



GBRMC

# Measurement and Analysis of Biorisk Management System Performance

Student Guide

2013



GLOBAL BIORISK MANAGEMENT CURRICULUM

## Measurement & Analysis of BRM System Performance



## Welcome & Introductions

GBRMC

### Introductions

- Instructors
- Students
  - Your name?
  - Where are you from?

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# Action Plan

By the end of this lesson, I would like to:

KNOW		FEEL		BE ABLE TO DO	
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*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*



## 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



## 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.

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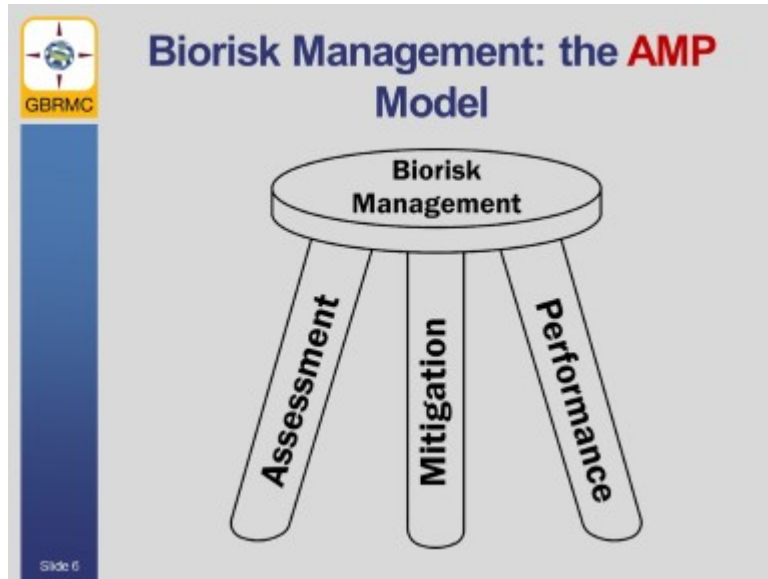
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## Measurement & Analysis of BRM System Performance

## Biorisk Management

Review the AMP model for Biorisk Management.



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## Key Components of Biorisk Management

- **Biorisk Assessment**
  - Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable



Slide 7

Define **Assessment**:

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### Key Components of Biorisk Management

- **Biorisk Mitigation**
  - Actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins



Slide 8

Define **Mitigation**:

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### Key Components of Biorisk Management

- **Biorisk Performance**
  - Improving biorisk management by recording, measuring, and evaluating organizational actions and outcomes to reduce biorisk.



Define **Performance**:

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## Measurement & Analysis of BRM System Performance


## Review of Key Principles of BRM

 **Biorisk Management Refresher**



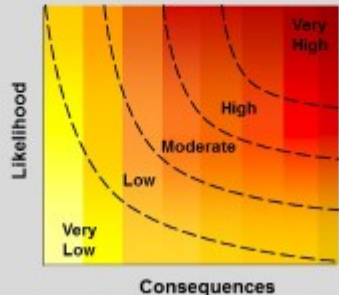
The diagram illustrates the components of Biorisk Management. On the left, a Venn diagram with five overlapping circles represents the pillars: Physical Security, Personnel Security, Information Security, Transport Security, and Material Control & Accountability. A biohazard symbol is centered in the intersection. On the right, a biohazard symbol is surrounded by three overlapping circles labeled Work Practices, Primary Barriers, and Secondary Barriers. The word "BIOSAFETY" is written across the bottom of this diagram.

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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



The risk matrix diagram plots Likelihood on the vertical axis and Consequences on the horizontal axis. The matrix is color-coded from yellow (low risk) to red (high risk). Dashed lines delineate risk levels: Very Low (bottom-left), Low, Moderate, High, and Very High (top-right).

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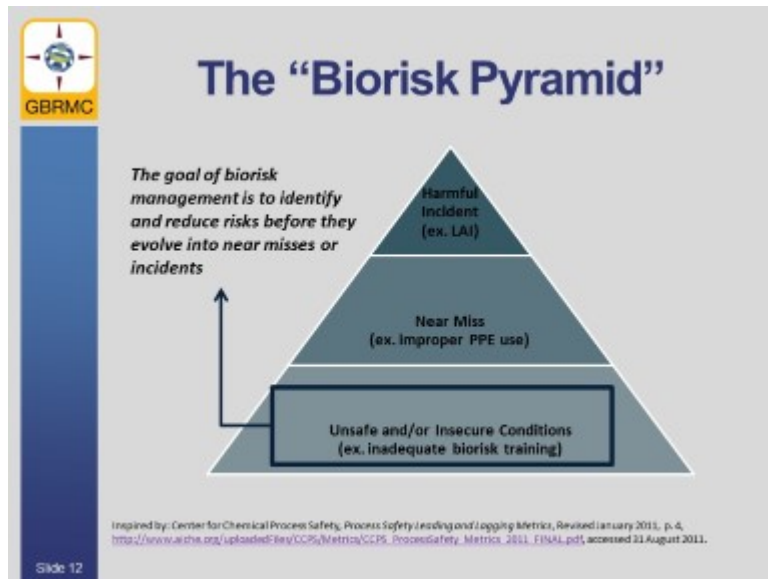
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## Measurement & Analysis of BRM System Performance

## Review of Key Principles of BRM



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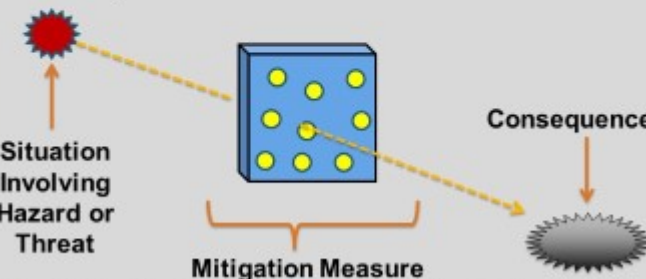
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## Measurement & Analysis of BRM System Performance

## Review of Key Principles of BRM

 **A “Swiss Cheese” Model of Risk**

Mitigation measure has “holes” or weaknesses that may enable undesired consequences




**Situation Involving Hazard or Threat**

**Mitigation Measure**

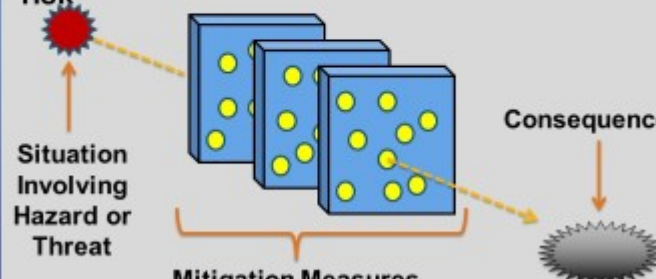
**Consequence**

References: Center for Chemical Process Safety, Process Safety Leading and Lagging Metrics, Revised January 2011, p. 4. [http://www.sich.org/assetUpload/CCPS/Metrics/CCPS\\_ProcessSafety\\_Metrics\\_2011\\_FINAL.pdf](http://www.sich.org/assetUpload/CCPS/Metrics/CCPS_ProcessSafety_Metrics_2011_FINAL.pdf), accessed 31 August 2011; J. Reason, “Human Error: Models and Management,” *BMJ* 2000, Vol. 320, pp. 768–770.

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 **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**

References: Center for Chemical Process Safety, Process Safety Leading and Lagging Metrics, Revised January 2011, p. 4. [http://www.sich.org/assetUpload/CCPS/Metrics/CCPS\\_ProcessSafety\\_Metrics\\_2011\\_FINAL.pdf](http://www.sich.org/assetUpload/CCPS/Metrics/CCPS_ProcessSafety_Metrics_2011_FINAL.pdf), accessed 31 August 2011; J. Reason, “Human Error: Models and Management,” *BMJ* 2000, Vol. 320, pp. 768–770.


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## Measurement & Analysis of BRM System Performance


## Review of Key Principles of BRM

 **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



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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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## Measurement & Analysis of BRM System Performance


## Review of Key Principles of BRM




### 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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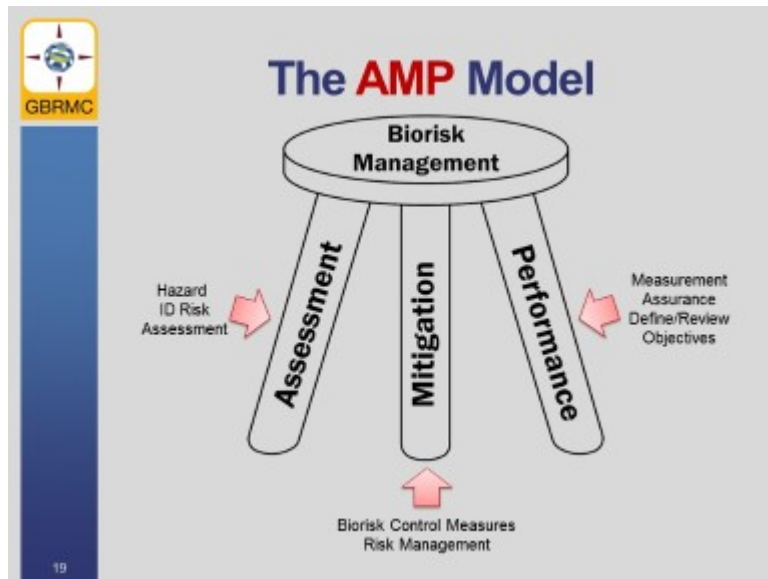
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## Measurement & Analysis of BRM System Performance

## Review of Key Principles of BRM



### Plan – Do – Check – Act

BRM systems should rely on a "Plan-Do-Check-Act" approach

**Goal – 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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CEN Workshop Agreement 15793:2008 – Laboratory Biorisk Management Standard

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## Measurement & Analysis of BRM System Performance


## Review of Key Principles of BRM

 **Measuring Performance**


- In the Laboratory:
  - Testing & Quality Control
  - Financial Management
  - Research Results
  - General Safety
  - Staff Performance
- Other Sectors Managing Hazards
  - Example: Chemical Industry



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 **PDCA and Performance**

- The focus of today's lesson is on the **performance** component of the **AMP Model**
- **PDCA** framework to design, implement and evaluate a system for **BRM performance measurement**
- Performance measurement is an important part of an effective BRM system



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## Measurement & Analysis of BRM System Performance

## Introduction to BRM Performance

Define **Biorisk Management System Performance**:



### Introduction to BRM Performance

**Group Exercise:**

**Question:**  
What is "**biorisk management system performance**"?

**In your groups**, please spend **5 minutes** to develop a definition for "**biorisk management system performance**." Write your answers on **sticky notes** and place them on your **flip chart**. Be prepared to share your definition with the class.

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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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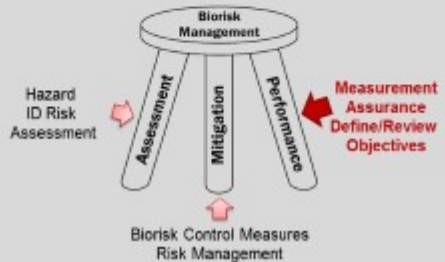
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## Measurement & Analysis of BRM System Performance


## Introduction to BRM Performance

 **Understanding Performance**


Performance is **integral** to successful biorisk management, but how do we **analyze** a system's performance?  
**We need measurements!**



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 **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?



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## Measurement & Analysis of BRM System Performance




## Introduction to BRM Performance

 **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**



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# 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 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.

## Measurement & Analysis of BRM System Performance


## Introduction to BRM Performance



### PPE

#### Scenario Step 1:

- Read the scenario
- **In your groups**, answer the following:
  1. What potential **issues or problems** related to BRM performance can you identify in this scenario?
  2. May performance measurement be used to help the facility better understand its BRM performance in any of these areas?
  3. What additional information would help the facility better understand its BRM performance?



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- 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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## Measurement & Analysis of BRM System Performance


## Introduction to BRM Performance

 **Measuring Biorisk Management Performance**

What does the international laboratory biorisk management standard (CWA 15793) say about **performance measurement**?





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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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### 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...”

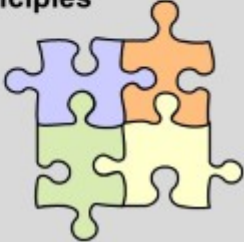
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### Performance Measurement

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)



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## Measurement & Analysis of BRM System Performance

## Introduction to BRM Performance



### 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://corpslikes.usace.army.mil/employees/perform/quotes.cfm>, accessed 11 October 2011

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### Performance Measurement Process

- Like other BRM processes, we can consider performance measurement in terms of PDCA:



- **Planning** is critical!

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## Measurement & Analysis of BRM System Performance

## Planning for BRM Performance Management



### Planning for Performance Measurement

#### Group Exercise:

##### Question:

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

**In your groups**, please spend **10 minutes**, to identify questions that should be answered during the **planning process**. An example is:

- What **resources** (human, financial, material) are available to measure performance?


Write your answers on your **flipchart**. Be prepared to share your questions with the class.

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

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## Measurement & Analysis of BRM System Performance

 **Planning for Performance Measurement**

- Many questions need to be answered **before** undertaking measurements and analysis
- Planning will help **focus your measurements** on the most important aspects of the BRM system!
  - More measurements are **not** necessarily better



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## Planning for BRM Performance Management

 **Planning – Role of Management**

- **What can facility leadership do?**
  - **Assign responsibilities**
    - Consider assembling a team to develop performance measurement priorities and goals
  - **Delegate authority**
  - **Communicate** performance measurement goals and expectations to staff
    - Transparent process
    - Establish timelines
  - **Dedicate resources**



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## Measurement & Analysis of BRM System Performance

## Planning for BRM Performance Management



### 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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## Measurement & Analysis of BRM System Performance

## Planning for BRM Performance Management



### Challenges to Measuring BRM Performance

- One possible approach: focus on measuring and analyzing **“what went wrong”**
  - Accidents, incidents, lab-acquired infections, equipment failures, near-misses, etc.
- This information is relevant, but what could be some **shortcomings** and **challenges** associated with a reliance on this approach?



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

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## Measurement & Analysis of BRM System Performance

## Planning for BRM Performance Management



### Measuring Performance, Part 2

#### Group Exercise:

##### Questions:

What are other potential **sources of information** we could to **measure performance**?

**In your groups**, please spend **10 minutes**, to consider the sources of information available at your facility that can be used in the course of a BRM performance measurement. Write each answer on a separate **sticky note** and place them on your **flipchart**.



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#### Potential Sources of Information:

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## Measurement & Analysis of BRM System Performance

## Planning for BRM Performance Management



### 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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## Measurement & Analysis of BRM System Performance


## Planning for BRM Performance Management



### PPE

#### Scenario Step 2:

- Return to the performance scenario
- **In your groups**, answer the following:
  1. Which laboratory staff should be involved in designing the process to measure BRM performance? Who should lead this effort?
  2. 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)
  3. Identify potential sources of information or data that could be available to use for performance measurement.



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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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## Measurement & Analysis of BRM System Performance

 **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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## BRM Performance Measurement Methods

 **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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## Measurement & Analysis of BRM System Performance

## BRM Performance Measurement Methods



### Audits and Inspections

- Audits and inspections are important methods of performance measurement
- Two types: **internal** and **external**
- CWA 15793 4.5.5:
  - *“The organization shall ensure that a programme of **inspection** and **audit** is conducted which is appropriate to the risk associated with the facility.”*



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What is an audit?

What is an inspection?

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## Measurement & Analysis of BRM System Performance


 **Audits and Inspections**

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





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## BRM Performance Measurement Methods

 **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 Safety Manual, 3rd Edition (2004)

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## Measurement & Analysis of BRM System Performance



### 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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## BRM Performance Measurement Methods



### Example: Chemical Process Safety

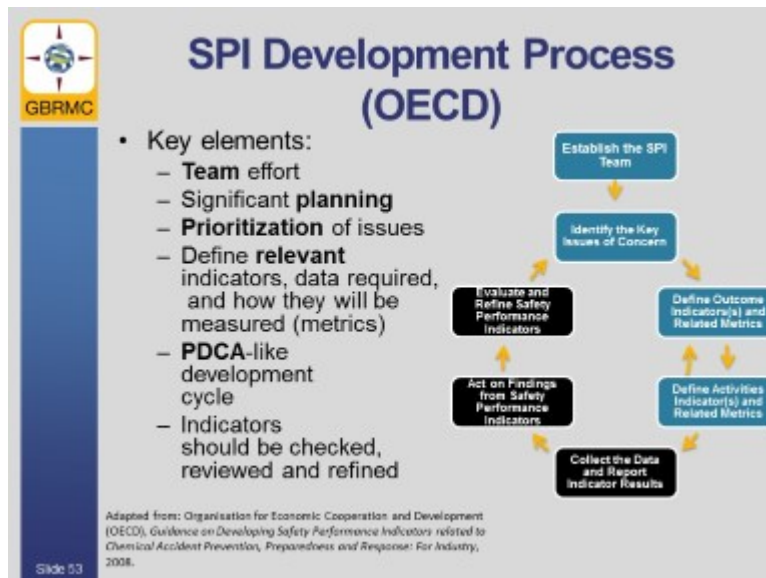
- Chemical industry:
  - Routinely manufactures, stores, handles and transports hazardous materials
  - Historically, has experienced major industrial incidents:
    - Seveso, Italy (1976)
    - Bhopal, India (1984)
    - Many smaller-scale incidents
- What performance measurement approaches have been developed?



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## Measurement & Analysis of BRM System Performance

## BRM Performance Measurement Methods



- Teamwork
- Planning
- Prioritization

## Measurement & Analysis of BRM System Performance



### 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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## BRM Performance Measurement Methods



### 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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## Measurement & Analysis of BRM System Performance

## BRM Performance Measurement Methods



### Measuring Indicators

- Indicators reflect what is being measured, but we must also determine **how** to measure them!
- The term **metrics** may be used to define how data is used to measure an indicator.
- How indicators are measured may depend on several factors including:
  - The method of data collection
  - Information available
  - How the data will be presented
  - Who will use the information



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

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## Measurement & Analysis of BRM System Performance

## BRM Performance Measurement Methods



### Indicators and Metrics - Example

- **Example OECD Indicator:**  
“Extent employees have been trained in accordance with the planned training programme”
- **Existing Data Source:** *Post-training test results*
- **Possible Metrics:**
  - % of total number of employees who sat for the test
  - % receiving passing grade
  - (% receiving passing grade) ÷ (threshold % passing value)
  - (% receiving passing grade) vs. time
  - Change in % receiving passing grade vs. time (ex. +5%)



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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?

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## Measurement & Analysis of BRM System Performance

## BRM Performance Measurement Methods



### BRM System Performance Indicators - Examples

**Management Performance Indicators**

- Acceptable level of biorisk management training is delivered
- Biorisk management program audits are performed
- Risk assessments are regularly checked and updated
- Biorisk management policy reflects current risk assessment

**Operational Performance Indicators**

- Equipment maintenance and/or certification is performed on time
- Rate of equipment performance failures or malfunctions
- Number of incidences of unauthorized laboratory access
- History of laboratory-acquired infections
- SOPs are understood and followed

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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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## Measurement & Analysis of BRM System Performance


## BRM Performance Measurement Methods



**PPE**

### Scenario Step 3:

- Return to the performance scenario
- In your groups**, provide answers to the following:
  - 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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- 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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### 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?



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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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## 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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## 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.

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# Action Plan

By the end of this lesson, I would like to:

KNOW		FEEL		BE ABLE TO DO	
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*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*