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Introduction to Measuring Biorisk Management Performance

February 29-March 2, 2012 *Regional INH Biorisk Management Workshop*

Day 3 *Instructors: William Pinard, Laura Grainger, and Thamer Imran*

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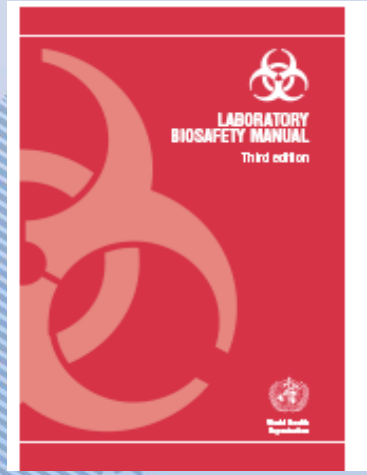
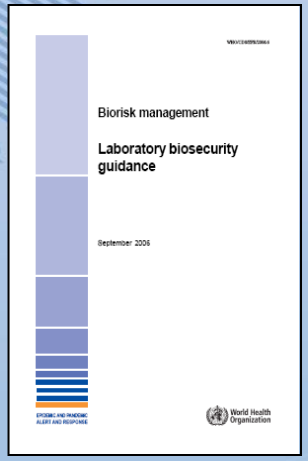
BIOSECURITY ENGAGEMENT PROGRAM

CBEP

Definitions

- **Laboratory biosafety**: containment principles, technologies, and practices implemented to prevent unintentional exposure to pathogens and toxins, or their unintentional release[1]
- **Laboratory biosecurity**: protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release. [2]



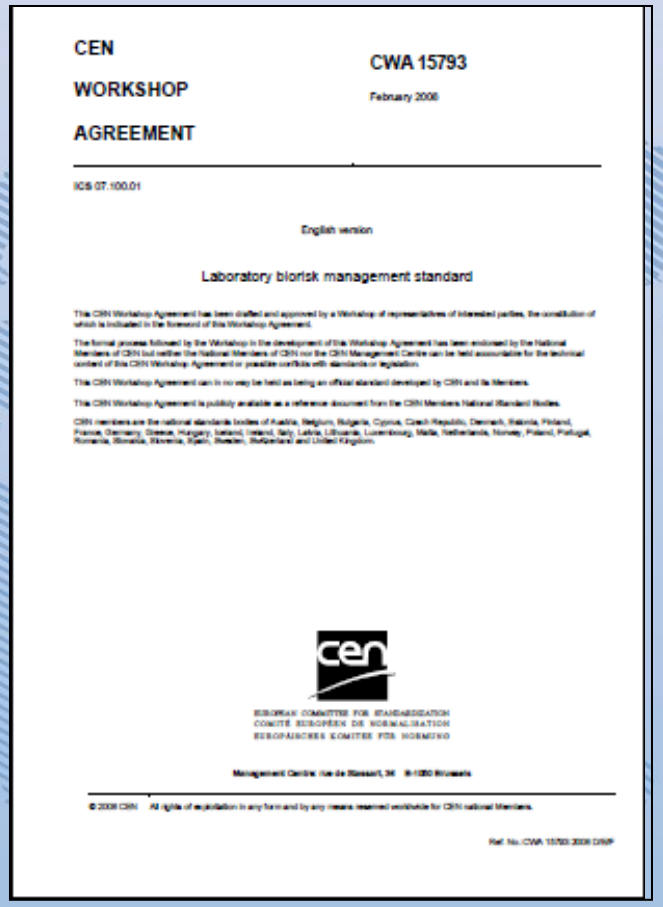


[1]Laboratory biosafety manual, Third edition (World Health Organization, 2004)

[2] Biorisk management - Laboratory biosecurity guidance (World Health Organization, 2006)

Laboratory Biorisk Management

- System or process to control safety and security risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities
- CWA 15793:2011



CEN

WORKSHOP

AGREEMENT

CWA 15793

February 2008

ICS 07.100.01

English version

Laboratory biorisk management standard

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Ref. No. CWA 15793:2008 D/NP

The AMP Model

Biorisk Management =
Assessment Mitigation Performance

Hazard ID
Risk Assessment

Biorisk Control Measures
Risk Management

Measurement
Assurance
Define/Review Objectives

What is Biorisk Management (BRM) Performance?

- **Group activity**
- Take 5 minutes to work with your group to define "**biorisk management system performance**"
  - Write your answers on sticky notes
  - Place your sticky notes on the central flip chart

The Concept of Performance

- **Biorisk Management System Performance:**
  The way in which a biorisk management system actually functions to manage or minimize biorisk.

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

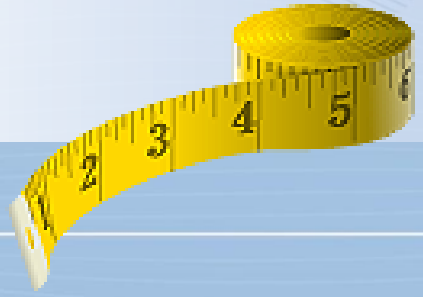
Assessing a Basic Process

1. Are the steps physically possible?
2. Are they the right steps?

3. Is the actual output equal to the desired output?
4. Is the output the right measurement for the process?

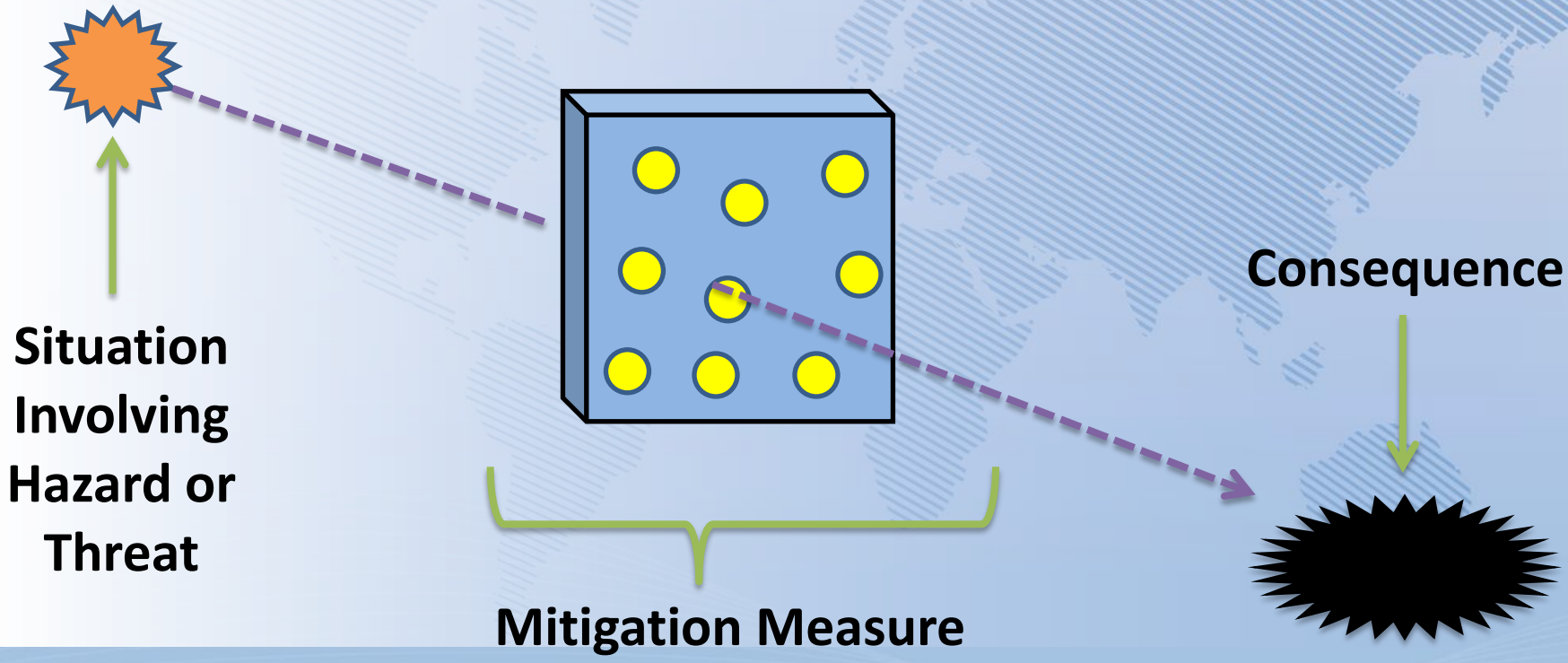
Measuring Performance

- In your groups:
- Take 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 answers on your group's flip chart



A "Swiss Cheese" Model of Risk

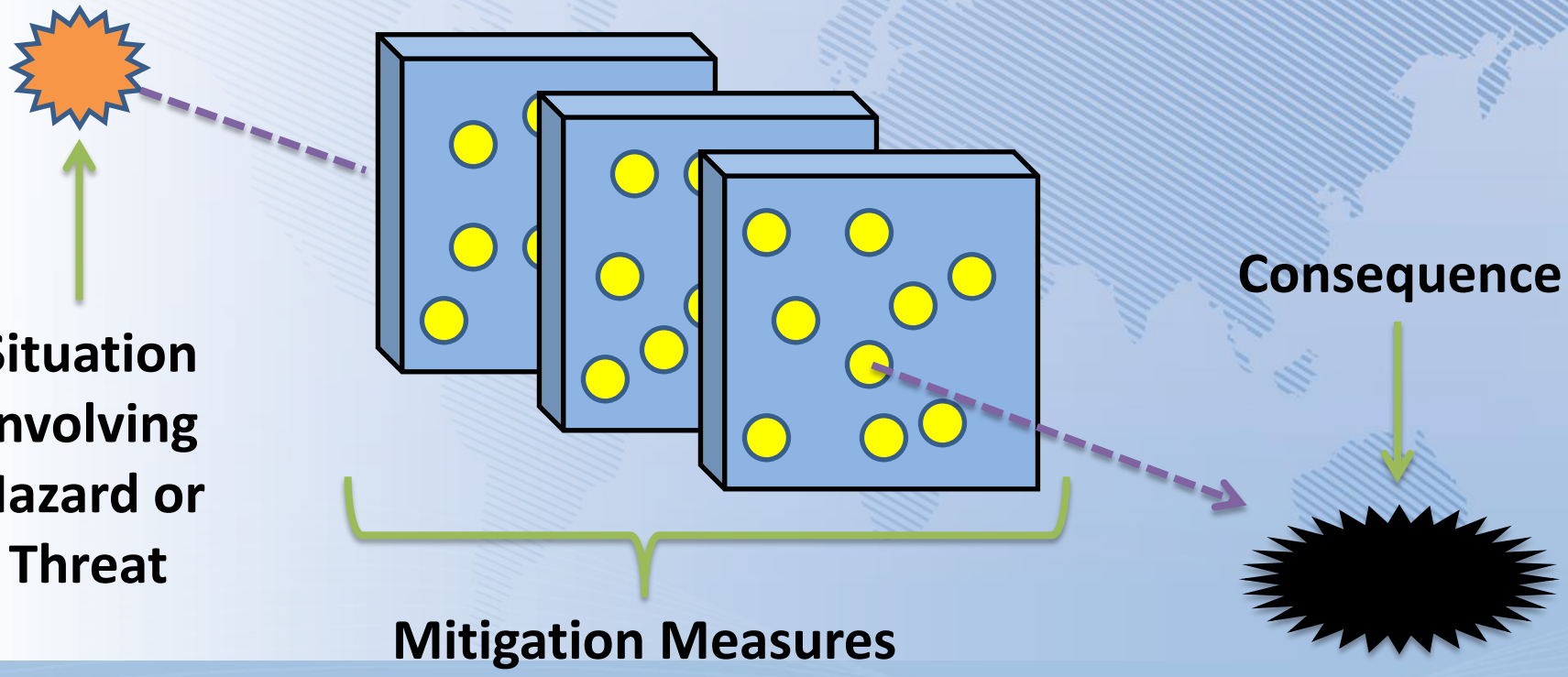
- **Mitigation measure has "holes" or weaknesses that may enable undesired consequences**



References: 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; J. Reason, "Human Error: Models and Management," *BMJ* 2000, Vol. 320, pp. 768 – 770.

A "Swiss Cheese" Model of Risk

- **Multiple mitigation layers can greatly reduce risk likelihood, but <u>not</u> eliminate risk**



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Incident Pyramid

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?

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**

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?

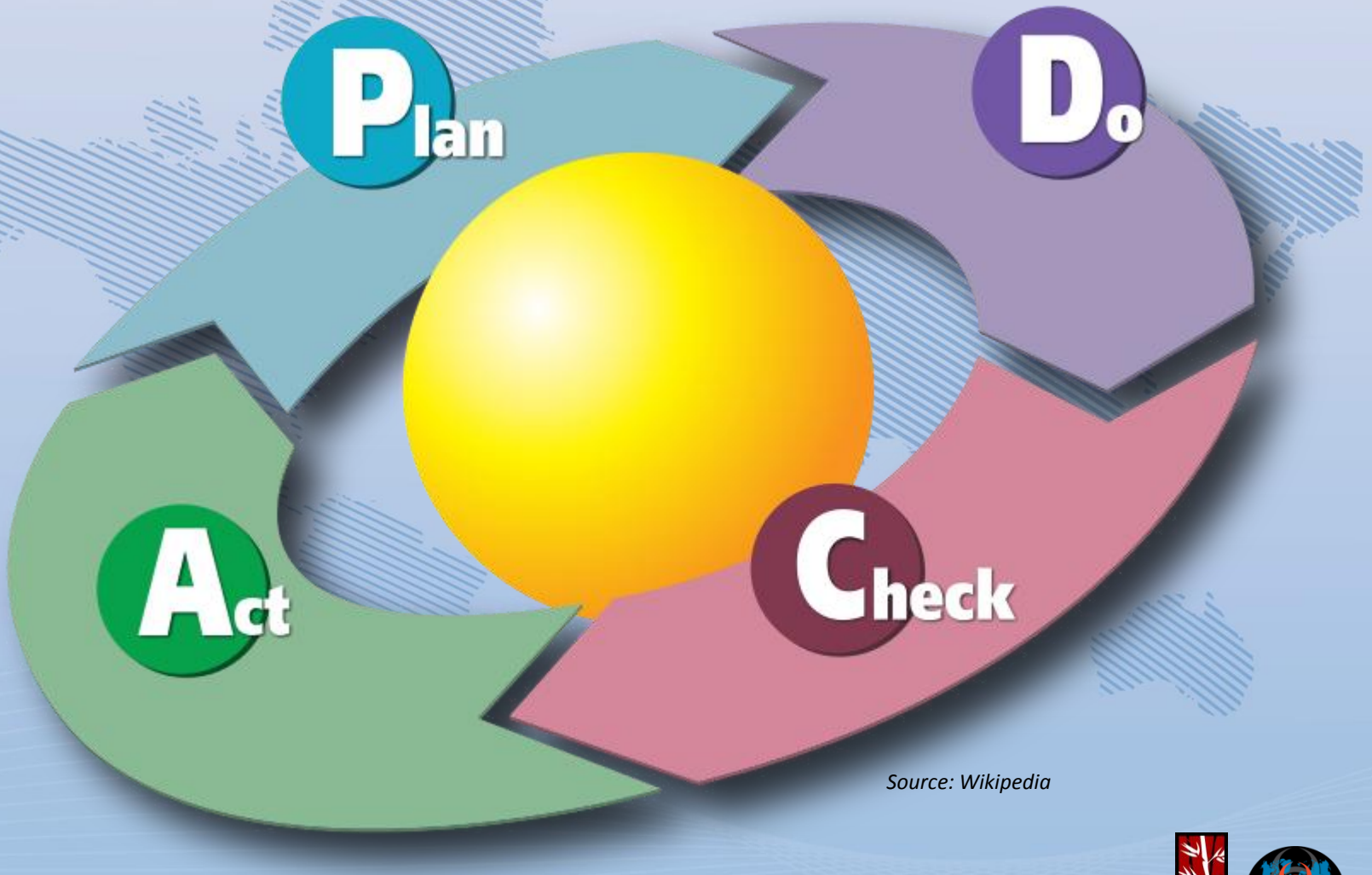
Another View on Performance

"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

Biorisk Management – Continuous Improvement



Source: Wikipedia

Plan – Do – Check – Act

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

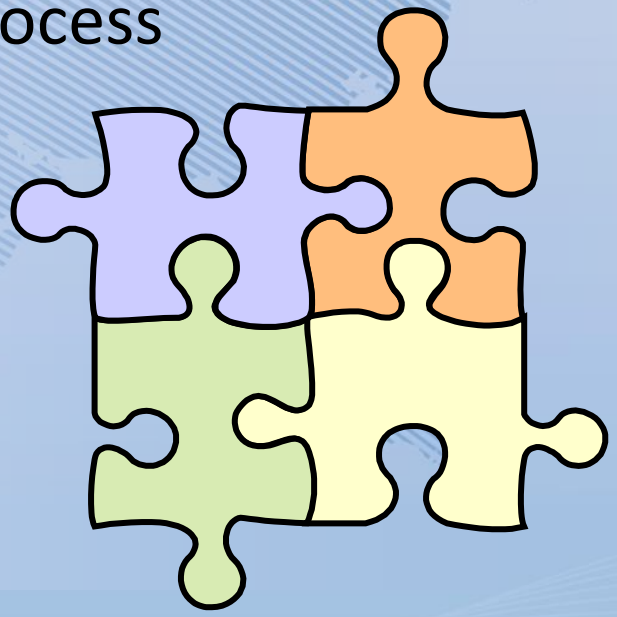
Goal – Continuous Improvement

- **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.

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

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)



Performance and the CWA

- **CWA 15793 4.5.1 Performance measurement and analysis**
  - ***"The organization shall ensure that appropriate data are determined, collected and analysed to assess the suitability and effectiveness of the biorisk management system and to evaluate where continual improvement of the system can be made."***

Performance and the CWA

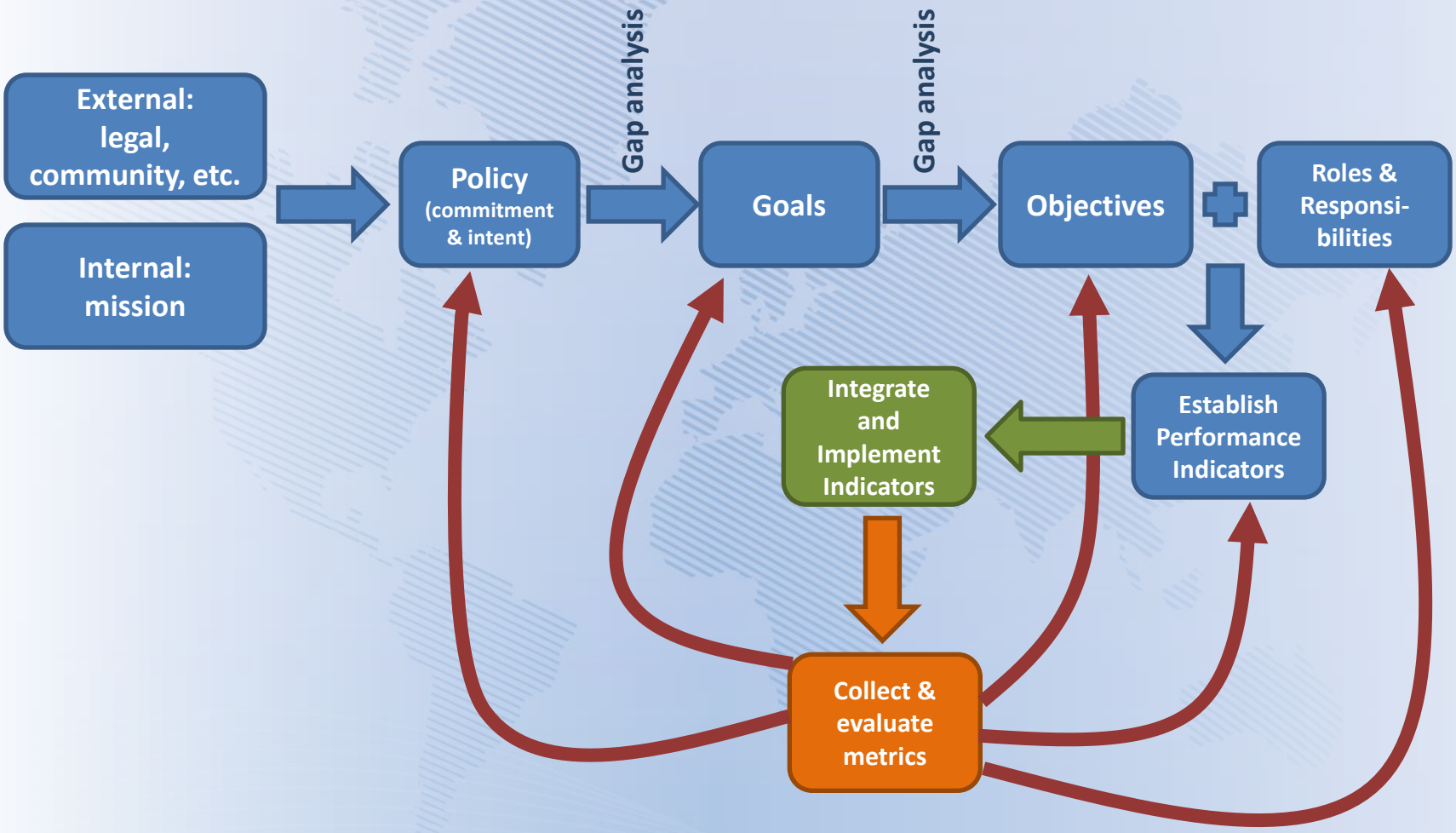
- **This directly leads to another key requirement: 4.6.1 Biorisk management review**
  - *"Top management shall **review** the organization's biorisk management system at planned intervals, **to ensure its continuing suitability, adequacy and effectiveness**. The review shall include **assessing opportunities for improvement** and the need for changes to the system, procedures, policies and objectives…"*

Performance Measurement Process

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

- **Planning is critical!**

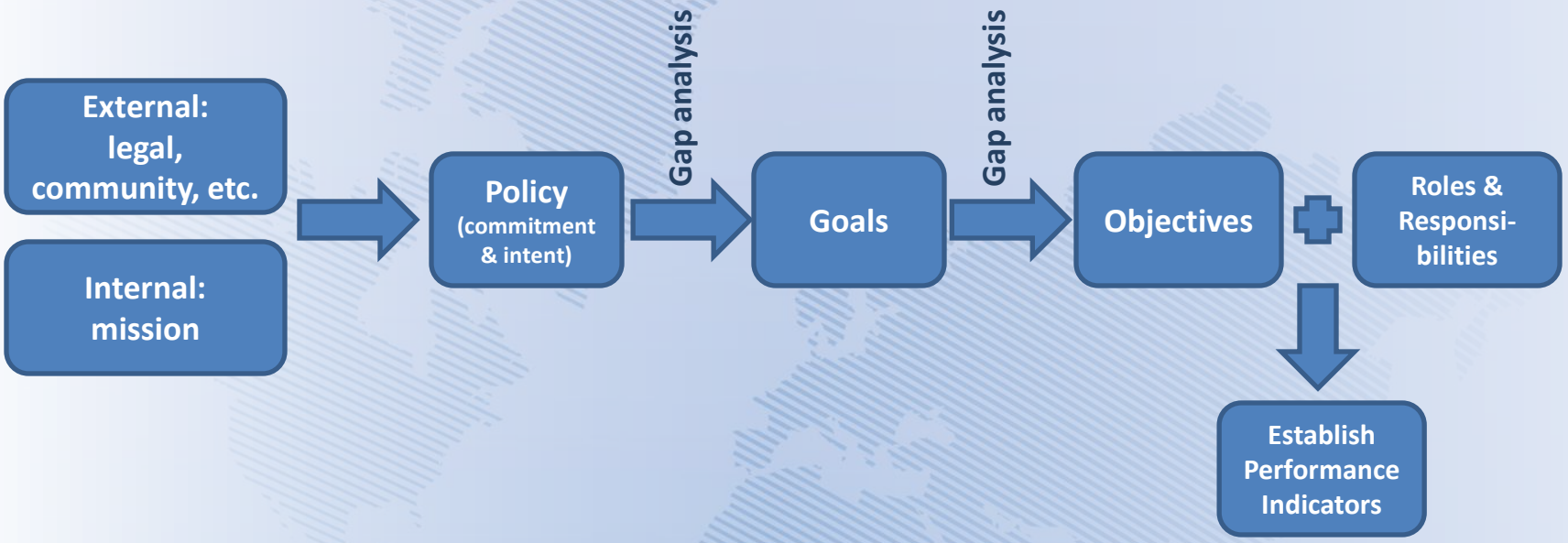
Plan-Do-Check-Act



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

Plan


External: legal, community, etc.
Internal: mission
Policy (commitment & intent)
Gap analysis
Goals
Gap analysis
Objectives
Roles & Responsi-bilities
Establish Performance Indicators

Planning – Identifying External & Internal Influences

- 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)

Planning – Setting Policy

"A policy is a temporary creed liable to be changed, but while it holds good it has got to be pursued with apostolic zeal"
Mahatma Gandhi

- A definite course of action *(www.dictionary.com)*
  - adopted for the sake of expediency, facility, etc.: *We have a new company policy.*
- A guiding principle that influences other actions.

What word is common to both definitions?

- Synonyms: strategy, principle, rule

A policy states commitment and intent

- **Commit** (verb)
  - to bind or obligate, as by pledge or assurance; pledge: to commit oneself to a promise; to be committed to a course of action. *(www.dictionary.com)*
- **Intent** (adjective)
  - firmly or steadfastly fixed or directed, as the eyes or mind: *an intent gaze*.
  - having the attention sharply focused or fixed on something: *intent on one's job.*
  - determined or resolved; having the mind or will fixed on some goal: *intent on revenge*.
  - earnest; intense: *an intent person*.

After writing policy. . .

- Remember that a policy establishes commitment and intent, but does not specify HOW to implement.
- Critical next steps:
  - Establishing roles and responsibilities to support the commitment to and intent for biorisk management
  - Stating specific goals
  - Setting objectives to accomplish those goals

Setting Goals & Objectives

- What is the difference between a goal and an objective?
  - Goal (an observable and measurable end result)
    - We want to aim our resources and efforts towards this outcome
  - Objectives
    - These are the steps we need to take, in a more or less fixed timeframe, to move towards and achieve the outcome

SMART Objectives

- **S**pecific
- **M**easurable
- **A**ttainable
- **R**easonable
- **T**ime-based

Exercise: Goals & Objectives

- **Policy**: Doors to laboratories must be locked when no one is in the lab
- **Goal**: Develop access control process for laboratory doors using key locks and keys
- **Objectives?** "SMART" ways to move towards the goal
- *Roles & Responsibilities*
- *Performance Indicators*

Roles & Responsibilities = Accountability

One Tool for Determining Responsibilities

Objective	Senior Mgmt	Line Mgmt (PI)	Biosafety Professional	Worker
Determine external and internal influences				
Write & communicate policy				
Set goals				
Set objectives				
Establish roles & responsibilities				
Establish performance indicator(s) for objective(s)				

A= Decision B = Involved C = Consulted D = Informed E = Not Informed

What should we be measuring?

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

Measurement Indicators

Lagging Performance Indicators

- Incidents
- Accidents
- Near Misses
- Enforcement Actions

Leading Performance Indicators

- Processes
- Culture
- Behavior
- Protective Barriers

PERHAPS THERE IS VALUE IN BOTH?

Differences Between Lagging & Leading Indicators

Lagging		Leading	
Benefits	**Challenges**	**Benefits**	**Challenges**
Reveals safety improvement opportunities	Limits our ability to showcase leadership	Using leading indicators increases management involvement	Management needs to agree with objectives and measures
Confirms intervention effectiveness, analyzes trends, and prioritizes safety initiatives	Measures Failure: Accidents must occur to obtain a conclusion	Specific to your site and provide opportunities for continuous improvement.	The act of collecting and monitoring leading performance indicators will not, in itself, cause improvement
Serves as a report card, pointing to successes and failures in the past, and trends in overall safety performance	Not appropriate for all levels of management and diminishes our proactive activities separating biosafety from the organization.	Focus on the practices that prevent accidents rather than measuring failures. Active participant by employees is required	What is then done with the information collected will mark the difference between success and failure.

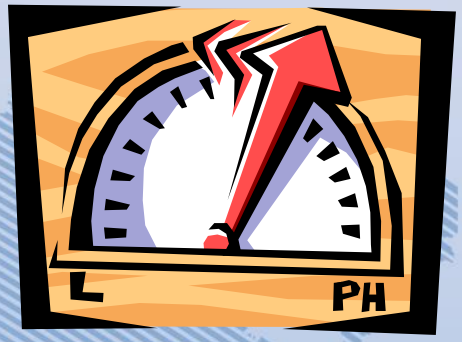
The scoreboard doesn't always reveal everything about the game!

Good Indicators

- Objective and practical
- Relevant to organization
- Immediate and reliable
- Cost efficient
- Understood and owned by workgroup
- Guides future action
- Provides new opportunities (not punitive ones)

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



Example: Chemical Process Safety

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

- What performance measurement approaches have been developed?

SPI Development Process (OECD)

- Key elements:
  - **Team** effort
  - Significant planning
  - **Prioritization** of issues
  - Define **relevant** indicators, data required, and how they will be measured (metrics)
  - **PDCA**-like development cycle
  - Indicators should be checked, reviewed and refined

Adapted from: Organisation for Economic Cooperation and Development (OECD), *Guidance on Developing Safety Performance Indicators related to Chemical Accident Prevention, Preparedness and Response: For Industry*, 2008.

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 programme**
- **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.

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

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%)

Exercise: Performance Indicators & Metrics

- For your group's assigned goal, determine:
  - At least 3 objectives
  - Roles & responsibilities for at least 2 roles
  - Performance Indicators for each R&R per objective
    - One of each: leading (activities) & lagging (outcome)
- Complete the provided matrix.

Goal:

			Performance Indicators	
Objective	Roles (who)	Responsibility (what/how)	Leading	Lagging
A.	1.			
	2.			
B.	1.			
	2.			
C.	1.			
	2.			

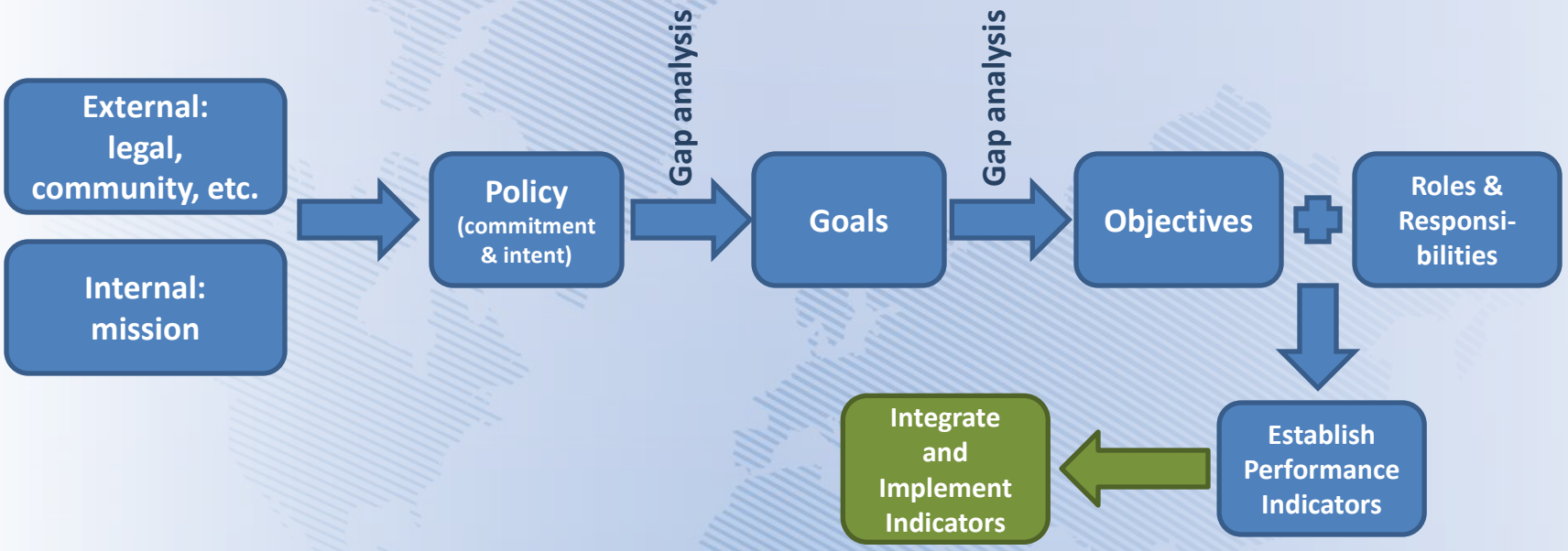
Module Review

Review

Let's discuss what we learned about **planning for biorisk management system performance**

What did we learn?	What does it mean?	Where do we go from here?

Plan-Do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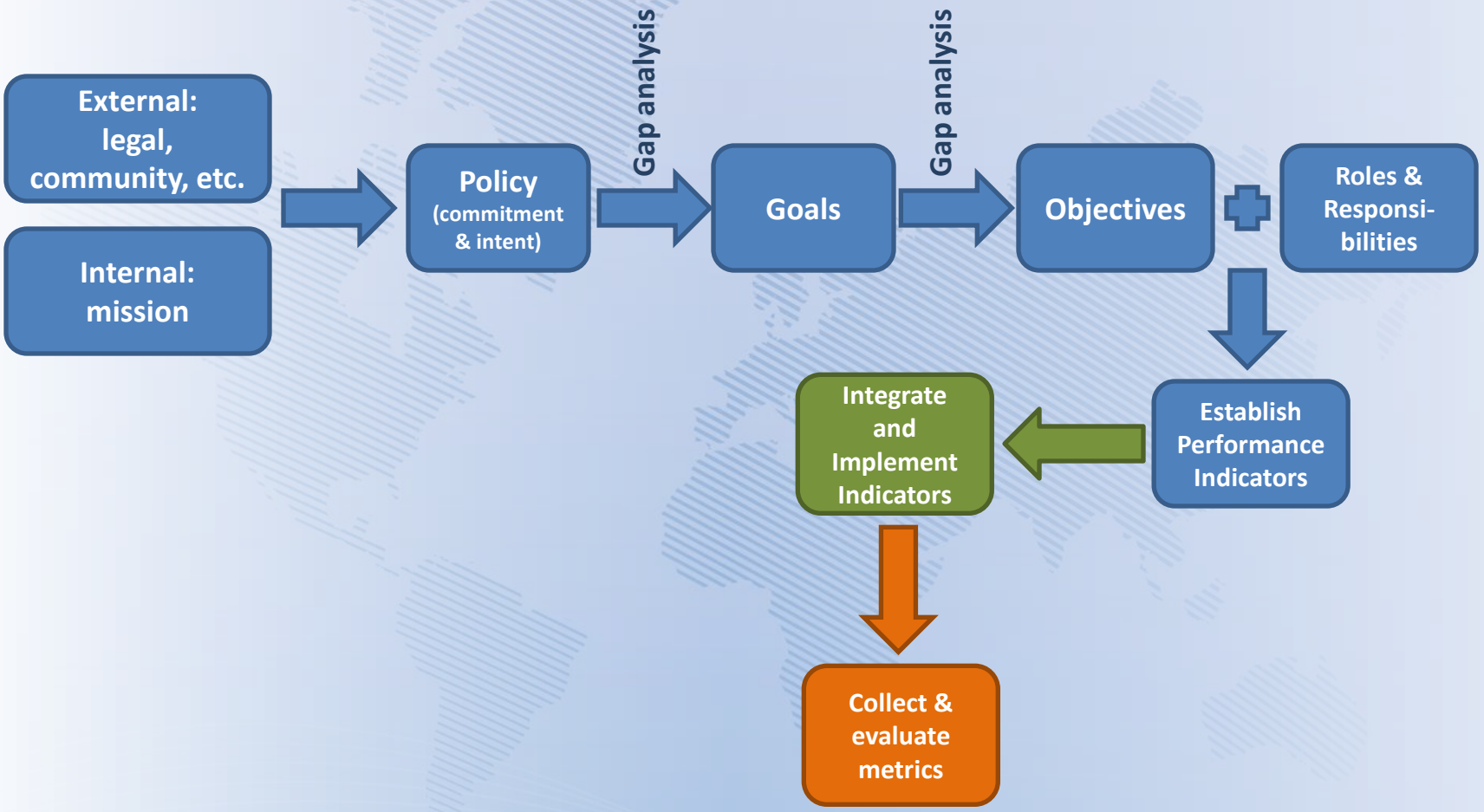
Policy (commitment & intent)
Gap analysis
Goals
Gap analysis
Objectives
Roles & Responsi-bilities
Establish Performance Indicators
Integrate and Implement Indicators

Do

- If you have followed the steps outlined for planning, you should have performance indicators **integrated** into the objectives for accomplishing your goal.
- The measurements may be collected during or after implementation, but they should NOT be after-thoughts.
- During implementation, other measurements may become obvious and should be noted and evaluated for inclusion during the Check and Act phases.

Plan-Do-Check



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

Assessing a Basic Process

1. Are the steps physically possible?
2. Are they the right steps?

3. Is the actual output equal to the desired output?
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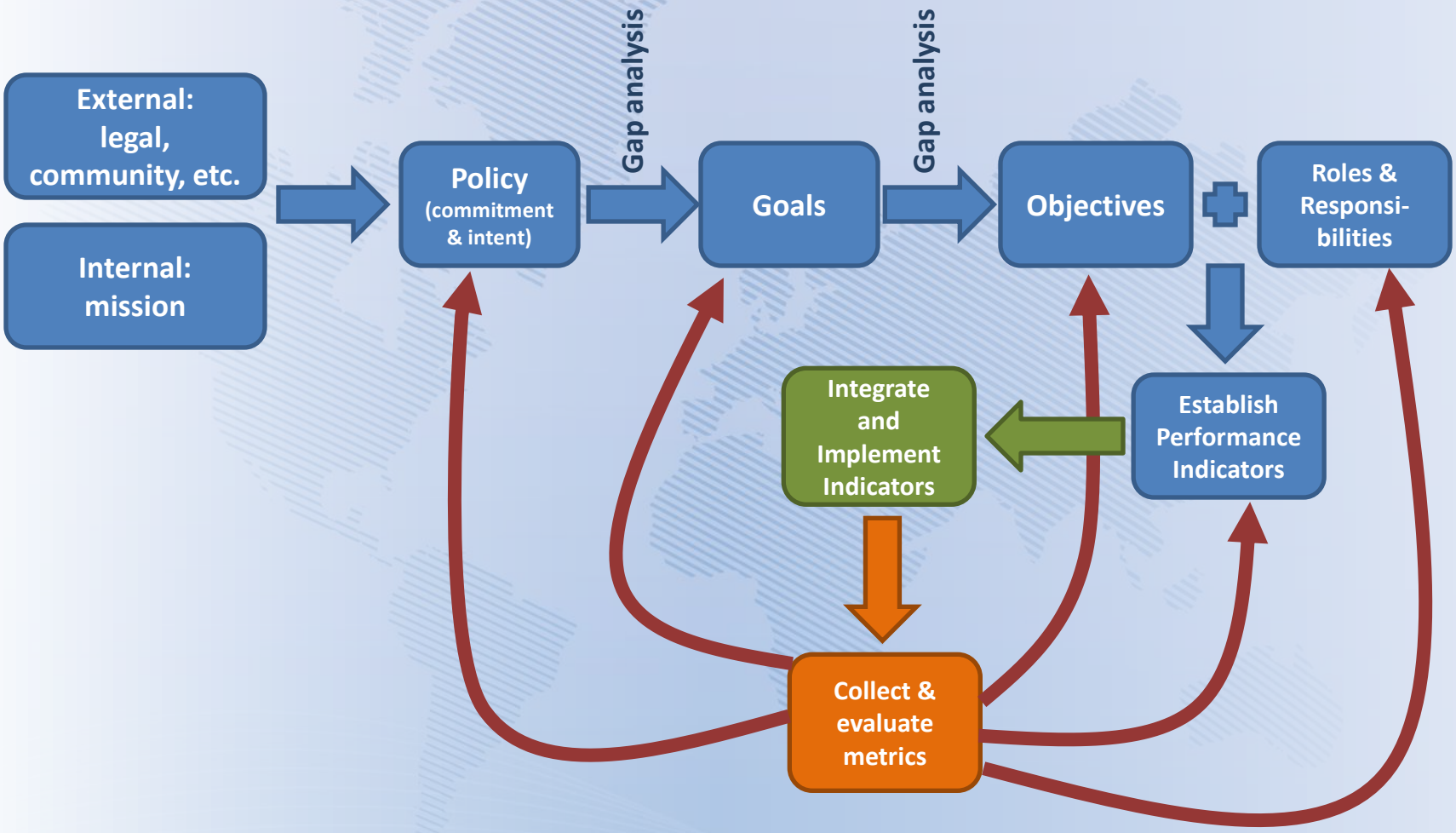
Plan-Do-Check-Act

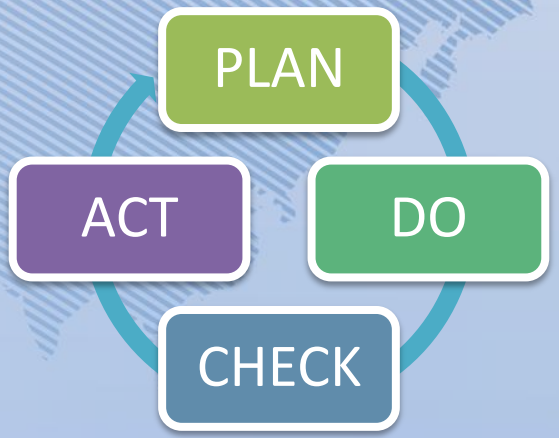


Reviewing Performance Information

- 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?

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?



Exercise: Do-Check-Act

- Look back at the performance indicators you developed in the previous exercise. Pick two indicators (one leading and one lagging).
- Discuss, in your small group, how to:
  - Integrate that measurement into the work
  - Evaluate the measurement to determine what it is telling you (hint: remember how to assess a basic process)
  - Assure that improvements, as determined in the Check phase, are implemented into planning.

Review of Performance Indicators

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?

Selected Resources

- European Committee for Standardization, CEN Workshop Agreement (CWA) 15793:2008 – Laboratory Biorisk Management Standard (2011)
- World Health Organization, Laboratory Biosafety Manual, 3rd Edition (2004)
- World Health Organization, Biorisk Management: Laboratory Biosecurity Guidance (2006)
- World Health Organization, Laboratory Quality Management System Handbook (2011)
- Organisation for Economic Cooperation and Development, Guidance on Developing Safety Performance Indicators Related to Chemical Accident Prevention, Preparedness and Response: For Industry, 2nd Edition, 2008.
- Center for Chemical Process Safety, Process Safety Leading and Lagging Metrics: You Don't Improve What You Don't Measure, Revised January 2011.
- Burnett, L. In D. O. Biological Safety Program Management in Fleming and D. L. Hunt (eds.*), Biological Safety Principles and Practice, 4th ed., ASM, Washington, DC (2006).*
- Roughton, J. and Mercurio, J. Developing an Effective Safety Culture: A Leadership Approach, Butterworth-Heinemann, Woburn, MA 2002
- Salerno, R.M. and Gaudioso, J. *Laboratory Biosecurity Handbook*, CRC Press, Boca Raton, FL, 2007.

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 course. 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?

Thank You!

Don't forget to complete your evaluation!

BIOSECURITY ENGAGEMENT PROGRAM

CBEP
COOPERATIVE BIOLOGICAL ENGAGEMENT PROGRAM

Introduction to Measuring Biorisk Management Performance

Student Guide – draft – January 2012

Sandia National Laboratories
International
BIOLOGICAL THREAT REDUCTION

BIOSECURITY ENGAGEMENT PROGRAM

CBEP
Cooperative Biological Engagement Program

Performance Measurement and Biorisk Management Systems

Laboratory biosafety definition:

Laboratory biosecurity definition:

CEN Workshop Agreement (CWA): a comprehensive framework for managing biorisks developed through international collaboration.

What is biorisk assessment?

What is biorisk mitigation (or control)?

What is biorisk management performance?

What defines biorisk management system PEFORMANCE?

How can ACTUAL performance differ from PLANNED or DESIGNED performance? Why?

What are some reasons why planned BRM effectiveness and actual BRM performance may not agree?

Why does BRM performance change with time?

Any plan or system is a series of processes. A process can be defined as starting with an INPUT, applying some combination of steps to the INPUT, which then results in the OUTPUT.

What are the benefits of measuring biorisk management system performance?

No mitigation measure solves everything.
What are examples of “holes” the occur with different mitigation strategies?

Multiple or redundant layers of protection can prevent a harmful or near miss situation more effectively than a single layer of protection.

However, the risk associated with the hazard or threat can NEVER be completely eliminated, short of removing the hazard entirely from the laboratory.

Often, there are indications that a system is not working BEFORE a catastrophic event. The goal of measuring performance is to observe those indicators and make adjustments prior to a more damaging event.

Performance measurement and analysis can help us understand the weaknesses in the BRM system, and therefore help identify priorities for continual improvement efforts.

Do these benefits match the benefits your group came up with?

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

Any measurement, quantitative or qualitative, that provides useful information concerning the status of the BRM system performance could be utilized: we do not necessarily need to focus on the more "quantitative" measurements.

Plan-Do-Check-Act for Performance

TWO SLIDES

Performance measurement and analysis should NOT be viewed as a separate process or "layer of bureaucracy" but as a key ingredient to a successful risk management scheme.

TWO SLIDES

Our goal, as with the biorisk management system as a whole, is to develop a system of performance measurement that can be continually improved through review, corrective action, and enhancement.

Within each step of the PDCA cycle, there are additional steps.

PLAN Performance Measurement

TWO SLIDES

What is an example of an EXTERNAL influence?

What is an example of an INTERNAL influence?

How does each of these impact the workings of a biorisk management system?

TWO SLIDES

TWO SLIDES

Why is it important for objectives to be:

Specific?

Measurable?

Attainable?

Reasonable?

Time-Based?

What are possible objectives to establish in developing an access control process?

Why is it important to biorisk management performance to establish roles and responsibility?

This tool can be used to help define responsibility, and particularly, accountability for any objective and any role.

Performance Measurements, Indicators, and Metrics

What methods can we utilize to keep tabs on the performance of the BRM system more regularly?

Not all measurements have to result in numbers. A simple “yes” or “no” is a measurement. It is valuable to measure the Activities of a biorisk management program, as well as the Outcomes.

Can you think of other benefits and challenges to:

Lagging Indicators?

Leading Indicators?

TWO SLIDES

TWO SLIDES

Are any of these indicators relevant for your facility?

What do you think could be some ways we could gather and evaluate data to address these indicators?

It is important to consider and clearly define both WHAT is being measured and HOW it is being measured.

Questions to ask as you develop indicators and metrics:

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

What does this indicator/data/metric NOT tell us?

See the worksheet on the next page!

Goal:				
			Performance Indicators	
Objective	Roles (who)	Responsibility (what/how)	Leading	Lagging
A.	1.			
	2.			
B.	1.			
	2.			
C.	1.			
	2.			

Slide 50

What are the key steps in PLANNING for biorisk management?

Why is it important to establish performance indicators in the PLANNING process?

What are one or two things you can do now to PLAN for performance measurement?

DO - Implement Performance Measurements

TWO SLIDES

CHECK Performance Measurements

TWO SLIDES

Questions to ask about performance measurements:

1. Is the measurement physically possible?
2. Does the measurement process provide the information needed (does it actually work)?
3. Is the measurement the right measurement?

ACT - Review and Improve Performance

TWO SLIDES

Some questions to ask:
Are measures still relevant to your biorisk management priorities (risk based)?

Are the performance measures you are using still providing the desired performance insights?

Based on the answers to these questions, are new performance measures required?

If so, what new information would be required? What methods and tools could be used to acquire this information? (note: this last question marks the transition to a new planning phase in performance measurement)

Performance Indicator (leading):
How to integrate and implement:

How to evaluate what the measurement is telling you:

What would need to be adjusted if you decided that:

a. There is no progress on the objective?

b. You are not measuring the right thing?

Performance Indicator (lagging):
How to integrate and implement:

How to evaluate what the measurement is telling you:

What would need to be adjusted if you decided that:

a. There is no progress on the objective?

b. You are not measuring the right thing?

Review & Wrap-Up

What is one thing to do:

- In planning to measure performance?
- To implement performance measurements?
- To check performance measurements?
- To act on results from performance measurements to improve biorisk management?

Why is it important to include the concept of performance in the entire PDCA cycle?

What next steps do you plan to take to focus on biorisk management performance in your facility?

TWO SLIDES