

# Identifying Legal Requirements that Impact Biorisk Management

## *Student Guide*





## *Identifying Legal Requirements that Impact Biorisk Management*

### *Welcome and Introductions*

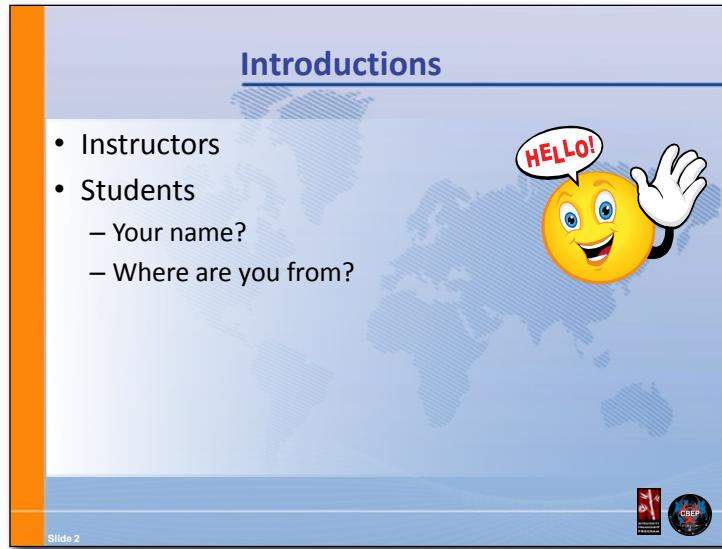
Welcome to Identifying Legal Requirements that Impact Biorisk Management





## *Identifying Legal Requirements that Impact Biorisk Management*

### *Welcome & Introductions*

A slide titled "Introductions" with a blue header and a world map background. It contains a list of questions for the audience and a cartoon emoji waving with a speech bubble that says "HELLO!".

**Introductions**

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

HELLO!

Slide 2



# Action Plan

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

| KNOW | FEEL | BE ABLE<br>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? |
|------------------------------------|---|--------------------------------------|---|
|                                    |   |                                      |   |
|                                    |   |                                      |   |
|                                    |   |                                      |   |

Slide 3

Use space on back, if needed





# *Identifying Legal Requirements that Impact Biorisk Management*

## *Key Messages*

## Notes:

## Key Messages

- Legal requirements derive from a variety of sources and cover a variety of aspects of biorisk management
- A best practice to determine alignment with legal requirements is to conduct a gap analysis
- Legal requirements are not the only drivers for biorisk management.





# *Identifying Legal Requirements that Impact Biorisk Management*

*Biorisk Management*

# Biorisk Management: the **AMP** Model



**Biorisk Management =  
Assessment, Mitigation, Performance**

## Record refresher notes on the AMP model and biorisk management.



# *Identifying Legal Requirements that Impact Biorisk Management*

*Biorisk Management*

# Key Components of Biorisk Management

## Define Biorisk Assessment:



## *Identifying Legal Requirements that Impact Biorisk Management*

### **Biorisk Management**

**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



Slide 7

Define Biorisk Mitigation:



## *Identifying Legal Requirements that Impact Biorisk Management*

### *Sources of Legal Requirements*

**Sources of Legal Requirements**

**Group Activity Step 1:**

**In your groups**, please spend **5 minutes** to think about the privilege of driving a car. **List** all the **regulations** and **requirements** involved with driving.

**Write** each item on an individual **sticky-note** and post them on your flip-chart.



Side 5

What are some Regulations and requirements involved with driving a car?



## *Identifying Legal Requirements that Impact Biorisk Management*

### *Sources of Legal Requirements*

What categories did the regulations and requirements fall into?

**Sources of Legal Requirements**

**Group Activity Step 2:**

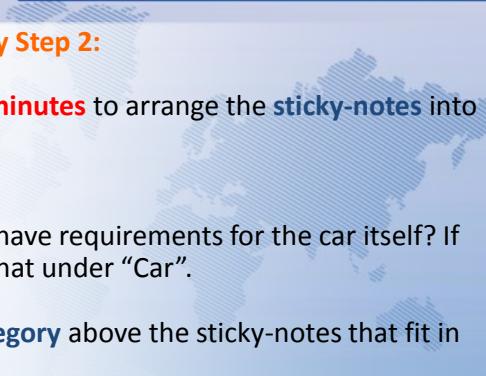
Take **5 more minutes** to arrange the **sticky-notes** into **categories**.

**For Example:**

- Do you have requirements for the car itself? If so, list that under "Car".

**Write the category** above the sticky-notes that fit in that category.

Slide 6

A stylized graphic of a world map with a blue and white color scheme, appearing as a watermark or background for the slide.



## *Identifying Legal Requirements that Impact Biorisk Management*

### *Sources of Legal Requirements*

Are there others?

**Suggested Answers . . .**

- Car Design:
  - Design Standards
  - Fuel Efficiency
  - Emission Controls
  - Crash “Resistance” Standards
  - Other Safety Standards
- Car Use:
  - Registration with local gov’t
  - Emissions Testing
  - Inspection
  - Parking Permits
- Fuel:
  - Production
  - Composition
  - Distribution Centers
  - Safety
- Driver:
  - Age
  - Vision
  - Physical Capability
  - Training
  - Examinations – written and hands-on
  - License
- Car maintenance
  - Diversity of standards and specifications
  - Training of maintenance workers
- Road:
  - Speed
  - Signals
  - Signs

Slide 7



## *Identifying Legal Requirements that Impact Biorisk Management*

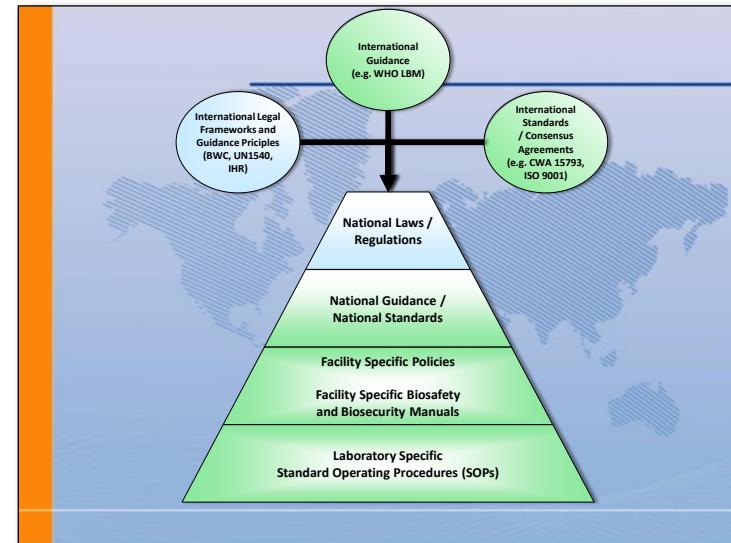
### *Sources of Legal Requirements*

#### **Sources of Legal Requirements**

Compare the categories of driving requirements to those of biorisk management:

- Car design = Lab & equipment design
- Car use = Lab & equipment operation
- Fuel = Laboratory materials – agents, reagents, specimens
- Driver = Lab worker (among other roles)
- Maintenance = Maintenance procedures and staff
- Road = Laboratory mission, deliverables

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## *Identifying Legal Requirements that Impact Biorisk Management*

**Legal Requirements impacting Biorisk Management**

**Discussion:**  
What are the legal requirements that impact these categories of biorisk management?

- Lab & equipment design
- Lab & equipment operation
- Laboratory mission, deliverables
- Lab worker
- Laboratory materials – agents, reagents

Slide 10

The logo for the Center for Biodefense and Emerging Pathogens (CBEP) is located in the bottom right corner of the slide.

## ***Legal Requirements and Biorisk Management***

What are the legal requirements that impact these categories of biorisk management?

Lab & Equipment Design:

Lab & Equipment Operation:

Laboratory Mission, Deliverables:

Lab Worker:

Laboratory Materials – Agents, Reagents:



# Legal Requirements impacting Biorisk Management

|                           | Int'l Guidance | Int'l Legal Frameworks | Int'l Standards | Nat'l Laws & Regulations | Nat'l Guidance & Standards | Provincial or Local Requirements |
|---------------------------|----------------|------------------------|-----------------|--------------------------|----------------------------|----------------------------------|
| Lab & Equipment Design    |                |                        |                 |                          |                            |                                  |
| Lab & Equipment Operation |                |                        |                 |                          |                            |                                  |
| Mission                   |                |                        |                 |                          |                            |                                  |
| Worker                    |                |                        |                 |                          |                            |                                  |
| Materials                 |                |                        |                 |                          |                            |                                  |
| Maintenance               |                |                        |                 |                          |                            |                                  |

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## Identifying Legal Requirements that Impact Biorisk Management

### Gap Analysis

#### Gap Analysis

A simple tool for checking compliance (or lack thereof) with legal requirements

Routine use of the same tool can serve as a performance indicator

In some cases, regulatory bodies provide checklists to use to determine compliance



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#### Gap Analysis Example

| Domain               | Subdomain            | Question  | Identify              | Follow                | No                    | Needs work            | Neutral               | Mostly in place       | Yes                   |
|----------------------|----------------------|---|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Operational Controls | Facility             | Is your workplace designed in a way that allows you to work safely and securely?  | <input type="radio"/> |
|                      | Engineering Controls | Is the equipment you work with reliable and safe?   | <input type="radio"/> |
|                      |                      | Do you work with equipment that is designed specifically to keep you safe?  | <input type="radio"/> |
|                      |                      | Is the equipment you work with maintained regularly and as necessary?   | <input type="radio"/> |
|                      |                      | Are you adequately trained to work with the equipment in your workplace?  | <input type="radio"/> |
| Work Practices/SOPs  |                      | Are there written procedures for conducting your work?  | <input type="radio"/> |
|                      |                      | Have you received adequate training on the procedures necessary to conduct your work?                                       | <input type="radio"/> |
|                      | PPE                  | Is personal protective equipment (PPE: gloves, gowns, head covers, eye protection, etc.) required for your work procedures? | <input type="radio"/> |
|                      |                      | Is adequate PPE available for you to perform your work safely and securely?   | <input type="radio"/> |
|                      |                      | Have you been provided adequate training in how to use PPE in your work?  | <input type="radio"/> |
|                      |                      | Is PPE available to you in sizes and configurations that are comfortable and fairly easy to use?                            | <input type="radio"/> |

Slide 13





## *Identifying Legal Requirements that Impact Biorisk Management*

## *Legal Requirements and Biorisk Management*

What happens when regulations are not in place?



**Regulation Isn't Everything!**

Legal requirements must be followed.

In combination with or in the absence of legal requirements, the **principles of biorisk management** must also apply.

**The lack of a regulation is not an excuse for the lack of biorisk management awareness and practice.**

Slide 14

The slide features a blue background with a world map. A vertical orange bar on the left contains the title and first two bullet points. The third bullet point is in red. A black square icon with a white scroll and the word "LAW" is in the center. Two small circular logos are at the bottom.



## *Identifying Legal Requirements that Impact Biorisk Management*

## *Review*

## Review of Legal Requirements

## Review: