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Administrative Controls for Biorisk Mitigation

Student Guide

2016

GLOBAL BIORISK MANAGEMENT CURRICULUM


Administrative Controls for
Biorisk Mitigation
2016
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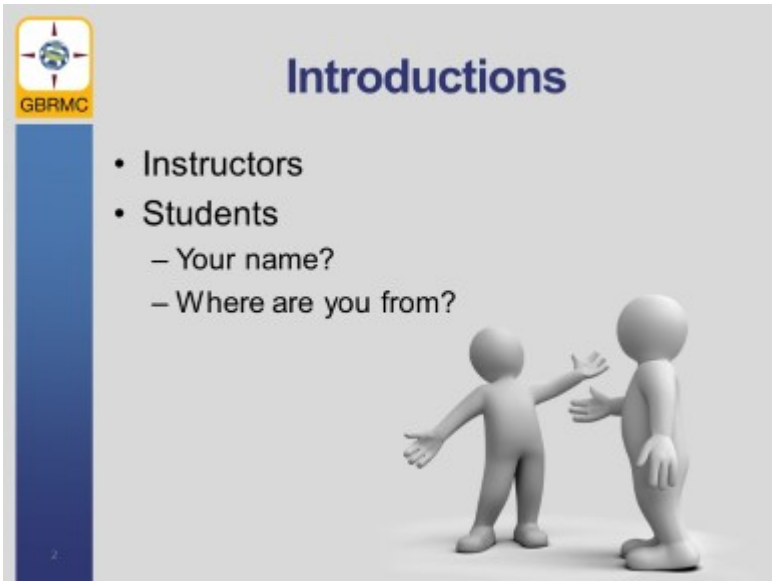
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Introductions
• Instructors
• Students
– Your name?
– Where are you from?

Action Plan

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

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?

3

Use space on back, if needed

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Key Messages

- Administrative controls are one of five categories of biorisk mitigation, and include policies, standards and guidelines used to control risks.
- Administrative controls complement the other biorisk mitigation categories in reducing the likelihood and consequences of biorisks.
- Administrative controls may be either external or internal to an organization.
- Administrative controls are essential for defining, planning, and implementing many functional areas of an organization's biorisk management system.
- CWA 15793:2011 establishes a number of requirements related to administrative controls and is a useful resource for organizations seeking to establish, improve, or review administrative controls.

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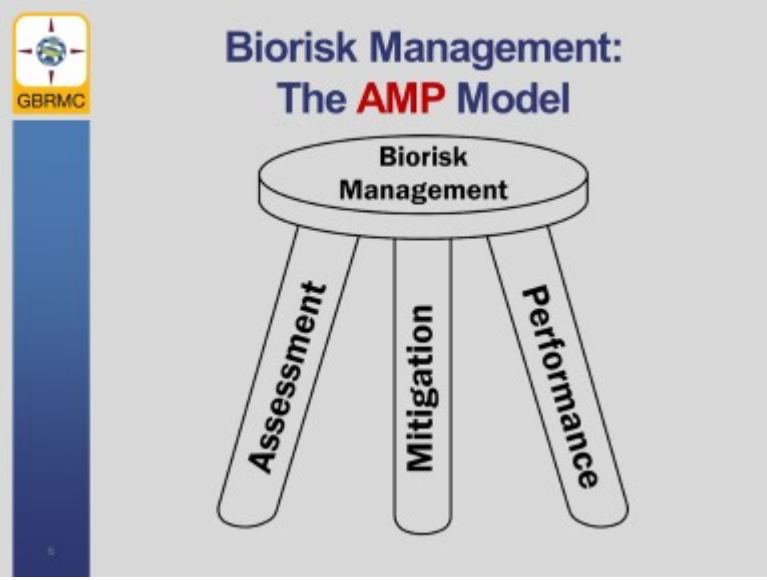
Laboratory Biorisk Management

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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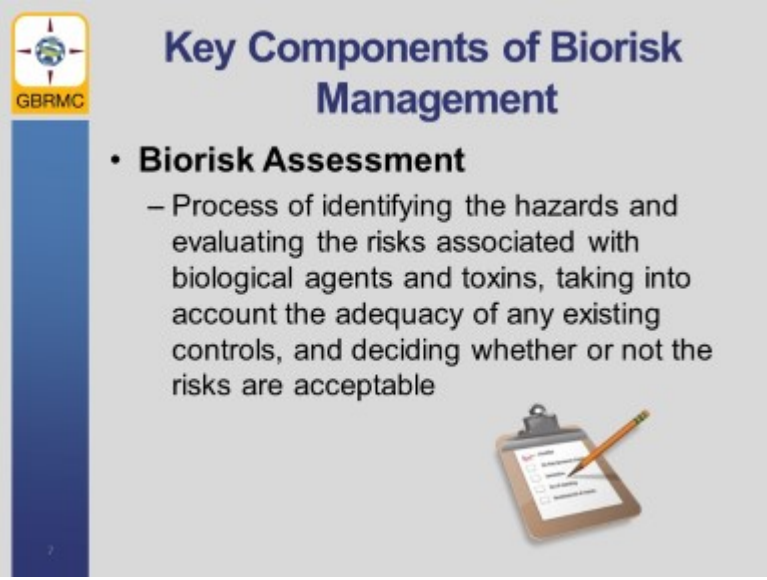
Biorisk Management: The AMP Model
Biorisk Management
Assessment
Mitigation
Performance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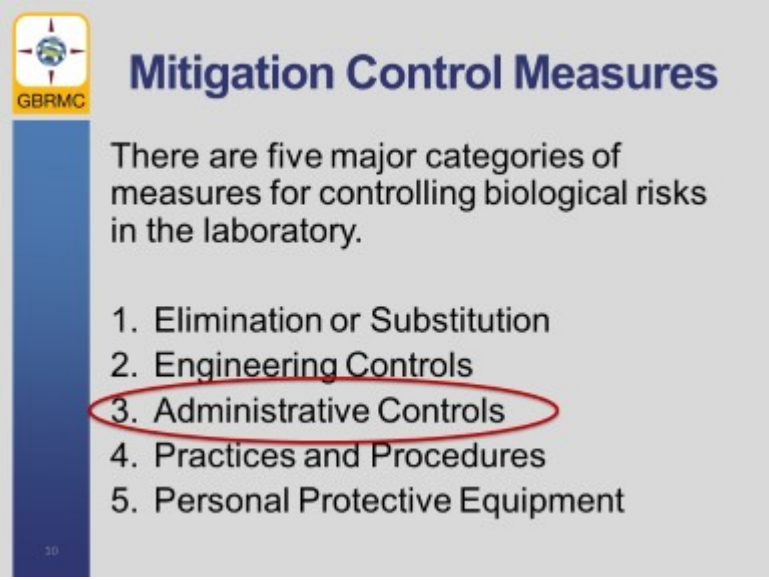
Key Components of Biorisk Management
• Biorisk Assessment
– Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable

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

- Biorisk **Performance**
  - Improving biorisk management by recording, measuring, and evaluating organizational actions and outcomes to reduce biorisk.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Mitigation Control Measures
There are five major categories of measures for controlling biological risks in the laboratory.
1. Elimination or Substitution
2. Engineering Controls
3. Administrative Controls
4. Practices and Procedures
5. Personal Protective Equipment


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Mitigation Control Measures
Administrative Controls: Policies, standards and guidelines used to control risks

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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]

1Laboratory biosafety manual, Third edition (World Health Organization, 2004)
2 Biorisk management - Laboratory biosecurity guidance (World Health Organization, 2006)

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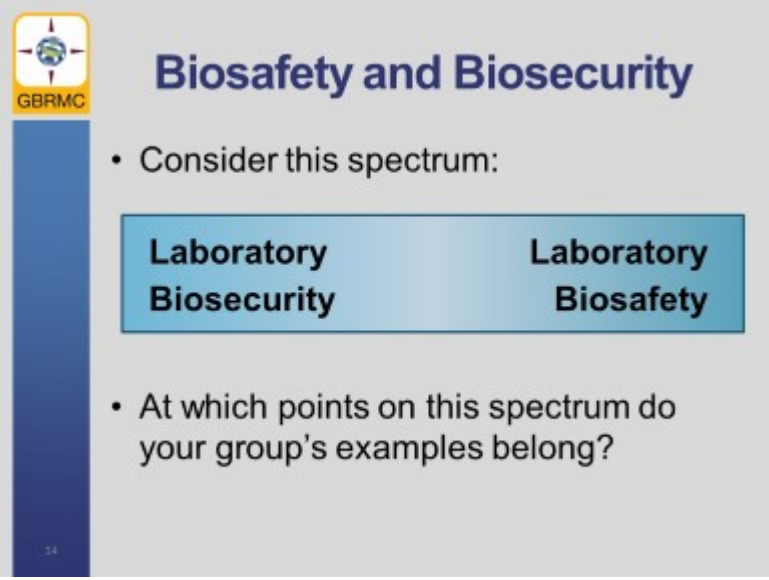
Administrative Controls for Biorisk Management

Small Group Activity – Step 1:

In your groups, please spend **10 minutes** to think about laboratories you have worked in, or worked with.

Identify **five or more examples** of administrative controls.

- Write each example on a separate sticky note.
- Be prepared to present your answers to the class.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Biosafety and Biosecurity
• Consider this spectrum:
Laboratory Biosecurity
Laboratory Biosafety
• At which points on this spectrum do your group's examples belong?
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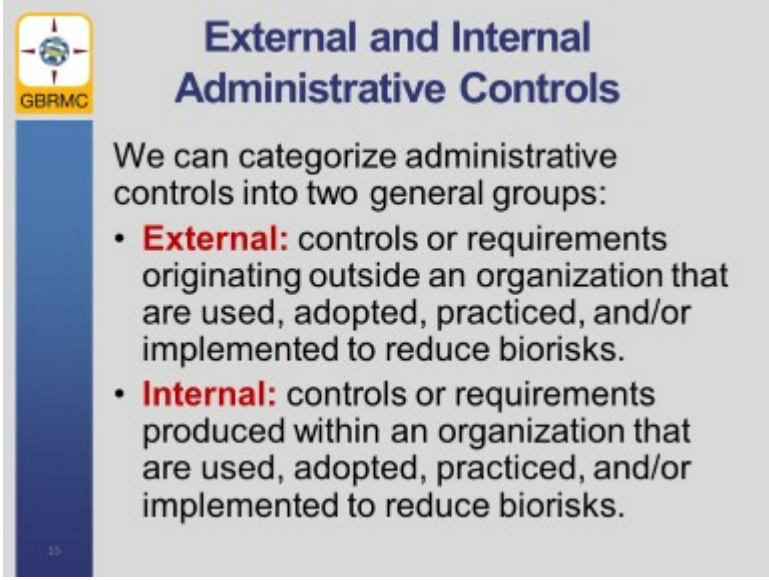
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External and Internal Administrative Controls
We can categorize administrative controls into two general groups:
• External: controls or requirements originating outside an organization that are used, adopted, practiced, and/or implemented to reduce biorisks.
• Internal: controls or requirements produced within an organization that are used, adopted, practiced, and/or implemented to reduce biorisks.
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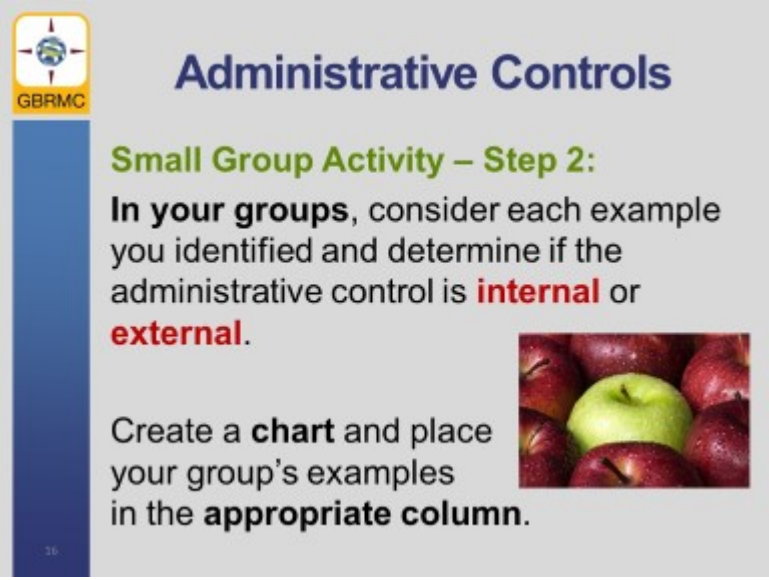
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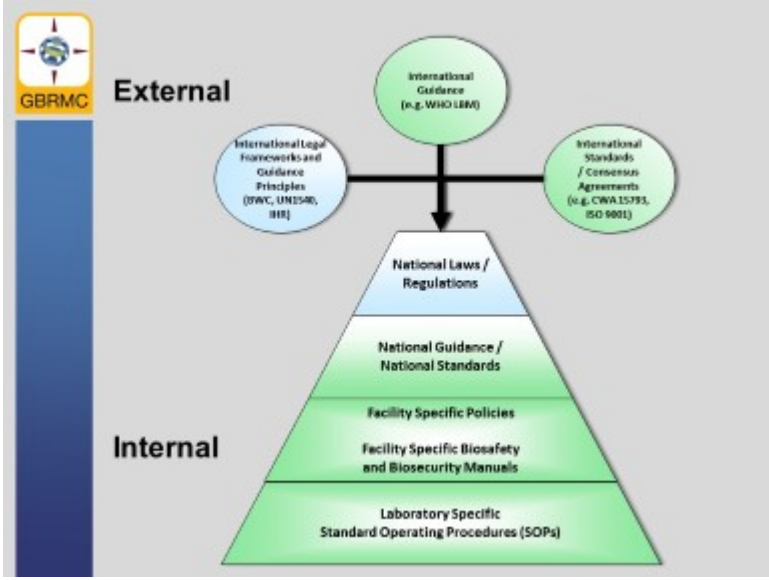
Administrative Controls
Small Group Activity – Step 2:
In your groups, consider each example you identified and determine if the administrative control is internal or external.
Create a chart and place your group's examples in the appropriate column.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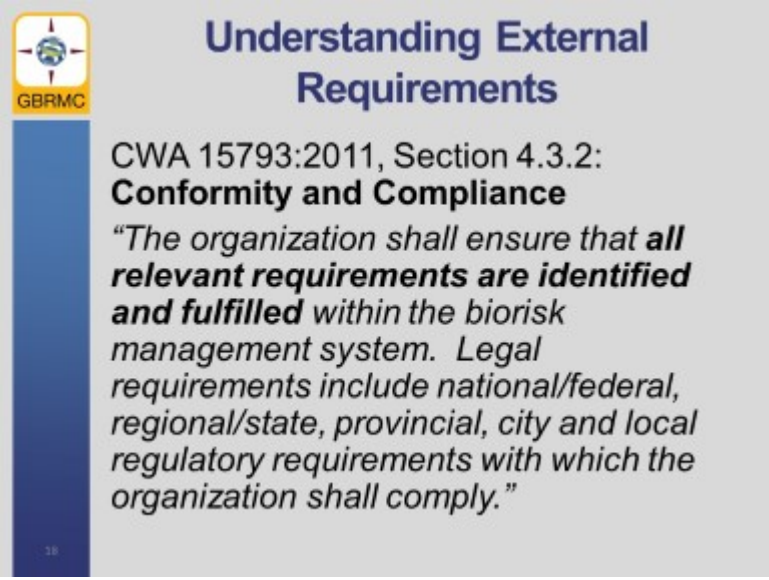
External
International Guidance (e.g. WHO LBM)
International Legal Frameworks and Guidance Principles (BWC, UN1540, IHR)
International Standards / Consensus Agreements (e.g. CWA 15793, ISO 9001)
National Laws / Regulations
National Guidance / National Standards
Facility Specific Policies
Facility Specific Biosafety and Biosecurity Manuals
Laboratory Specific Standard Operating Procedures (SOPs)
Internal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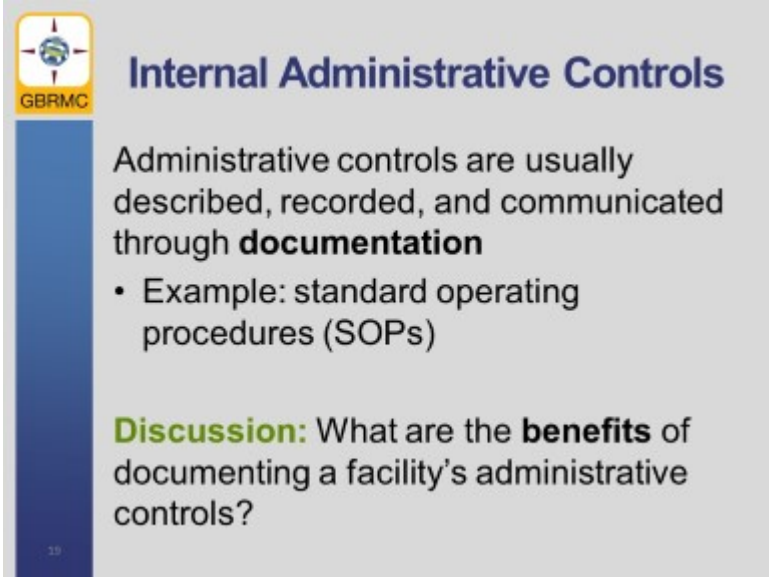
Understanding External Requirements
CWA 15793:2011, Section 4.3.2:
Conformity and Compliance
"The organization shall ensure that all relevant requirements are identified and fulfilled within the biorisk management system. Legal requirements include national/federal, regional/state, provincial, city and local regulatory requirements with which the organization shall comply."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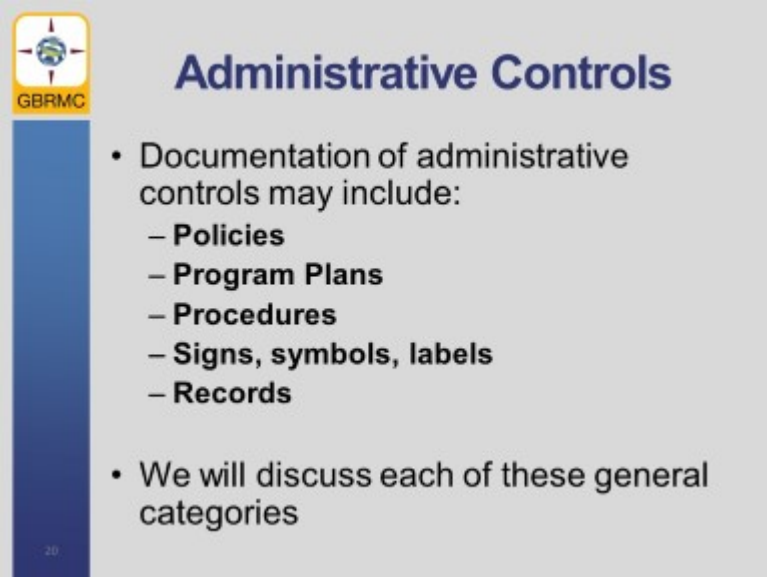
Internal Administrative Controls
Administrative controls are usually described, recorded, and communicated through documentation
• Example: standard operating procedures (SOPs)
Discussion: What are the benefits of documenting a facility's administrative controls?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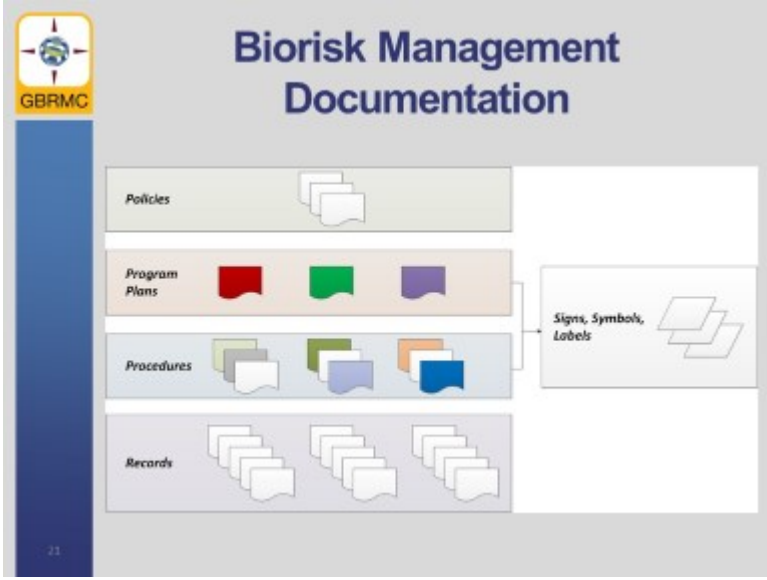
Administrative Controls
• Documentation of administrative controls may include:
– Policies
– Program Plans
– Procedures
– Signs, symbols, labels
– Records
• We will discuss each of these general categories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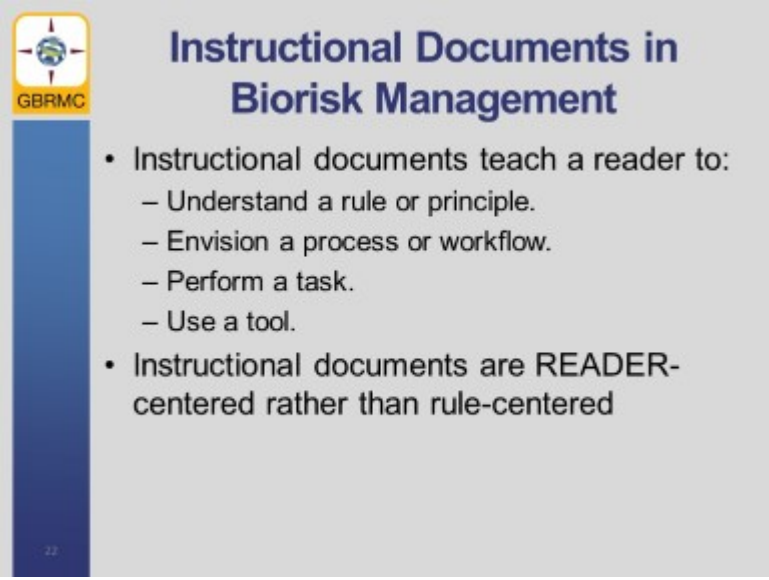
Biorisk Management Documentation
Policies
Program Plans
Procedures
Records
Signs, Symbols, Labels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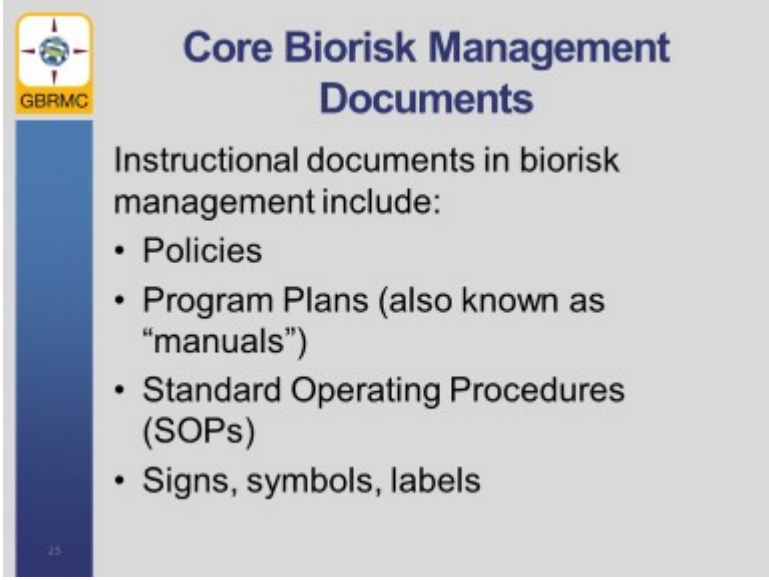
Instructional Documents in Biorisk Management
• Instructional documents teach a reader to:
– Understand a rule or principle.
– Envision a process or workflow.
– Perform a task.
– Use a tool.
• Instructional documents are READER-centered rather than rule-centered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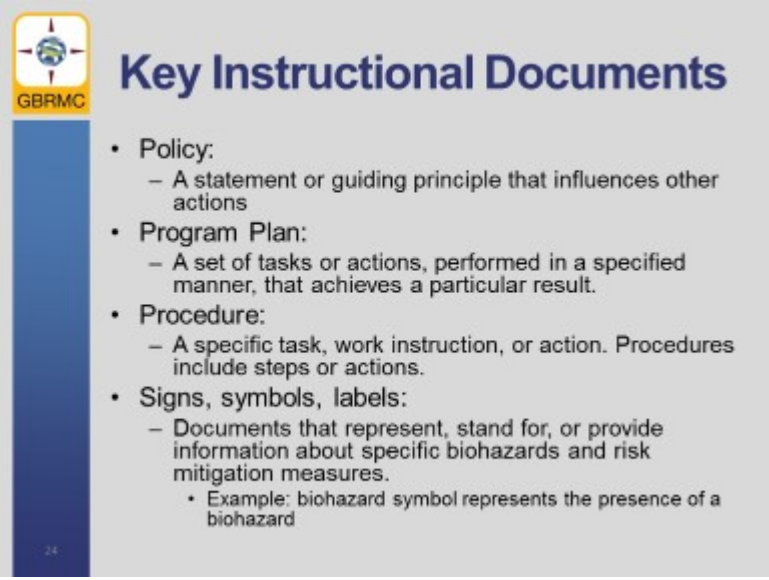
Core Biorisk Management Documents
Instructional documents in biorisk management include:
• Policies
• Program Plans (also known as "manuals")
• Standard Operating Procedures (SOPs)
• Signs, symbols, labels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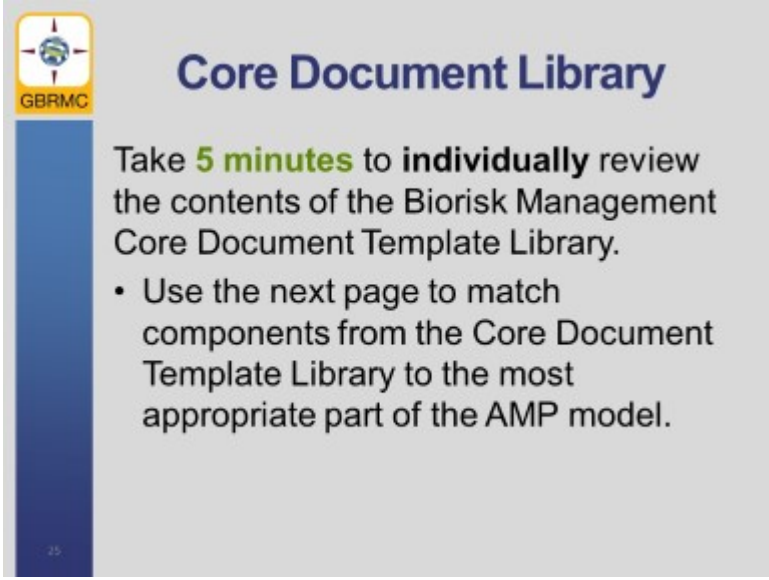
Key Instructional Documents
• Policy:
– A statement or guiding principle that influences other actions
• Program Plan:
– A set of tasks or actions, performed in a specified manner, that achieves a particular result.
• Procedure:
– A specific task, work instruction, or action. Procedures include steps or actions.
• Signs, symbols, labels:
– Documents that represent, stand for, or provide information about specific biohazards and risk mitigation measures.
• Example: biohazard symbol represents the presence of a biohazard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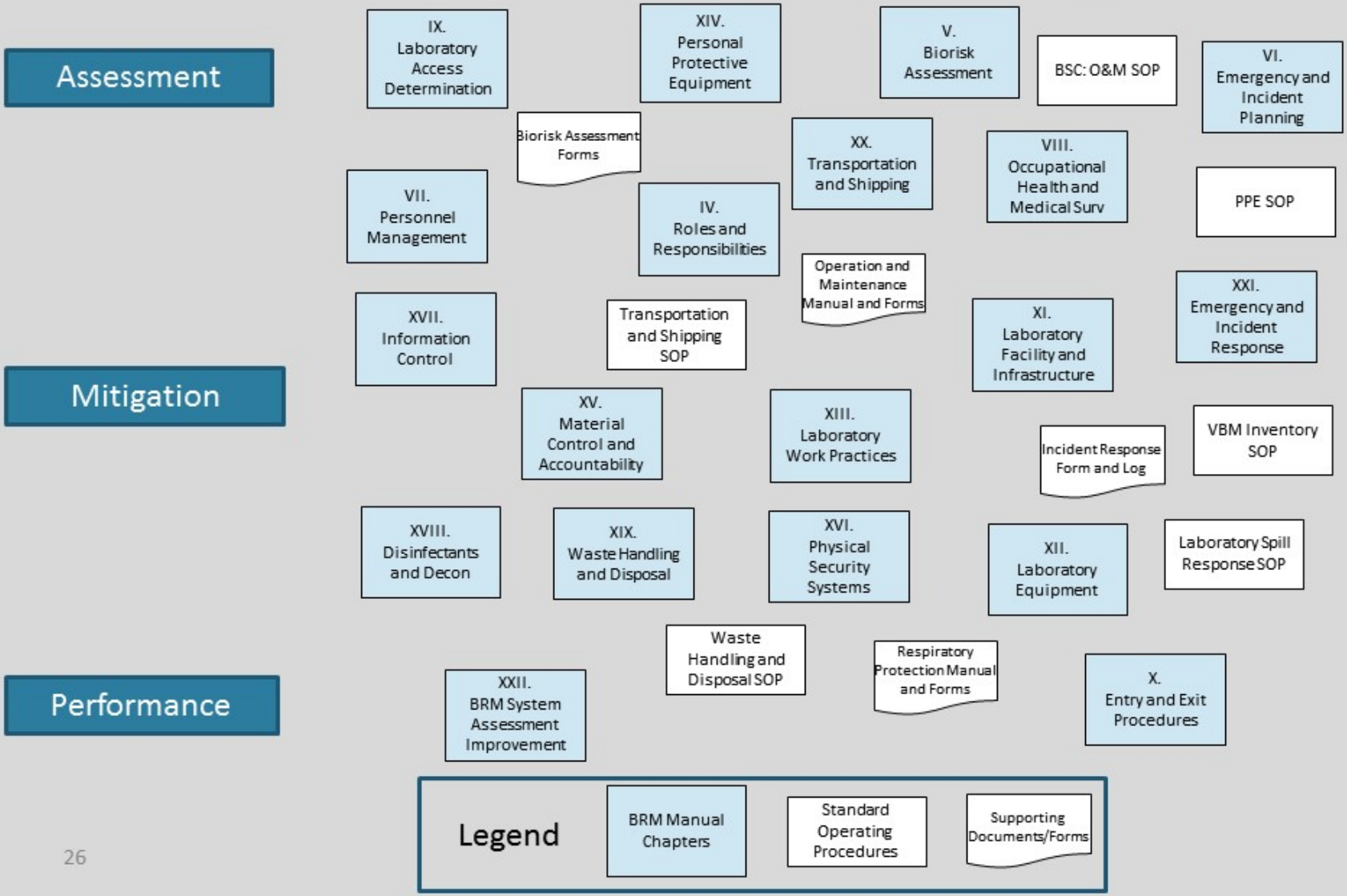
Core Document Library
Take 5 minutes to individually review the contents of the Biorisk Management Core Document Template Library.
• Use the next page to match components from the Core Document Template Library to the most appropriate part of the AMP model.

Core Document Library



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Policy

Policy: A plan or guiding principle that influences other actions

- Examples:
  - Biorisk management policy (CWA 15793:2011 – 4.2)
  - Occupational health and safety policy
  - Security policy
  - Environmental management policy
  - Others?
- Policy documents may be separate or integrated, depending on the organization

What is a 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**
  - 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


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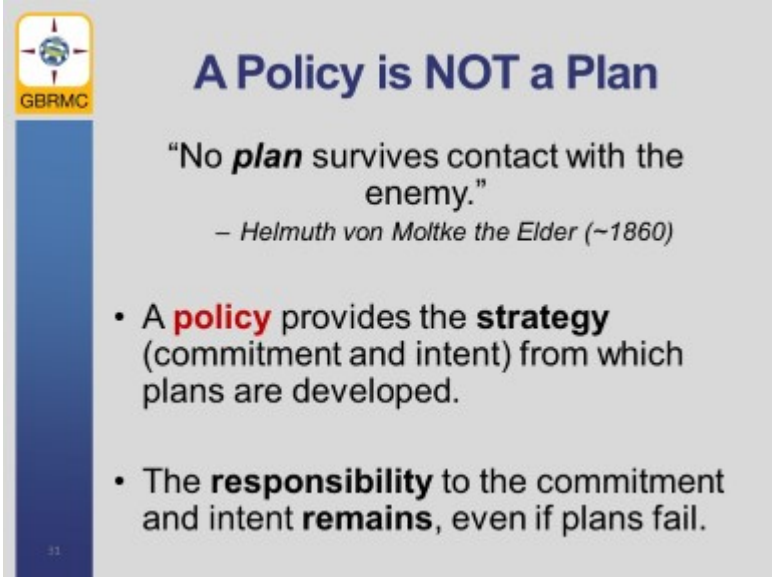
A Policy States Commitment and Intent
Commit (verb)
• to bind or obligate, as by pledge or assurance; pledge: to commit oneself to a promise; to be committed to a course of action.
Intent (adjective)
• firmly or steadfastly fixed or directed, as the eyes or mind: an intent gaze.
• having the attention 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.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A Policy is NOT a Plan
"No plan survives contact with the enemy."
– Helmuth von Moltke the Elder (~1860)
• A policy provides the strategy (commitment and intent) from which plans are developed.
• The responsibility to the commitment and intent remains, even if plans fail.

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CWA 15793:2011

4.2.1 Biorisk management policy

- The organization's top management shall develop, authorize and sign a policy concerning the management of laboratory biorisk (laboratory biosafety and laboratory biosecurity). It shall clearly state the overall biorisk management objectives and a commitment to improving biorisk management performance.
- The policy shall be appropriate to the nature and scale of the risk associated with the facility.

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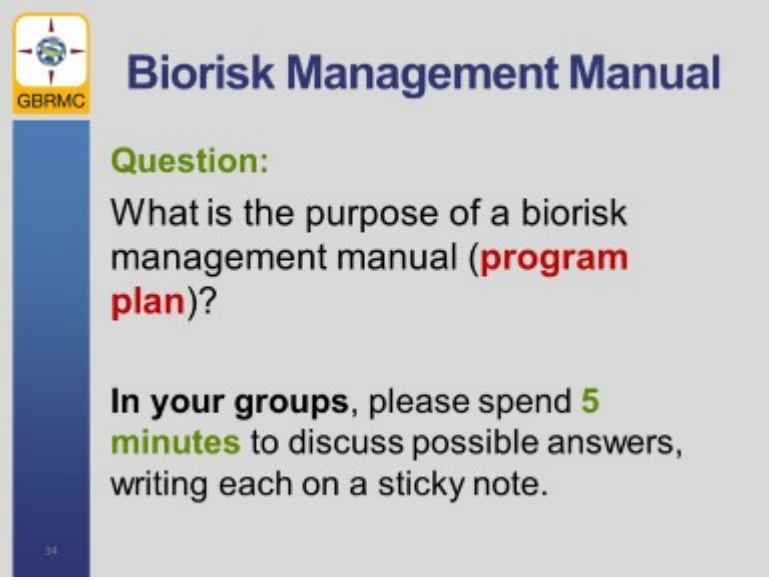
Program Plans

Program Plan: A set of tasks or actions, performed in a specified manner, that achieves a particular result.

- Examples:
  - Biorisk Management (Biosafety & Biosecurity)
  - Incident Response
  - Waste Disposal and Treatment
  - Animal Care and Use
  - Others?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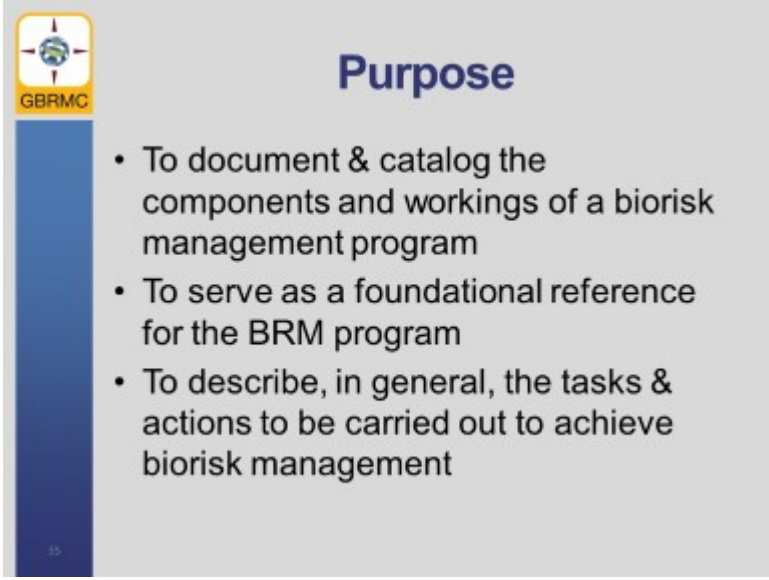
Biorisk Management Manual
Question:
What is the purpose of a biorisk management manual (program plan)?
In your groups, please spend 5 minutes to discuss possible answers, writing each on a sticky note.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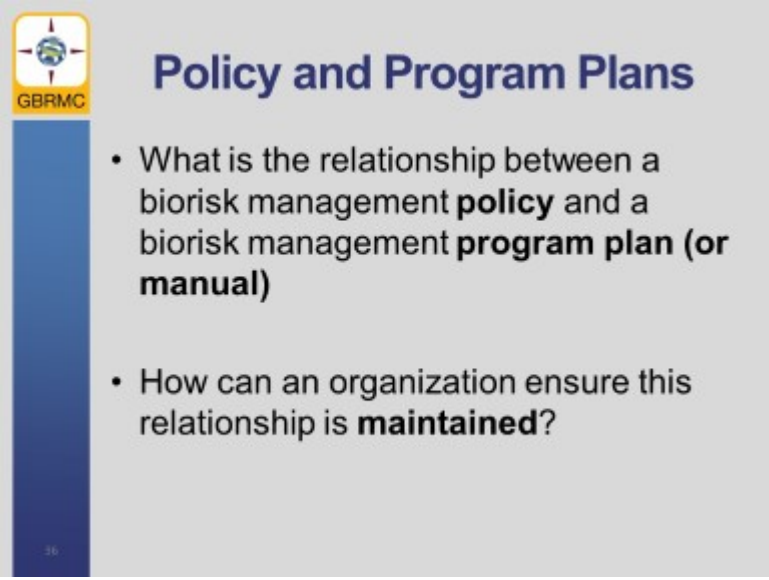
Purpose
• To document & catalog the components and workings of a biorisk management program
• To serve as a foundational reference for the BRM program
• To describe, in general, the tasks & actions to be carried out to achieve biorisk management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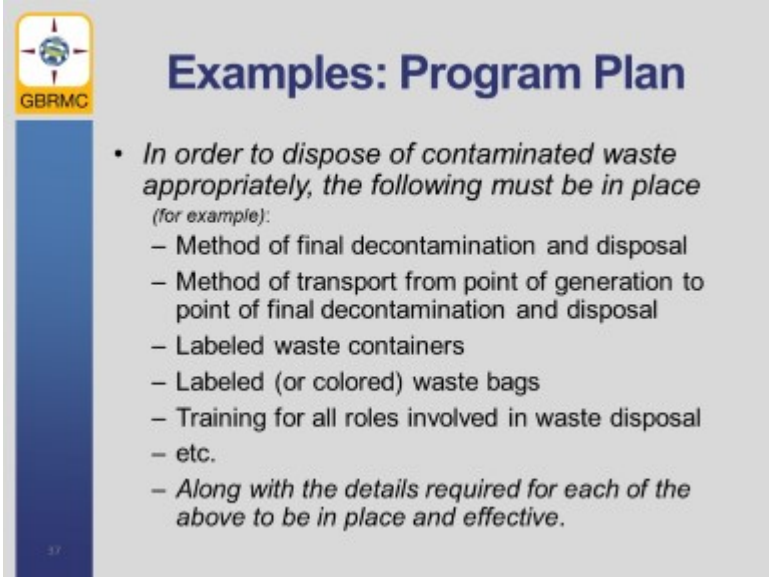
Policy and Program Plans
• What is the relationship between a biorisk management **policy** and a biorisk management **program plan (or manual)**
• How can an organization ensure this relationship is **maintained**?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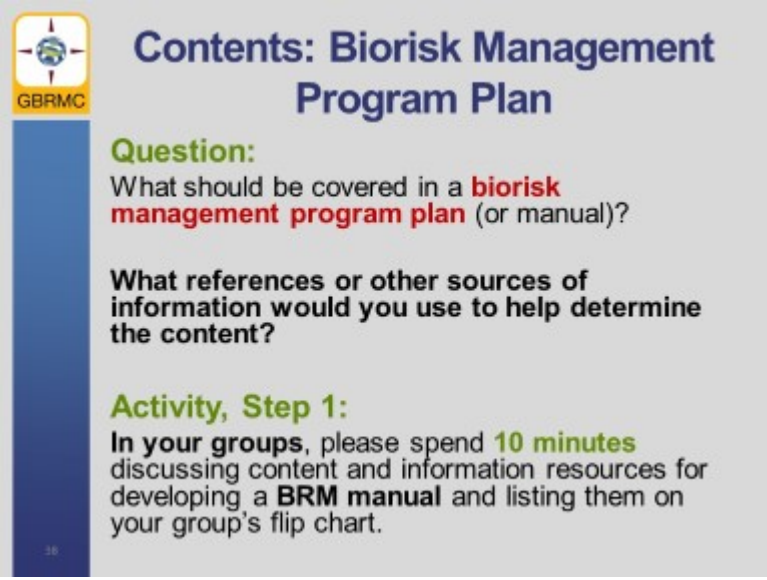
Examples: Program Plan
• *In order to dispose of contaminated waste appropriately, the following must be in place*
(for example):
– Method of final decontamination and disposal
– Method of transport from point of generation to point of final decontamination and disposal
– Labeled waste containers
– Labeled (or colored) waste bags
– Training for all roles involved in waste disposal
– etc.
– *Along with the details required for each of the above to be in place and effective.*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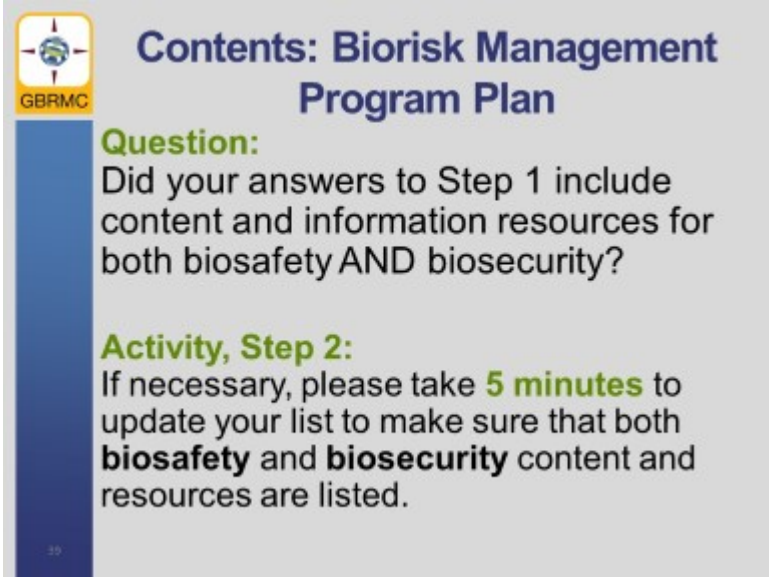
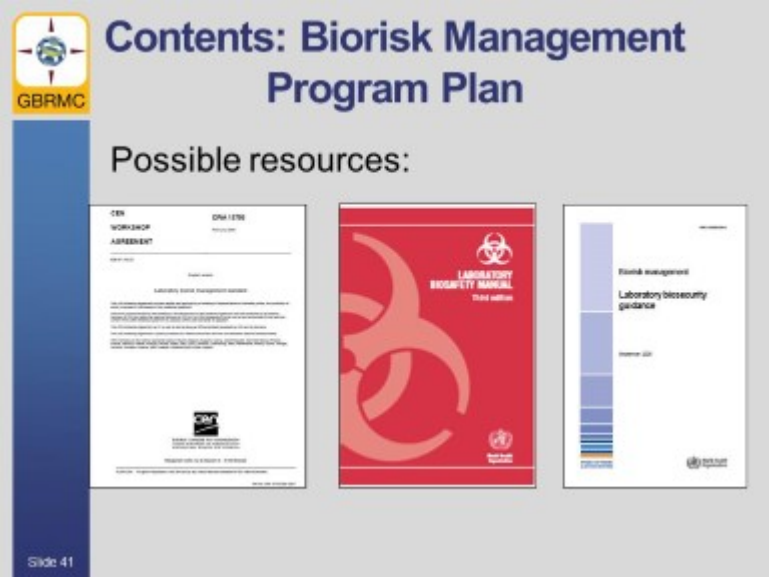
Contents: Biorisk Management Program Plan
Question:
What should be covered in a biorisk management program plan (or manual)?
What references or other sources of information would you use to help determine the content?
Activity, Step 1:
In your groups, please spend 10 minutes discussing content and information resources for developing a BRM manual and listing them on your group's flip chart.


GBRMC
Contents: Biorisk Management Program Plan
Question:
Did your answers to Step 1 include content and information resources for both biosafety AND biosecurity?
Activity, Step 2:
If necessary, please take 5 minutes to update your list to make sure that both biosafety and biosecurity content and resources are listed.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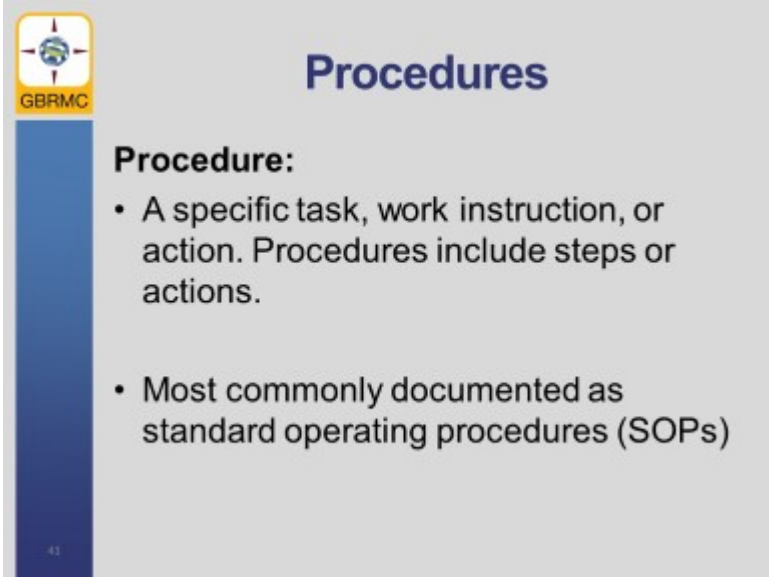
Contents: Biorisk Management Program Plan
Possible resources:
LABORATORY BIOSAFETY MANUAL
Laboratory biosecurity guidance
Slide 41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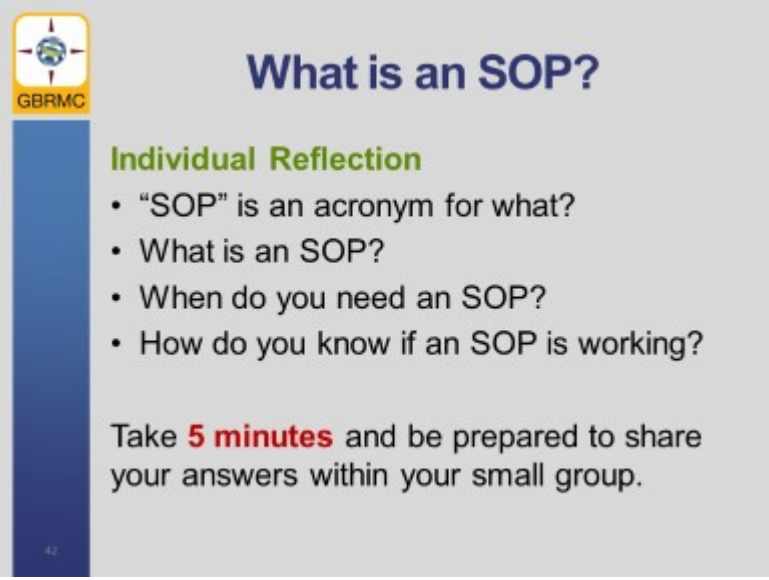
Procedures
Procedure:
• A specific task, work instruction, or action. Procedures include steps or actions.
• Most commonly documented as standard operating procedures (SOPs)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What is an SOP?
Individual Reflection
• "SOP" is an acronym for what?
• What is an SOP?
• When do you need an SOP?
• How do you know if an SOP is working?
Take 5 minutes and be prepared to share your answers within your small group.


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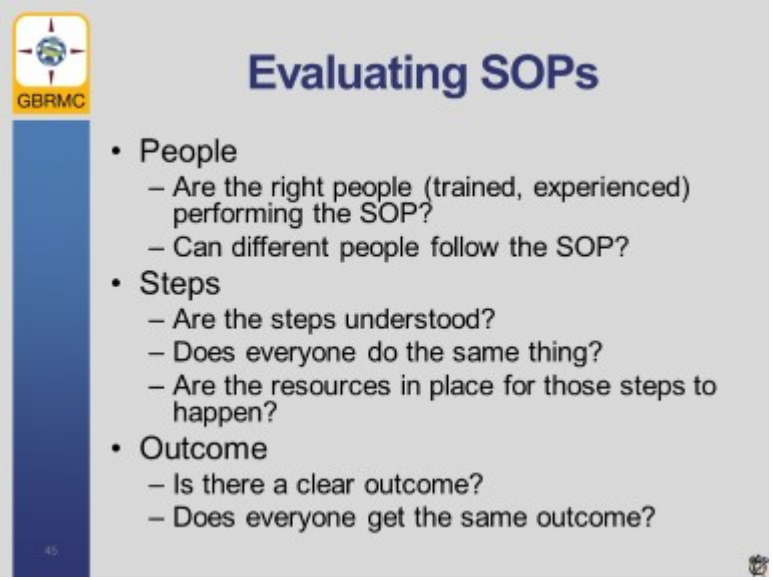
The goal of an SOP:
• Different people
• Doing the same thing
• Getting the same result
– S.G. Kaufman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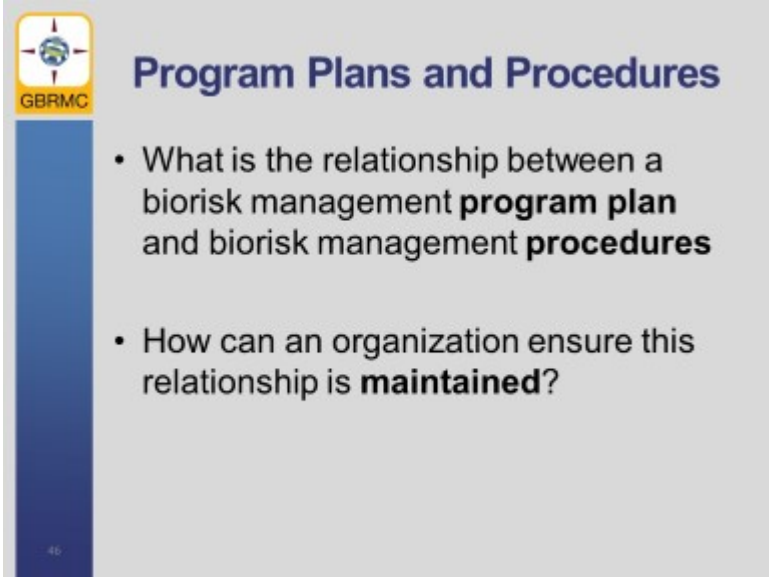
Evaluating SOPs
• People
– Are the right people (trained, experienced) performing the SOP?
– Can different people follow the SOP?
• Steps
– Are the steps understood?
– Does everyone do the same thing?
– Are the resources in place for those steps to happen?
• Outcome
– Is there a clear outcome?
– Does everyone get the same outcome?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Program Plans and Procedures
• What is the relationship between a biorisk management **program plan** and biorisk management **procedures**
• How can an organization ensure this relationship is **maintained**?

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SOPs and Biorisk Management

Group activity:

- What are some examples of biorisk management-related procedures that may be documented as SOPs in the laboratory?
- **Discuss** with your group and **record** each example.

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Signs, Symbols, and Labels

- We may define these generally as **documents that represent, stand for, or provide information about specific biohazards and risk mitigation measures.**

- Can you think of any examples of **signs**, **symbols**, or **labels** relevant for **biorisk management**?


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Examples
VISITORS
MUST REPORT TO MAIN OFFICE
BIOHAZARD


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Relationship with other Administrative Controls
In what ways does the use of **signs, symbols, and labels** support other biorisk mitigation controls, including other administrative controls?

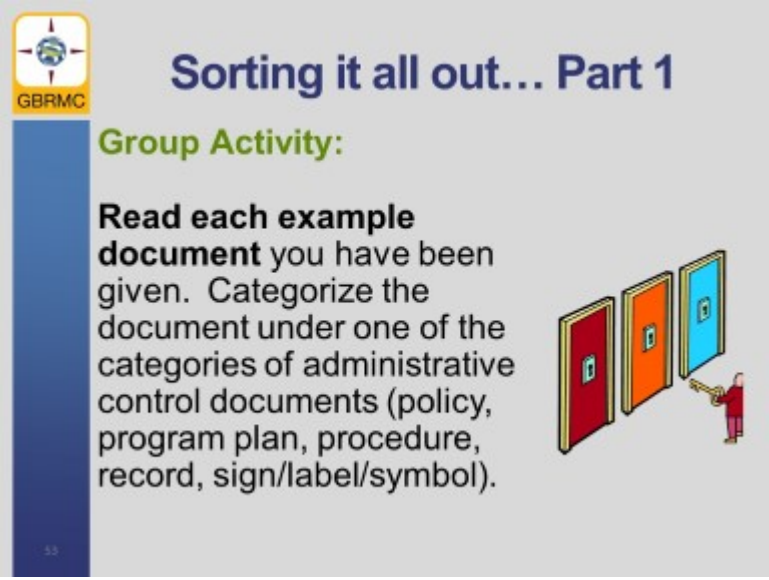
Records

Records: "document stating results achieved or providing evidence of activities performed" (from CWA 15793:2011)

- Where, when and how are records created?
- How can the creation and maintenance of records help to reduce biosafety and biosecurity risks?
- Are there other reasons record-keeping is important?

Records

- Examples of **records**:
  - Equipment usage logs
  - Material sign-out sheets
  - Safety equipment test logs
  - Security equipment test logs
  - Maintenance logs
  - Visitor logs
  - Incident reports
  - Training attendance/ training evaluation data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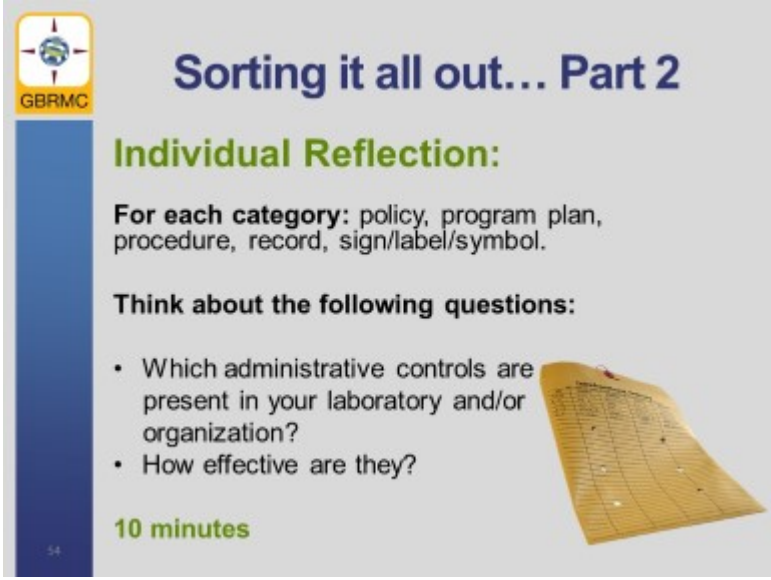
Sorting it all out… Part 1
Group Activity:
Read each example document you have been given. Categorize the document under one of the categories of administrative control documents (policy, program plan, procedure, record, sign/label/symbol).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Sorting it all out… Part 2
Individual Reflection:
For each category: policy, program plan, procedure, record, sign/label/symbol.
Think about the following questions:
• Which administrative controls are present in your laboratory and/or organization?
• How effective are they?
10 minutes


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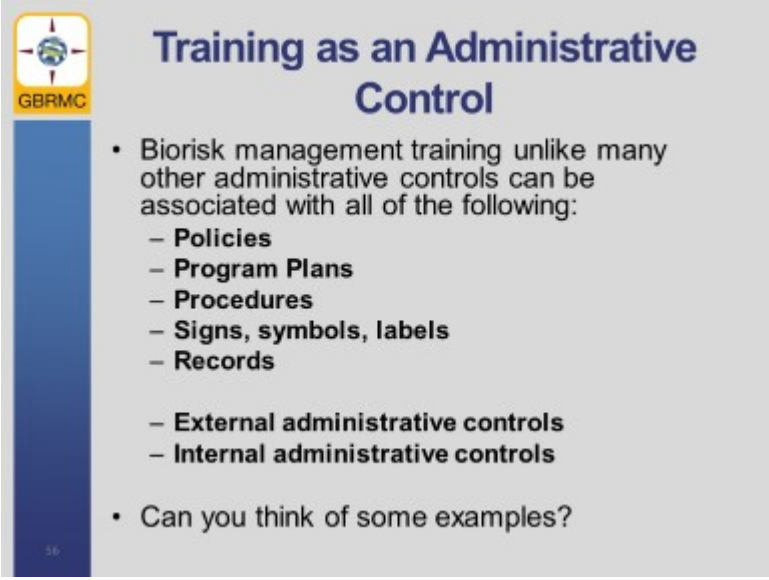
Biorisk Management Training
Question:
Is biorisk management training an administrative control?
Person
Knowledge, Skills, & Abilities
Desired Actions & Behaviors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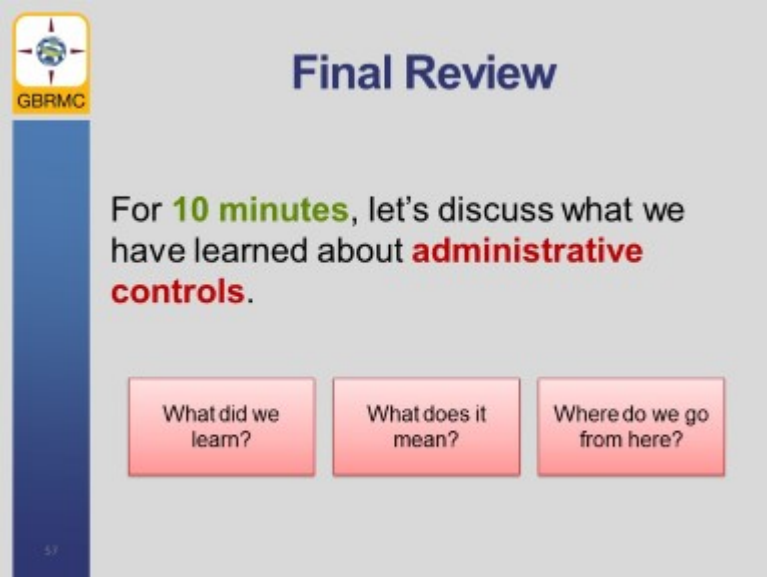
Training as an Administrative Control
• Biorisk management training unlike many other administrative controls can be associated with all of the following:
– Policies
– Program Plans
– Procedures
– Signs, symbols, labels
– Records
– External administrative controls
– Internal administrative controls
• Can you think of some examples?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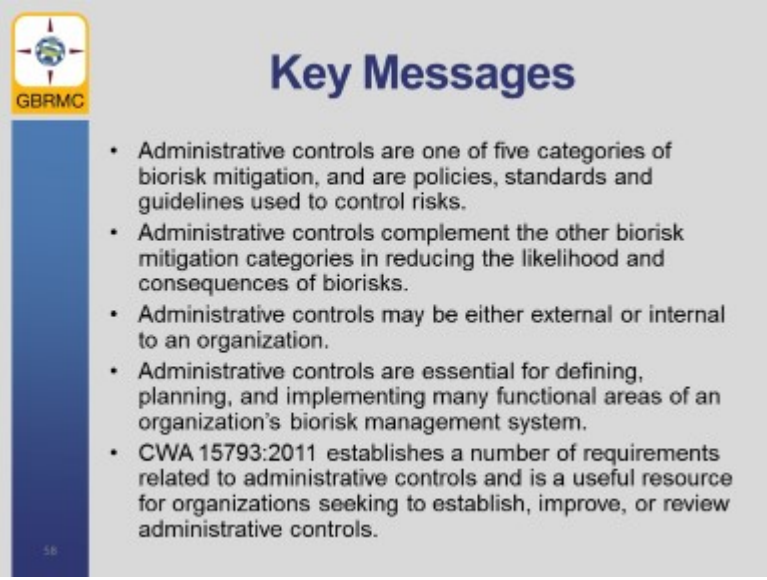
Final Review
For 10 minutes, let's discuss what we have learned about administrative controls.
What did we learn?
What does it mean?
Where do we go from here?


GBRMC
Key Messages
• Administrative controls are one of five categories of biorisk mitigation, and are policies, standards and guidelines used to control risks.
• Administrative controls complement the other biorisk mitigation categories in reducing the likelihood and consequences of biorisks.
• Administrative controls may be either external or internal to an organization.
• Administrative controls are essential for defining, planning, and implementing many functional areas of an organization's biorisk management system.
• CWA 15793:2011 establishes a number of requirements related to administrative controls and is a useful resource for organizations seeking to establish, improve, or review administrative controls.

Action Plan

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

KNOW		FEEL		BE ABLE TO DO	

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

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

Use space on back, if needed