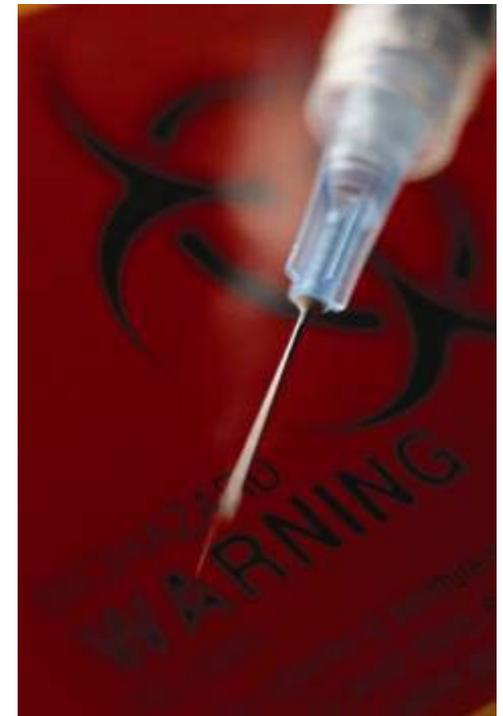


- International -
Laboratory Biorisk Management
Standard
CWA 15793:2008



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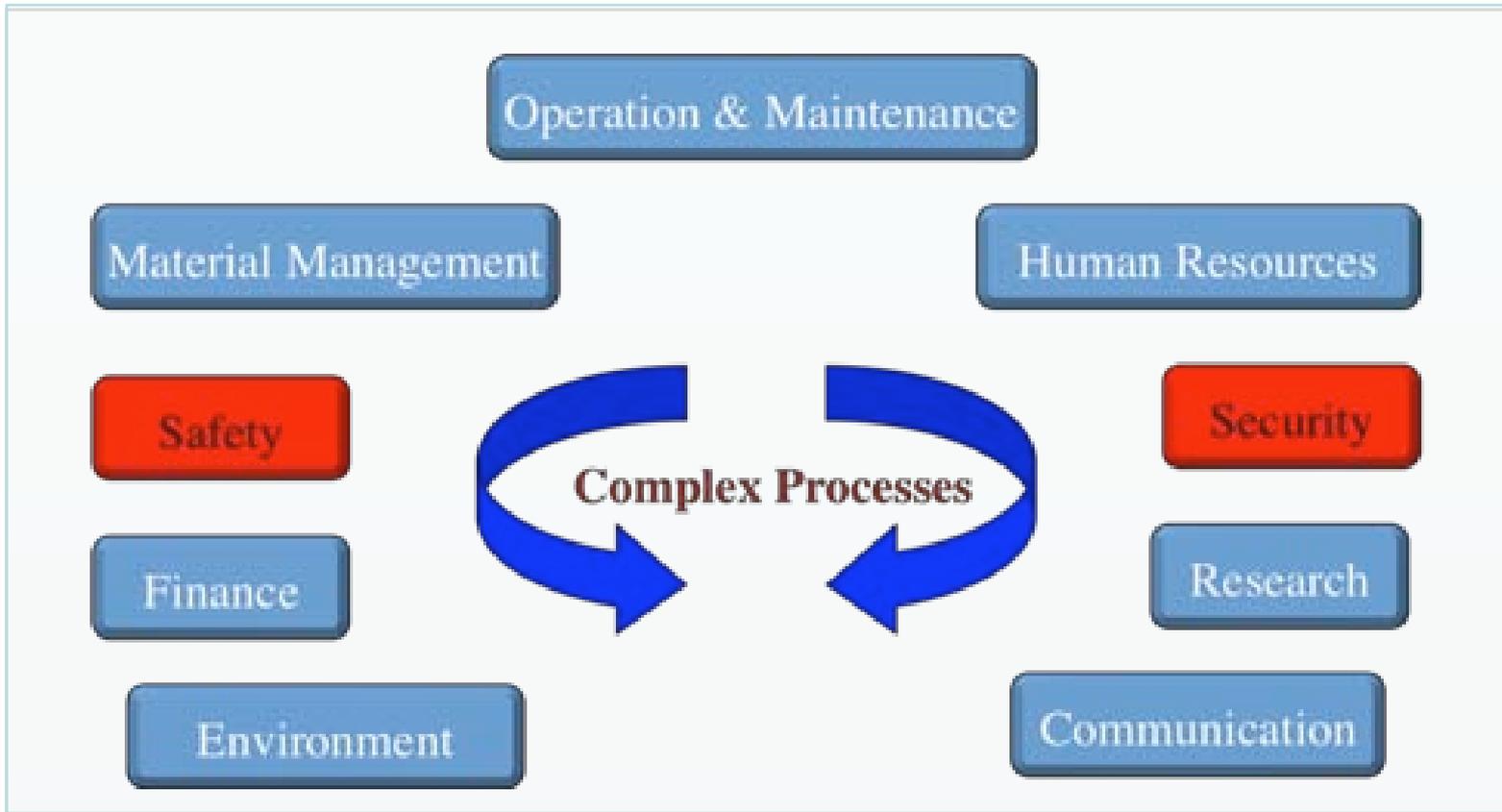


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Laboratory Biorisk Management Standard CWA 15793



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Overview

- In 2007, the document was adopted, and published as **CWA 15793:2008** by CEN in 2008
 - 76 participants from 24 countries developed a management system approach to biosafety and biosecurity in the laboratory
 - CEN in Brussels facilitated the process with funding by the European Commission

CWA 15793:2008
is a
Management System Standard

Consistent with other international standards such as ISO 9001 / 14001 and OSHAS18001

Contains definitions, requirements and notes for guidance

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A Management System Approach

What is a Management System?

- A framework that integrates best practices and procedures
- Ensures that an organization can effectively achieve all of its objectives
- Frequently built around the **Plan, Do, Check, Act** cycle



Laboratory Biorisk Management Standard CWA 15793:2008

What is Biorisk Management?

- Biorisk encompasses biosafety and biosecurity, where the hazards are biological agents and their products
- Establishes systems and policies to manage the laboratory biorisk
- Integral in the day-to-day operations of the institute / organization, both in normal times and times of emergency

CEN **CWA 15793**
WORKSHOP February 2008
AGREEMENT

ICS 07.100.01

English version

Laboratory biorisk management standard

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Purpose of the CWA 15793:2008

The Standard can be used for:

- Improving overall laboratory biorisk performance
- Increasing awareness of biosafety and biosecurity risks
- Effective management of complex laboratory safety and security processes
- Improving international laboratory collaboration and safety harmonization
- Basis for new or revised legislation or regulations
- Support laboratory certification/accreditation, audits/inspections



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- The Standard is **not** a technical document
- The Standard is **performance** oriented
 - Describes what needs to be achieved
 - How to do it is up to the organization

- The Standard is not intended to replace any national or sub-national regulatory requirements that may apply to the laboratory/facility
- Compliance with regulatory requirements is mandatory

- The standard is designed to complement other management standards
 - ISO9001 (Quality)
 - ISO14001 (Environmental)
 - OHSAS18001 (Occupational Health and Safety)

CWA 15793:2008

- Extensive Definition Section
- **Policy, Planning, Implementation & Operation, Checking and Corrective Action, Review**

Examples of topics covered:

- Biorisk Management Policy
- **Hazard Identification, risk assessment, and risk control**
- **Roles, responsibilities, and authorities**
- Training, awareness and competence
- Operational control
- Emergency response and contingency plans
- **Inventory monitoring and control**
- **Accident and incident investigation**
- Inspection and audit
- Biorisk management review

Local solutions for local problems

International Approach

- Not country specific
- Based on international, acceptable best practices
- Local solutions possible
- The Standard is based around the current WHO Biosafety and Biosecurity Guidelines

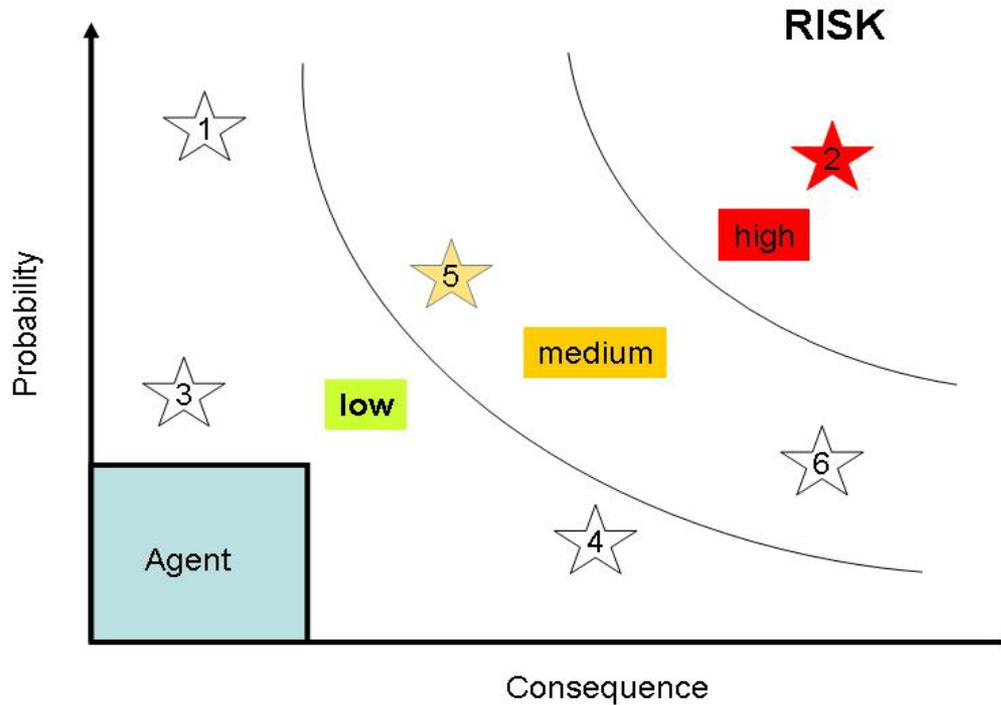


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Risk Assessment



<http://www.biosafetyriskassessment.org/>

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- Occupational Health

4.4.1.6 Occupational health

The organization shall have access to appropriate occupational health expertise and establish an occupational health program commensurate with the activities and risk of the facility.

Key differences

	CWA 15793	BMBL, LBM etc.
Management System	yes	no
Policy	yes	Generic (if at all)
Continual Improvement	yes	no
Roles & Responsibilities	yes	some
Document Control	yes	no
Auditing	yes	some
Objectives	yes	no
Certification (accredited)	yes	no

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CWA 15793:2008

- Comprehensive blueprint for biosafety & biosecurity (biorisk) program

Next Steps

- CWA 15793:2008 has a life-cycle of 3 years
 - Renewal, change, termination
- Learning experience for the community
 - Implementation by laboratories

Next Steps...

- Document now available on CEN website
- **New 2010 CEN workshop:
"Guidance Document"**
- Clearinghouse for user experiences
- Training and education seminars and workshops

<http://www.cen.eu/cenorm/businessdomains/technicalcommitteesworkshops/workshops/ws31.asp>

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- CWA 15793:2008 "Guidance Document"
 1. Meeting in Europe
 2. Meeting in Africa
 3. Meeting in North America

Conclusions

- The Laboratory Biorisk Management Standard has been developed by the community for the community
- Addresses biorisk holistically, and is directly applicable for controlling hazardous biological agents and toxins in the laboratory



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Conclusions...

- *Adoption and implementation of the CWA 15793:2008 will be an integral part of the future biorisk management agenda for laboratories worldwide, and a necessity to protect people and the environment as well as building community confidence*

<http://www.cen.eu/CENORM/Sectors/technicalcommitteesworkshops/workshops/ws31.asp>



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Strengthening Biological Risk Management

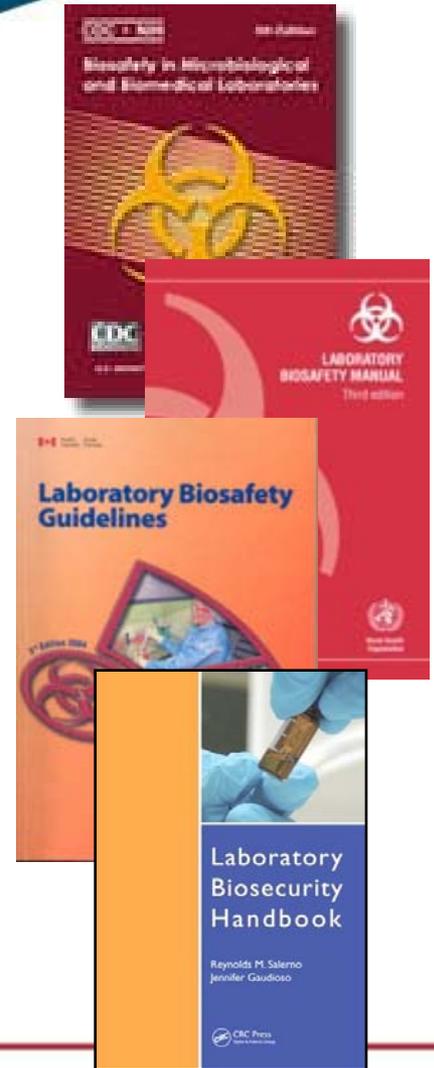


Vision for Integrated BioRisk Management:

- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs and establish accountability through development of Country "report cards"

References: Guidelines

- *Laboratory Biosafety Manual, 3rd Edition*
 - World Health Organization
- *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition,*
 - CDC/NIH: extensive recommendations on biosecurity
- *Laboratory Biosafety Guidelines, 3rd Edition*
 - Public Health Agency Canada
- *Biorisk Management: Laboratory Biosecurity Guidance*
 - WHO/FAO/OIE joint international biosecurity guidelines
- *Laboratory Biosecurity Handbook*
 - Sandia National Laboratories
- Organization for Economic Co-operation and Development (OECD) is establishing biosecurity guidelines



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