



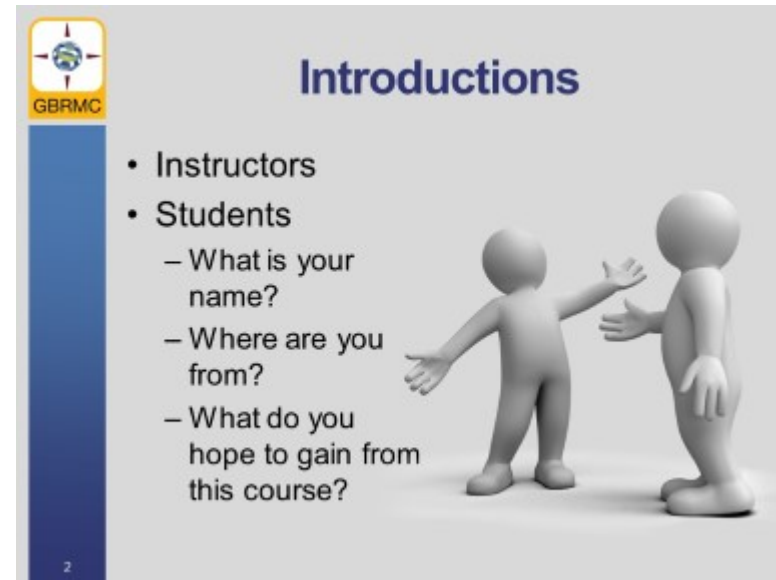
Orientation to Biorisk Management

Student Guide

2014



GLOBAL BIORISK MANAGEMENT CURRICULUM



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?		

Use space on back, if needed



Key Messages

- "Biosafety", "biosecurity", "biorisk", and "biorisk management system" are common biorisk terms that relate to and support each other.
- AMP (Assessment, Mitigation, and Performance) is a simple but powerful model for managing biorisks.
- Implementing a comprehensive biorisk management system is critical to reduce both the safety and security risks associated with biological agents.
- Some key factors for establishing and implementing a successful biorisk management system include commitment by top management and a focus on continual improvement.
- CWA 15793 is a comprehensive framework for managing biorisks developed through international collaboration.

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Working with Biological Materials

Group Exercise


In your group, discuss and answer the following two questions:

1. What are the **risks** when working with biological materials?
2. **Where** does work with biological materials occur?



Take **10 minutes** and write down your answers; be prepared to share your answers with the class.



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 **Definitions**

- **Laboratory biosafety:** containment principles, technologies, and practices implemented to prevent **unintentional** exposure to pathogens and toxins, or their unintentional release¹
- **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** release²

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


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 **Biosafety and Biosecurity**

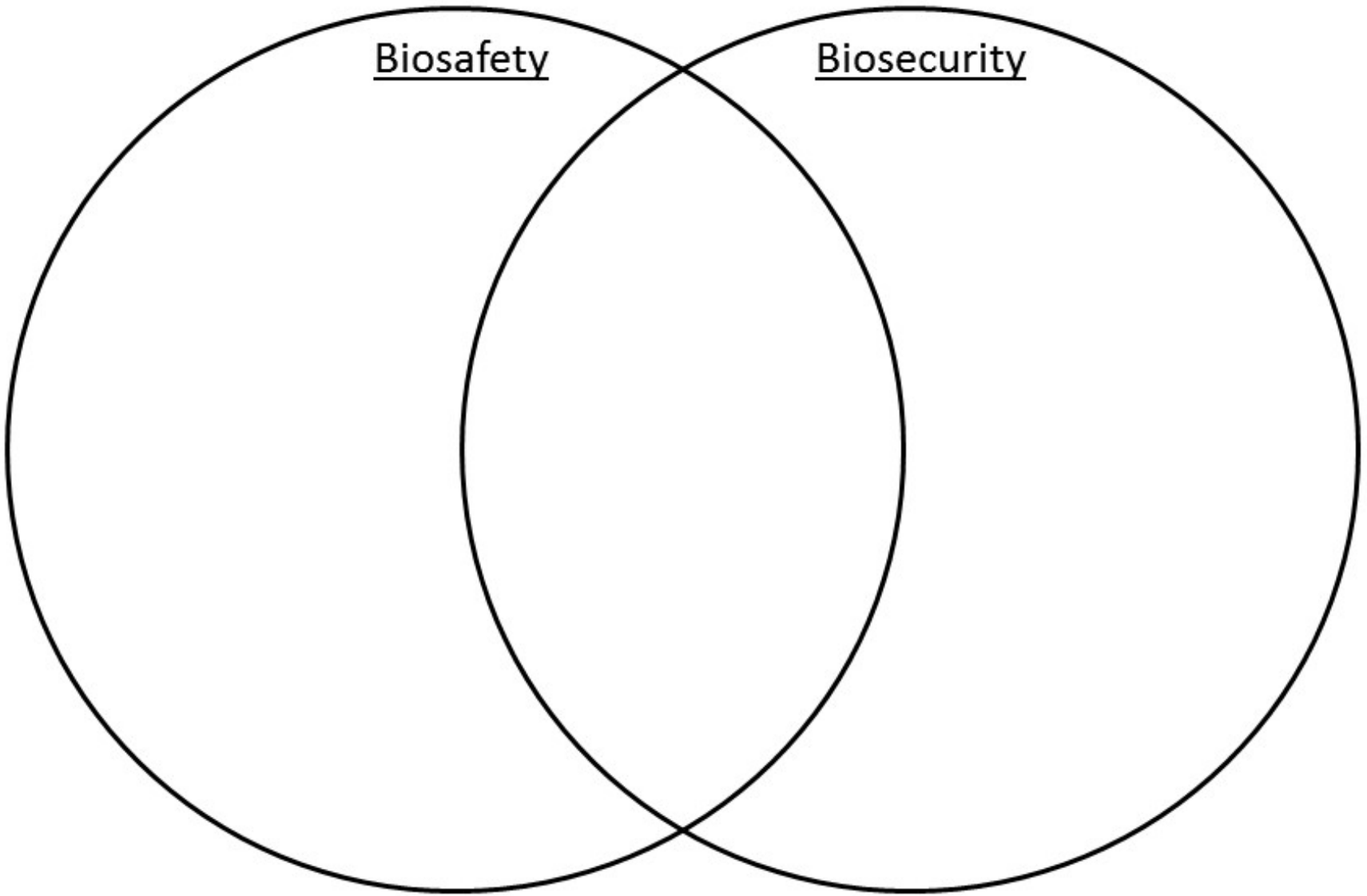
Group Exercise
In your group, discuss and answer the following questions:

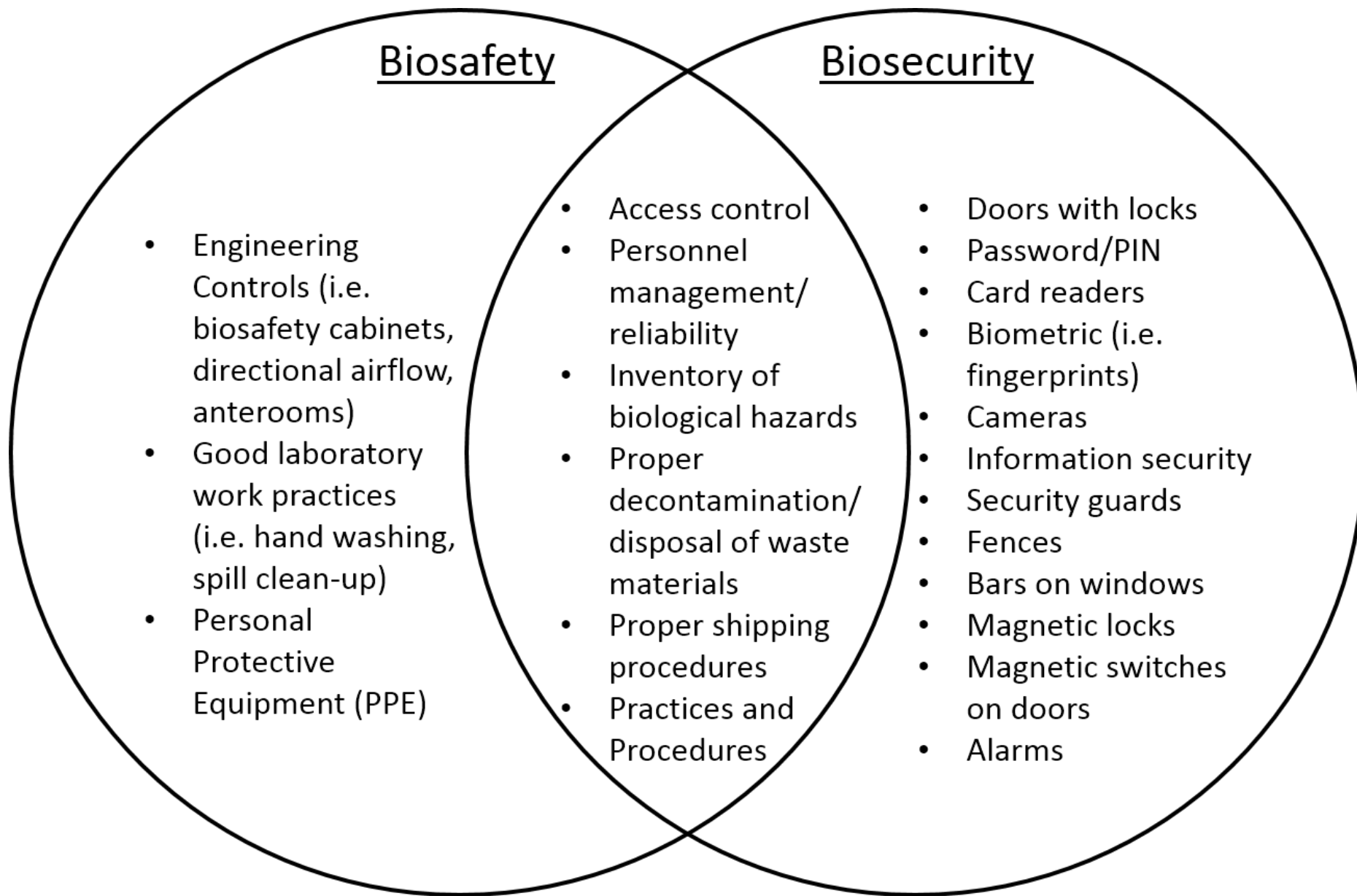
1. What is one example of a **biosafety measure**?
2. What is one example of a **biosecurity measure**?

Take **5 minutes** and write down your answers on **sticky notes**, one idea per note. Be prepared to share your answers with the class.



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What is Biorisk?

Risk associated with biological materials

Biorisk = Biosafety + Biosecurity Risks

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Risks: Step 1

Group Exercise

In your group, discuss and answer the following three questions:

1. How do you **identify** biorisks?
2. What are some things you can do to **manage** these risks?
3. How do you know that your risk management is **working**, and will continue to work?

Take **10 minutes** and write down your answers on **sticky notes**, one idea per note.

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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



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Define 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 Mitigation:



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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Define Performance:



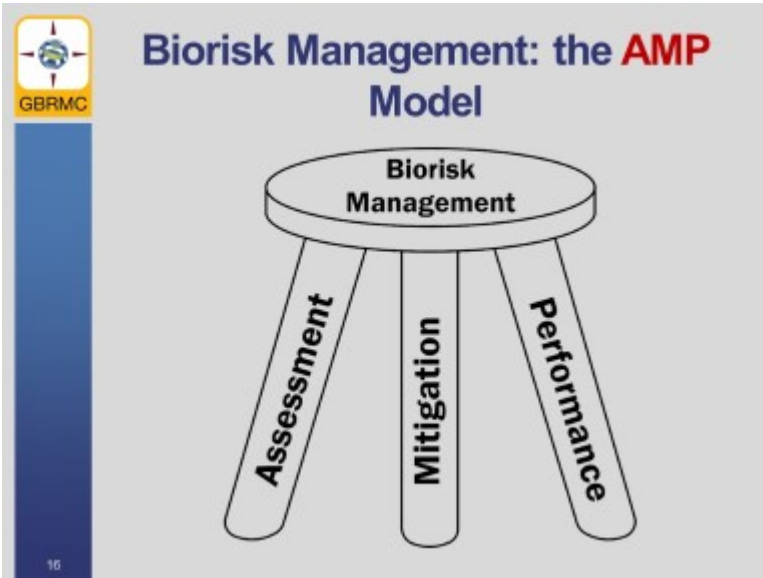
Risks: Step 2

Group Exercise

Let's get organized. Take the **sticky notes**, and place them under the **appropriate category**:

Assessment	Mitigation	Performance
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Review the AMP Model for Biorisk Management:



Management System

A management system is a set of interrelated elements used to establish policy and objectives and to achieve those objectives.¹

Group Exercise:

In your group, discuss and answer the following question:


What results would you expect in a situation with a **good management** system in place versus **no management** system at all?

Take **10 minutes** and write down your answers; be prepared to share your answers with the class.

¹CWA 15793 – Laboratory biorisk management (GEN, 2011)


Important Elements of a Management System






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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CWA 15793 – Laboratory Biorisk Management

- Comprehensive **framework** for a biosafety & biosecurity (biorisk) program
- Based on a management systems approach
- Designed for **all** laboratories that handle biological materials
- **Freely available** on the CEN website:
ftp://ftp.cenorm.be/CEN/Sectors/TCandWorkshops/Workshops/CWA15793_September2011.pdf


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 **CWA 15793 – International Approach**

- Derived from the current **WHO Biosafety and Biosecurity Guidelines**
- Consistent with other international standards such as
 - ISO 9001/14001 and OSHAS18001
- **Not country specific**
 - **Local solutions possible**
 - Compliance with national and local regulations mandatory



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 **CWA 15793 – Major Sections**

4.1 General Requirements	4.2 Policy
4.3 Planning	4.4 Implementation and Operation
4.5 Checking and Corrective Action	4.6 Review

- **Assessment**
 - Hazard Identification
 - Risk Assessment
- **Mitigation**
 - Good microbiological technique
 - Waste management
 - Physical security
- **Performance**
 - Performance measurement and analysis of data
 - Management review

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CWA 15793 is Performance-Oriented

- Describes **what** needs to be achieved
- Allows **organizations** to determine how best to achieve those objectives
- **Not** a technical document
- Example:

4.4.4.5.3 Waste Management
The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins



Biorisk Management

Group Exercise: Step 1

Individually, carefully read the exercise.

Split into groups:

- **Identify problems with Biorisk Management.** These problems could be associated with assessment, mitigation, or performance.
- Use **sticky notes**, one for each problem. Place the post-it notes on your flip chart.
- Discuss how these problems affected the institution.

Share your results with the class.



Biorisk Management

Group Exercise: Step 2

Choose **one** biorisk management **problem** from the previous exercise:

- Identify the **specific paragraphs** in **CWA 15793** that apply to this problem. Is the organization in **conformance** with **CWA 15793**?
- **Recommend specific changes** in biorisk management that the leadership can implement to address this problem.

Record your conclusions on a **flip chart**.

Share your results with the class.



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CWA 15793 – Implementation

How to implement CWA 15793?
How would you eat a dinosaur?



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CWA 15793 – Implementation

How to implement CWA 15793?
One bite at a time



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Biorisk Management

Discussion:

Process for the implementation of a biorisk management system

1. What needs to be in place before starting?
2. Where would you start?
3. Are there past experiences that may provide guidance?

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Individual Reflection

If you could make **three changes** to the management system at your facility today, what would be your **top three priorities**?

- 1.?
- 2.?
- 3.?



Biorisk Management System

Group Exercise

In your group, discuss and answer the following question:

What are the key challenges or factors to consider in establishing and implementing a biorisk management system?



Take **5 minutes** and write down at least 3 – 5 factors; be prepared to share your answers with the class.




Review

For **10 minutes**, let's discuss what we have learned about **biorisk management**.

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

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