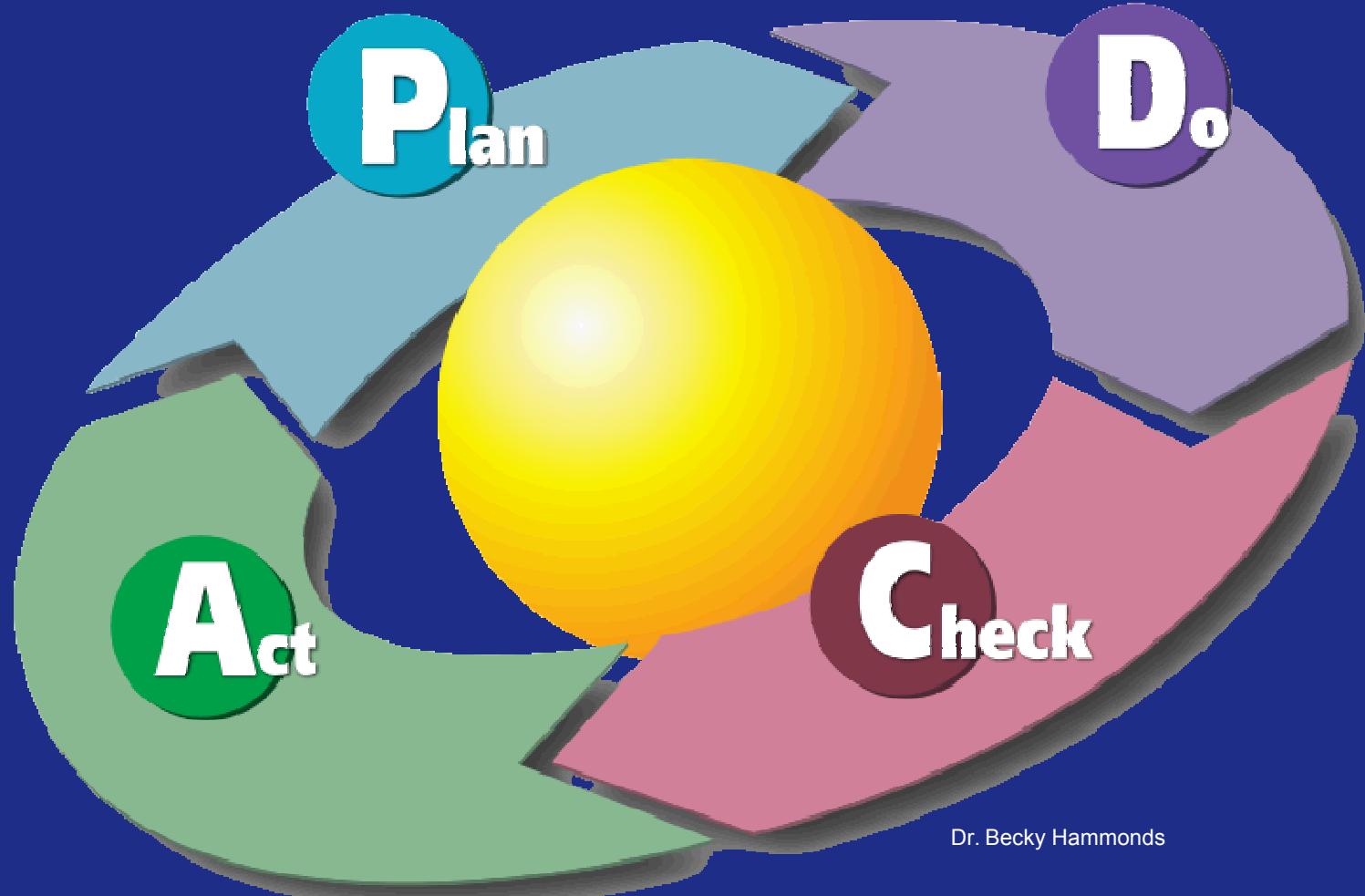
- “Plan-Do-Check-Act” approach: a goal of *continuous improvement*
- **Plan**
 - *Planning*, including identification of hazards and risks and establishing program goals
- **Do**
 - *Implementing*, including training and operational issues
- **Check**
 - *Checking*, including monitoring and corrective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



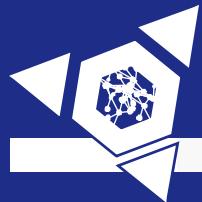
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Systematic Approach



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Plan, Do , Check Act Within the AMP Model

- **Assessment = Plan, Do, Check, Act**
- **Mitigation = Plan, Do, Check, Act**
- **Performance = Plan, Do, Check, Act**
- **Mitigation is improved and sustained when performance measures are included**

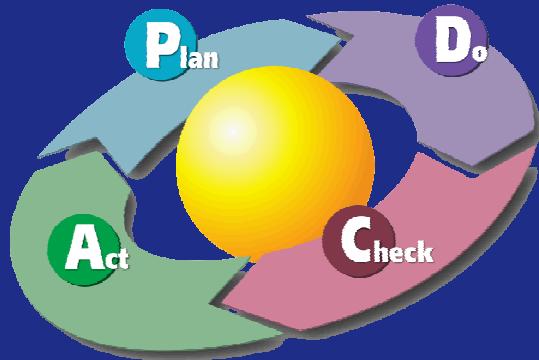


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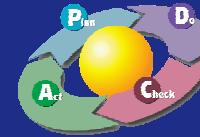
Requirements of a Management System

- 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

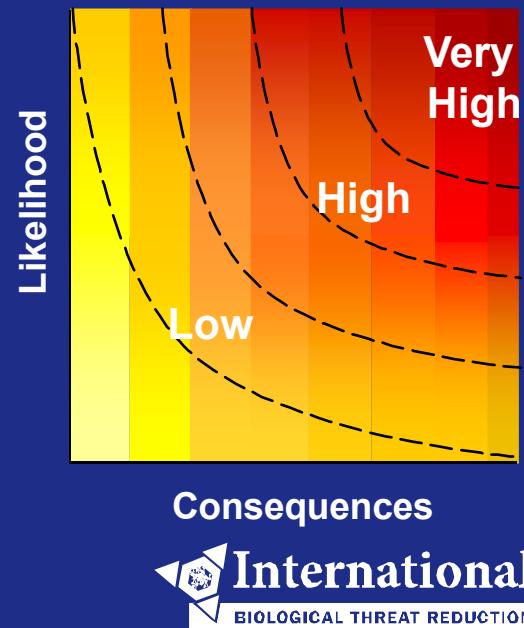




Plan

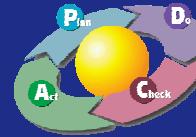


- Define specific Biorisk Program objectives
- Ensure compliance with all national and international requirements
- Effectively allocate limited resources to address highest risks first
- Perform a risk assessment
- Make risk mitigation decisions

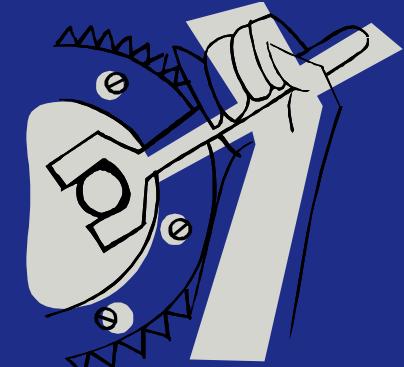




Do

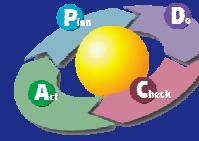


- **Determine roles and responsibilities**
- **Provide standard training**
 - Although this is NOT sufficient, it is only a start
- **Provide personnel knowledge and skills**
- **Implement risk mitigation measures**
- **Perform Facility maintenance**

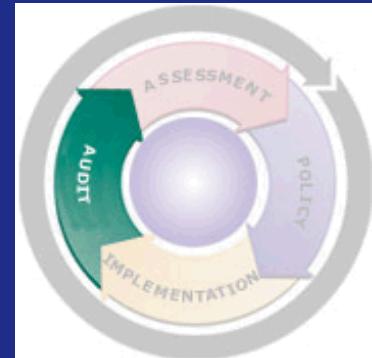


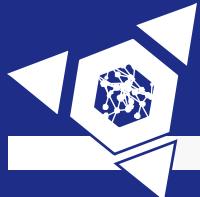


Check

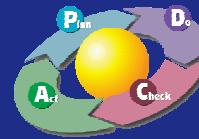


- Biorisk management program must be **documented**
- Documents need to be **reviewed and updated at regular intervals**, and after any incidents
- Regular **audits** are vital tools to assess program effectiveness, and evaluate opportunities for improvement
- Internal and external inspections

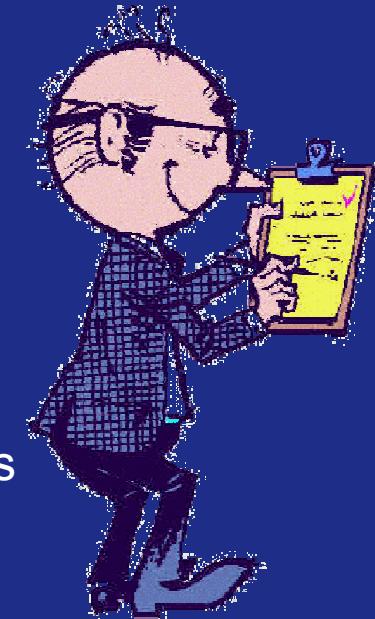




Act

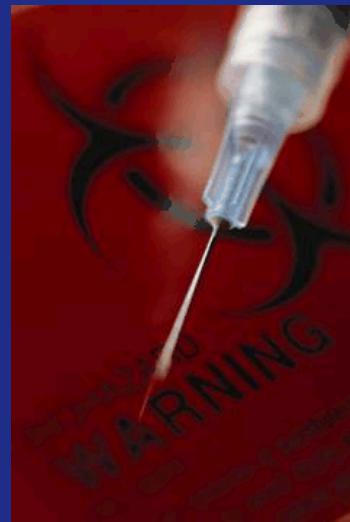


- **Biorisk management program should be regularly reviewed and updated**
- **Review information should include**
 - Audit results
 - Work activities
 - Status of risk assessment activities
 - Status of preventative and corrective actions
 - Follow-up actions from previous management reviews
 - Results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





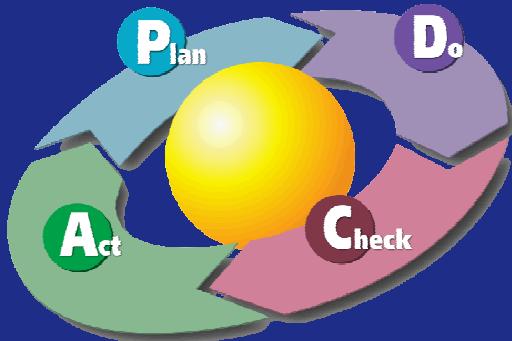
What program management systems and resources are available for biorisk?



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Laboratory Biorisk Management Standard

CWA 15793:2008



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

CEN
WORKSHOP
AGREEMENT

CWA 15793
February 2008

ISO 100100.01

English version

Laboratory biorisk management standard

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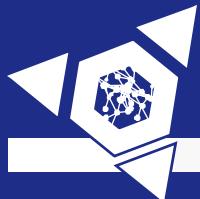
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Conclusions

- **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**

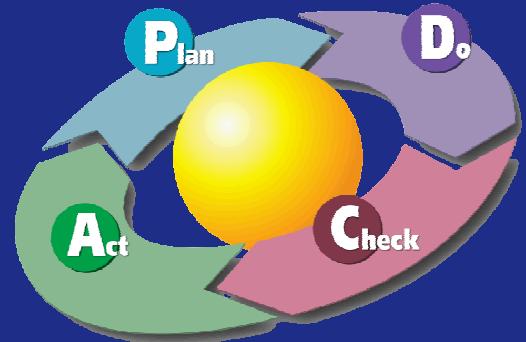


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Conclusions

- **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

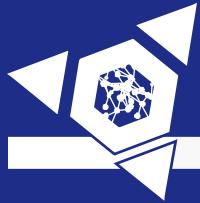
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BACKUP SLIDES

