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Measurement and Analysis of Biorisk Management System Performance

Student Guide

2013

GLOBAL BIORISK MANAGEMENT CURRICULUM


Measurement & Analysis of Biorisk Management System Performance
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Introductions
• Instructors
• Students
– Your name?
– Where are you from?
Slide 2

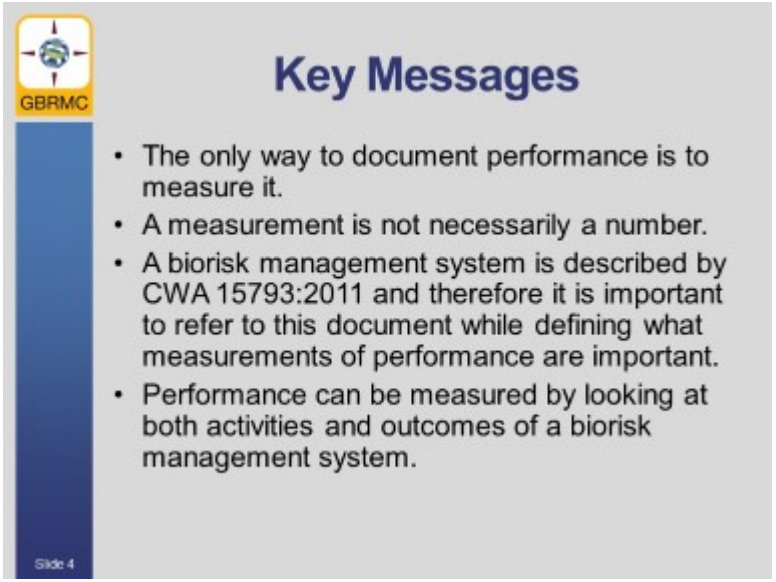
Action Plan

By the end of this lesson, I would like to:					
KNOW		FEEL		BE ABLE TO DO	

Your learning doesn't stop with this lesson. Use this space to think about what else you need to do or learn to put the information from this lesson into practice.

What more do I need to know or do?	How will I acquire the knowledge or skills?	How will I know that I've succeeded?	How will I use this new learning in my job?

Use space on back, if needed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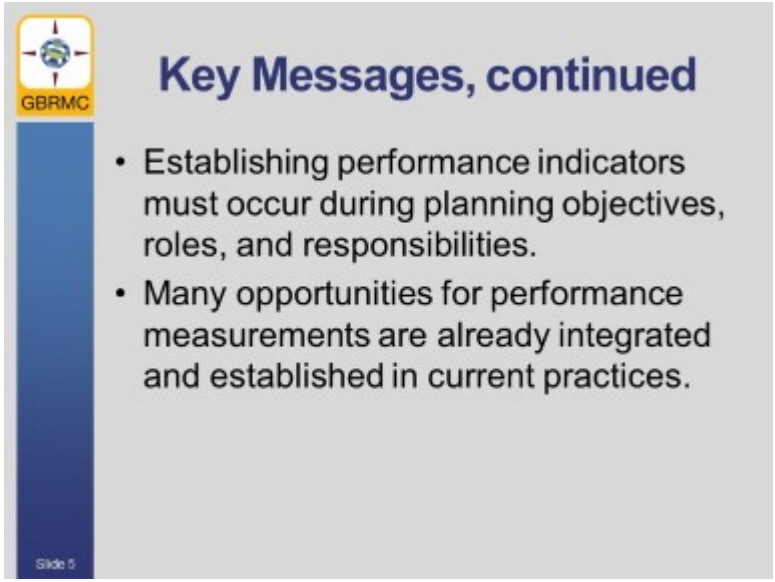
Key Messages
• The only way to document performance is to measure it.
• A measurement is not necessarily a number.
• A biorisk management system is described by CWA 15793:2011 and therefore it is important to refer to this document while defining what measurements of performance are important.
• Performance can be measured by looking at both activities and outcomes of a biorisk management system.
Slide 4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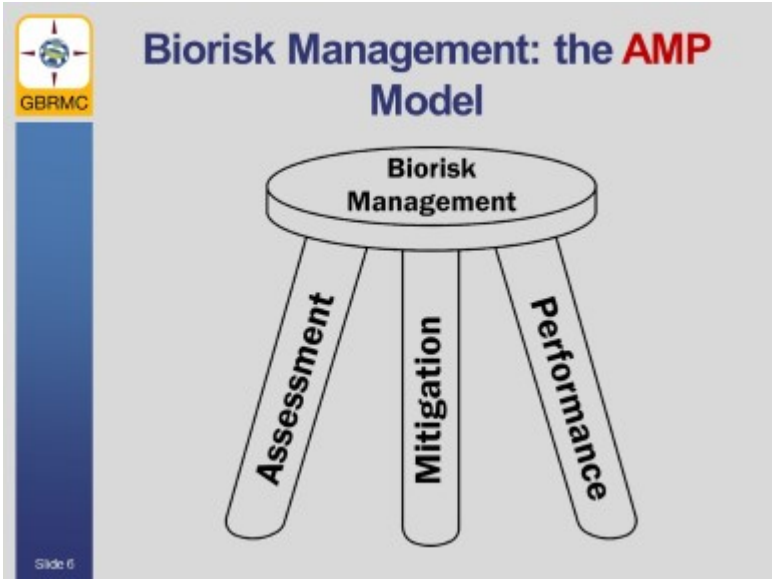
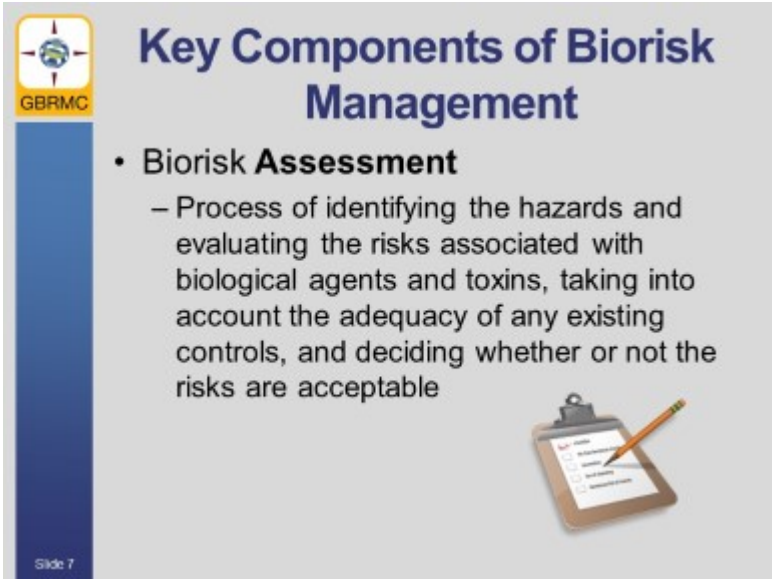
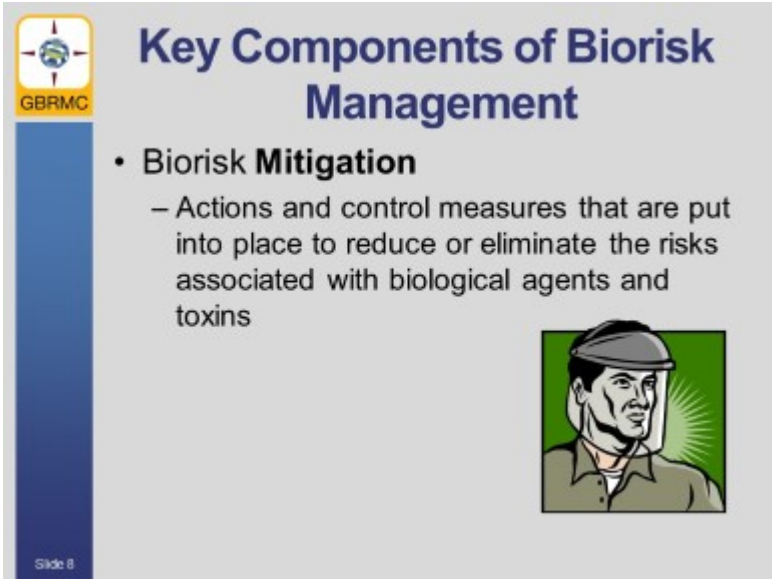
Key Messages, continued
• Establishing performance indicators must occur during planning objectives, roles, and responsibilities.
• Many opportunities for performance measurements are already integrated and established in current practices.
Slide 5



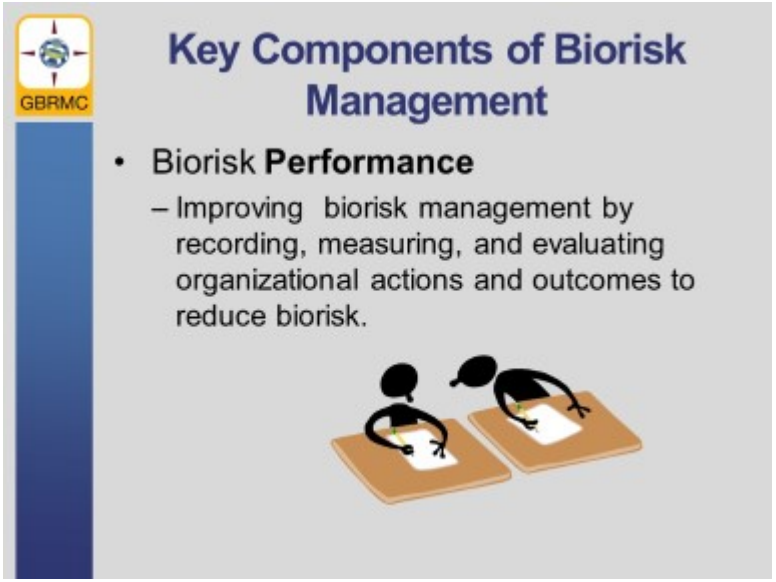
Review the AMP model for Biorisk Management.



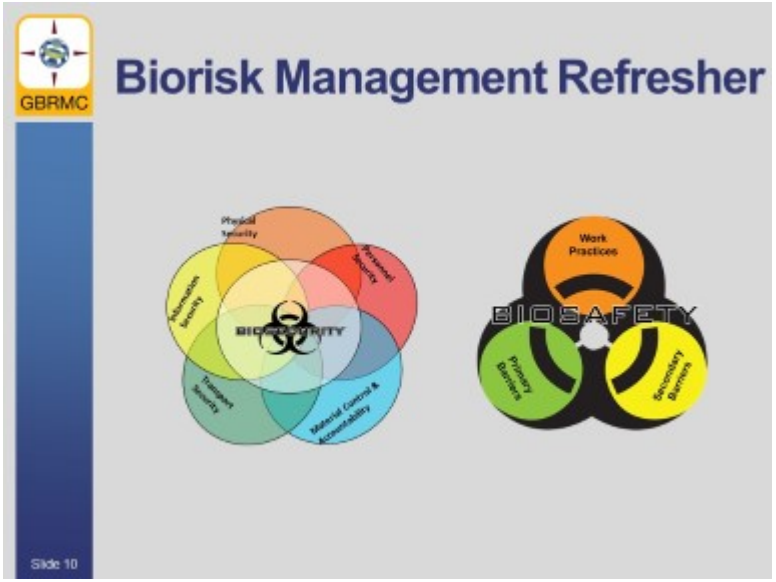
Define **Assessment**:



Define **Mitigation**:



Define **Performance**: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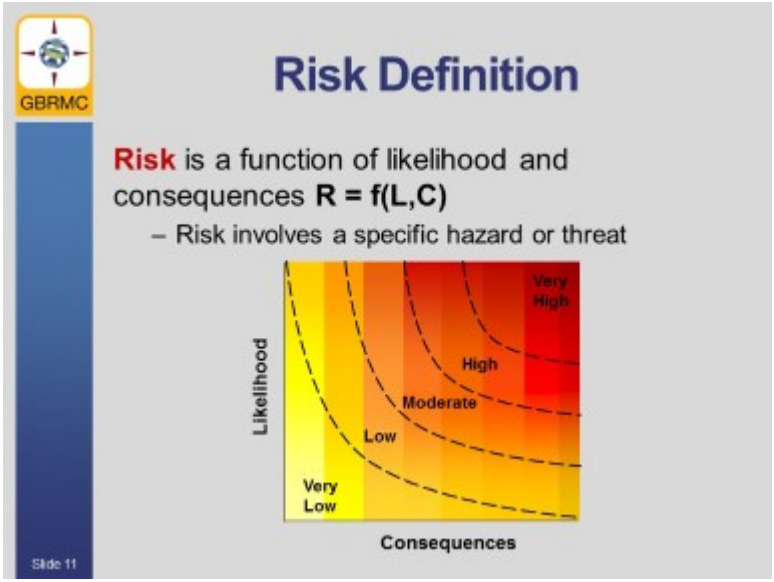
Biorisk Management Refresher
Work Practices
BIOSAFETY
Primary Barriers
Secondary Barriers
Material Control & Accountability
Slide 10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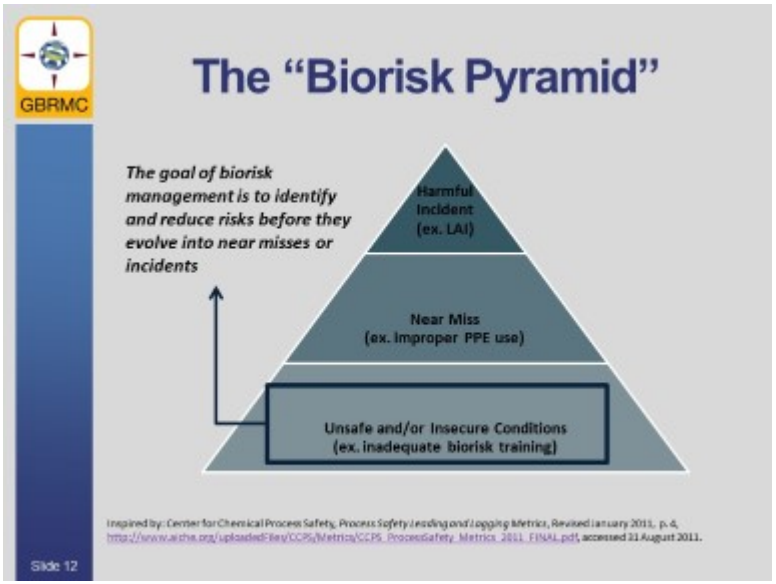
Risk Definition
Risk is a function of likelihood and consequences R = f(L,C)
– Risk involves a specific hazard or threat
Likelihood
Consequences
Very High
High
Moderate
Low
Very Low
Slide 11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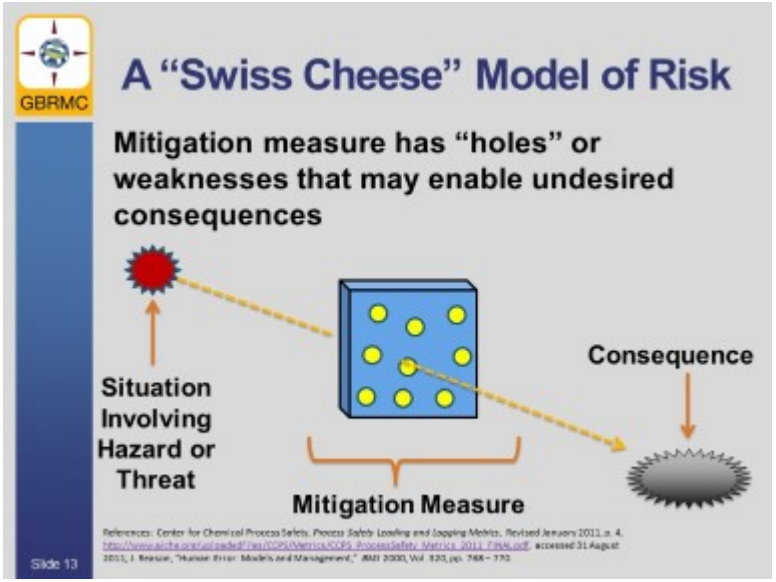
The "Biorisk Pyramid"
The goal of biorisk management is to identify and reduce risks before they evolve into near misses or incidents
Harmful Incident (ex. LAI)
Near Miss (ex. improper PPE use)
Unsafe and/or Insecure Conditions (ex. inadequate biorisk training)
Inspired by: Center for Chemical Process Safety, Process Safety Leading and Lagging Metrics, Revised January 2011, p. 4, http://www.aiche.org/uploadedFiles/CCPS/Metrics/CCPS_ProcessSafety_Metrics_2011_FINAL.pdf, accessed 31 August 2011.
Slide 12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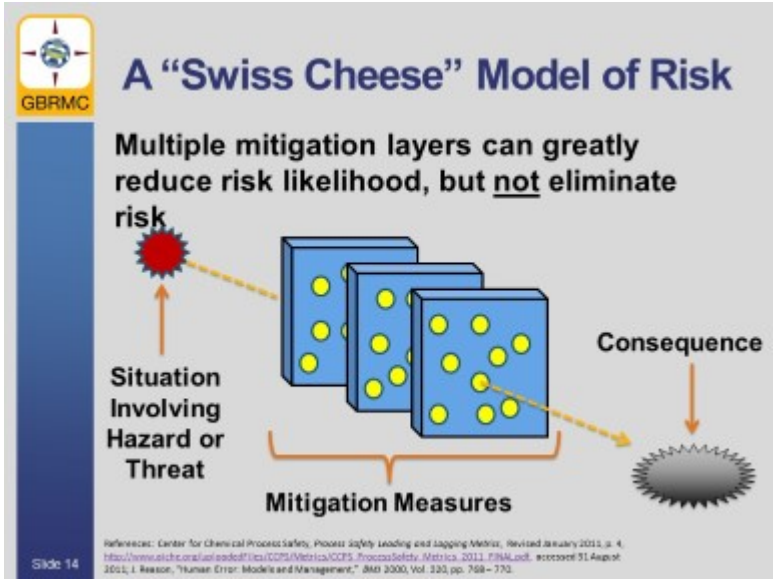
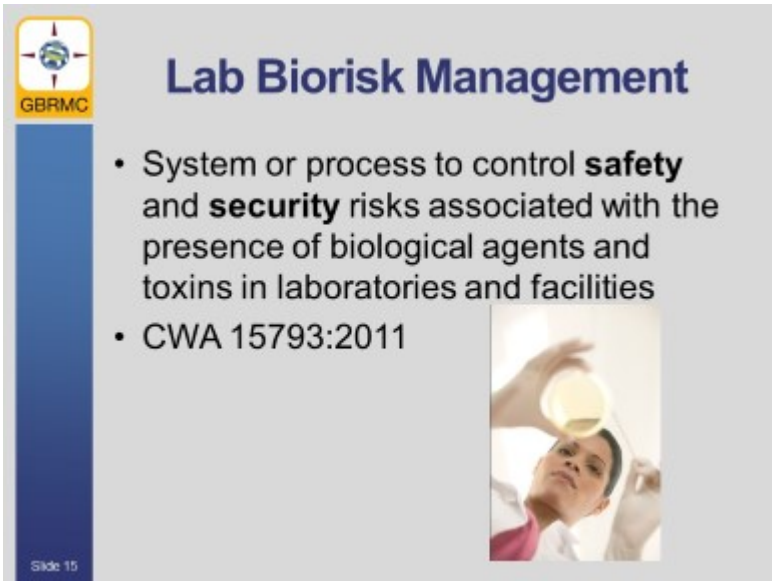
A "Swiss Cheese" Model of Risk
Mitigation measure has "holes" or weaknesses that may enable undesired consequences
Situation Involving Hazard or Threat
Mitigation Measure
Consequence
Slide 13


GBRMC
A "Swiss Cheese" Model of Risk
Multiple mitigation layers can greatly reduce risk likelihood, but not eliminate risk
Situation Involving Hazard or Threat
Mitigation Measures
Consequence
Slide 14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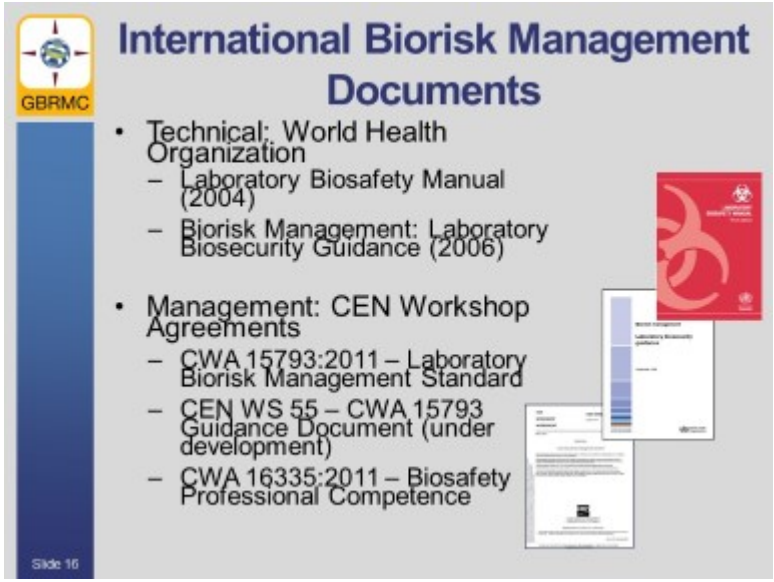
Lab Biorisk Management
• System or process to control **safety** and **security** risks associated with the presence of biological agents and toxins in laboratories and facilities
• CWA 15793:2011
Slide 15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International Biorisk Management Documents
• Technical: World Health Organization
– Laboratory Biosafety Manual (2004)
– Biorisk Management: Laboratory Biosecurity Guidance (2006)
• Management: CEN Workshop Agreements
– CWA 15793:2011 – Laboratory Biorisk Management Standard
– CEN WS 55 – CWA 15793 Guidance Document (under development)
– CWA 16335:2011 – Biosafety Professional Competence
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BRM Standard CWA 15793:2011

Enables organizations to:

- **Establish and maintain a biorisk management system** to control or minimize risk to acceptable levels
- **Provide assurance** that the requirements are in place and implemented effectively
- Provide a framework that can be used as **basis for training and awareness raising**
- **Seek and achieve certification or verification** by an independent third party

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CWA 15793 and Performance

- CWA 15793 is a **performance-based standard**
  - Establishes biorisk management requirements, but **does not** specify how institutions must meet those requirements
  - **Organizations are responsible** for demonstrating "appropriate and validated risk reduction procedures have been established and implemented."
- Today, we will discuss some requirements pertaining to performance and performance measurement

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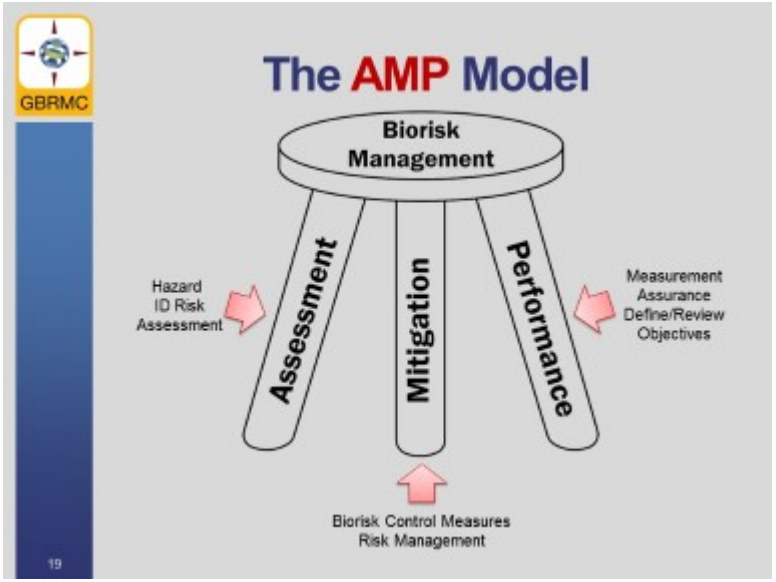
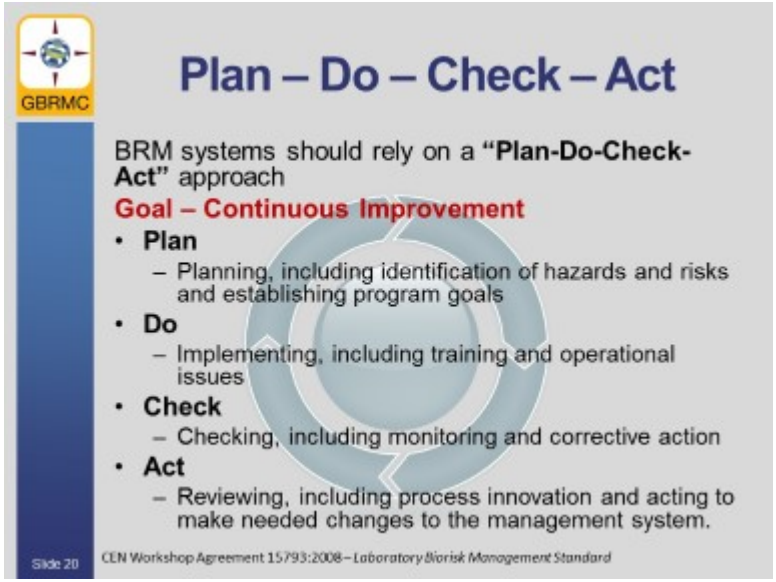
Measurement & Analysis of BRM System Performance

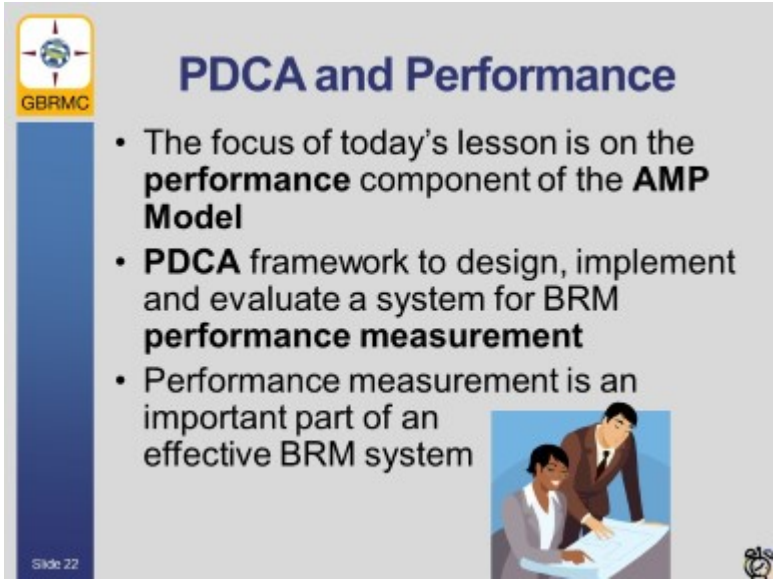


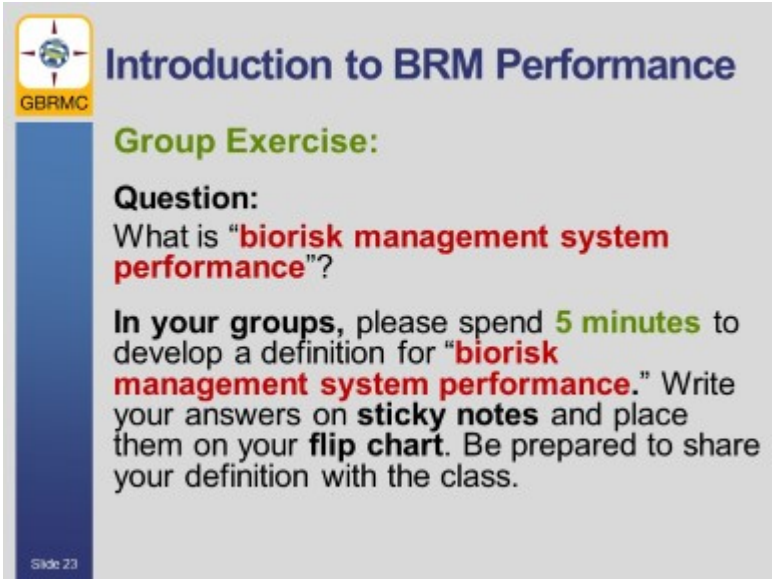
Review of Key Principles of BRM



Measurement & Analysis of BRM System Performance

Review of Key Principles of BRM





Define **Biorisk Management System Performance**:

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The Concept of Performance

Biorisk Management System Performance:

The way in which a biorisk management system **actually functions** to manage or minimize biorisk.

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The Concept of Performance

Characteristics of BRM System Performance:

- BRM **performance** is a result of all the activities and efforts of ALL people in a facility
- Actual BRM system performance may **not** match the planned level of risk management effectiveness
  - **Performance measurement – assess the differences**
- Performance changes over time: a sustained level of performance requires a continual effort

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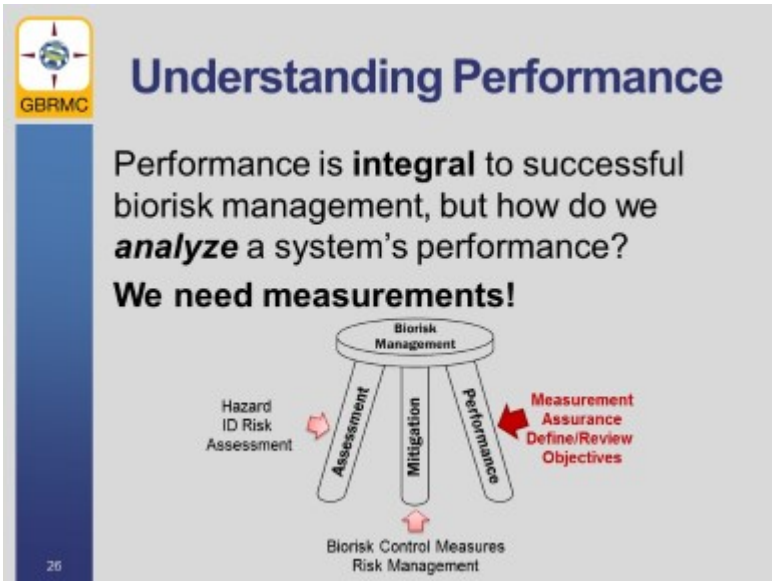
GBRMC
Understanding Performance
Performance is **integral** to successful biorisk management, but how do we ***analyze*** a system's performance?
We need measurements!
Biorisk Management
Hazard ID Risk Assessment
Assessment
Mitigation
Performance
Measurement Assurance Define/Review Objectives
Biorisk Control Measures Risk Management
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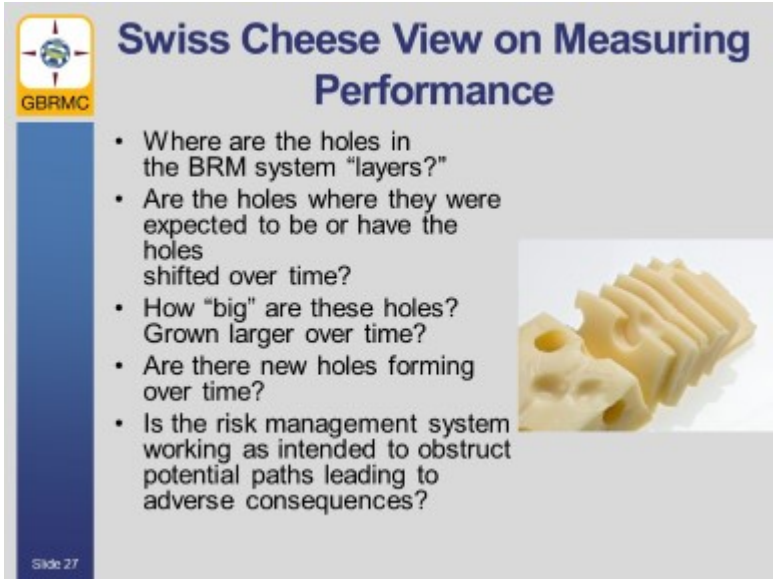
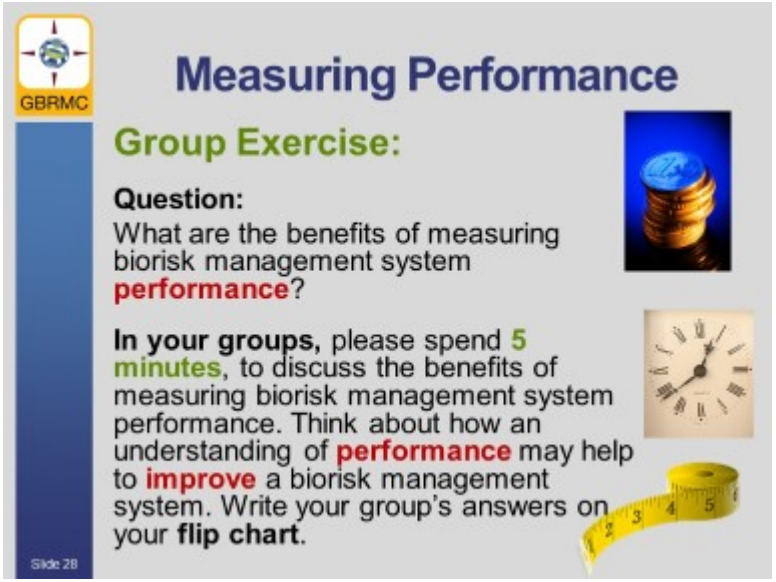

GBRMC
Swiss Cheese View on Measuring Performance
• Where are the holes in the BRM system "layers?"
• Are the holes where they were expected to be or have the holes shifted over time?
• How "big" are these holes? Grown larger over time?
• Are there new holes forming over time?
• Is the risk management system working as intended to obstruct potential paths leading to adverse consequences?
Slide 27


GBRMC
Measuring Performance
Group Exercise:
Question:
What are the benefits of measuring biorisk management system performance?
In your groups, please spend 5 minutes, to discuss the benefits of measuring biorisk management system performance. Think about how an understanding of performance may help to improve a biorisk management system. Write your group's answers on your flip chart.
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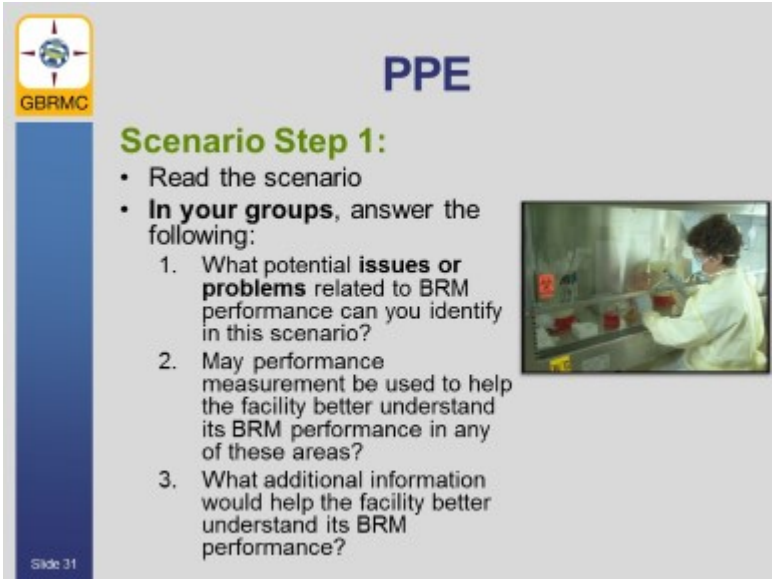
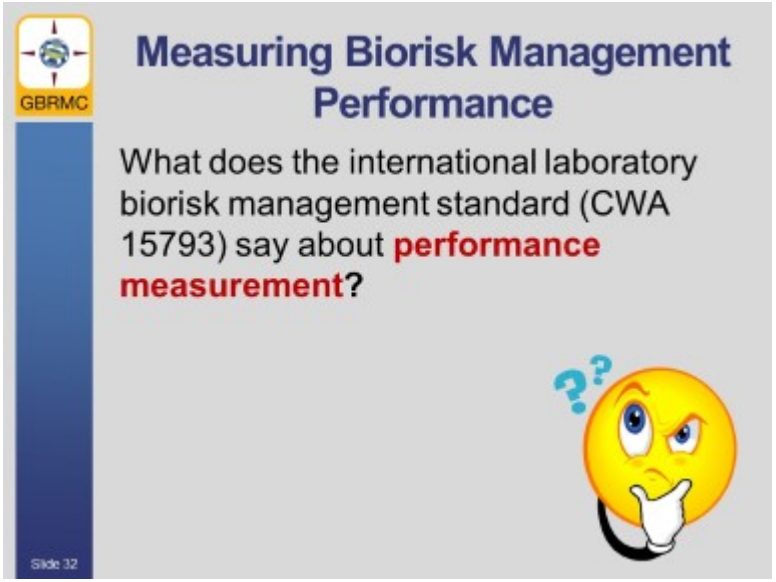
The Benefits of Performance Measurement
Determine which parts of the BRM system are meeting stated goals or benchmarks
Provides a demonstrable record of system performance
– May support facility certification/accreditation process
Helps identify areas for improvement using a consistent framework
Provides assurance that the risk is acceptable
Facilitates maintenance and sustainability of the system
Can save money and time (by enabling resource prioritization)
Helps to prevent incidents
Slide 29

PPE Performance Scenario

- Acme Labs is a small diagnostic testing company that performs routine infectious disease testing on human clinical samples, and maintains a laboratory operating at BSL-2. The company developed a comprehensive lab biosafety policy twelve years ago, and once a year conducts a mandatory, ½-day biosafety training program for all lab staff based on this policy. Every lab staff member must also pass a standard biosafety written exam every two years with a score of 80% in order to maintain access to the laboratory. No one has ever failed the test. Currently, eight personnel have laboratory access.
- Recently, the laboratory's designated biosafety officer, who was recently hired, observed several incidents while walking through the laboratory in which laboratory staff appeared to not properly utilize required personal protective equipment (PPE). This included one incident in which a staff member told the biosafety officer she had seen a colleague open the refrigerator in the break room while still wearing disposable gloves. She said her colleague claimed that this wasn't a big deal since he had not yet handled any samples that morning. Because no apparent harm resulted from any of these incidents, the biosafety officer decided not to formally document them, or report them to the laboratory's director. Instead, the biosafety officer requested permission from the director to update the laboratory's biosafety-related standard operating procedures (SOPs). The director agreed to consider updated SOPs.
- The biosafety officer suspected that the laboratory staff were not deliberately ignoring the biosafety policy, but that some staff members were unfamiliar with the all the PPE donning and doffing requirements. Working alone, the biosafety officer wrote a detailed SOP that described PPE requirements and proper donning and doffing procedures, based on the laboratory's own written biosafety policy, international best practices, and the biosafety officer's prior experience working in a BSL-3 laboratory. After the SOP was verbally endorsed by the laboratory's director, the biosafety officer sent it to every member of the staff, announced it during a recent staff meeting, and posted the SOP in a visible location outside the laboratory where staff don their PPE prior to entering.
- Thus far, all staff members appear to be trying to follow the new SOP. However, one senior staff member was overheard complaining to a co-worker that the new SOP was unnecessary and unreasonable given the biosafety risks associated with working in the laboratory, despite the fact that the formal risk assessment has not been reviewed or updated in several years. This person pointed out that no one in the laboratory had been seriously injured or suffered a laboratory acquired infection in at least seven years, and questioned the authority of the biosafety officer to make changes to the SOP, especially considering the biosafety officer just started working at the lab.



- What potential issues or problems related to BRM performance can you identify in this scenario?
- May performance measurement be used to help the facility better understand its BRM performance in any of these areas?
- What additional information would help the facility better understand its BRM performance?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Measuring Biorisk Management Performance
What does the international laboratory biorisk management standard (CWA 15793) say about performance measurement?
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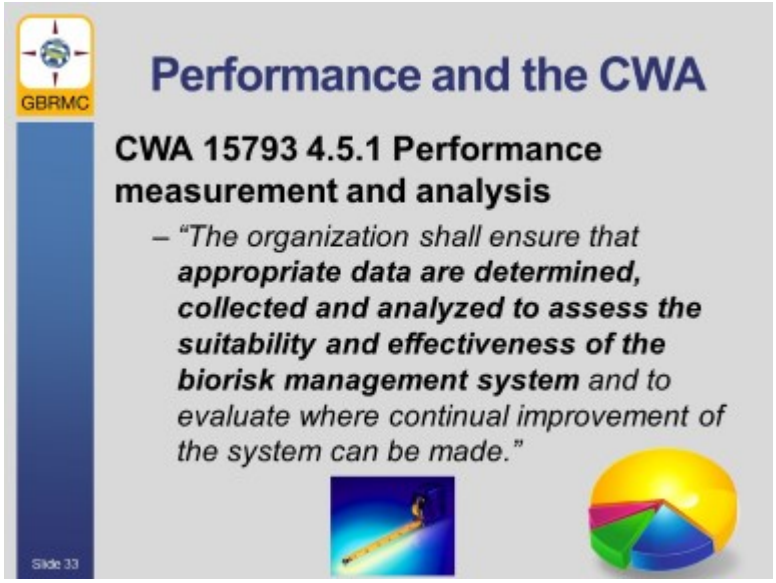
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Performance and the CWA
CWA 15793 4.5.1 Performance measurement and analysis
– "The organization shall ensure that appropriate data are determined, collected and analyzed to assess the suitability and effectiveness of the biorisk management system and to evaluate where continual improvement of the system can be made."
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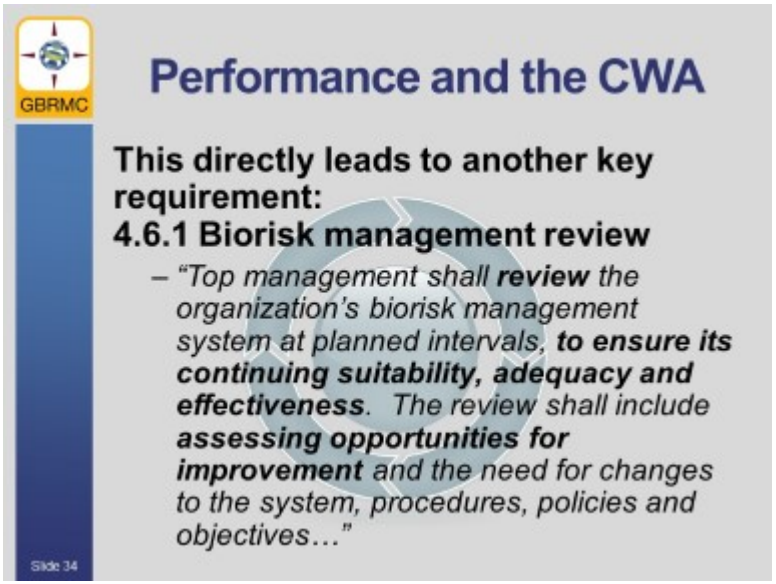
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Performance and the CWA
This directly leads to another key requirement:
4.6.1 Biorisk management review
– "Top management shall **review** the organization's biorisk management system at planned intervals, **to ensure its continuing suitability, adequacy and effectiveness**. The review shall include **assessing opportunities for improvement** and the need for changes to the system, procedures, policies and objectives…"
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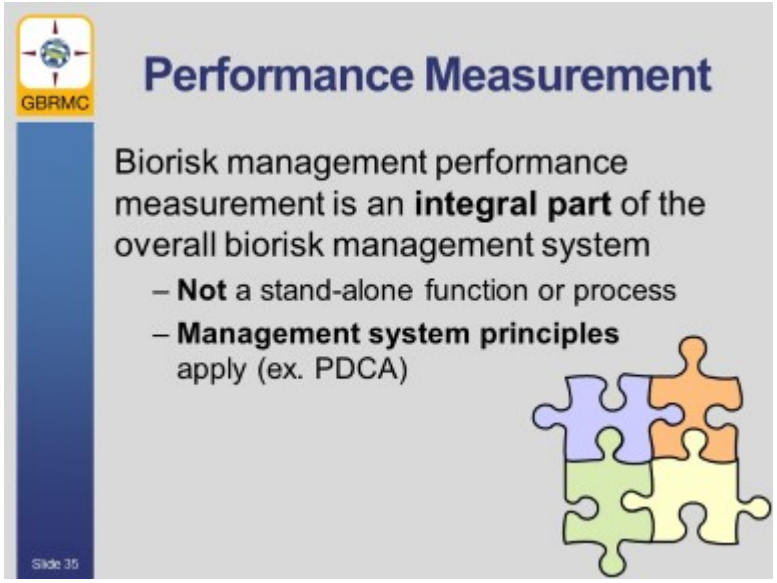
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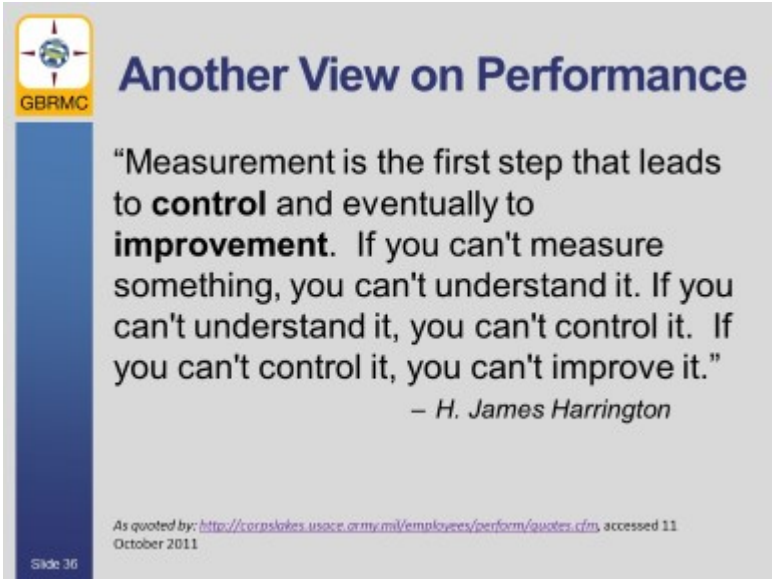
Performance Measurement
Biorisk management performance measurement is an **integral part** of the overall biorisk management system
– **Not** a stand-alone function or process
– **Management system principles** apply (ex. PDCA)
Slide 35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Another View on Performance
"Measurement is the first step that leads to **control** and eventually to **improvement**. If you can't measure something, you can't understand it. If you can't understand it, you can't control it. If you can't control it, you can't improve it."
– H. James Harrington
As quoted by: http://corpslakes.usace.army.mil/employees/perform/quotes.cfm, accessed 11 October 2011
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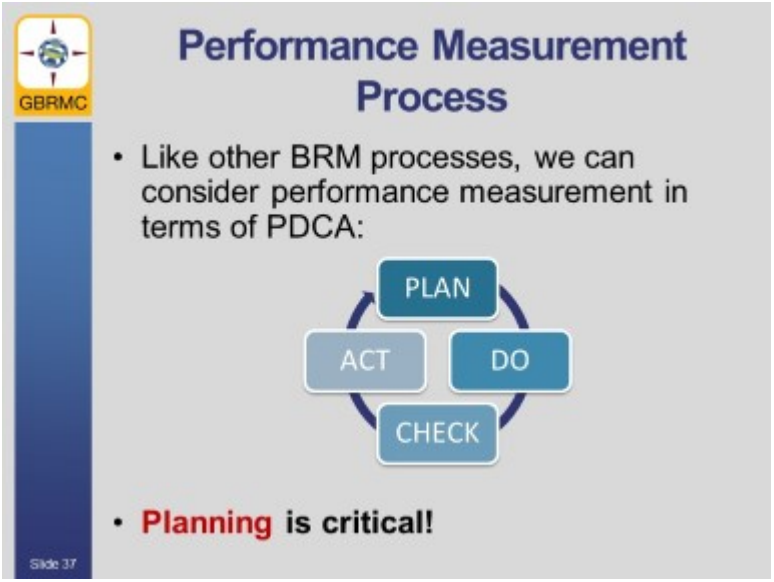
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Performance Measurement Process
• Like other BRM processes, we can consider performance measurement in terms of PDCA:
PLAN
DO
CHECK
ACT
• Planning is critical!
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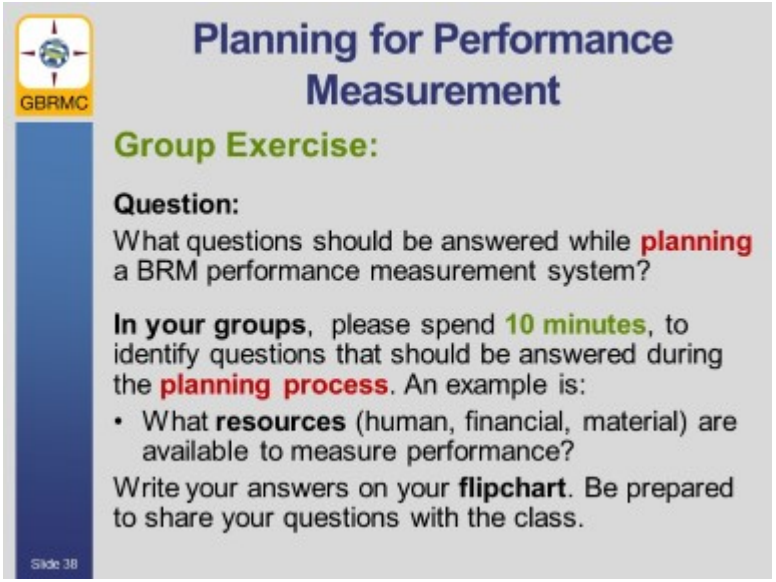
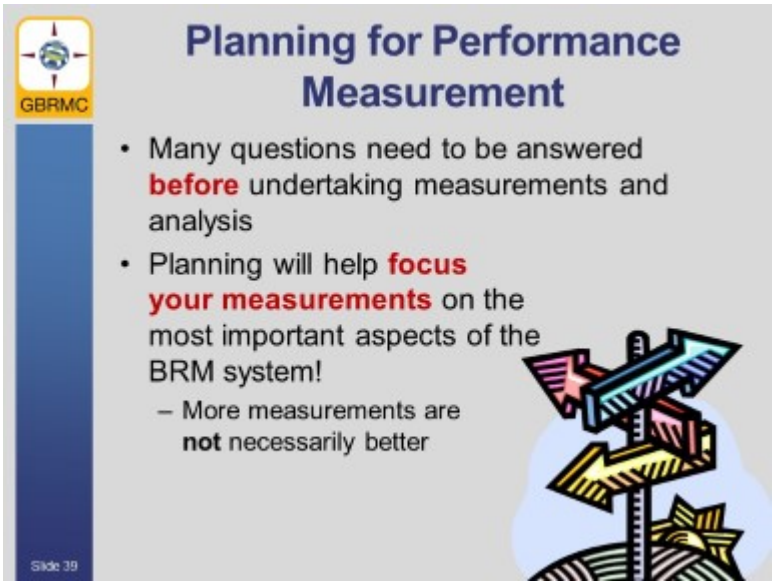


What questions should be answered while **planning** a BRM performance measurement system?

Measurement & Analysis of BRM System Performance



Planning for BRM Performance Management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Planning – Identifying Priorities
• Focus on the most critical areas, but do not neglect other aspects of the BRM system
– Priority areas for BRM improvement
– Scope based on risk assessment
• What are areas of concern from biorisk standpoint?
– Requirements (ex. regulations; standards)
• CWA 15793:2011
• Set goals
– Compare outcomes with stated goals (benchmarks)
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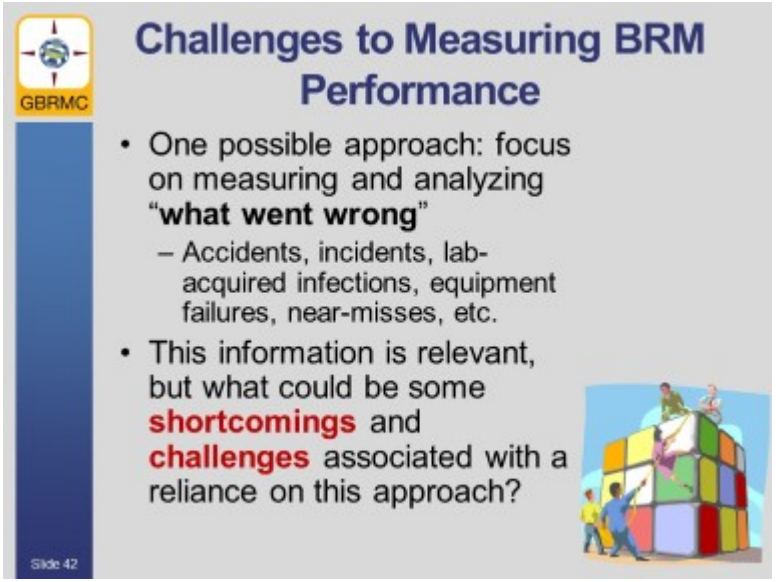
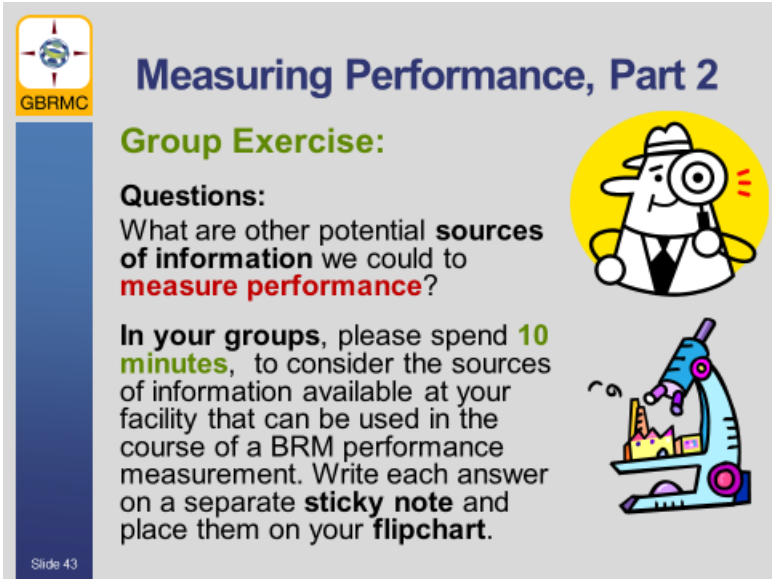


What issues could one encounter by relying heavily on "mishaps" to measure BRM system performance?



Potential Sources of Information: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Measuring Performance, Part 2
Inventory records
Staff Testing and Training Results; Personnel records
Voluntary Reports by Staff
Risk Assessment Results
Accident, Injury, Near-Miss Investigation Data
Direct Behavioral Observations
Instrument & Equipment Data; Performance Test Results
Results of Exercises, Drills, Tabletops
Data from Surveys & Questionnaires of Staff
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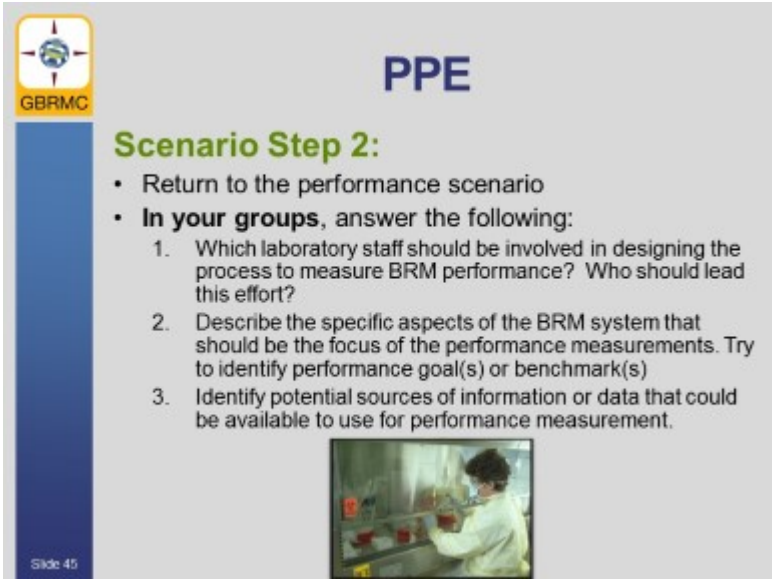

- Which laboratory staff should be involved in designing the process to measure BRM performance? Who should lead this effort?
- Describe the specific aspects of the BRM system that should be the focus of the performance measurements. Try to identify performance goal(s) or benchmark(s).
- Identify potential sources of information or data that could be available to use for performance measurement.

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Performance Measurement Methods

- **Challenge**: Effectively and efficiently select and deploy performance measurement tools to understand BRM system performance
- **Solution**: Systematic approaches to measuring and analyzing performance are required



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Potential Measurement Methods

- **Audits and Inspections**
- **Performance Indicators**
- **Observations**
- **Interviews**
- **Surveys and Questionnaires**

- We won't cover all of these approaches today, but the principles for their application are similar

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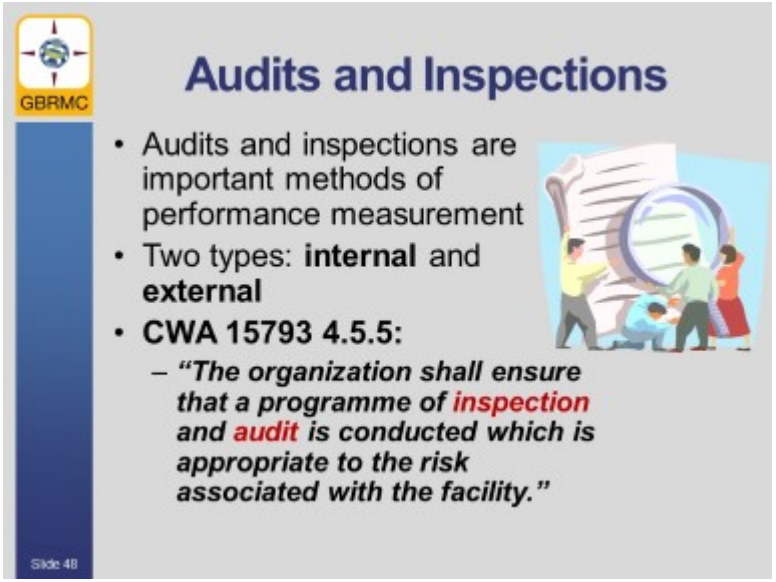

What is an audit?

What is an inspection?

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Audits and Inspections

What are the benefits of **internal audits**?

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Audits – Some Important Considerations

- Management commitment and leadership is essential
- Audits should lead to actions
  - Correct deficiencies and nonconformities
  - Document opportunities for improvement and actions taken
  - Verification of follow-up activity
- Auditors (whether internal or external) should be technically competent and **independent** of the areas under audit

References: World Health Organization, *Laboratory Quality Management System Handbook* (2011); World Health Organization, *Laboratory Biosafety Manual, 3rd Edition* (2004)

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Performance Indicators

- Performance indicators (sometimes called metrics) are **observable measures** that provide useful performance-related information
- Intent: enable a regular and consistent approach to measuring performance over time
  - Show deviations from expected performance or plans
  - Provide warning before an incident
  - Support and compliment other less frequent forms of performance monitoring, such as audits

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Example: Chemical Process Safety

- Chemical industry:
  - Routinely manufactures, stores, handles and transports hazardous materials
  - Historically, has experienced major industrial incidents:
    - Seveso, Italy (1976)
    - Bhopal, India (1984)
    - Many smaller-scale incidents

- What performance measurement approaches have been developed?

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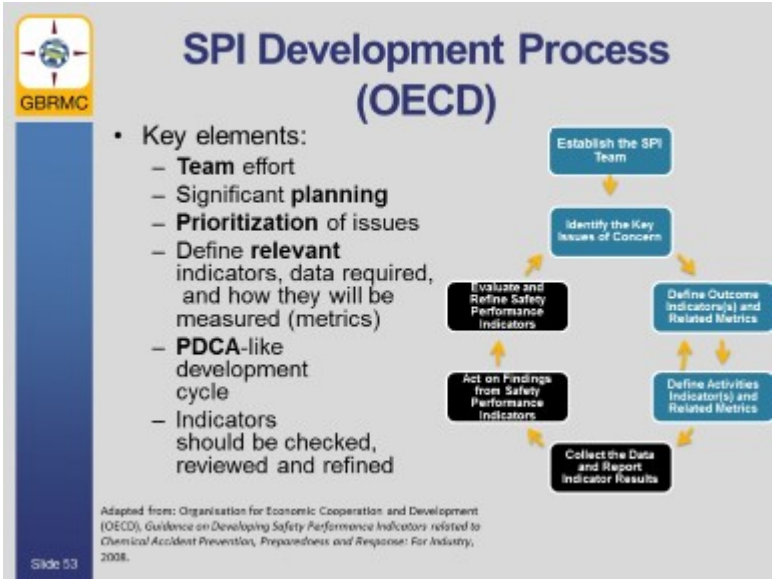
Measurement & Analysis of BRM System Performance



BRM Performance Measurement Methods

- **Teamwork**
- **Planning**
- **Prioritization**

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Examples of Safety Performance Indicators

- Extent to which procedures established in the safety management system are applied by employees
- Extent employees have been trained in accordance with the planned training program
- Are there procedures for ensuring that employees use personal protective equipment (PPE) to the extent appropriate?
- Extent to which audits and technical reviews are completed in relation to the number planned
- Are there systematic procedures for hazard identification and risk assessment?
- Extent the facility's design, engineering and construction are consistent with current standards, codes of practices and guidance
- Is there an adequate on-site emergency preparedness plan?

Are any of these indicators relevant for your facility?

Adapted from: OECD, *Guidance on Developing Safety Performance Indicators related to Chemical Accident Prevention, Preparedness and Response: For Industry*, 2008.

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Characteristics of Good Performance Indicators

- In general: the fewer, the better
- Indicators should be measurable
- Use indicators based on what ***needs* to be measured:**
  - What are the BRM system **performance priorities?**
  - **NOT necessarily what is *easy* to measure**
- Examine **all levels** of the laboratory
- Adaptable

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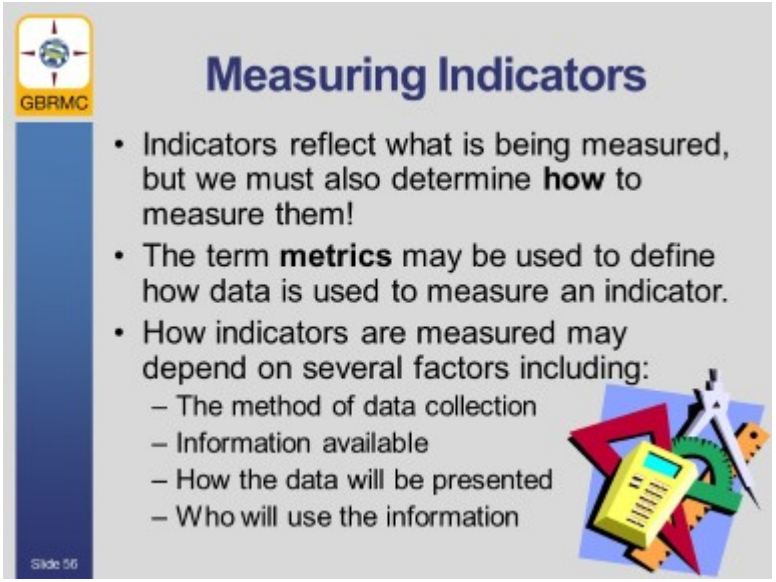
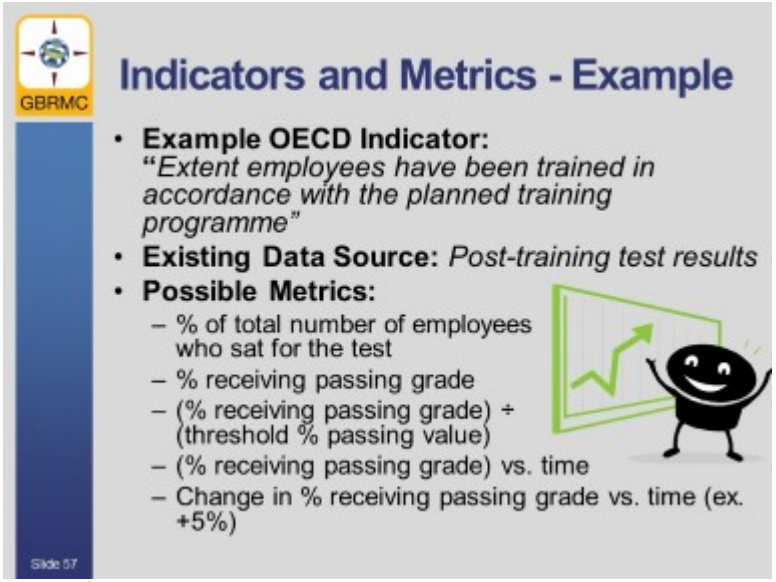
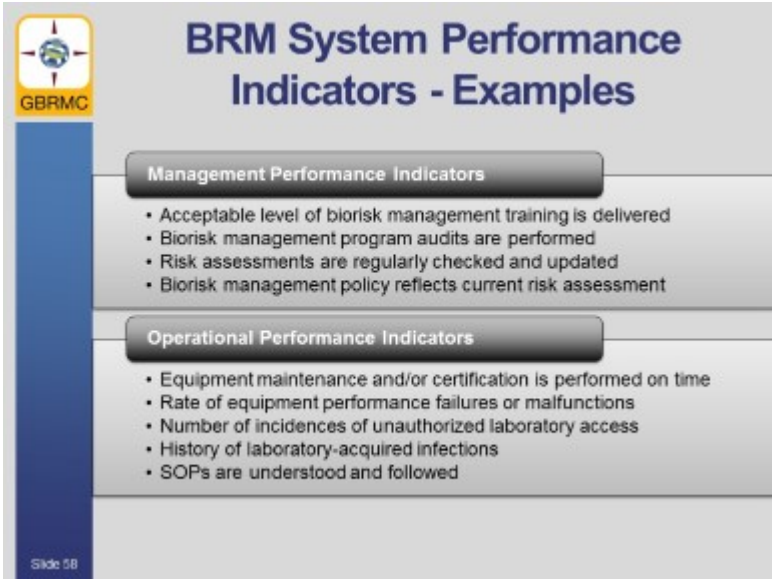


Clearly define both **what** is being measured and **how** it is being measured!



Does measuring this indicator, using this data and metric alone, ensure that the indicator is being fully measured?

What does this indicator/data/metric **not** tell you?



Suggestions for other BRM performance indicators:

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How Often to Collect Data?

- The answer should be based on **risk**!
  - In what timeframe do you need to be able to detect changes in performance levels?
- Other considerations:
  - Method of data collection
  - Cost of data collection
  - Staff or consultant time
  - Disruptions to normal operations

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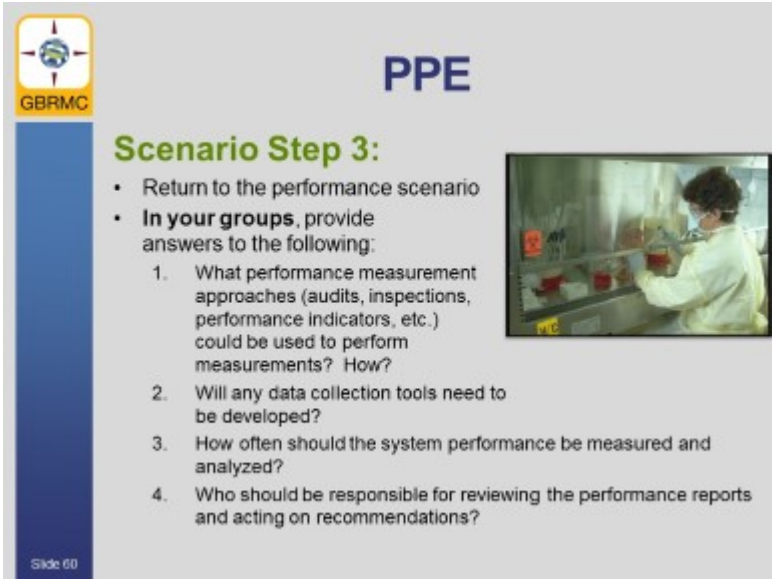
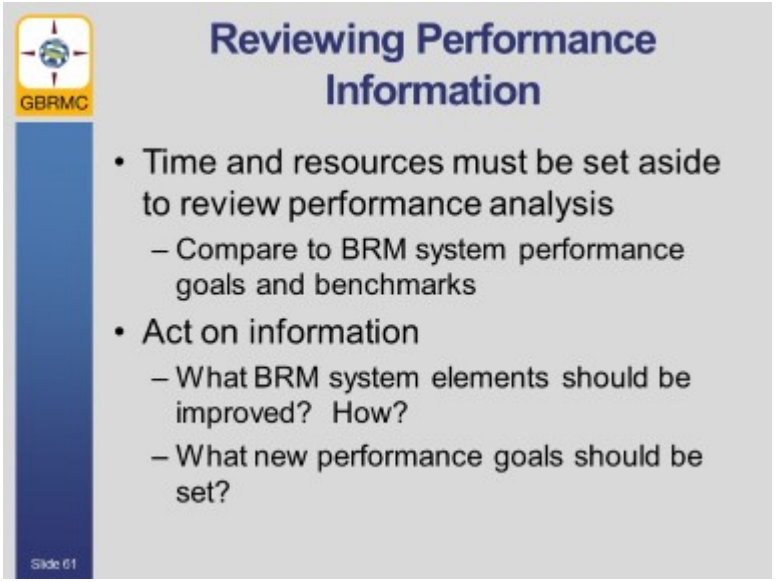


BRM Performance Measurement Methods

- What performance measurement approaches (audits, inspections, performance indicators, etc.) could be used to perform measurements? How?
- Will any data collection tools need to be developed?
- How often should the system performance be measured and analyzed?
- Who should be responsible for reviewing the performance reports and acting on recommendations?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Reviewing Performance Information
• Time and resources must be set aside to review performance analysis
– Compare to BRM system performance goals and benchmarks
• Act on information
– What BRM system elements should be improved? How?
– What new performance goals should be set?
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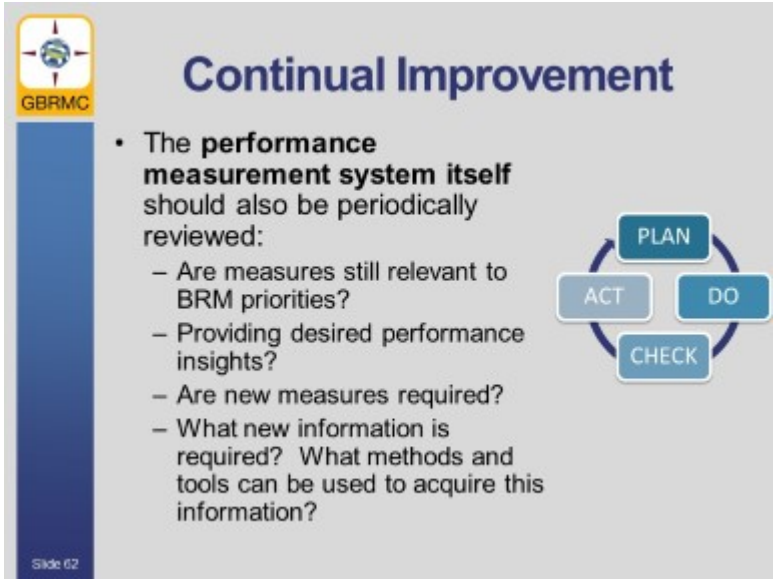
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Continual Improvement
• The performance measurement system itself should also be periodically reviewed:
– Are measures still relevant to BRM priorities?
– Providing desired performance insights?
– Are new measures required?
– What new information is required? What methods and tools can be used to acquire this information?
PLAN
DO
CHECK
ACT
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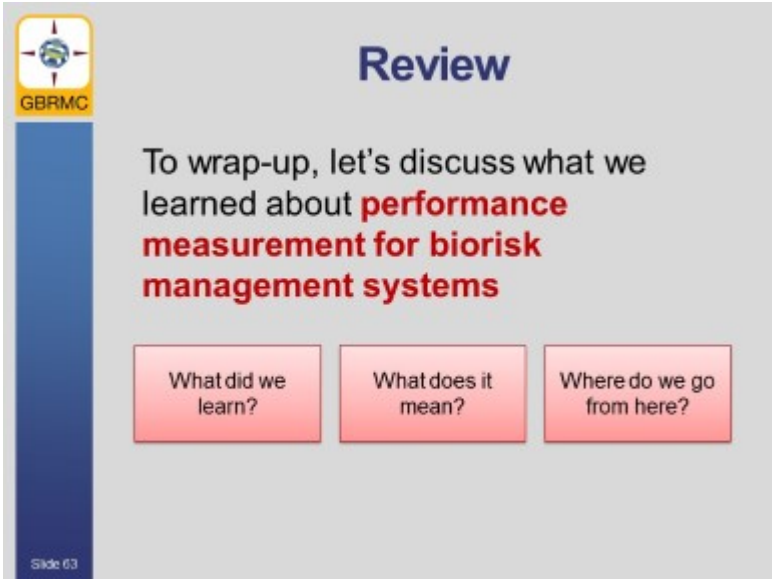
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Review
To wrap-up, let's discuss what we learned about performance measurement for biorisk management systems
What did we learn?
What does it mean?
Where do we go from here?
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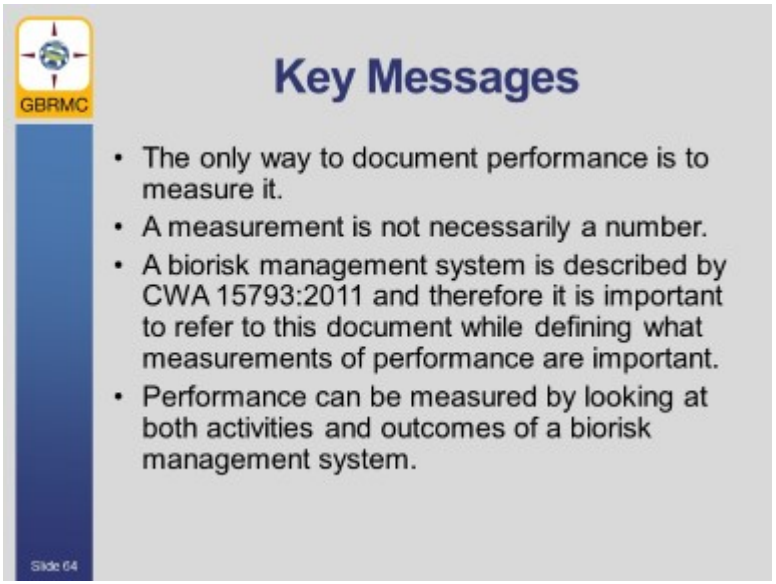
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Key Messages
• The only way to document performance is to measure it.
• A measurement is not necessarily a number.
• A biorisk management system is described by CWA 15793:2011 and therefore it is important to refer to this document while defining what measurements of performance are important.
• Performance can be measured by looking at both activities and outcomes of a biorisk management system.
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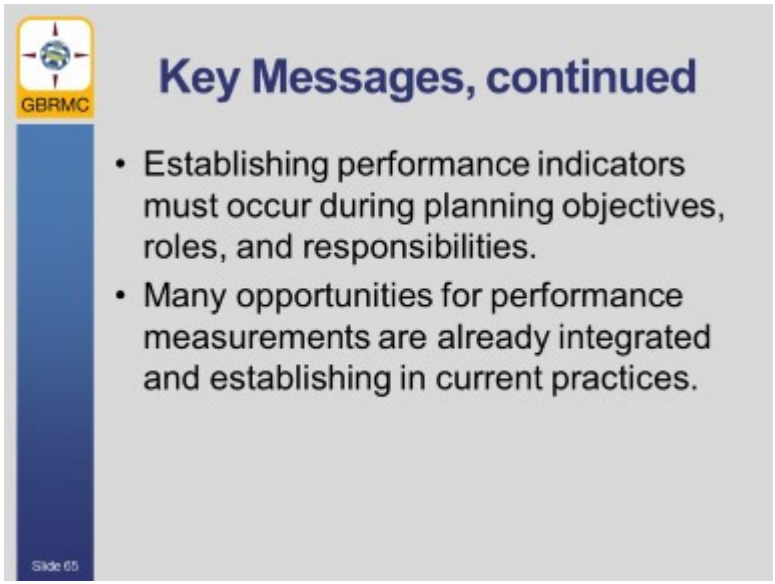
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Key Messages, continued
• Establishing performance indicators must occur during planning objectives, roles, and responsibilities.
• Many opportunities for performance measurements are already integrated and establishing in current practices.
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Action Plan

By the end of this lesson, I would like to:					
KNOW		FEEL		BE ABLE TO DO	

Your learning doesn't stop with this lesson. Use this space to think about what else you need to do or learn to put the information from this lesson into practice.

What more do I need to know or do?	How will I acquire the knowledge or skills?	How will I know that I've succeeded?	How will I use this new learning in my job?

Use space on back, if needed