

Egyptian Biosafety Association

January 2013



A world map rendered in a light blue color with a diagonal line pattern. The map is centered on the Atlantic Ocean. In the bottom left corner, there are several thin, white, curved lines that resemble a stylized globe or a network of connections.

Biorisk Management: An Overview

Presentation Outline

- **The Concept of Biorisk**
- **The “AMP” Model for Biorisk Management**
- **Biosafety and Biosecurity**
- **Biorisk Management Systems and CWA 15793**

Biorisk

- The risk associated with biological materials in the laboratory
- Biorisk encompasses biosafety and biosecurity

Spectrum of Biorisks

**Accidental
exposure**

**Accidental
loss or
release**

Negligence

**Theft or
Diversion**

**Intentional
unauthorized
release**



Important Questions for Your Lab

How do you identify biological risks?

What are some things you can do to manage these risks?

How do you know that your risk management is working, and will continue to work?



Biorisk Management: The **AMP** Model

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

Key Components of Biorisk Management

How do you identify biological risks?

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



Key Components of Biorisk Management

What are some things you can do to manage these risks?

Biorisk Mitigation

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



Key Components of Biorisk Management

How do you know that your risk management is working, and will continue to work?

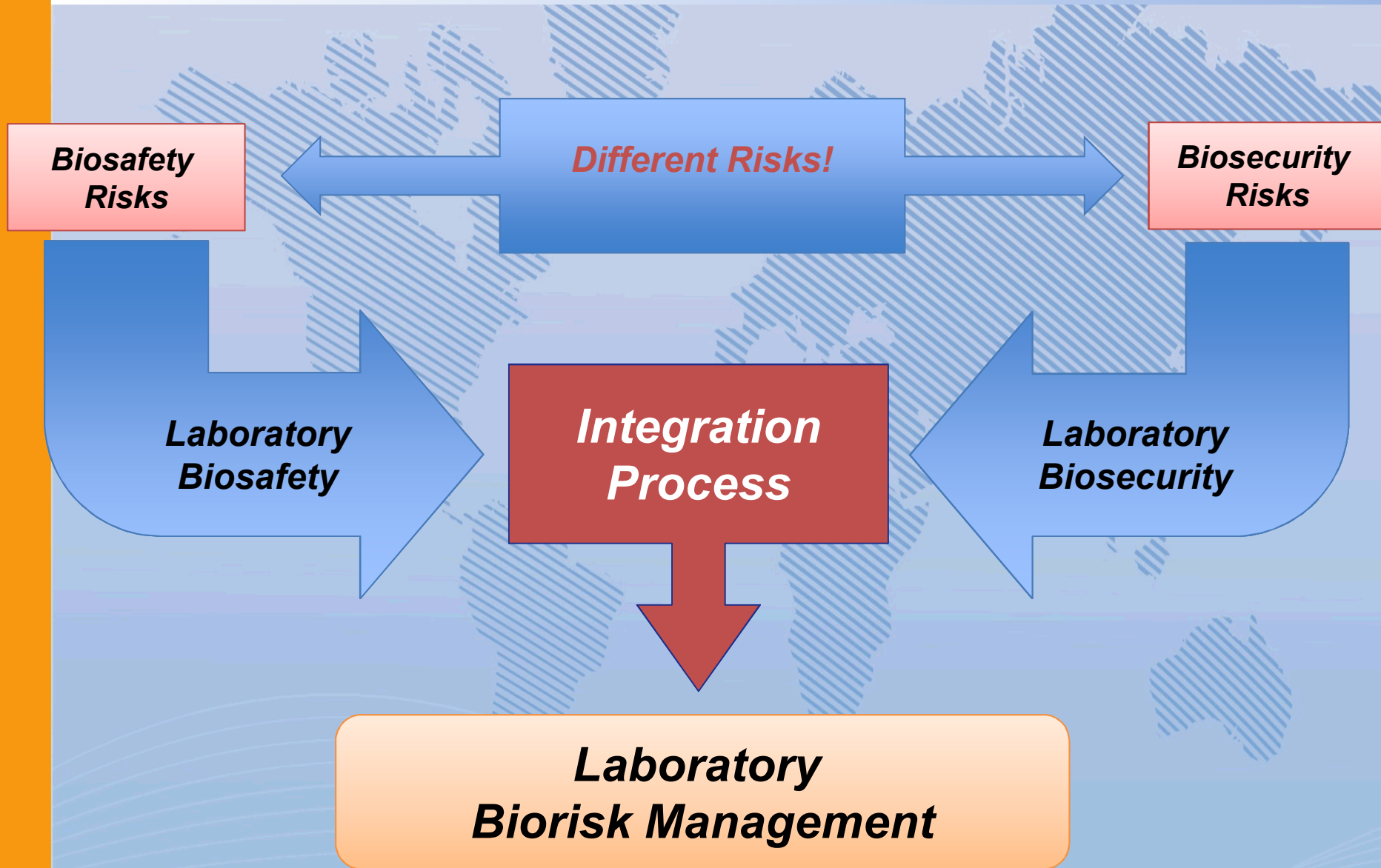
Performance

- The implementation of the entire biorisk management system, including evaluating and ensuring that the system is working the way it was designed. Another aspect of performance is the process of continually improving the system.

Biorisk Management: The **AMP** Model

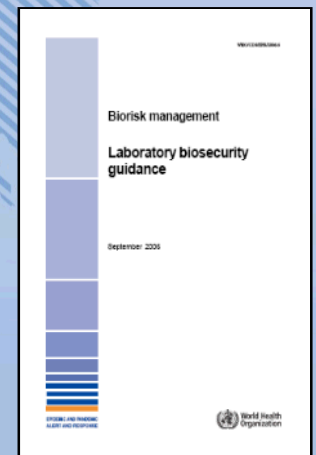
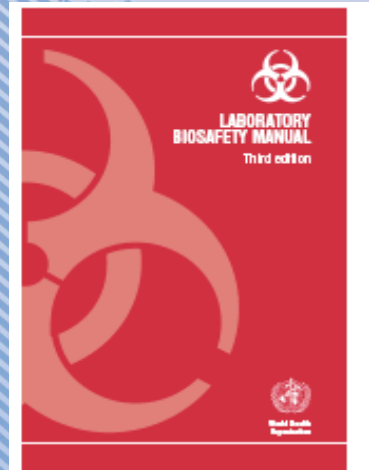
**Biorisk Management =
Assessment, Mitigation, Performance**

Lab Biosafety and Biosecurity Integration



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 release.²

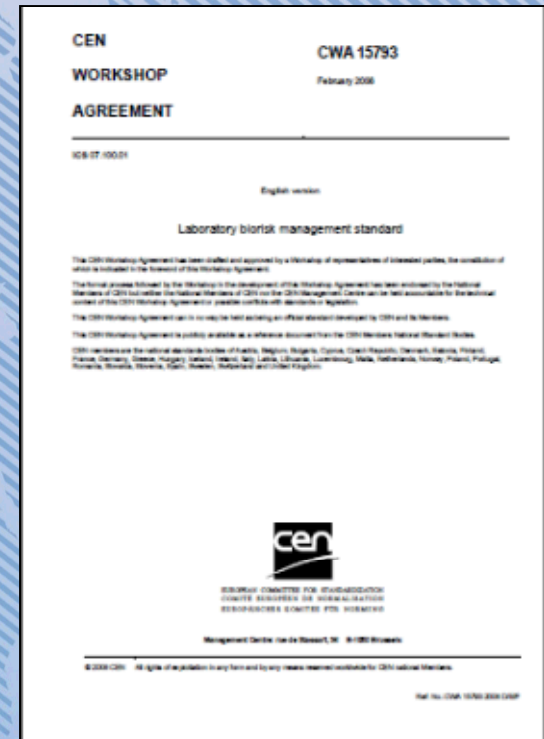


¹Laboratory biosafety manual, Third edition (World Health Organization, 2004)

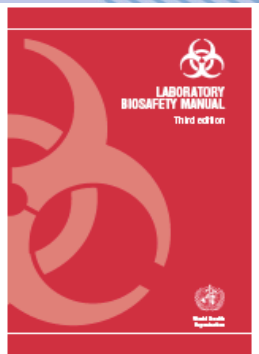
² Biorisk management - Laboratory biosecurity guidance (World Health Organization, 2006)

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

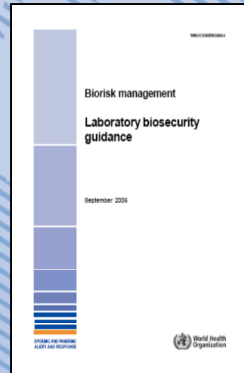


Selected Key International Documents



2004 –
WHO LBM,
3rd Edition
(WHO)

2006 –
Biorisk
Management:
Laboratory
Biosecurity
Guidance
(WHO/FAO/OIE)



2008 –
CWA 15793:2008
– Laboratory
biorisk
management
standard (CEN)

2010 –
Laboratory
biorisk
management for
laboratories
handling
pandemic
influenza A
(H1N1) 2009
virus (WHO)

2011 –
CWA
16335:2011 –
Biosafety
Professional
Competence
(CEN)

2012 –
CWA
16393: 2012 –
Guidelines for
Implementation
of CWA 15793



Technical guidance

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

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



International Approach

- Extensive definition section
- Not country specific
- Based on international, acceptable best practices
- Local solutions possible
- Derived from the current WHO Biosafety and Biosecurity Guidelines



Review of Biorisk Management

- Biorisk Management = Biosafety + Biosecurity
- **Biorisk Management System** is a means to reduce Biorisk
- AMP = Assessment, Mitigation, Performance
- CWA 15793 outlines a comprehensive, international biorisk management system framework