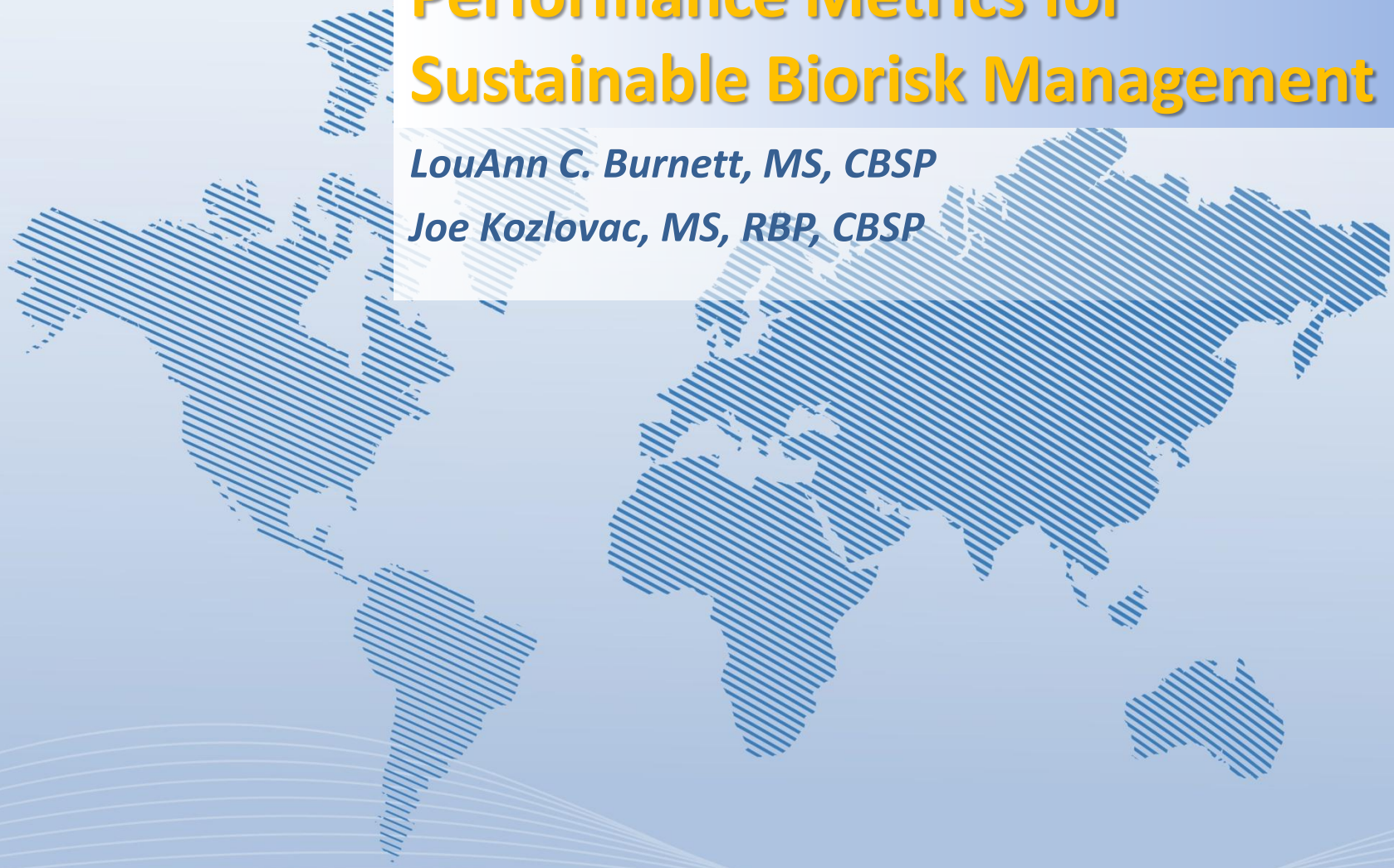
SAND2012-1211 C

SAND2012-1211C

Performance Metrics for Sustainable Biorisk Management

LouAnn C. Burnett, MS, CBSP

Joe Kozlovac, MS, RBP, CBSP



Sandia National Laboratories is a multi-program laboratory managed and operated by Sandia Corporation, a wholly owned subsidiary of Lockheed Martin Corporation, for the U.S. Department of Energy's National Nuclear Security Administration under contract DE-AC04-94AL85000.

Acknowledgements

Introductions

- Instructors
- Students
  - Your name?
  - Where are you from?
  - What is an example of a measurement you use everyday?

Agenda

- Welcome
- Introduction to Performance Measurement and Biorisk Management Systems
- Plan-Do-Check-Act
  - Plan
  - Do
  - Check
  - Act
- Review and Wrap-Up

Action Plan

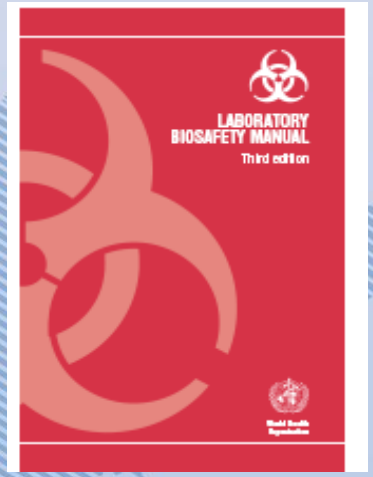
By the end of this lesson, I would like to:					
KNOW		FEEL		BE ABLE TO DO	

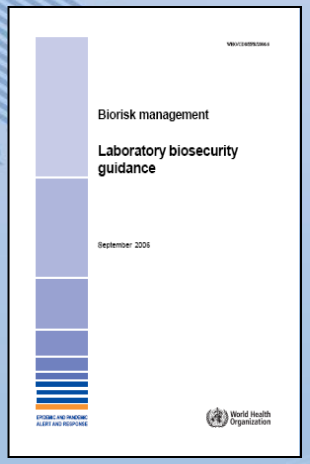
Your learning doesn't stop with this course. Use this space to think about what else you need to do or learn to put the information from this course into practice.

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?

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]





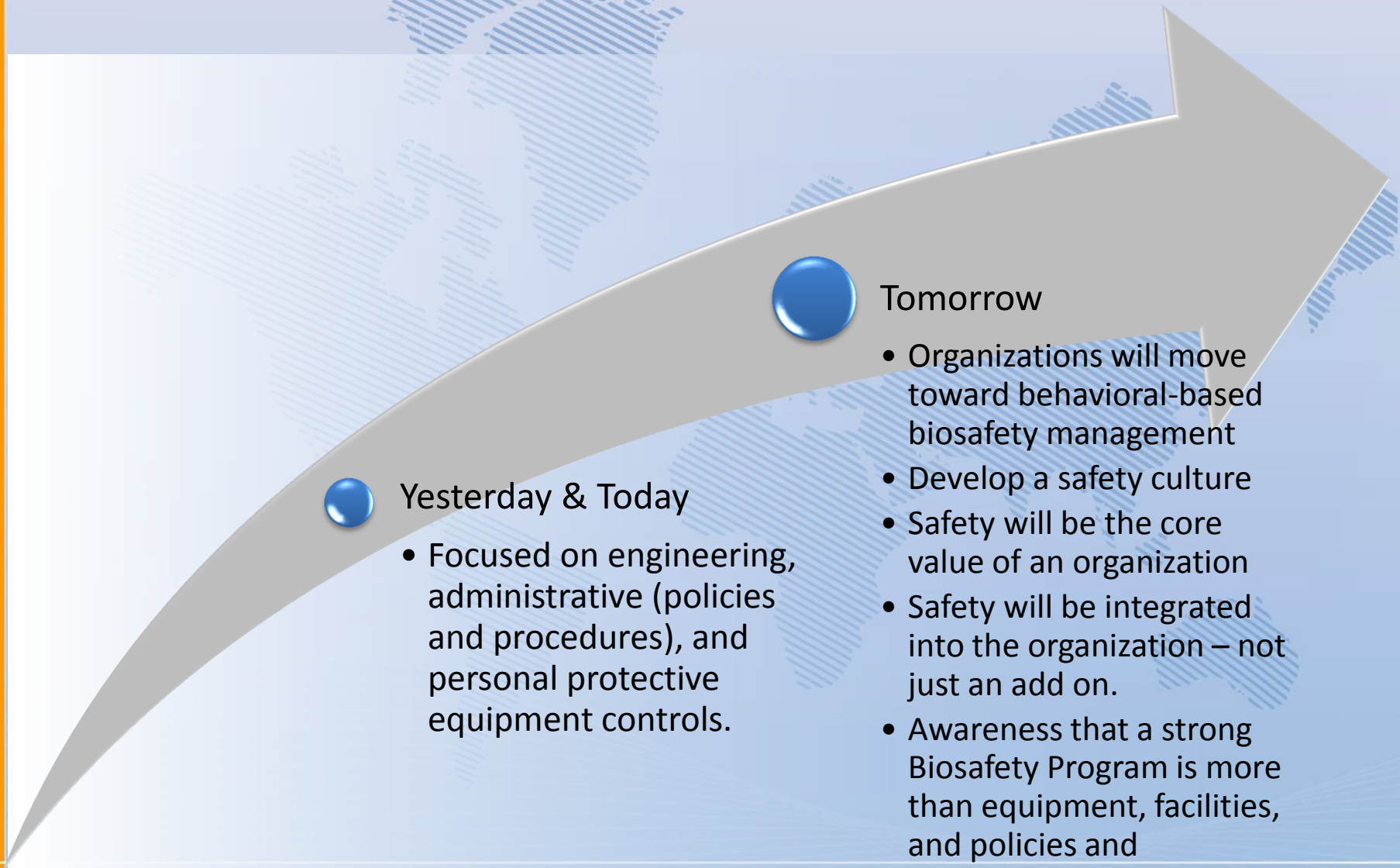
[1]Laboratory biosafety manual, Third edition (World Health Organization, 2004)

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

Biosafety Management Program

A framework comprised of organizational structure, policies, practices, and biosafety guidance instituted and supported by management that provides procedures and accountability for preventing occupationally-acquired infections or release of harmful organisms to the environment.

Biosafety Management (Yesterday, Today, and Tomorrow)



Yesterday & Today

- Focused on engineering, administrative (policies and procedures), and personal protective equipment controls.

Tomorrow

- Organizations will move toward behavioral-based biosafety management
- Develop a safety culture
- Safety will be the core value of an organization
- Safety will be integrated into the organization – not just an add on.
- Awareness that a strong Biosafety Program is more than equipment, facilities, and policies and procedures.

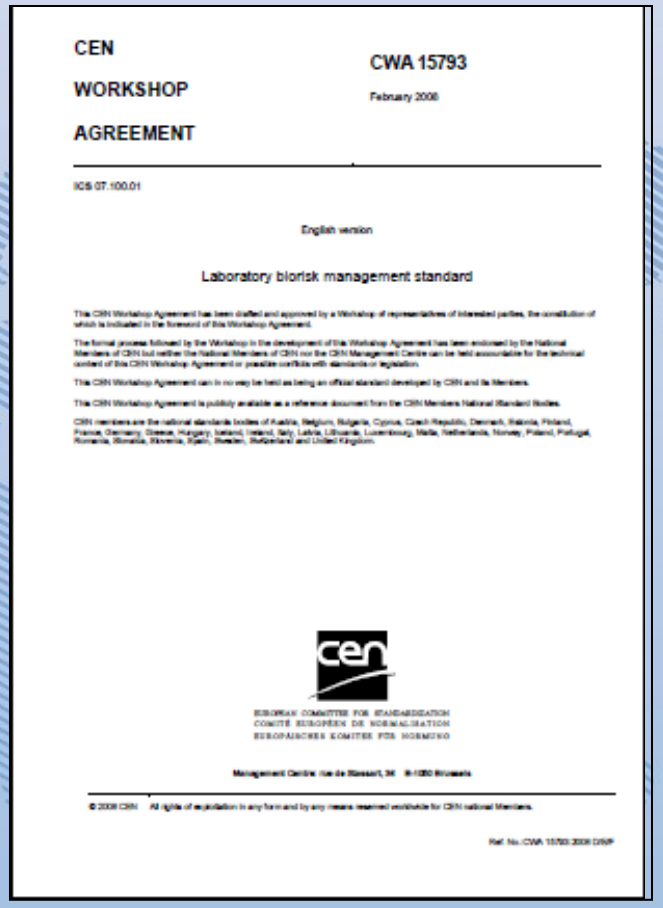
Biosafety Management Program Elements

"Behind every unsafe behavior or unsafe act, there is a reason. A lot of times, that has to do with the management system – the way people are measured and rewarded, the culture of the organization that leads to unsafe behavior to be O.K."

- Dan Petersen (1997)

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

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is included in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its Members.

This CEN Workshop Agreement is publicly available as a reference document from the CEN Members National Standard Bodies.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

cen

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. CWA 15793:2008 D/NP

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

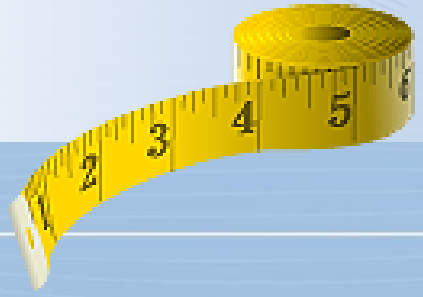
Basic Process

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?**

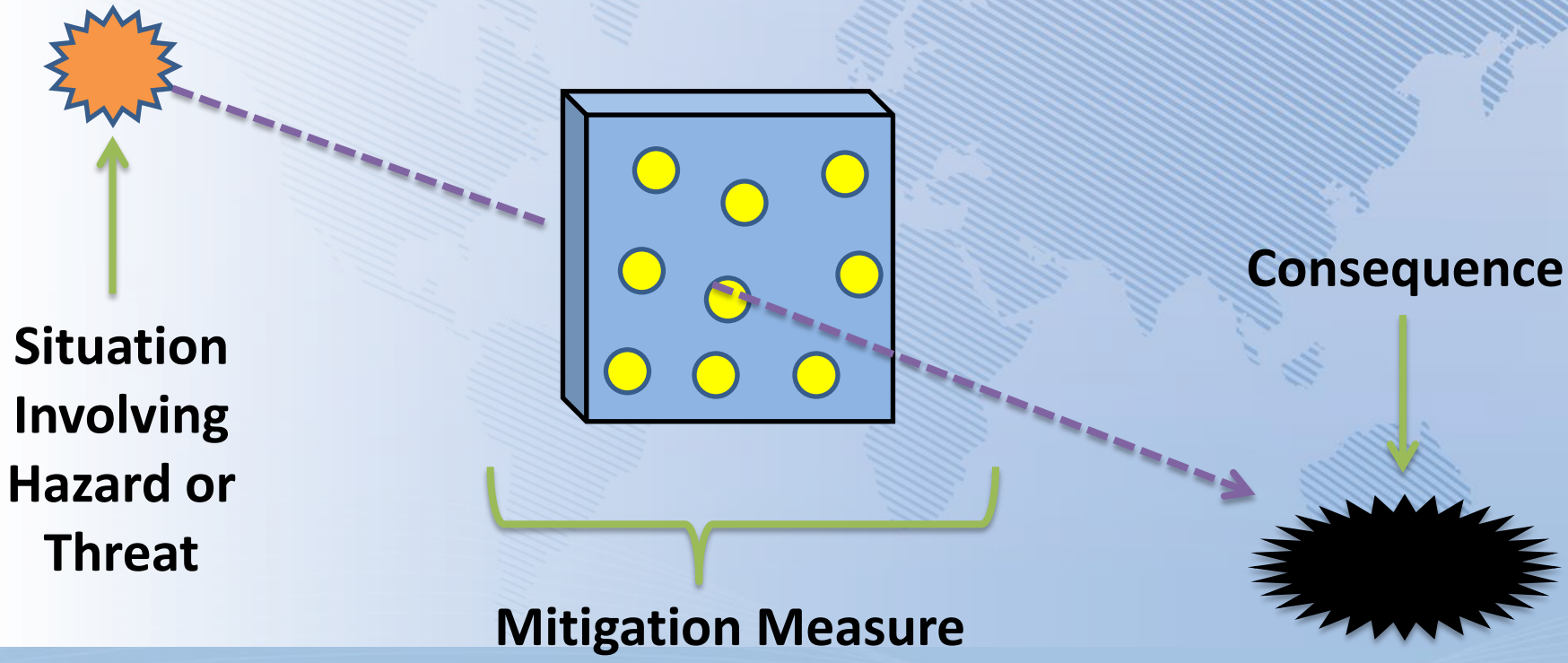
Measuring Performance

- 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

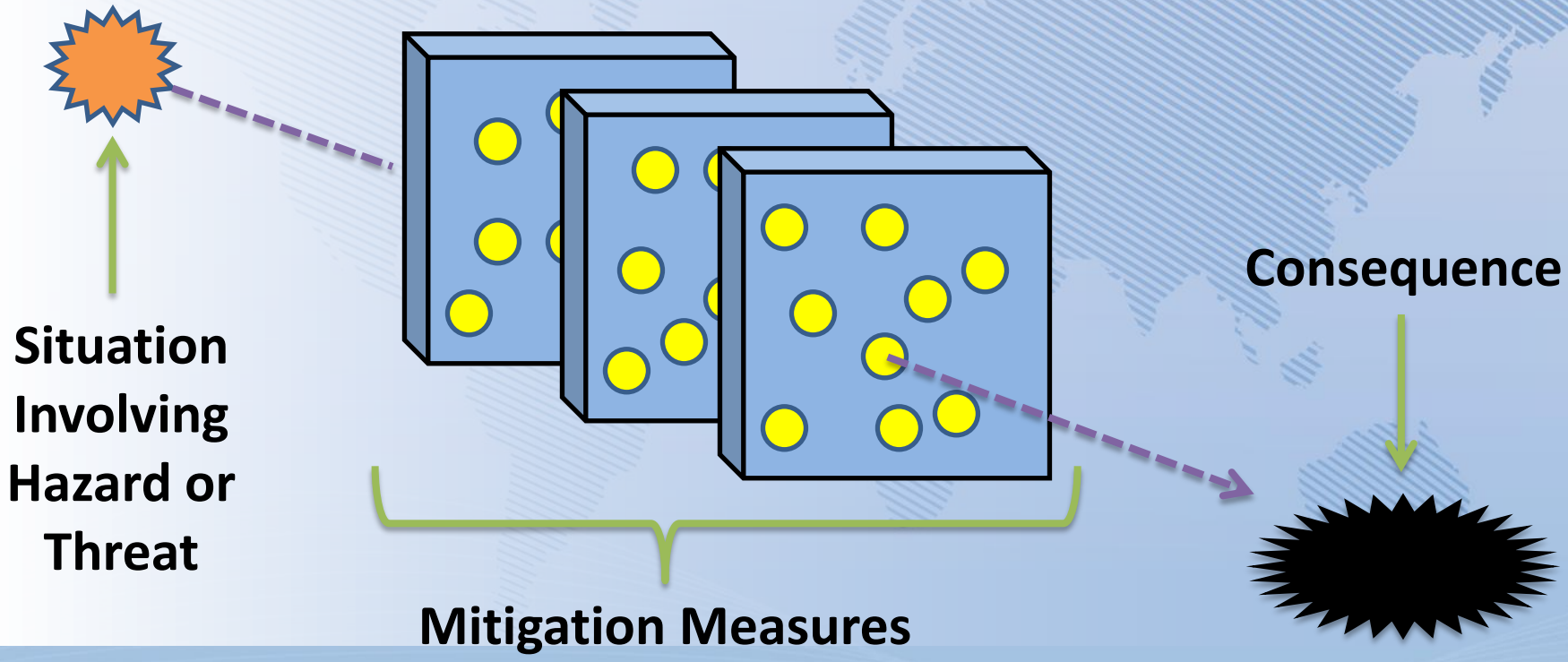
- **Mitigation measure has "holes" or weaknesses that may enable undesired consequences**



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 not eliminate risk**

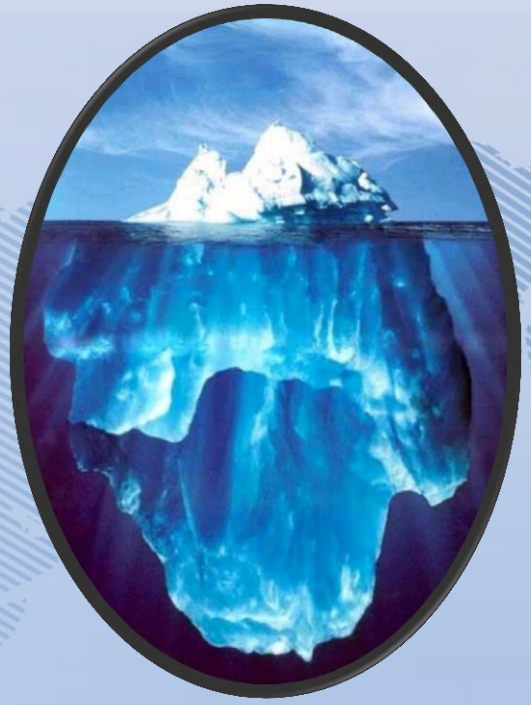


References: Center for Chemical Process Safety, *Process Safety Leading and Lagging Metrics*, Revised January 2011, p. 4, http://www.aiche.org/uploadedFiles/CCPS/Metrics/CCPS_ProcessSafety_Metrics_2011_FINAL.pdf, accessed 31 August 2011; J. Reason, "Human Error: Models and Management," *BMJ* 2000, Vol. 320, pp. 768 – 770.

Incident Pyramid

Direct and Indirect Costs of Incidents

- Direct Costs
  - Regulatory Agency Fines/Penalties
  - Workers Compensation
    - Medical Costs
    - Indemnity Payments
- Indirect Costs
  - Train and pay replacement
  - Repair and downtime
  - Incident investigation
  - Implementing corrective action
  - Legal expenses



OSHA Estimated Cost of Infection

Assumed the baseline values of 1 instance and 3% profit margin.

Estimator can be found at www.osha.gov/dcsp/smallbusiness/safetypays/estimator.html

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?

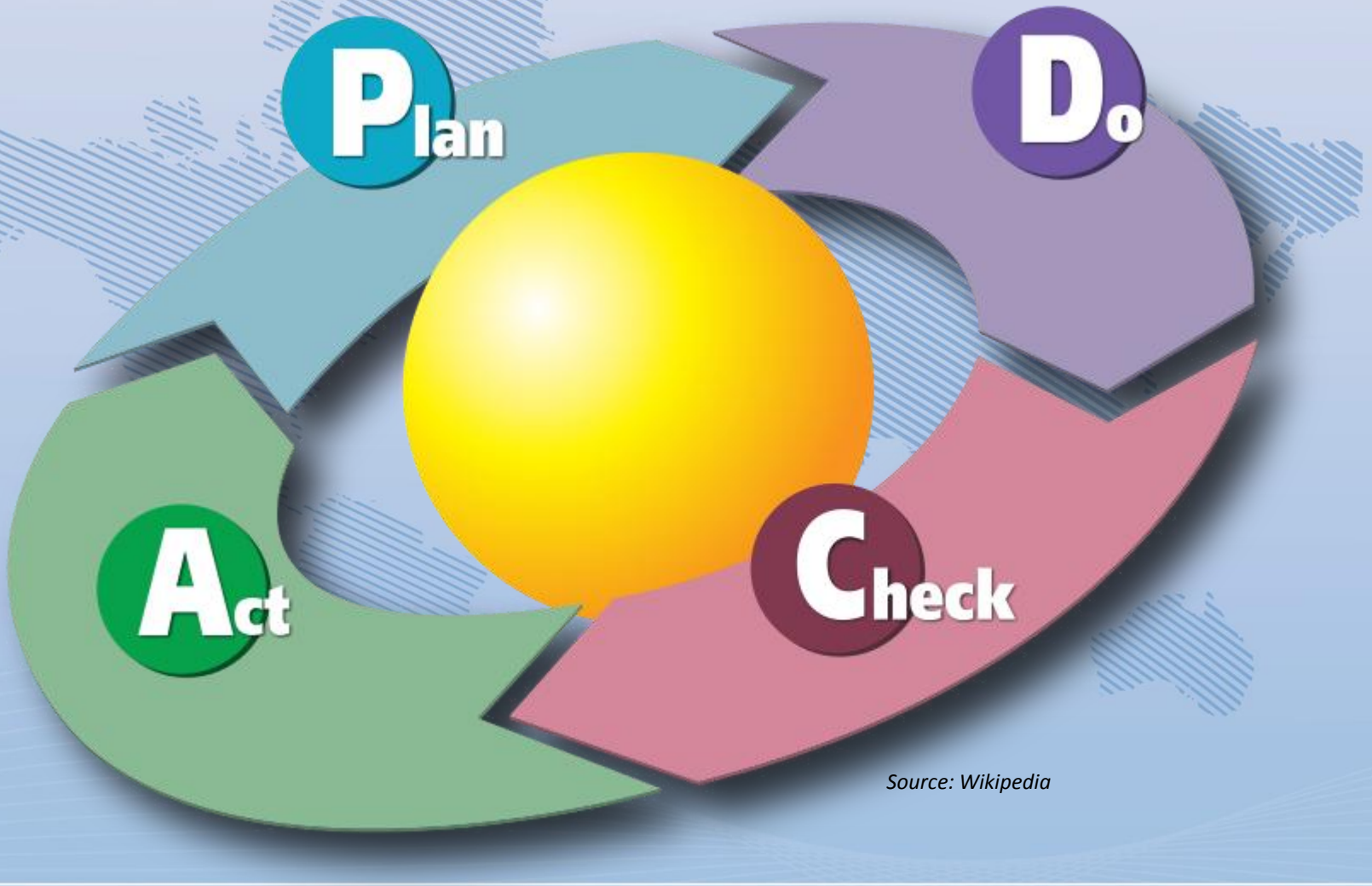
Another View on Performance

"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

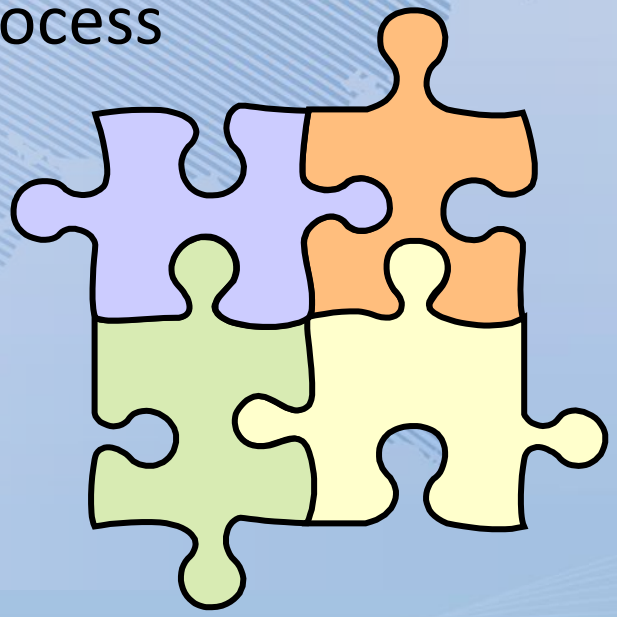
Goal – Continuous Improvement

- **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

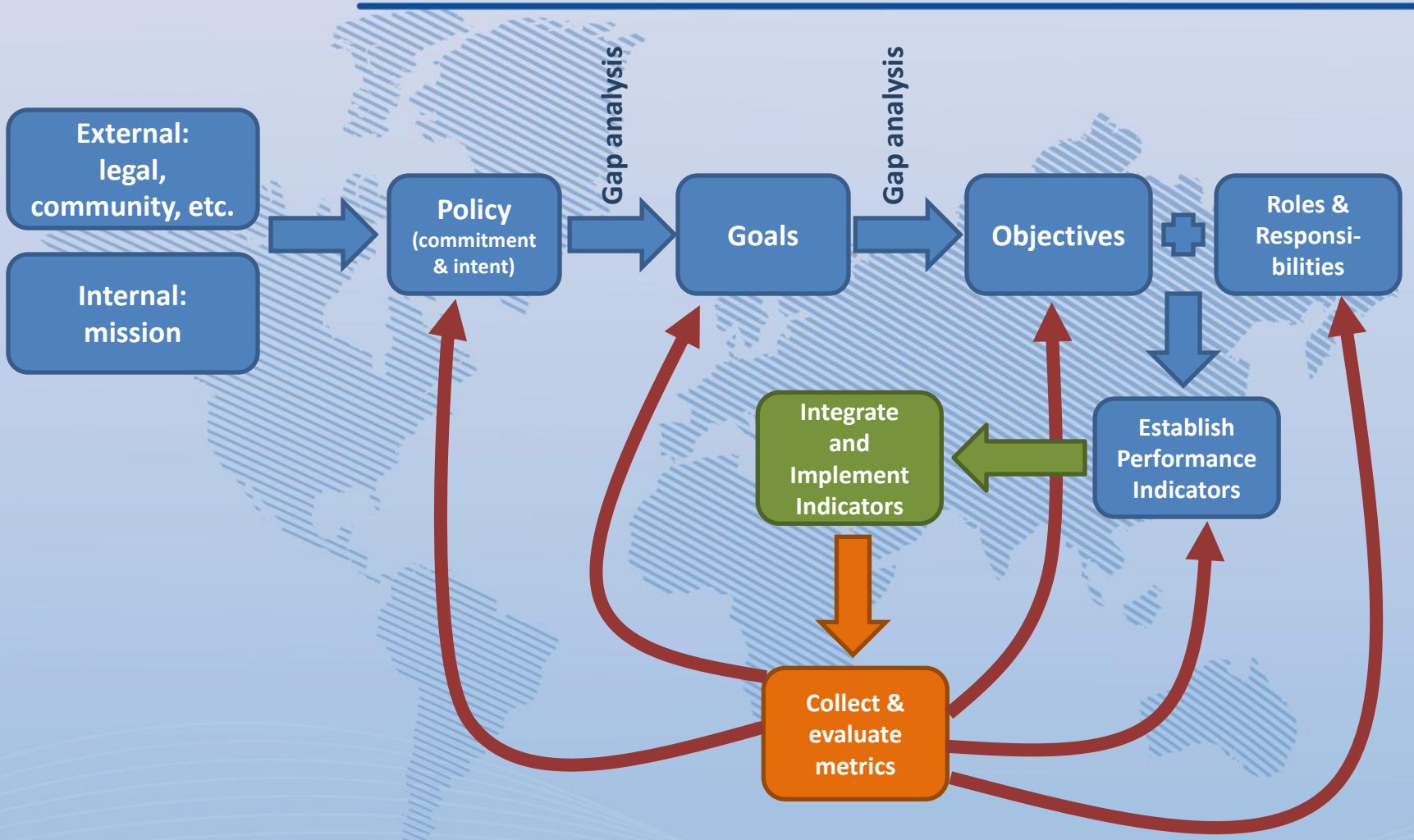
- **This directly leads to another key requirement: 4.6.1 Biorisk management review**
  - *"Top management shall **review** the organization's biorisk management system at planned intervals, **to ensure its continuing suitability, adequacy and effectiveness**. The review shall include **assessing opportunities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

Biosafety Policy Advice

- Start with the end in mind.
- Your written policy is just another means of communicating “The Policy”
- The real policy is management and your attitude toward employee’s safety.
- What management and you do or fail to do, speaks louder than what is written.
- A safety culture is created by what we and other managers demonstrate personally and what we reward and tolerate in others.

In this case –
little brother is watching!

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)

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

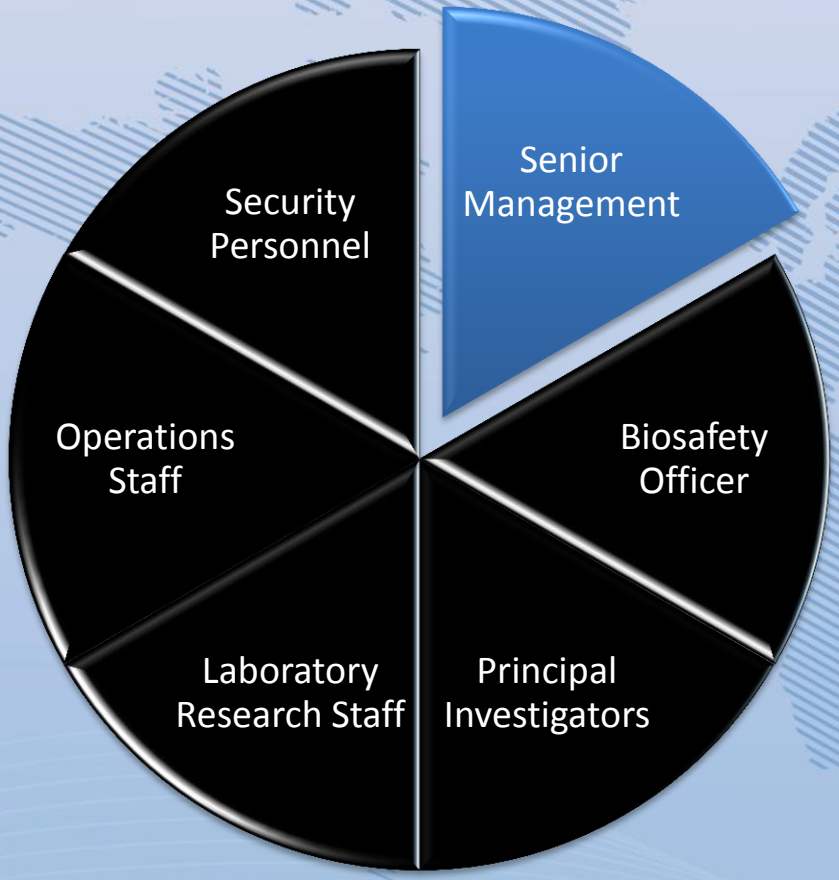
SMART Objectives

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

Exercise: Goals & Objectives

- **Policy**: All travel from the Crowne-Plaza Ravinia to downtown Atlanta (and back) must be conducted in a sustainable manner.
- **Goal**: Travel tomorrow afternoon using MARTA. Be back in time for the reception!
- **Objectives? "**SMART" ways to move towards the goal
- ***Roles & Responsibilities***
- ***Performance Indicators***

Sharing Responsibility for Biosafety



In short –
everyone in the organization is responsible for biosafety!

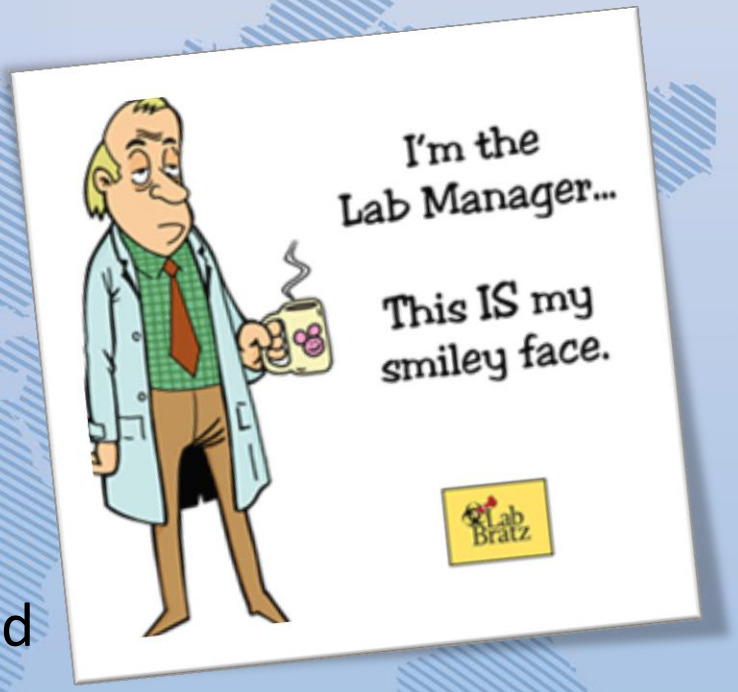
We must develop accountability

Senior Management

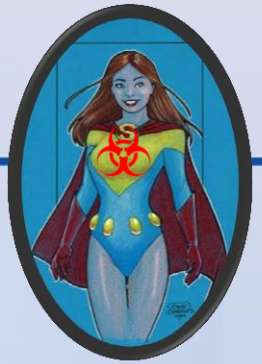
- Assures compliance
- Develops and implements policy
- Provides leadership and resources
- Promotes the development and implementation of biosafety program
- Sets organizational and individual performance goals
- Evaluates performance and effectiveness of biosafety program

Line Management and Principal Investigators

- Protect individuals in laboratory
- Continuously assess laboratory risks
- Select biosafety level for project
- Provide training to employees and visitors
- Ensure staff is proficient in practice and procedures
- Enforcement of safe work practices



Biosafety Officer



- Sets goals
- Develops biosafety policies and procedures
- Guides development of biosafety plans and rules
- Establishes an institutional biosafety training program
- Directs biosafety compliance activities

- Provides technical leadership in risk assessment
- May serve as the Responsible Official (RO) or alternate RO
- Serves as a liaison between all service departments needed to keep a laboratory running (science, animal care, operations, security, safety)

Today's biosafety professional can assist their senior management in three leadership activities: saying the right things about safety and health; measuring the right things; and holding his/her lieutenants accountable.

Employee Responsibilities

- Know hazards of work
- Control hazards
- Attend training
- Develop proficiency
- Know Emergency and Security Procedures
- Integrate safety into work practices
- Report unsafe situations
- Know one person affects all

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)

Biosafety Program Elements Measured

- Laboratory Inspections
- Deficiencies Identified and Resolved
- Facility Testing and Certification
- Protocol Review and Approval/Disapproval
- Training by Biosafety and Leadership Staff
- Accident and Incident Investigations

To maximize the effectiveness these should be linked to the results contributing to organizational goals.

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

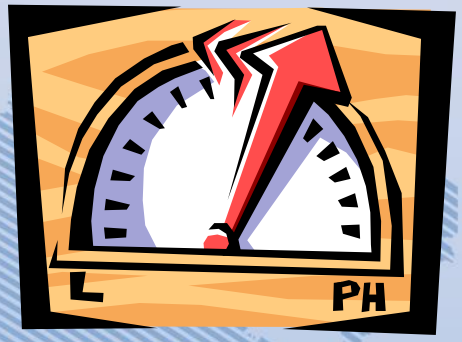
- **Extent to which procedures established in the safety management system are applied by employees**
- **Extent employees have been trained in accordance with the planned training programme**
- **Are there procedures for ensuring that employees use personal protective equipment (PPE) to the extent appropriate?**
- **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.

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



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.

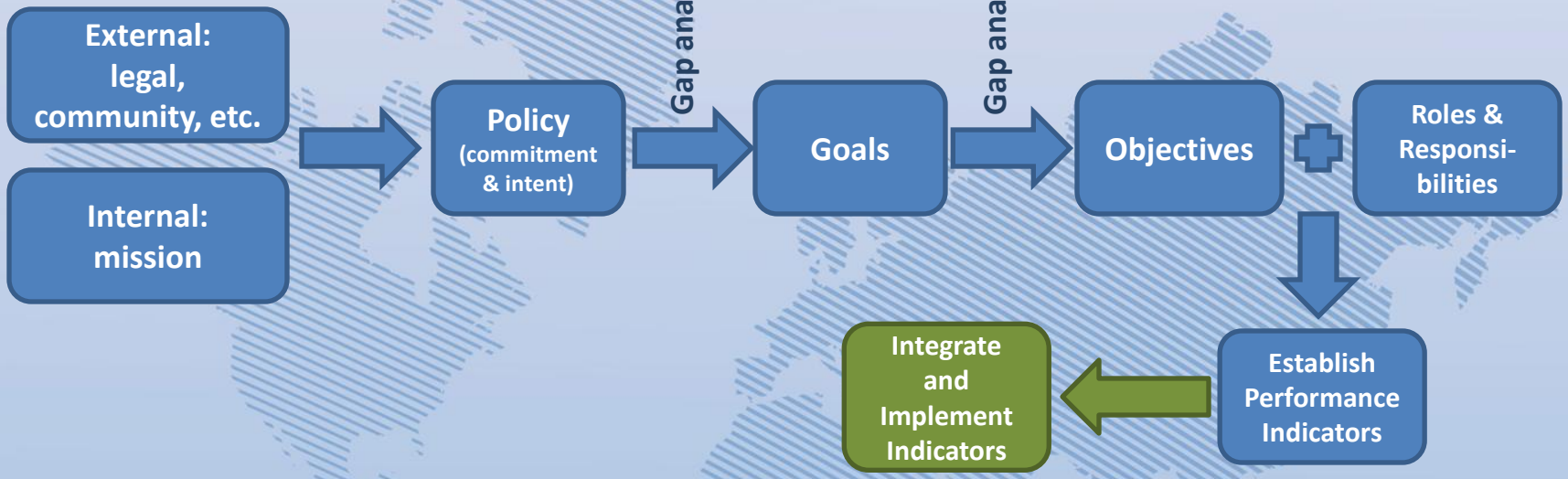
Module Review

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


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

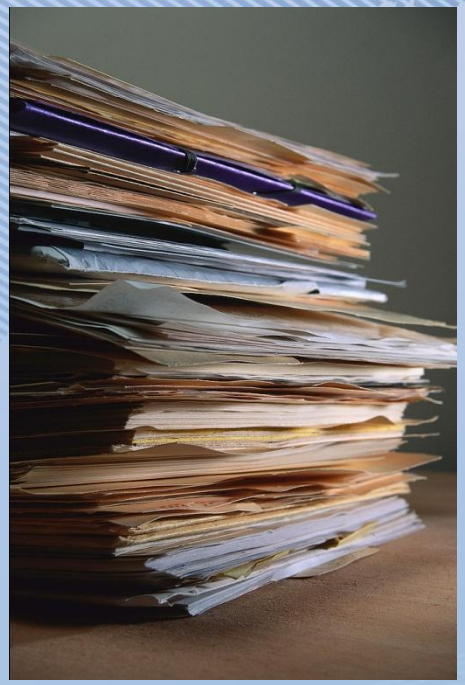
"Records merely take time and paper to create;
results take time and attention. The difference is enormous!"

- John DeLaHunt (2005)

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

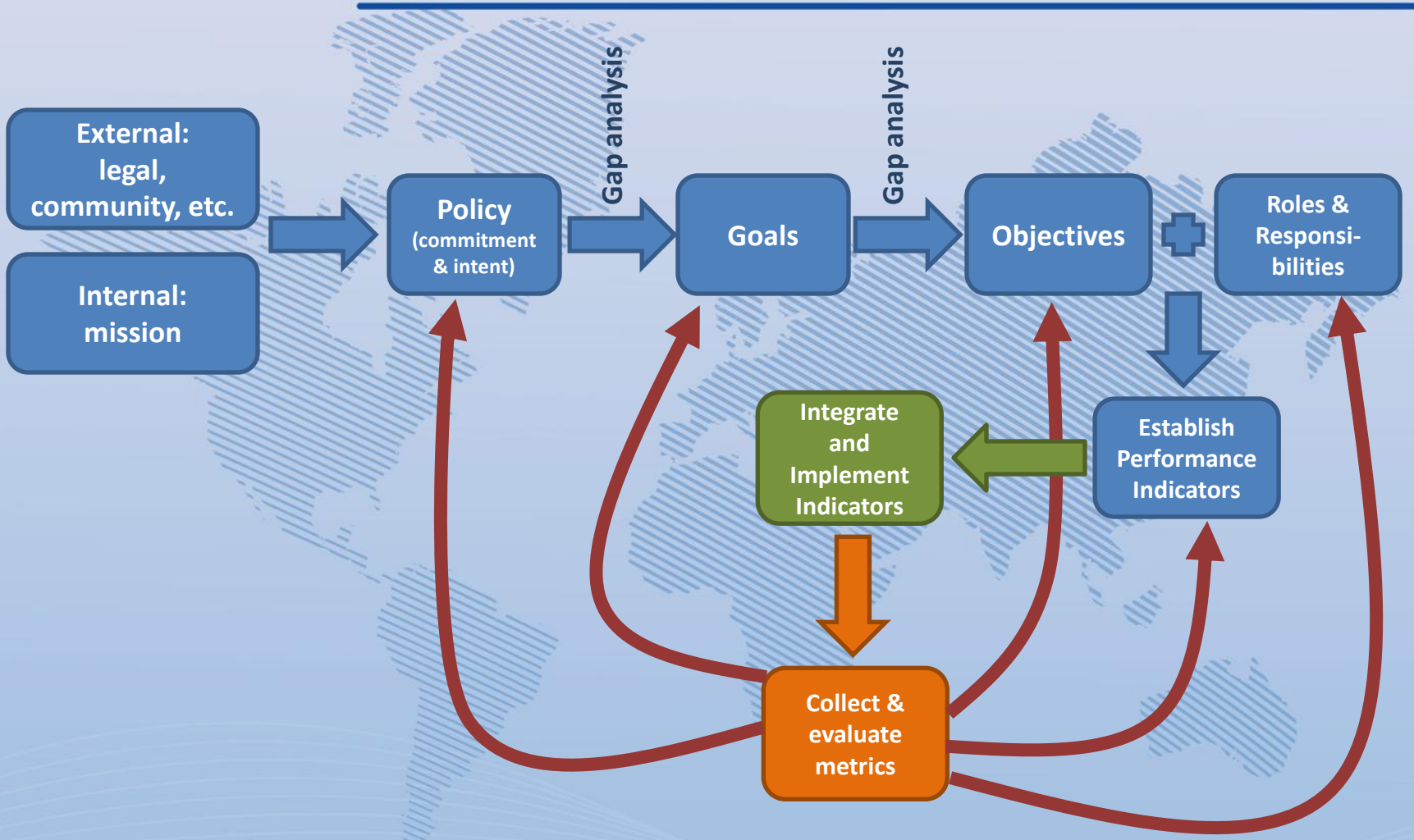


Basic Process

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?**

Plan-Do-Check-Act

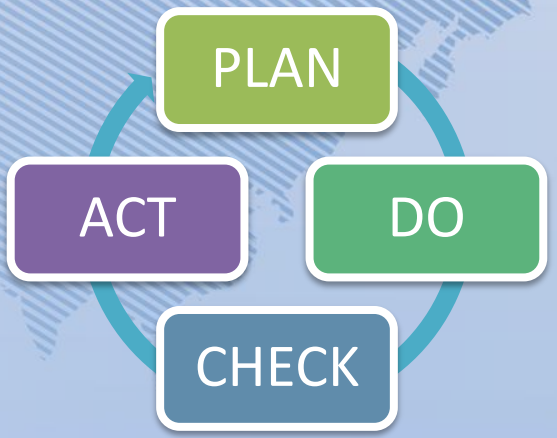


Reviewing Performance Information

- 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?



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!