

# Identifying Legal Requirements that Impact Biorisk Management

SAND2012-4777P

## *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*

### Introductions

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



Slide 2


# 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



## *Identifying Legal Requirements that Impact Biorisk Management*

### *Key Messages*

Notes:

### Key Messages

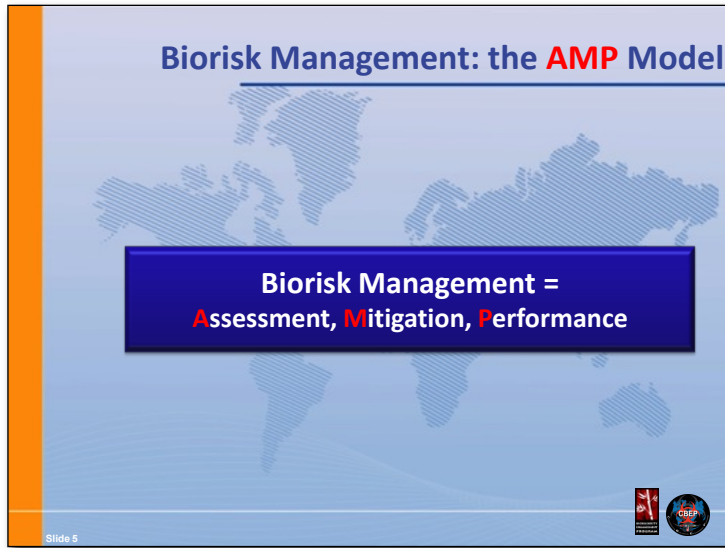
- Legal requirements derive from a variety of sources and cover a variety of aspects of biorisk management
- A best practice to determine alignment with legal requirements is to conduct a gap analysis
- Legal requirements are not the only drivers for biorisk management.

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## *Identifying Legal Requirements that Impact Biorisk Management*

## *Biorisk Management*



Record refresher notes on the AMP model and biorisk management.




## *Identifying Legal Requirements that Impact Biorisk Management*

## *Biorisk Management*

**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

Slide 6

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

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CBEP

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.



Slide 5

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

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## 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.

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## *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

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## Identifying Legal Requirements that Impact Biorisk Management

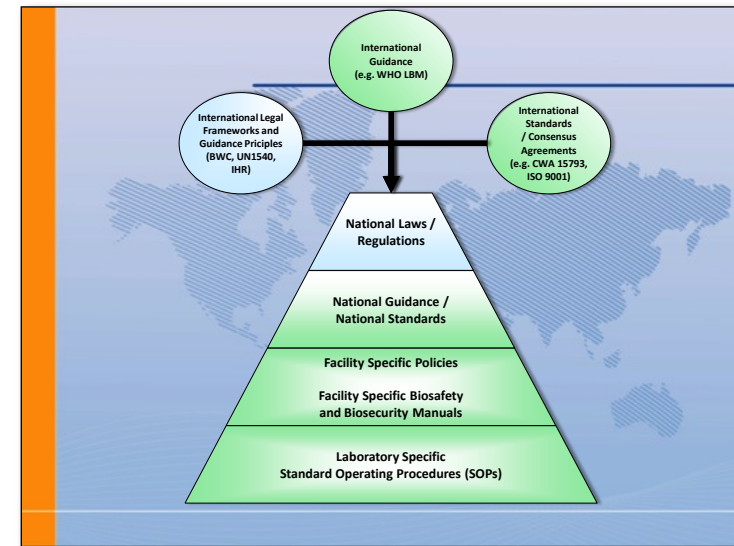
## Sources of Legal Requirements

### 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

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## *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

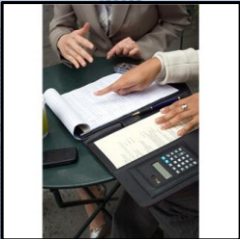
## Gap Analysis

### 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	Don't know	No	Mostly work	Mostly not	Mostly work	Yes
Operational Controls	Facility	Is your workplace designed in a way that allows you to work safely and securely?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Engineering Controls	Is the equipment you work with reliable and safe?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
		Do you work with equipment that is designed specifically to keep you safe?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
		Is the equipment you work with maintained regularly and as necessary?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
		Are you adequately trained to work with the equipment in your workplace?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Work Practices/SOPs		Are there written procedures for conducting your work?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
		Have you received adequate training on the procedures necessary to conduct your work?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
PPE		Is personal protective equipment (PPE: gloves, gowns, head covers, eye protection, etc.) required for your work procedures?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
		Is adequate PPE available for you to perform your work safely and securely?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
		Have you been provided adequate training in how to use PPE in your work?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
		Is PPE available to you in sizes and configurations that are comfortable and fairly easy to use?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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## *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.**

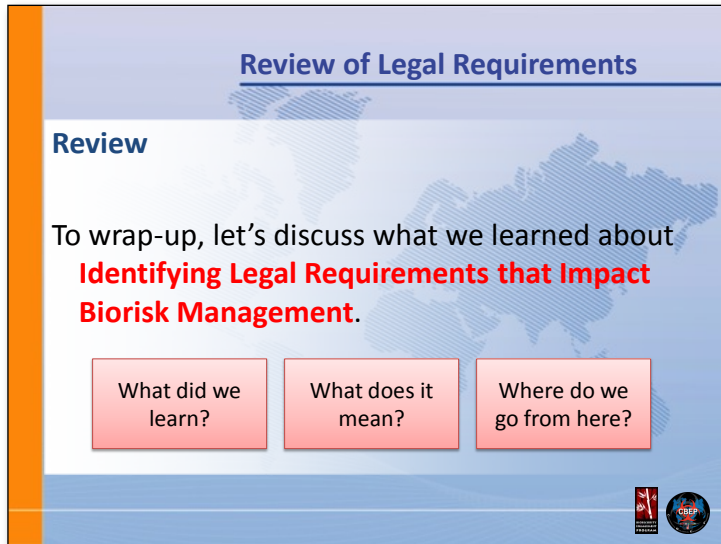


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## *Identifying Legal Requirements that Impact Biorisk Management*

*Review*

Review:



The slide is titled "Review of Legal Requirements" in blue text at the top. Below the title, the word "Review" is written in blue. The main text says "To wrap-up, let's discuss what we learned about **Identifying Legal Requirements that Impact Biorisk Management.**" in black and red. At the bottom, there are three red boxes with white text: "What did we learn?", "What does it mean?", and "Where do we go from here?". In the bottom right corner, there are two small logos: a red one with a white 'S' and a blue one with the letters 'CBEP'.
