



Biorisk Management Systems 101

Sandia National Laboratories
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Course Goals

- **For you to understand a management systems applicability to all layers within an institution**
- **For you to see the nature and value of a management system**
- **To understand the concepts of the plan, do, check, and act cycle**
- **For you to know the key elements of the CWA 15793 Biorisk Management System Standard**
- **For you to be able to assess situations and identify problems and solutions based on resources outlined in the CWA 15793 Biorisk Management System Standard**
- **For you to become an advocate for Biorisk Management Systems**



How will we get there?

- **We will visualize the impact of a management system**
- **We will derive the concepts of management systems**
- **We will review and use the CWA 15793:2008 Biorisk Management System**
 - See how the elements apply inside of a lab
 - Review a lab for compliance
 - Define any next steps for the lab



- **Quick Review**



International Laboratory Biorisk Management Documents

- **Technical: World Health Organization**
 - Laboratory Biosafety Manual (2004)
 - Biorisk Management: Laboratory Biosecurity Guidance (2006)
- **Management: CEN Workshop Agreements**
 - CWA 15793 Laboratory Biorisk Management Standard
 - CEN WS 55 – CWA 15793 Guidance Document (under development)
 - CEN WS 53 – Biosafety Professional Competence





What is CEN?

- **CEN = Comité Européen de Normalisation**
 - 30 national members
 - Produce technical specifications, technical reports, and European Standards (EN)
- **CEN Workshop Agreements (CWA):**
 - Produced by any interested parties
 - Consensus documents
 - Valid for 3 years
 - **Withdraw, renew, amend, or convert (CEN Technical Specification, European standard, or ISO standard)**



CWA 15793: 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**





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
- Framework for biorisk management systems
- Audits and inspections
- **Certification and accreditation activities**
- Support for funding
- International collaboration and recognition
- Training



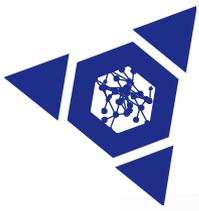
Examples of Topics Covered in CWA 15793





Examples of Topics Covered in CWA 15793





Example: Waste Management

4.4.4.5.3 Waste Management

The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins.

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 Management vs Technical Manuals

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



Summary: Why Implement CWA 15793?

- **Enables organizations to:**
 - **Establish** and **maintain** a biorisk management system to control or minimize risk to acceptable levels
 - Provide **assurance** that the requirements are in place and implemented effectively
 - Provide a framework that can be used as basis for **training** and **awareness raising**
 - Seek and achieve **certification** or **verification** by an independent third party





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

* IAF includes American Association for Laboratory Accreditation



- **Document available on CEN website**
<ftp://ftp.cenorm.be/PUBLIC/CWAs/workshop31/CWA15793.pdf>
- **Development of a “Guidance Document”**
 - Kick-off meeting in Brussels, Feb 2010
 - Seoul Korea, June 2010
 - Atlanta GA USA, Dec 2010
- **Training and education seminars and workshops**



- **Special thanks to Stefan Wagener**



Now lets talk about how to implementing the CWA 15793





How did we do?

