

Establishing Biorisk Management Goals, Objectives, Roles & Responsibilities



**Sandia
National
Laboratories**

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Introductions

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



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



Biorisk Management: the **AMP** Model

Biorisk Management =
Assessment, Mitigation, Performance

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



Key Components of Biorisk Management

Biorisk Mitigation

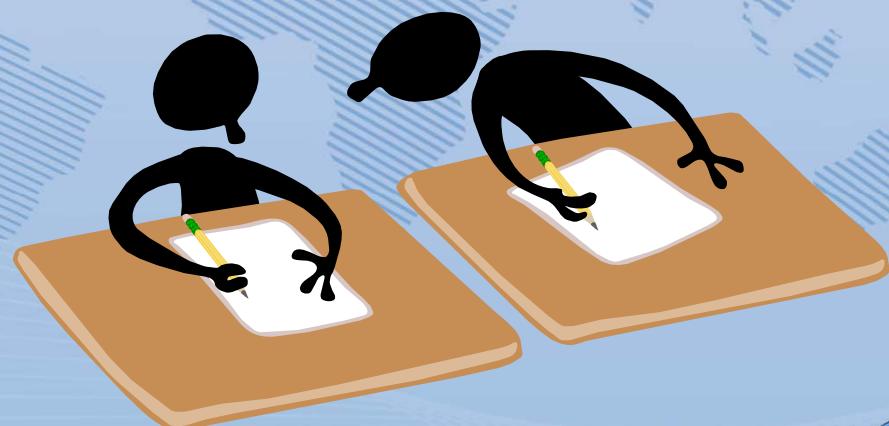
- Actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins



Key Components of Biorisk Management

Performance

- The implementation of the entire biorisk management system, including evaluating and ensuring that the system is working the way it was designed. Another aspect of performance is the process of continually improving the system.



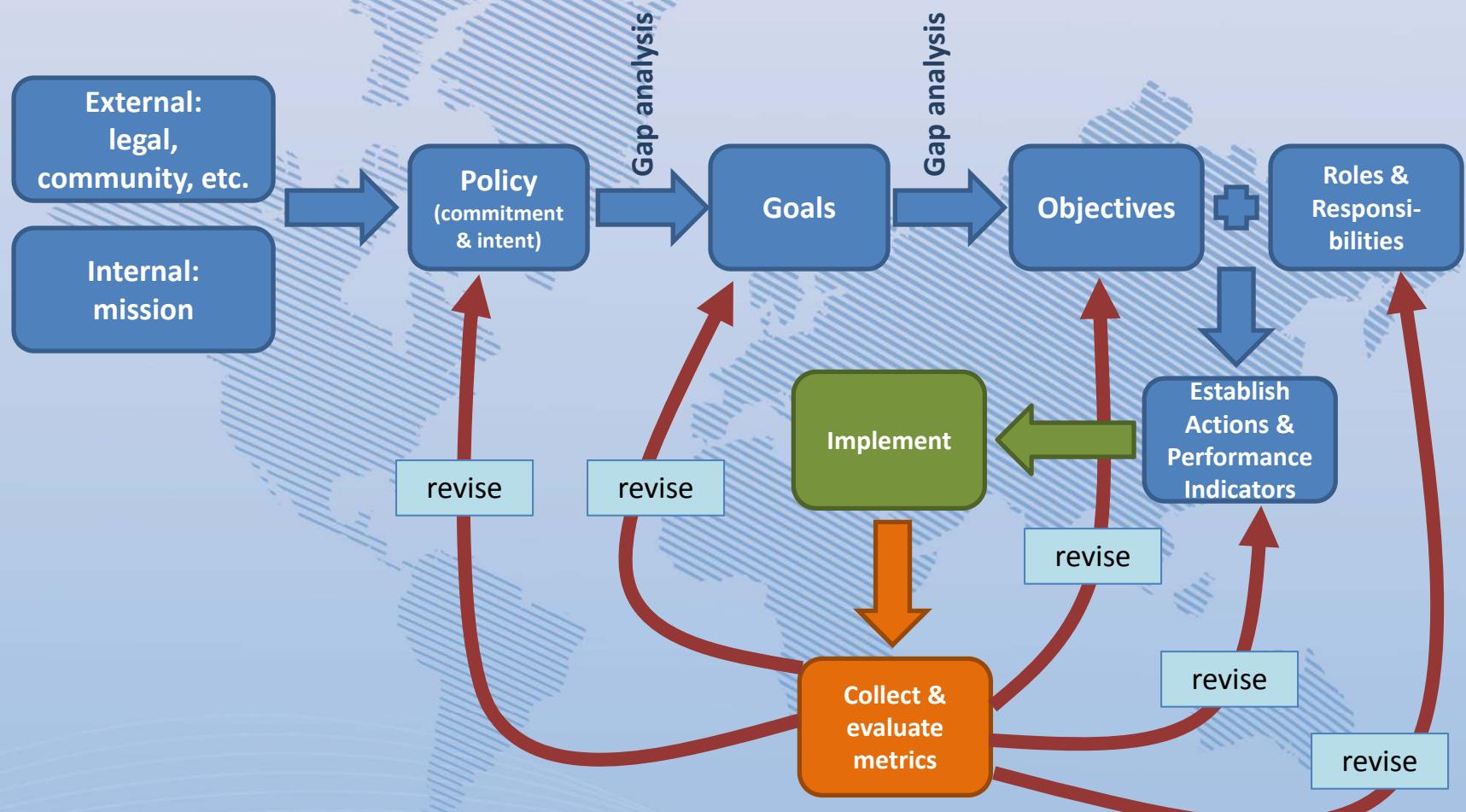
What is the Difference Between. . .

Group Activity:

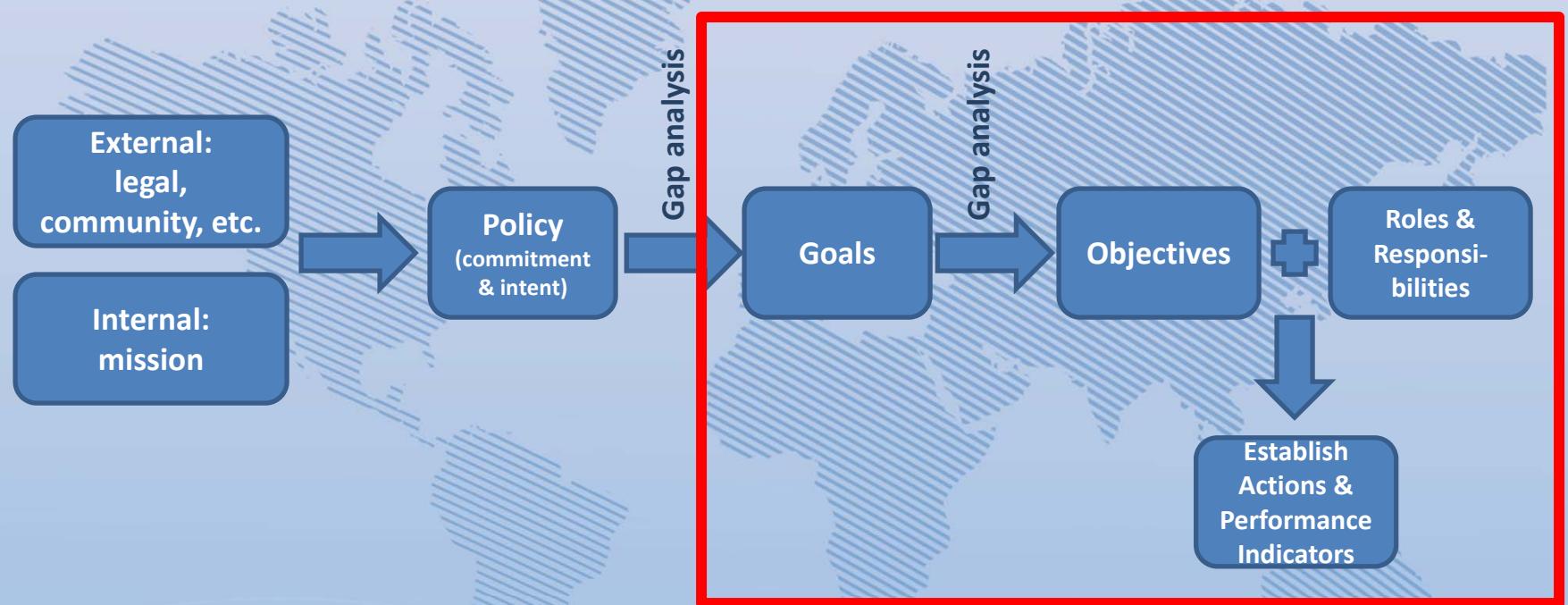
- A **policy**,
- A **goal**, and
- An **objective**?
- Sometimes these words are used interchangeably.

In your groups, please spend **5 minutes** to discuss how they are the **same** and how they **differ**. Write your answers in your **workbook**.

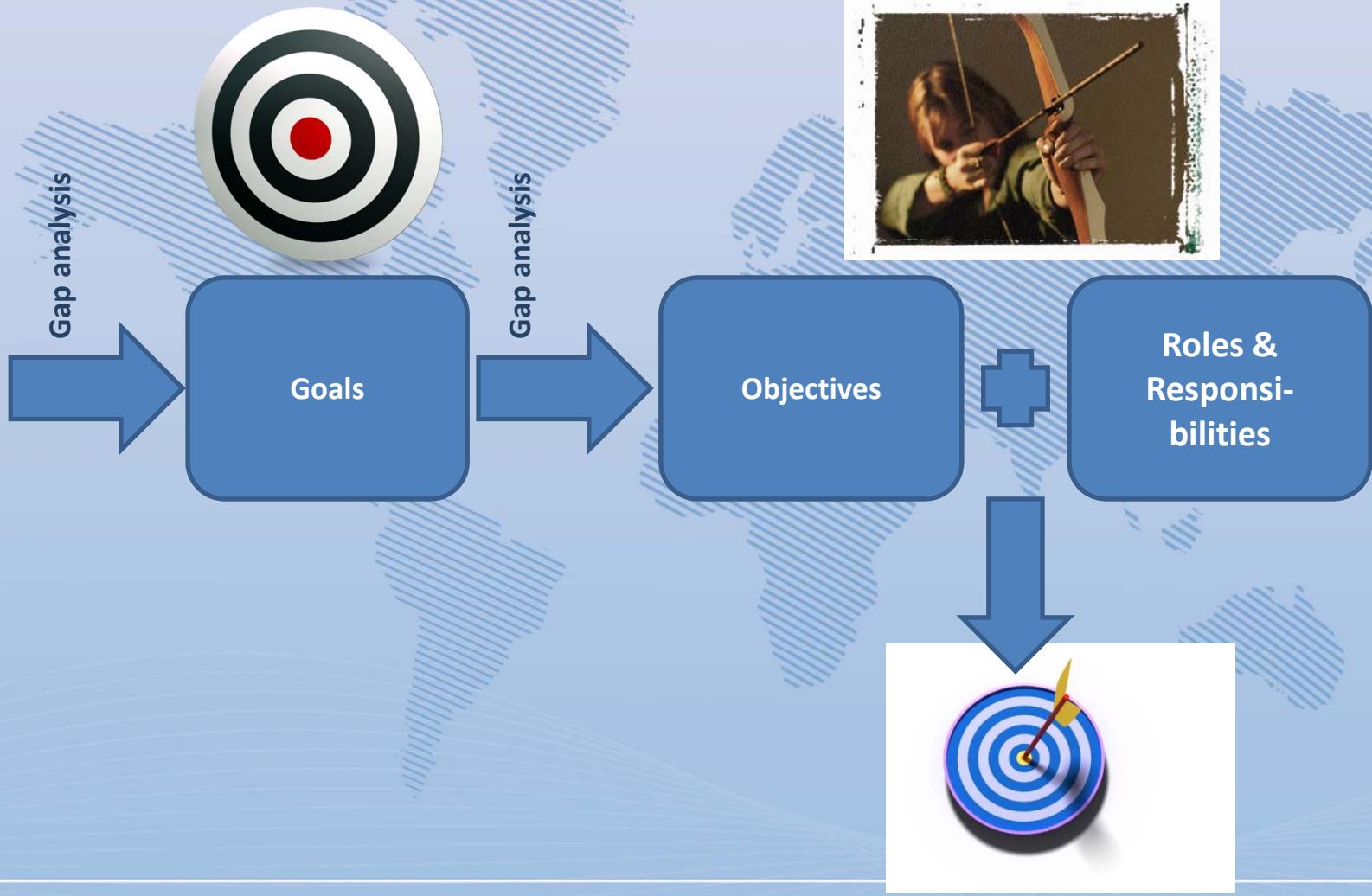
Plan-Do-Check-Act



Plan

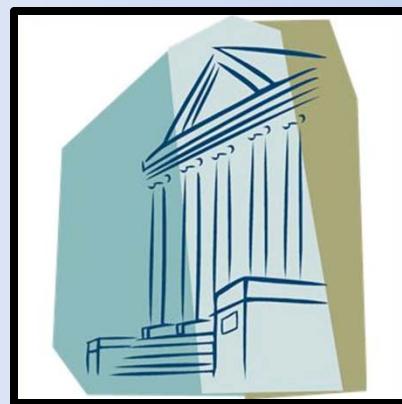


Goals, Objectives, Roles, & Responsibilities



4.3.3.1 Biorisk control objectives and targets

- The organization shall establish, implement and maintain documented biorisk control objectives and targets for an effective control of biorisk at relevant functions and levels in the organization.



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

CWA 15793:2011

A Good Starting Place for GOALS

4.4.4 Operational control

4.4.4.1 General safety

4.4.4.2 Biological agents and toxin inventory and information

4.4.4.3 Work programme, planning and capacity

4.4.4.4 Change management

4.4.4.5 Work practices, decontamination and personnel protection

4.4.4.5.1 Good microbiological technique

4.4.4.5.2 Inactivation of biological agents and toxins

4.4.4.5.3 Waste Management

4.4.4.5.4 Clothing and Personal Protective Equipment (PPE)

4.4.4.6 Worker health programme

4.4.4.6.1 Vaccination of personnel

4.4.4.7 Behavioral factors and control of workers

4.4.4.7.1 Personnel reliability

4.4.4.7.2 Contractors, visitors and suppliers

4.4.4.7.3 Exclusion

4.4.4.8 Infrastructure and operational management

4.4.4.8.1 Planning, design and verification

4.4.4.8.2 Commissioning and decommissioning

4.4.4.8.3 Maintenance, control, calibration, certification and validation

4.4.4.8.4 Physical security

4.4.4.8.5 Information security

4.4.4.8.6 Control of supplies

4.4.4.9 Transport of biological agents and toxins

4.4.4.10 Personal security

4.4.4.5.3 Waste Management

- The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins.
 - *Why does a waste management policy need to be established?*
 - *What is “appropriate waste management”?*
 - *What are the steps to assuring appropriate waste management?*

CWA 16393:2012 - Guidance

To ensure that waste is properly managed and disposed of in a safe, efficient and cost effective manner and to ensure any biological waste which may have additional hazards (e.g. radioactivity) is investigated, considered, and addressed.

- **Identify:**

- roles and responsibilities;
- nature of the waste (e.g. liquid or solid waste);
- the appropriate decontamination processes; and
- local and environmental waste management policies.



SMART Objectives

- Specific
- Measurable
- Attainable
- Reasonable
- Time-based



Exercise: Goals & Objectives

- **Policy:** Biological agents and toxins are disposed and/or destroyed appropriately
- **Goal:** Establish a waste management policy to assure that biological agents and toxins are appropriately disposed and/or destroyed.
- **Objectives?** “SMART” ways to move towards the goal

Exercise: Goals & Objectives

“SMART” objectives to move towards the goal

- Step 1. **Ask questions to gather information.** For example:
 - Find out how biological agents and toxins can be disposed or destroyed.
 - Find out how to determine what methods are “appropriate”
- Step 2. **Shape these questions into SMART tasks.** For example:
 - “In Month 1, survey laboratories to determine what types of biological agents may be contained in waste materials.”
 - “In Month 2, using the results of the survey, create a list of the types of waste and the biological agents and toxins likely contained in each type of material.”

Roles & Responsibilities (R&R)

- You have your target (**goal**).
- You have your arrows (**objectives**).
- Now, you need an archer to direct the arrow towards the target. (**Role**)
- And instructions on how to direct the arrow (**Responsibilities**)



Why are R&R Important?

Activity:

What are the **consequences** of **NOT** establishing **roles & responsibilities**?

In your group, take **5 minutes** to list 3 to 5 consequences of NOT establishing roles & responsibilities. Write these in your workbook.

What are Challenges in Establishing R&R?

Discussion:

- What kinds of **obstacles** might keep you from establishing roles & responsibilities?
- What **steps** can you take to **overcome** these challenges?

What Roles Impact Biorisk Management?

Question: What roles impact or influence biorisk management?

As a group, take **5 minutes** to brainstorm all the roles within a facility that can impact or influence biorisk management. Write each role on a separate sticky note.

Take another **5 minutes** to brainstorm all the roles outside of a facility that can impact or influence biorisk management. Write each role on a separate sticky note.

What Roles Impact Waste Mgmt?

Question: Which of these roles impact or influence waste management?

As a group, look at your answers for the roles that impact biorisk management. Determine which of these roles impact or influence **waste management in a bioscience facility**.

Determining Responsibility

- Before writing specific responsibilities, it can be helpful to determine the **basic level of responsibility**.
- One model for levels of responsibility:
 - **Decision**
 - **Involved**
 - **Consulted**
 - **Informed**
 - **Not Informed**



Determining Responsibility

- **Decision** – The ultimate decision-maker who is accountable for the objective. Only 1 per objective.
- **Involved** – Actively contributes to and shapes the actions to accomplish the objective.
- **Consulted** – Possesses and contributes key information while the actions for accomplishing the objectives are being determined
- **Informed** – Must be aware of and, possibly perform, an action, but who is not involved in shaping the action.
- **Not Informed** – No role in the action or objective.

One Tool for Determining Responsibilities

<i>Objective</i>	Top Mgmt	Lab Mgmt	Biosafety Professional	Worker
In Month 1, survey laboratories to determine what types of biological agents may be contained in waste materials.”				
In Month 2, using the results of the survey, create a list of the types of waste and the biological agents and toxins likely contained in each type of material.”				
Objective 3. . .				
Objective 4. . .				

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



Actions

- **Actions** are specific responsibilities for each role to accomplish an objective.
- Actions must be **SMART**.

By [this time], [this role] must do [this action] using [these steps] and reporting it [this way] to [this role].

Create an Action

Activity:

Objective: In Month 1, survey laboratories to determine what types of biological agents may be contained in waste materials.

- Look at the Responsibility Level chart you just completed.
- Write one SMART action for one role related to the objective above.



Step 1. Small Group Activity

Group Activity Step 1:

In your groups, please spend **5 minutes** to choose one topic from CWA 15793:2011 4.4.4. (slide#11) and **write a goal** for that topic. Write the topic and goal on your group's **flipchart**.

Step 2. Small Group Activity

Group Activity Step 2:

In your groups, please spend **15 minutes** to write 3 to 5 **SMART objectives** for that goal . Write them on your group's **flipchart**.

Step 3. Small Group Activity

Group Activity Step 3:

In your groups, please spend **10 minutes** to list the **roles** that influence or impact each objective. Write them on your group's **flipchart**.

Step 4. Small Group Activity

Group Activity Step 4:

In your groups, please spend **10 minutes** to **assign a responsibility** level to each role . Write your answers on your group's **flipchart**.

Tool for Determining Responsibilities

Goal:

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



Step 5. Small Group Activity

Group Activity Step 5:

In your groups, please spend **10 minutes** to write a specific, SMART responsibility (**action**) for one objective for each role with an assigned responsibility level. Write your answers on your group's **flipchart**.

Tool for Determining Responsibilities

Goal:

Objective:

Role:

SMART Action to be taken by that role



Prioritizing Goals & Objectives

Discussion:

Not all **goals** & **objectives** can be pursued at the same time.

- What are some **reasons** that would keep a goal from being addressed?
- What are some of the **factors** that influence the priority by which goals are addressed?

Priority Assessment

Assessing the consequences of NOT addressing a goal and the likelihood that those consequences would occur is a type of **risk assessment**.

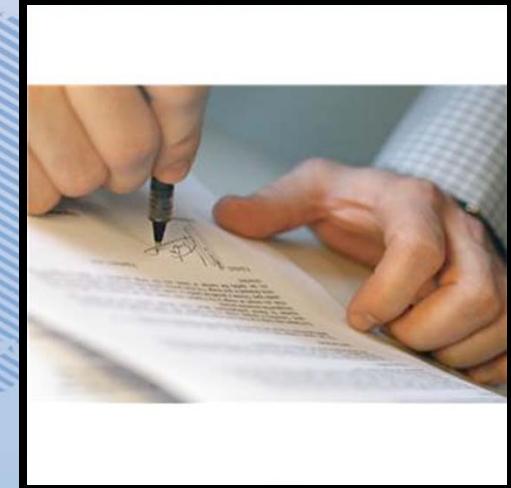
A biosafety or biosecurity risk assessment feeds into this type of priority assessment.

For example, if a biosafety risk assessment reveals that a pathogen is likely to be spread via untreated waste, then the goal of establishing a waste management policy and program may receive high priority.



Priority Assessment, continued

- It may be acceptable to **DO NOTHING**, if the biorisk and priority assessments show that taking NO action would **not raise the risk**.
- The **biorisk management system** approach requires that this decision-making process be **documented**.



Communication

Group Activity:

What happens if **goals, objectives, roles, and responsibilities** are not **communicated**?

In your group, take **5 minutes** to list **3 to 5 actions** for effectively communicating goals, objectives, roles, and responsibilities. **Discuss** steps to take to be sure that these have been communicated.

Review and Revision

Discussion:

Goals & objectives will change over time.

- What are some **reasons** that they will change?
- How do you know when it is time to **review** and, possibly, **revise** goals & objectives?
- What **steps** should you take to review and revise goals, objectives, roles, and responsibilities?



Review & Wrap-Up

Review

To wrap-up, let's discuss what we learned about
**Establishing Goals, Objectives, Roles, and
Responsibilities.**

What did we
learn?

What does it
mean?

Where do we
go from here?



Action Plan

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Thank You!

Don't forget to complete your evaluation!





Break

