



# Developing, Conducting, and Maintaining a Hazard Inventory

Student Guide

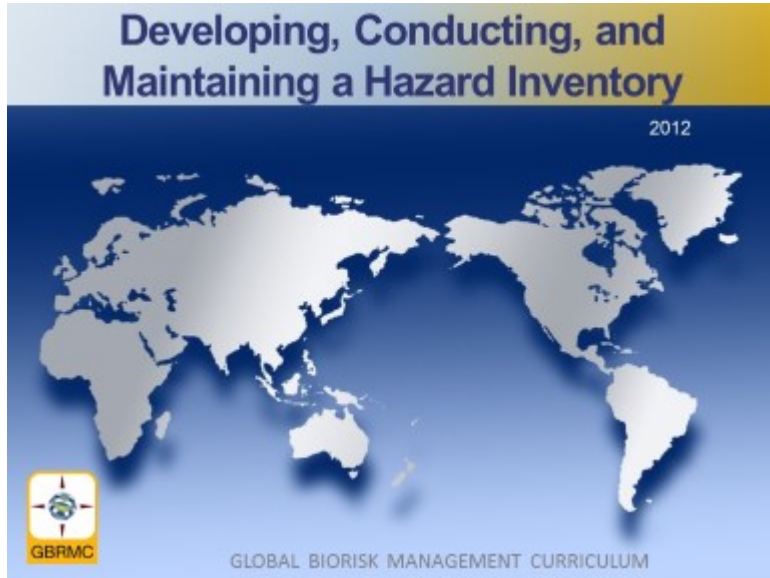
2012



GLOBAL BIORISK MANAGEMENT CURRICULUM

***Developing, Conducting, & Maintaining a Hazard Inventory***

***Welcome & Introductions***



Welcome to Developing, Conducting, and Maintaining a Hazard Inventory!

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## Introductions

- Instructors
- Students
  - What is your name?
  - Where are you from?
  - Something fun about yourself.



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# Action Plan

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

KNOW		FEEL		BE ABLE TO DO	
<i>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.</i>					
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?



## Key Messages

- Biological hazards can be grouped according to risk group schemes and aid in risk assessment.
- There are unique roles and responsibilities when working with the hazard inventory.
- The inventory system should capture information about each hazard to effectively track the hazard. In addition, the system should be reviewed regularly and allow for continual improvement.

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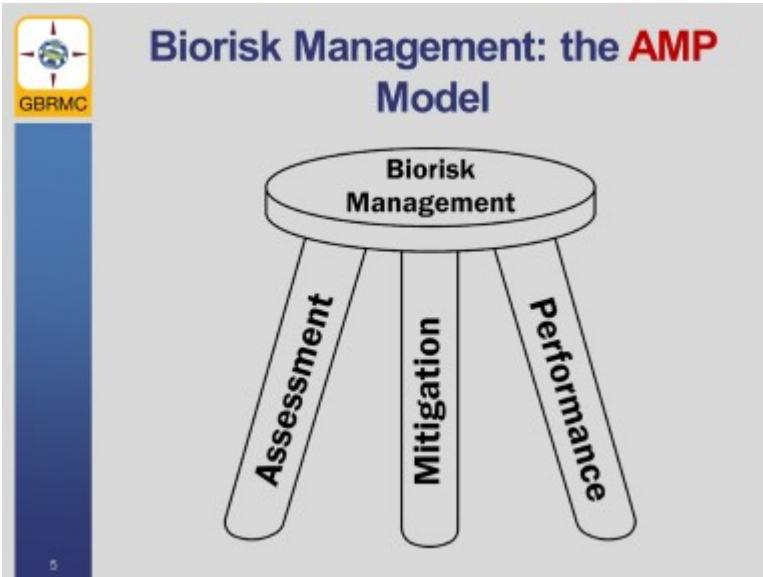
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- Key Components of Biorisk Management**
- **Biorisk Assessment**
    - Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable
- 
- The slide lists the key components of biorisk management. The first component is "Biorisk Assessment", which is defined as the process of identifying hazards and evaluating risks associated with biological agents and toxins, while considering existing controls and determining if risks are acceptable. An icon of a clipboard with a pencil is shown in the bottom right corner. The GBRMC logo is in the top left corner.

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## Key Components of Biorisk Management

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



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## Key Components of Biorisk Management

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



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### **CWA 15793: Laboratory Biorisk Management**

- Is a management system standard consistent with other international standards such as
  - ISO 9001 / 14001 and OSHAS18001
- The Standard is performance oriented
  - Describes what needs to be achieved
  - How to do it is up to the organization
- Does not replace national regulations
  - Compliance with local regulations is mandatory under CWA 15793
- Designed to be comprehensive framework for biosafety & biosecurity (biorisk) program
  - Risk-based; applicable to broad range of organizations, not just high containment labs

What is the CWA 15793 and how is it useful?

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### **Purpose of the CWA 15793:2011**

The Standard is used for:

- Improving overall laboratory biorisk management and performance
- Increasing awareness and the adoption of performance (outcome) based approaches for biosafety and biosecurity
- Improving international laboratory collaboration and safety harmonization
- Supporting laboratory certification/accreditation, audits/inspections



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What is the purpose of the CWA 15793?

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## Developing, Conducting, & Maintaining a Hazard Inventory


## CWA and PDCA Management System



### Plan – Do – Check – Act (PDCA)

All biorisk management systems should rely on a “**Plan-Do-Check-Act**” approach with the goal of **continuous improvement**

- **Plan**
  - Planning, including identification of hazards and risks and establishing program goals
- **Do**
  - Implementing, including training and operational issues
- **Check**
  - Checking, including monitoring and corrective action
- **Act**
  - Reviewing, including process innovation and acting to make needed changes to the management system.



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Continual improvement through a cycle of planning, implementing, checking, and review and evaluation.

List additional examples for:

Plan –

Do –

Check –

Act –

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## Developing, Conducting, & Maintaining a Hazard Inventory

## CWA and PDCA Management System



### Implementing CWA 15793:

Enables organizations to:

- **Establish and maintain a biorisk management system** to control or minimize risk to acceptable levels to employees, the community and others
- **Provide assurance** that the requirements are in place and implemented effectively
- Provide a framework that can be used as **basis for training and awareness raising**
- **Seek and achieve certification or verification** by an independent third party



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Benefits of implementing the CWA include:

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## Developing, Conducting, & Maintaining a Hazard Inventory

## Identifying and Classifying Lab Hazards



### Identifying Lab Hazards

A **hazard** is a source that has a potential for causing harm:



- In the lab, there may be many types of **hazards**:
  - Biological (our focus today)
  - Chemical
  - Radiological
  - Physical (fire, electrical, ergonomic, sharps, heat, cold, pressure, laser, and so on...)
- A **hazard** is not a risk, without a specific environment or situation

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Define what a hazard is:

Note that there are many types of hazards in the laboratory

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## Biological Hazards

### Group Exercise

- Today, we will be focusing on **biological hazards**, but many of the principles of this course may be applied for **all hazards**
- What types of **biological hazards** may be found in your facility?
  - Discuss **in your group**
  - Write each answer on one **sticky note**
  - When you are finished, place your **sticky notes** on the **flip chart** at the front of the room

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What types of biological hazards may be found in your facility?

(You may wish to record your answers here along with on the provided post-it notes)

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## Developing, Conducting, & Maintaining a Hazard Inventory

## Identifying and Classifying Lab Hazards



### Biological Hazards

**Group Exercise**

Why do we need to identify and inventory all biological hazards in our facilities?



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Why do we need to identify all the biological hazards in our laboratories?

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## Developing, Conducting, & Maintaining a Hazard Inventory

## Identifying and Classifying Lab Hazards



### Hazards and Risks

If we know what hazards we have, we can properly assess and manage **risk**



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Hazard identification is necessary in order to perform a proper assessment of the risk posed by the biological hazards in the laboratory.

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## Developing, Conducting, & Maintaining a Hazard Inventory

## Identifying and Classifying Lab Hazards



### Material Control and Accountability

- Biological hazard inventory is an important aspect of a laboratory's risk-based **material control and accountability (MC&A)** system
- MC&A helps dissuade adversaries (insiders) from stealing biological hazards
- The inventory should include all biological materials that are subject to MC&A measures
  - Including **accountable individual**
- Decisions must be made:
  - **Which** materials are subject to MC&A
  - **Who** is **accountable** for them



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The objective of MC&A measures is to dissuade adversaries (especially insiders) from stealing or misusing the hazardous biological materials at your facility.

Control – ensures that material is confined to known, legitimate use

Accountability – ensures oversight by formally associating materials with people and information records

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## Developing, Conducting, & Maintaining a Hazard Inventory

## Identifying and Classifying Lab Hazards



### Classification of Biohazards

- We can classify and prioritize biological hazards by examining factors associated with **safety** and **security**
- Example: Safety-related factors
  - Pathogenicity
  - Mode of transmission and host range
  - Local availability of effective preventative measures
  - Local availability of effective treatment
- Characterization of the hazards and associated safety factors enable **risk assessment**

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Categorize biological hazards according to their characteristics.

- Characteristics associated with biosafety:
  
  
  
  
  
  
  
  
  
  
- Characteristics associated with biosecurity:

## Developing, Conducting, & Maintaining a Hazard Inventory

## Identifying and Classifying Lab Hazards



The infographic features the GBRMC logo in the top left corner. The title "WHO Risk Groups" is centered at the top. To the right of the text is an illustration of a person standing next to a large wooden cabinet with multiple drawers, with a box on the floor nearby. The text is organized into a list of four risk groups, followed by a note about national variations and a URL. A red warning statement is at the bottom.

**WHO Risk Groups**

- **Risk Group 1** – no or low individual and community risk
- **Risk Group 2** – moderate individual risk, low community risk
- **Risk Group 3** – high individual risk, low community risk
- **Risk Group 4** – high individual and community risk

Some countries/regions have developed RG classification schemes:  
<http://absa.org/riskgroups/index.html>

**Risk groups do NOT directly equate to biosafety levels for laboratory work**

The World Health Organization (WHO) has developed guidelines on biosafety “risk groups.”

Risk Group 1 – a microorganism that is unlikely to cause human or animal disease


Risk Group 2 – A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection but effective treatment and preventative measures are available and the risk of spread of infection is limited

Risk Group 3 – A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventative measures are available.

Risk Group 4 – A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventative measures are not usually


## Developing, Conducting, & Maintaining a Hazard Inventory

## Identifying and Classifying Lab Hazards



### What about security?

- Related but distinct view of biological hazards
- A safety hazard concern **does not necessarily equate** to a security concern
- Focus analysis on whether an agent's properties would make it an effective weapon



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Hazard characterization based on biosecurity-related characteristics is focused on analyzing those agent properties, which could make it an effective weapon in the hands of a malicious person or group.

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# Developing, Conducting, & Maintaining a Hazard Inventory

# Identifying and Classifying Lab Hazards



## Malicious Use Risk Groups

Malicious Use Risk Group	Task Complexity	Potential Consequences	Examples
<b>Nonpathogenic</b>	Not applicable	Little or no consequences if used maliciously	Non-infectious forms of pathogens (e.g., insect and nematode) and toxins (e.g., ricin, botulinum toxin, aflatoxin, hepatitis, and various Bacteroides)
<b>Low</b>	High – may be difficult or require one hard to produce in sufficient quantities, and unsuitable for dissemination	Low – low population impact, little to no economic damage, and are expected to have a low psychological impact on the general population	Malicious use of toxins, small quantities of toxins (i.e., less than the threshold for the Infect Agent Unit), agents manufactured primarily by genetic or viral expression (e.g., influenza, hepatitis, and pneumonic anthrax), genetic food strains of E. coli, salmonella, streptococcus, and
<b>Moderate</b>	Moderate – many of the steps associated with successfully deploying these agents will be relatively easy, but perhaps one or two of the critical steps are difficult	Moderate – localized consequences with low mortality rates, moderate to significant economic damage, and the potential to cause pervasive anxiety	Chemically derived agents that pose a direct primary threat (e.g., Salmonella, E. coli O157:H7, and Shigella) or toxin (e.g., ricin, anthrax and Cryptosporidium), and large quantities of some toxins
<b>High</b>	Low – not particularly difficult to deploy as weapons	Moderate to High – national or international consequences, moderate to high mortality and/or economic damage, and the potential to cause mass panic and significant social disruption	Biofilm pathogens, Pneumonia pathogens, Cholera bacteria, Foot-and-mouth disease virus, and Ebola virus
<b>Catastrophic</b>	None as High but they receive a higher classification because they are not found in nature	None as High	Various super virus, and could include genetically engineered agents, if they were suspected of representing a high risk



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Risk groups related to biosecurity can be created as well.

## Developing, Conducting, & Maintaining a Hazard Inventory

## Identifying and Classifying Lab Hazards



### Summary

#### Exercise:

**In your workbook**, write down three important items you learned during this module

#### Share your responses with your group

- Write the three top items from your group on your **flip chart**
- Why did your group pick those items?

#### Now what?

- How can we perform hazard identification and inventory in the lab?

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Write down three important items you learned during this module:

Be prepared to share with your group and the class.

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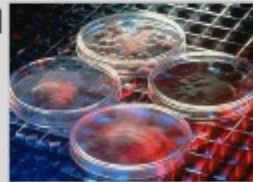
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## Hazard Inventory

- What is an **inventory** of biological hazards (agents and toxins)?
  - An **accurate** and **up-to-date** record of biological hazard holdings of a unit (facility, laboratory, etc.)
- A properly implemented inventory is a **central element** of the hazard identification (**and risk assessment**) process!



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What do we mean when we talk about a biological hazard inventory?

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## Benefits and Challenges

**Group Exercise:**  
**In your groups**, complete the following table in your workbooks:

Benefits of a Comprehensive Biological Hazard Inventory System in Your Facility	Challenges Associated with Implementing an Inventory System

Do the benefits outweigh the challenges?

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Complete the table provided. Fill free to include more answers here if needed.

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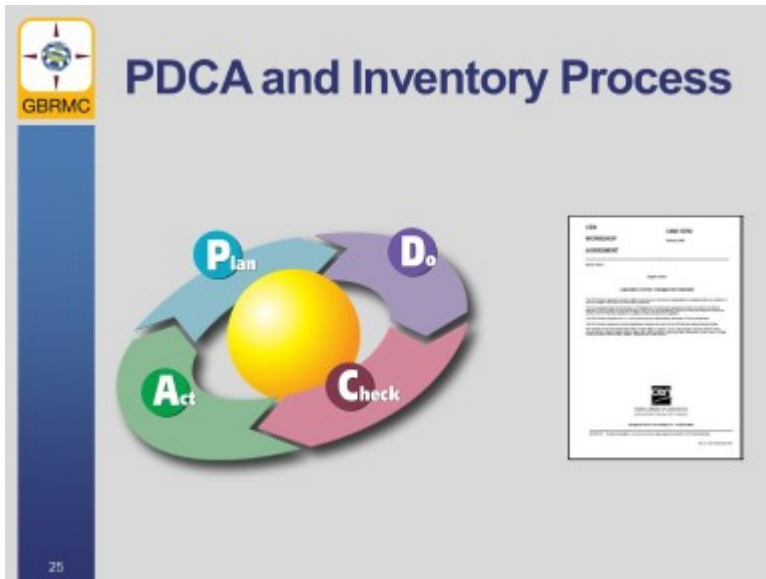
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## Developing, Conducting, & Maintaining a Hazard Inventory

## Hazard Inventory



A hazard inventory control process can be designed, implemented, evaluated, and optimized using the PDCA process.

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## Plan - Hazard Identification

- Hazard identification is important for a comprehensive risk assessment and biorisk management program
- CWA 15793:2011, Section 4.3.1.3:
  - *“The hazards associated with proposed work shall be identified and documented.”*
- Define an **approach** for conducting hazard identification that meets this standard requirement
- We’re focusing on biological hazards, but remember this applies for **all** potential hazards at your facility!!



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The first step of the PDCA cycle is Planning.

- In order to plan a practical and effective hazard inventory system, we must have some sense of what the biological hazards are that we will be dealing with.
- It is important to devise a systematic, reproducible, and reliable approach to hazard identification in the laboratory. This is imperative in order to compare data over time and measure process improvements (or degradation).



## PDCA Training Scenario

**Scenario:**

Your group is the decision-making council for a large research laboratory that works with several biological agents and toxins. Due to a recent incident in which several old vials containing small amounts of a potent toxin were lost, the council is considering establishing a standard inventory system for the entire facility.

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## Hazard Information

**Discussion:**  
Using the scenario information and your experience:

1. What types or categories of information could be available to you and your staff that would enable a biological hazard identification process?
2. Who can provide this information?
3. What are the benefits and limitations of each category?
  - Discuss within your group
  - Write your answers in **your workbook**



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What types or categories of information could be available to you and your staff that would enable a biological hazard identification process?

Think about who in your laboratory could provide this information?

Finally, not all sources of information will necessarily give you everything you need. Hazard identification involves putting together pieces of information from multiple sources to create the most comprehensive picture possible. Think about the benefits and limitations of the information types that you listed.

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## Developing, Conducting, & Maintaining a Hazard Inventory

## Hazard Inventory



This slide shows potential information sources based on CWA 15793.

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## Hazard Identification – Key Messages

- Hazard identification is a key first step for biorisk assessment
- Proper hazard identification requires multiple sources of information
- Hazard identification should utilize diverse expertise from a team of personnel
  - CWA 15793: "hazard identification process requires a multidisciplinary risk management team..."



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Hazard identification requires that your team consult multiple sources of information.

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## Developing, Conducting, & Maintaining a Hazard Inventory


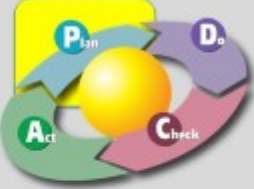
## PLAN Hazard Identification



### Plan – Establish Specific Steps

What specific determinations or actions are required to **plan for** a new or updated hazard inventory that meets the CWA requirements?

- Working with a partner, try to identify five items
- Think about your role as a facility leader



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In your workbooks, you will find the CWA requirements for “biological agents and toxins inventory and information.”

Working with a partner at your table, discuss what specific steps can you take in planning stage for a new or updated hazard inventory that meets the CWA requirements?

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### **CWA 15793 – Key Requirements**

#### **4.4.4.2 Biological agents and toxin inventory and information**

- The organization shall ensure that an accurate and up-to-date biological agents and toxin inventory is established and maintained.**
- It shall ensure that records relating to the inventory of biological agents and toxins are current, complete and stored securely with adequate backup provision.**
- It shall ensure that transfers of biological agents and toxins between laboratories at the facility or into and out of the facility are recorded and controlled in line with the level of the risk.**

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CWA Key Requirements for Hazard Inventory:

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## Developing, Conducting, & Maintaining a Hazard Inventory

## PLAN Roles and Responsibilities

### Plan - Personnel Responsibilities

How would you assign roles and responsibilities among **you** and **your staff**? Work with your groups to complete the table in your workbooks.



Category of Personnel	Responsibility	PDCA Component
Laboratory Staff	•Catalogue all biological agents in the laboratory under supervision of laboratory manager.	•Do
Laboratory Staff	•Report hazards encountered during work	•Check

Think about the categories of personnel we discussed earlier when we talked about hazard identification, and for each major category of laboratory or external personnel, assign specific hazard inventory responsibilities to them. For each responsibility you come up with, try to categorize it in terms of the PDCA cycle.

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## Developing, Conducting, & Maintaining a Hazard Inventory

## PLAN Roles and Responsibilities



### Leadership Roles & Responsibilities

What are some of your key roles & responsibilities?

- **Decide** to establish or upgrade a hazard inventory system
- **Establish** or **update** policies that support and fund the establishment and conduct of hazard inventories and hazard identification
- **Allocate** any necessary resources (funding, staff time, training)
- **Assign** roles and responsibilities
- **Communicate** expectations, roles, responsibilities for hazard identification and inventory processes to your staff
- **Monitor** and **review** the inventory system through the PDCA cycle



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List the essential functions you can play in hazard inventory:

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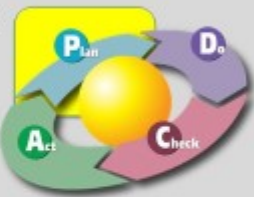
# Developing, Conducting, & Maintaining a Hazard Inventory

## PLAN Roles and Responsibilities



### PLAN – Key Points

- A hazard inventory system requires **resources** (financial, manpower, time, etc.), but the benefits outweigh the costs
- A hazard inventory system should be **risk-based**, and may be planned, implemented, checked, and optimized based on the PDCA management cycle
- **Laboratory leadership** has several important responsibilities in planning a hazard inventory system.
- Management should **communicate** the need for, and the mechanisms to conduct and maintain, a hazard identification process and inventory



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Review PLAN of PDCA with respect to Hazard Inventory.

Additional Notes/Examples:

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# Developing, Conducting, & Maintaining a Hazard Inventory

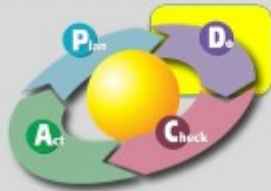
## DO Implement the System



### Do – Implement the System

#### Discussion:

In your groups, discuss what are the most important actions for you and your staff to take to **implement** a hazard inventory system. Write your answers in your workbooks (10 minutes).



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What actions are required to **implement** a hazard inventory system based on plans developed during the first stage?

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## Sample Information

**Scenario Exercise:**

For an experimental pathogenesis study, your Lead scientist has ordered a replacement sample of the toxin to replace the lost vials.



– **What information about this toxin sample should be captured in the inventory?**

Write down your answers (**5 minutes**), then discuss your answers in your groups (**10 minutes**). Write down your group's answers on your **flip chart**.

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What information about the toxin sample should be captured in the inventory?

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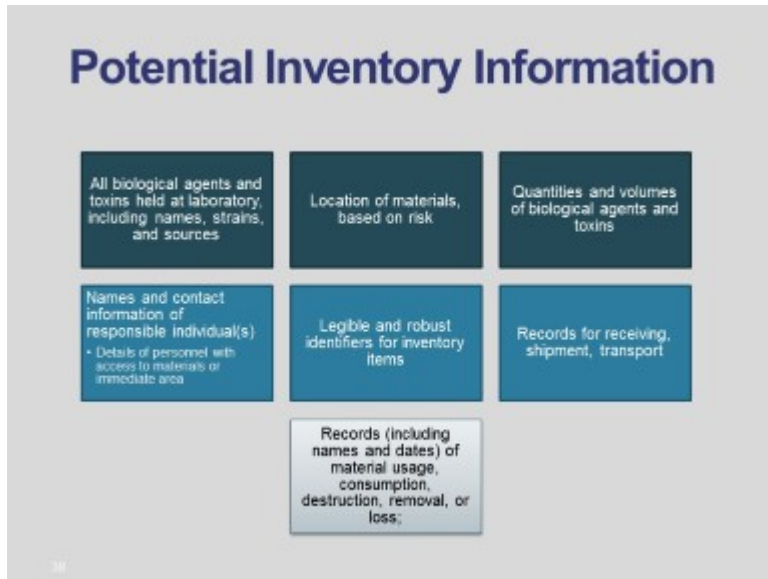
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## Developing, Conducting, & Maintaining a Hazard Inventory

## DO Implement the System



CWA 15793 and other guides (Laboratory Biosecurity Handbook) have identified some specific types of information regarding biological agents and toxins that should be captured in the inventory.

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## Developing, Conducting, & Maintaining a Hazard Inventory



## DO Implement the System



### DO – Key Points

The “DO” stage of the PDCA cycle involves the actual implementation of the hazard inventory plan. Proper implementation of hazard inventory policies and procedures enhances lab biorisk management by:

- Informing risk assessment
- Enabling hazardous samples to be effectively controlled and accounted for by responsible lab staff
- Ensuring that hazardous samples are stored safely and securely in designated areas
- Tracking movements of hazardous samples inside and outside the laboratory



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Review DO of PDCA with respect to Hazard Inventory.

Additional Notes/Examples:

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## Developing, Conducting, & Maintaining a Hazard Inventory

### CHECK Does the System Work?



### Check – Does the System Work?

#### Discussion

In your groups, discuss what are the most important actions for you and your staff to take to **check** a hazard inventory system. Write your answers in your workbooks (10 minutes).



Discuss what are the most important actions for you and your staff to take to check a hazard inventory system?

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### Inventory as a Tool

**Scenario:**

Six months after your facility's new hazard inventory is complete, a scientist who worked with the toxin samples several months ago finds her laboratory's door **unlocked** and **open** when she arrives in the morning. She is accountable for the toxin samples. Her colleague left in a hurry last night, and he does not remember if he closed and locked the door or not.



1. What could have happened?
2. Can the facility's *hazard inventory* be useful in this situation?

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How can the facility's hazard inventory be useful in the situation?

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## Developing, Conducting, & Maintaining a Hazard Inventory

## CHECK Does the System Work?



### CHECK – Key Points

- The “**CHECK**” stage of the PDCA cycle is focused on monitoring the implementation of the hazard inventory system, and taking corrective actions if necessary
- The hazard inventory may also be useful as a tool to check other aspects of the lab biorisk management system



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Review CHECK of PDCA with respect to Hazard Inventory.

Additional Notes/Examples:

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# Developing, Conducting, & Maintaining a Hazard Inventory

## ACT How to Get Better?



### Act – How To Get Better?

#### Discussion:

In your groups, discuss what are the most important actions or steps to take to review, innovate, and **act to improve** a hazard inventory system. Write your answers in your workbooks (10 minutes).



Discuss what are the most important actions to take to review, innovate, and act to improve a hazard inventory system?

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## Developing, Conducting, & Maintaining a Hazard Inventory

## ACT How to Get Better?



### ACT – Key Points

The “**ACT**” stage involves regular review of the biological hazard inventory system and acting on this information to enable continual improvement



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Review ACT of PDCA with respect to Hazard Inventory.

Additional Notes/Examples:

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### Protecting Inventory Information

In your laboratory, who currently has **access** to your inventory records?



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In your laboratory, who currently has access to your inventory records?

Do other personnel who don't need access as part of their functions, such as maintenance staff or visitors, have access to records?

Would it be possible for unauthorized individuals to access inventory-related information in your facility?

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## Protecting Inventory Information

- CWA 15793: ***"The organization shall have a policy and procedure in place to identify sensitive information; a review and approval process shall be used to control access to such information."***
- Is your hazard inventory information considered sensitive information?
  - The answer depends on your **risk**
  - **assessment**
  - **MC&A information should be protected**
  - **Protect information that is too sensitive for public distribution**
  - **Risks to information include**
    - Loss of integrity
    - Loss of confidentiality
    - Loss of availability
- As leaders, **you** must ensure that a robust system is in place at your laboratories to ensure this determination is made properly.



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According to the CWA, organizations should have policies and procedures in place to identify sensitive information, and a review and approval process shall be used to control access to this information.

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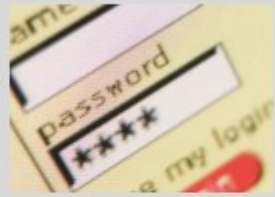
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### Key Aspects of Information Security

- Graded protection based on risk
- Restrict access to employees with a need
- Secure storage (paper and electronic)
  - IT security
- Review & approval policies governing transmission and transport of sensitive information
- Effective destruction procedures (paper and electronic)
- System performance should be monitored and evaluated for improvement (PDCA)



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The level of protection applied should be risk-dependent.

Some key principles and procedures common to information security systems include:

- Restrict access to sensitive information
- Store your hazard inventory information securely
- When sensitive information is no longer required, it should be destroyed in a secure fashion. This is true for both physical and electronic records
- Finally, as with all elements of the lab biorisk management system, the performance of your lab's information security procedures should be monitored, evaluated, corrected, and improved over time

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## Reflection

- Consider what measures your facility has in place to protect hazard inventory information.
- What are you currently doing well?
- What improvements could you consider?
  - Write your thoughts in your workbooks.



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What are you currently doing well?

What improvements could you consider?

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# Developing, Conducting, & Maintaining a Hazard Inventory

Review



## Review

To wrap-up, let's discuss what we learned about **Developing, Conducting and Maintaining a Hazard Inventory...**

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

- Biological hazards can be grouped according to risk group schemes and aid in risk assessment.
- There are unique roles and responsibilities when working with the hazard inventory.
- The inventory system should capture information about each hazard to effectively track the hazard. In addition, the system should be reviewed regularly and allow for continual improvement.

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# Action Plan

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

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

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