



Recent Developments in International Laboratory Biorisk Management

Pakistan – U.S. Bioengagement Workshop
Istanbul, Turkey

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www.biosecurity.sandia.gov

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The Concept of Biorisk

“combination of the probability of occurrence of harm and the severity of that harm where the source of harm is a biological agent or toxin.”
- CWA 15793:2008

Accidental exposure

Accidental loss or release

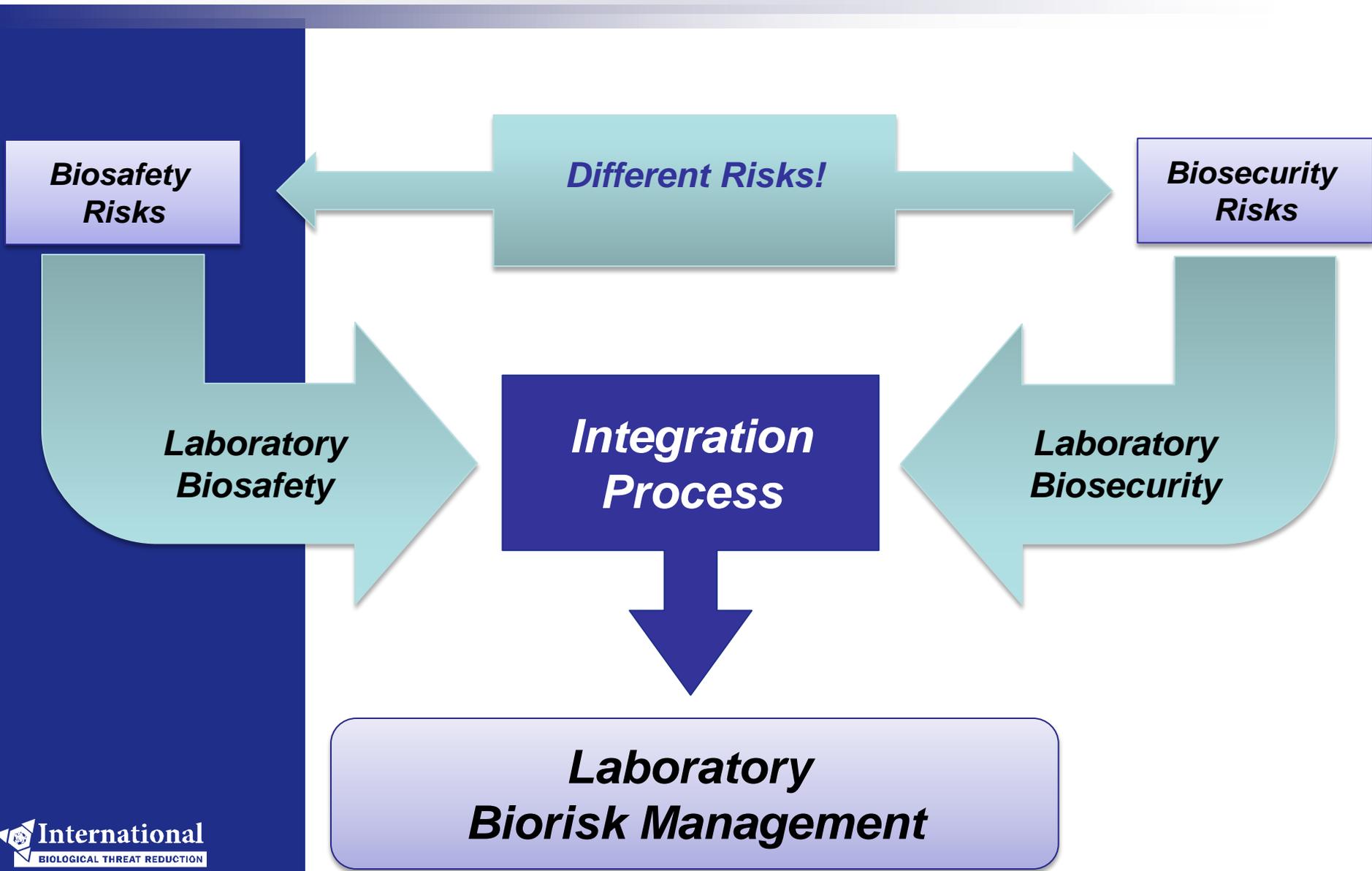
Negligence

Theft or Diversion

Intentional unauthorized release



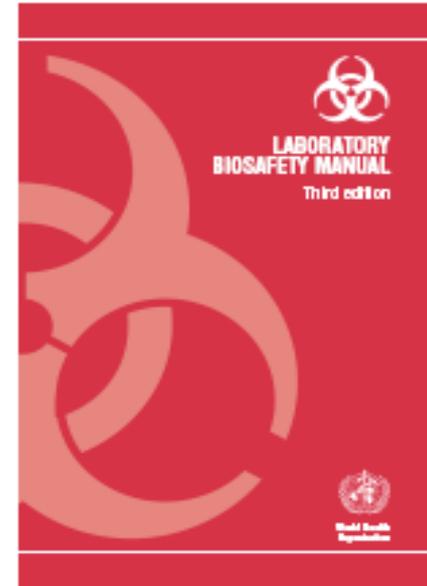
Lab Biosafety and Biosecurity Integration





Key Definitions¹

- **Laboratory biosafety:**
 - “containment principles, technologies, and practices implemented to prevent **unintentional exposure** to pathogens and toxins, or their accidental release.”
- **Laboratory biosecurity:**
 - “institutional and personal security measures designed to prevent the **loss, theft, misuse, diversion, or intentional release** of pathogens and toxins.”

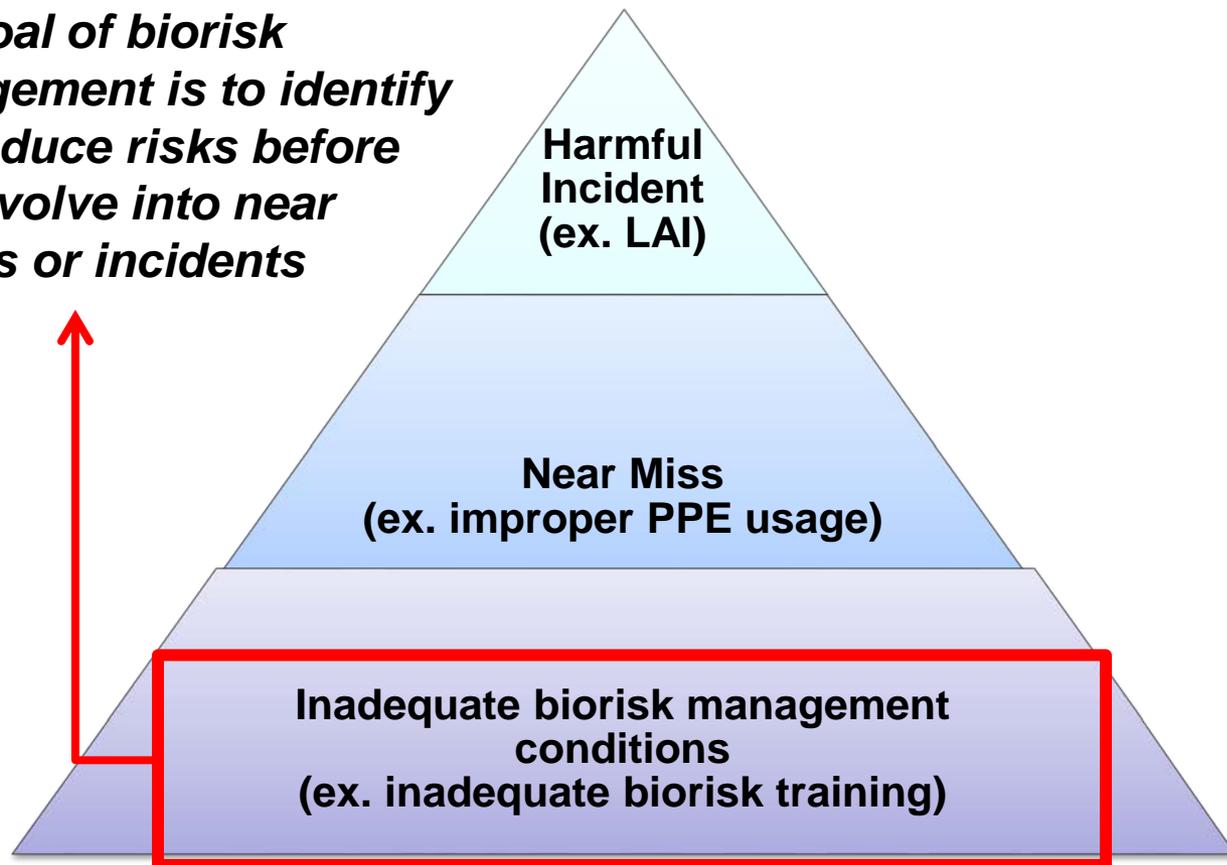


¹Laboratory biosafety manual, Third edition (World Health Organization, 2004)



Addressing the Core Biorisk Factors

The goal of biorisk management is to identify and reduce risks before they evolve into near misses or incidents





Laboratory Biorisk Management - Elements

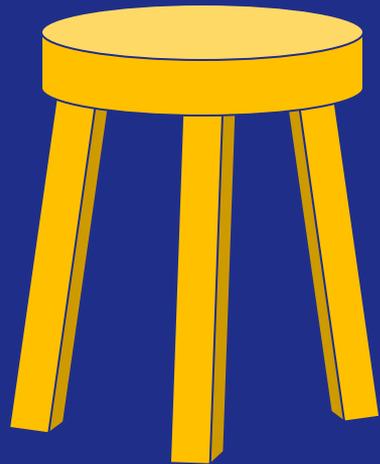
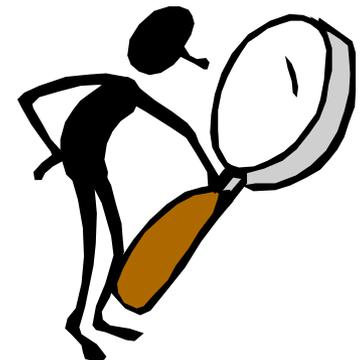
- We can think of laboratory biorisk management as being composed of three elements:

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



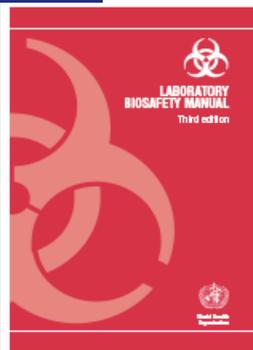
The AMP Model

- **Assessment**
 - A process to **identify** the hazards and **evaluate** the risks associated with biological agents and toxins
- **Mitigation**
 - Actions and control measures that are put into place to **reduce** or **eliminate** the risks
- **Performance**
 - Evaluating and ensuring that the system is working the way it was designed, and identifying opportunities for **system improvement**

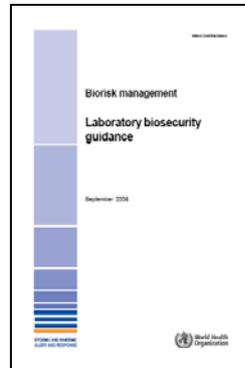




Selected Key International Documents



2004 –
WHO
LBM, 3rd
Edition
(WHO)



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

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



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

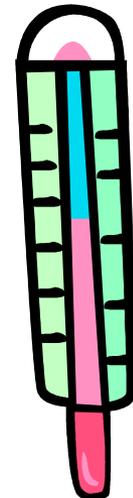
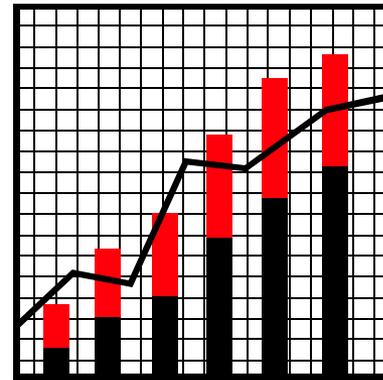
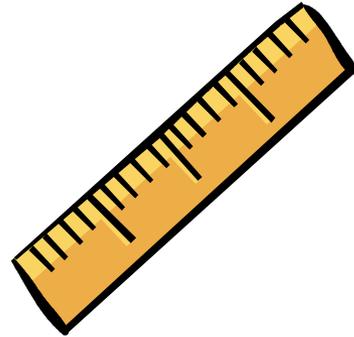
2011 –
CWA
16335:2011 –
Biosafety
Professional
Competence
(CEN)

CEN WS 55 –
CWA 15793
Guidance
Document
(under
development)

Technical guidance



Towards a Biorisk Management Standard...



CWA 15793:2008 - Laboratory Biorisk Management

- **Developed by 76 participants from 24 countries**
- **Is a management system standard consistent with other international standards**
- **The Standard is *performance* oriented**
- **Does not replace national regulations**
- **Designed to be a blueprint for biosafety & biosecurity (biorisk) program**





CWA 15793: An 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**

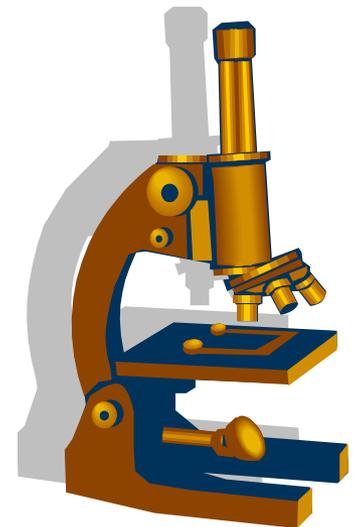




Current Status



- **CWA 15793:2008 published in 2008**
 - Consensus document
 - Valid for **3** years
- **CWA 15793:2011 recently published**
 - Replaces CWA 15793:2008
- **The two standards are identical**
- **Next Steps...**





Uses of CWA 15793:2008

- **CWA 15793 is a Management System Standard that may be used for:**
 - Improving laboratory biorisk management and performance
 - Increasing awareness and the adoption of performance-based approaches for biosafety and biosecurity
 - Effective management of complex laboratory safety and security processes
 - Improving international lab collaboration and safety harmonization
 - Internal/external audits and inspections

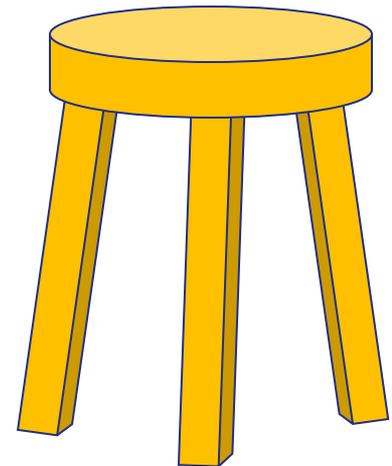




How can CWA 15793:2008 be utilized?

As a basis for:

- Good biosafety and biosecurity practices and guidance
- Regulatory support and basis for new or revised legislation
- Supporting laboratory certification/accreditation
- Training



Continual Improvement – The PDCA Principle

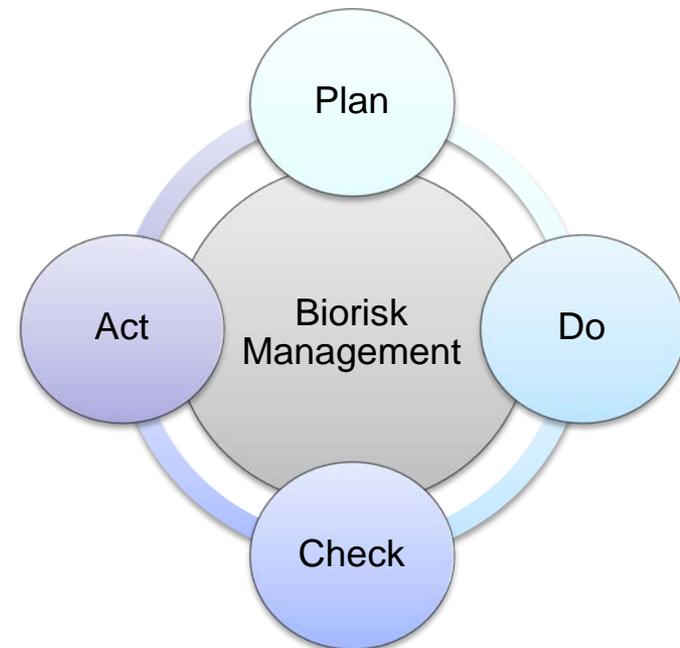
Biorisk management - utilize a “Plan-Do-Check-Act” approach with a goal of continuous improvement

1. Plan

2. Do

3. Check

4. Act





CWA 15793:2008 - Example

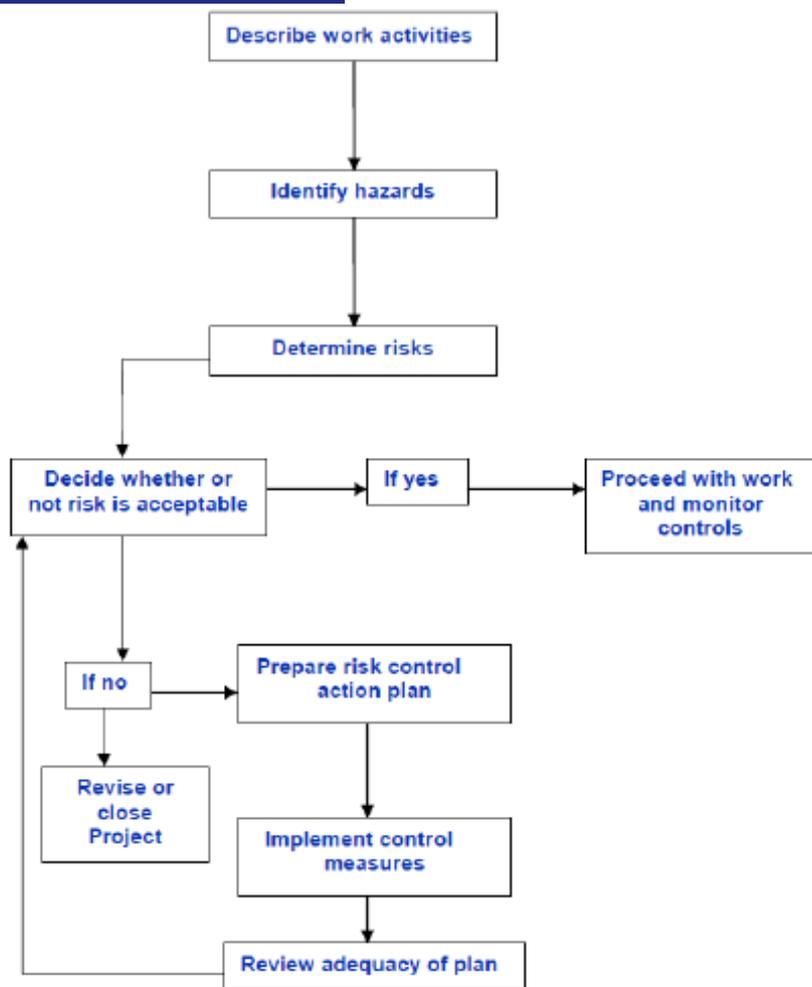


Figure 1 — Risk assessment strategy

- Risk Assessment Strategy

Reminders:

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

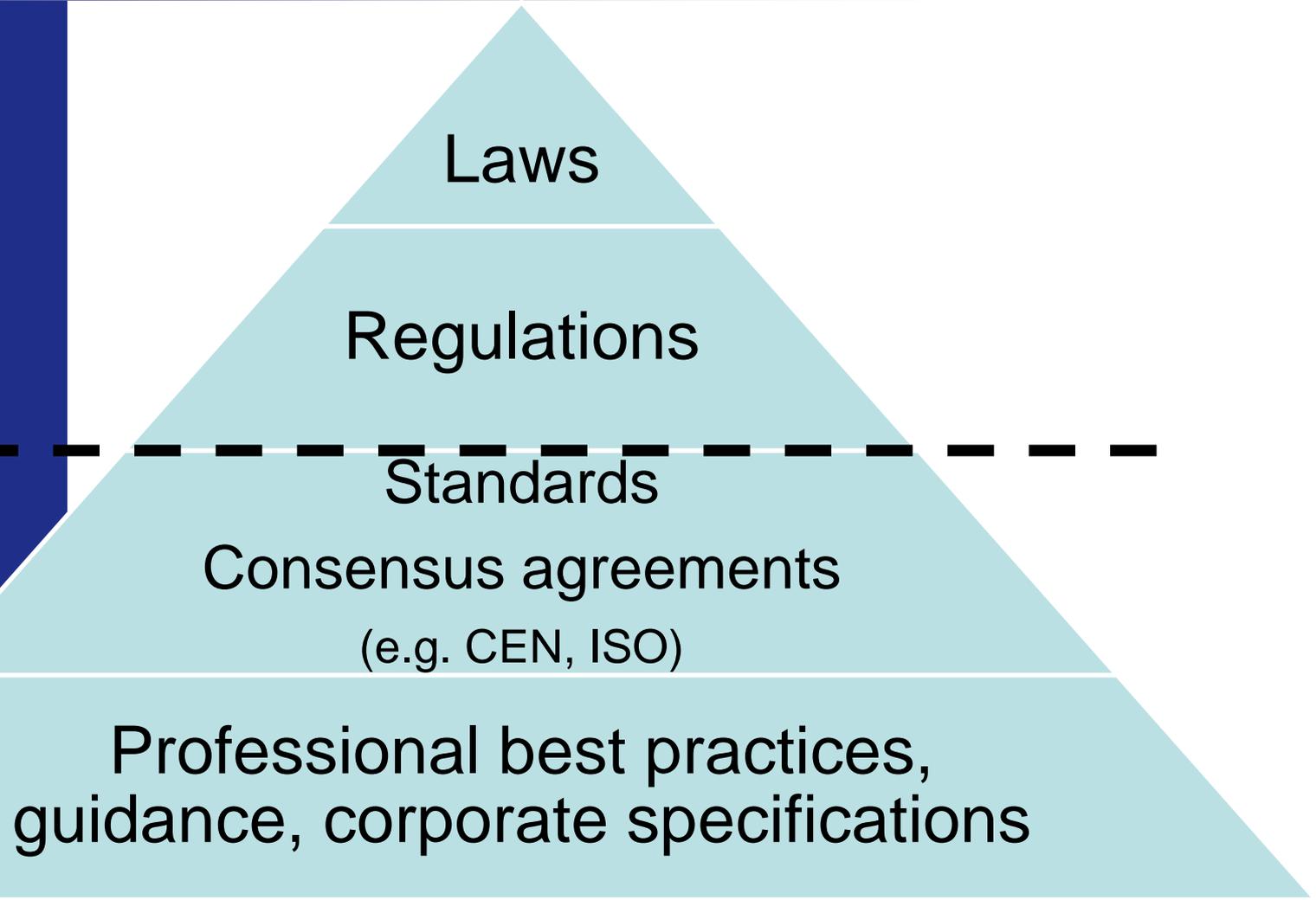


Key Differences

Content & Requirements	CWA 15793	BMBL, LBM etc.
PDCA	yes	no
Management Policy	yes	no
Roles & Responsibilities	yes	minimal
Comprehensive Risk Assessment	yes	minimal
Performance Objectives	yes	none
Performance Measurements (Audits)	yes	Minimal or limited to local regulations
Document Control	yes	Limited to local regulations
Accredited Certification	-	no
Technical Biorisk Details	no	yes



Standards, Regulations, Best Practice



Mandatory

Voluntary



Typical Accredited Certification of Management Systems

ISO

- Makes the rules

International
Accreditation Forum

- Harmonized world-wide interpretation of the rules

Accreditation Body

- Quality control of the checker

Certification Body

- Checks the implementation of the rules

Organization

- Implements the rules



Lab Biorisk Management System – Current Picture

CEN

- Makes the rules (CWA 15793)

- International harmonization?

Accreditation Body

- Example: PNAC

Certification Body

- Self-certification, private consultants

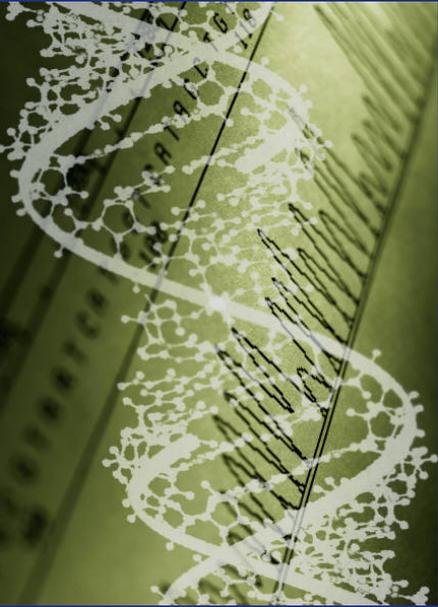
Organization

- Some laboratories beginning to implement CWA



Recent Developments – CEN Workshop 55

- **Guidance Document for CWA 15793:2008**
 - Intended to help users implement CWA 15793
 - Enhance understanding of CWA requirements
- **Kick-off meeting – February 2010 (Brussels)**
 - International effort
- **Early 2011 – Public Comment Period**
- **Final version not yet published**





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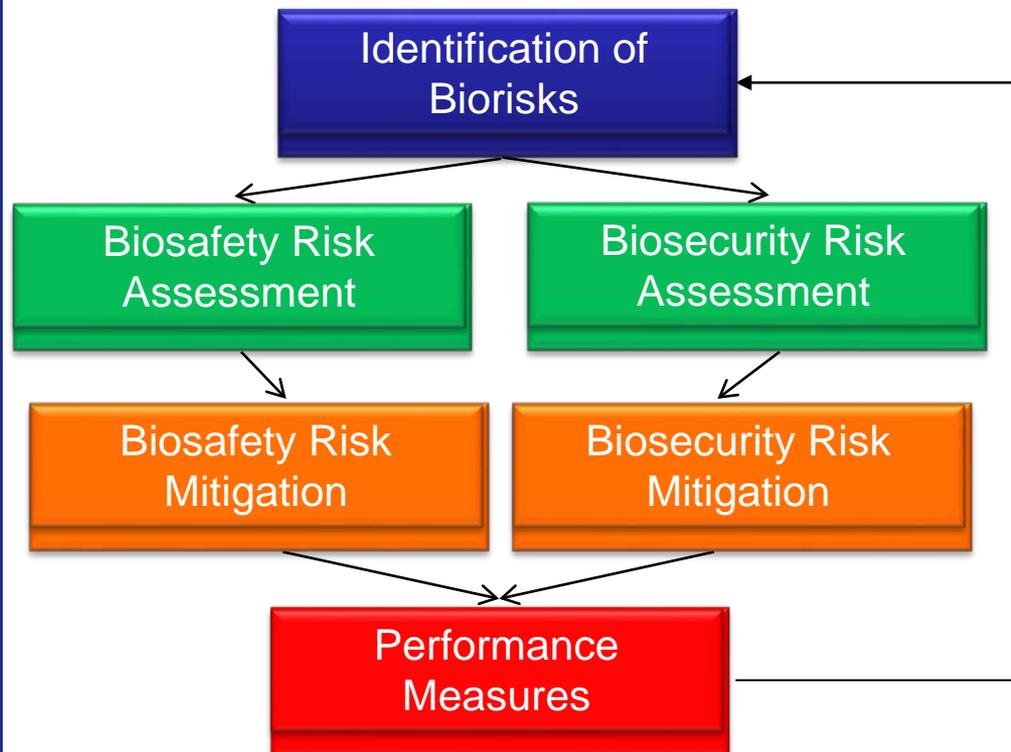
- **Biosafety Professional Competence**
 - Intended to help define the requirements for biosafety professionals
 - **Role**
 - **Knowledge**
 - **Experience**
 - **Tasks**
 - Curriculum development
- **Could serve as a framework for certification programs for BSPs**
- **Public Comment Period**
 - Concluded Jan. 2011
- **Final CWA published September 2011**
 - CWA 16335:2011





Summary

- Evolution of lab biorisk management from technical guidance to management system standard





- **Special thanks to Stefan Wagener**