



Identifying Legal Requirements that Impact Biorisk Management

Student Guide




GLOBAL BIORISK MANAGEMENT CURRICULUM

Identifying Legal Requirements that Impact Biorisk Management

Welcome and Introductions




Welcome to Identifying Legal Requirements that Impact Biorisk Management



Introductions

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



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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?

Use space on back, if needed



Key Messages

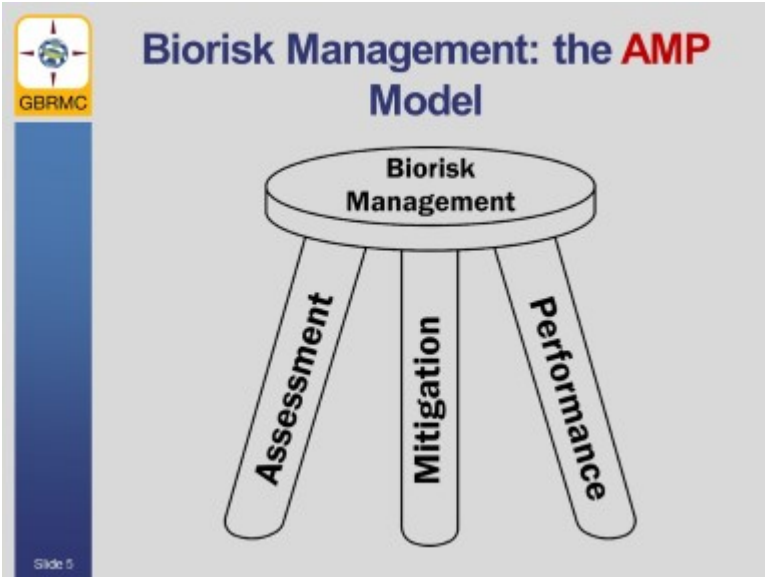
- Legal requirements derive from a variety of sources and cover a variety of aspects of biorisk management
- A best practice to determine alignment with legal requirements is to conduct a gap analysis
- Legal requirements are not the only drivers for biorisk management.

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Notes:

Identifying Legal Requirements that Impact Biorisk Management

Biorisk Management



Record refresher notes on the AMP model and 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



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Define Biorisk Assessment:



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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Define Biorisk Mitigation:



Key Components of Biorisk Management

- **Biorisk Performance**
 - The recording and evaluation of measurements to provide evidence that an organization is reliably and continuously conducting accurate biorisk assessments and implementing biorisk mitigation strategies that effectively reduce or eliminate identified biorisks to an acceptable degree.




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Define Performance:

Identifying Legal Requirements that Impact Biorisk Management


Sources of Legal Requirements



Sources of Legal Requirements

Group Exercise 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**.

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

Identifying Legal Requirements that Impact Biorisk Management

Sources of Legal Requirements



Sources of Legal Requirements

Group Exercise 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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What categories did the regulations and requirements fall into?

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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

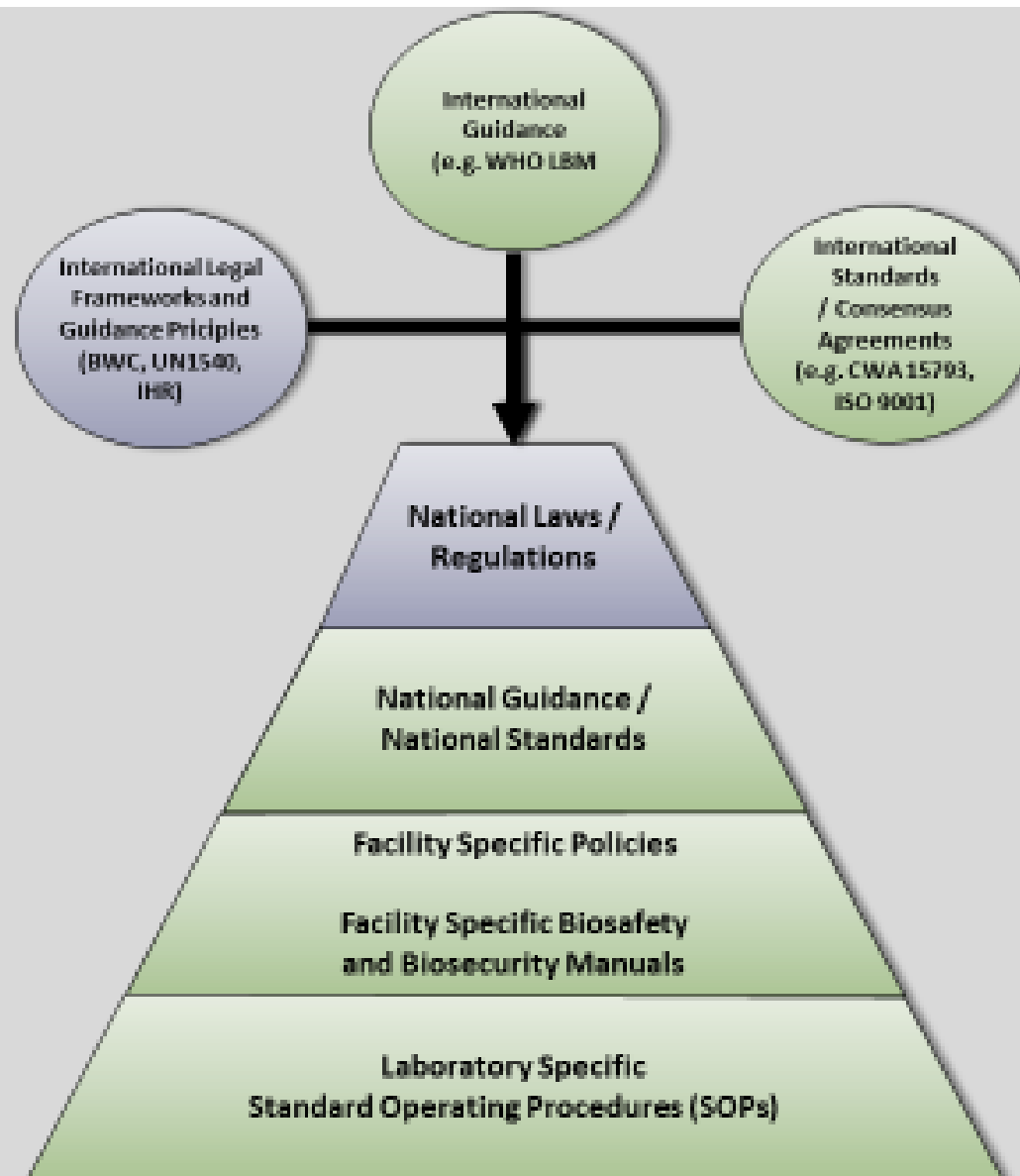


Sources of Legal Requirements

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 and 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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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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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	I don't know	No	Needs work	Neutral	Mostly in place	Yes
Operational Controls	<i>Facility</i>	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"/>
	<i>Engineering Controls</i>	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"/>
	<i>Work Practices/SOPs</i>	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"/>
	<i>PPE</i>	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"/>

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:

Review of Legal Requirements

To wrap-up, let's discuss what we learned about **Identifying Legal Requirements that Impact Biorisk Management**.

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

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Identifying Legal Requirements that Impact Biorisk Management

Review

Action Plan

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