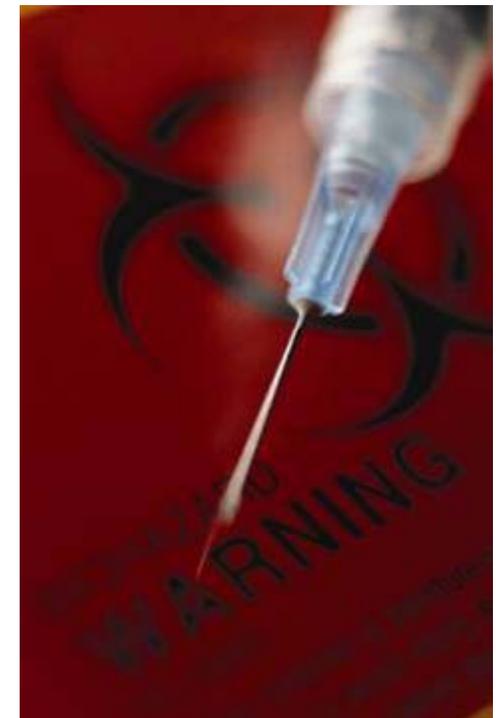


Laboratory Biorisk Management Standard CWA 15793:2008

- International -
Laboratory Biorisk Management
Standard
CWA 15793:2008



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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



Laboratory Biorisk Management Standard CWA 15793:2008

CWA 15793:2008

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 Management System is a framework that integrates best practices and procedures - frequently built around the Plan, Do, Check, Act cycle



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Laboratory Biorisk Management Standard CWA 15793:2008

Purpose of the CWA 15793:2008

The Standard can be used for:

- Improving overall laboratory biorisk performance
- Increasing awareness and the adoption of management system approaches for biosafety & biosecurity
- Effective management of complex laboratory safety and security processes
- Improving international laboratory collaboration and safety harmonization



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- The Standard is **not** a technical document
- The Standard is based around the current WHO Biosafety and Biosecurity Guidelines
- The Standard is **Performance** oriented

- 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

CWA 15793:2008

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



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- 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

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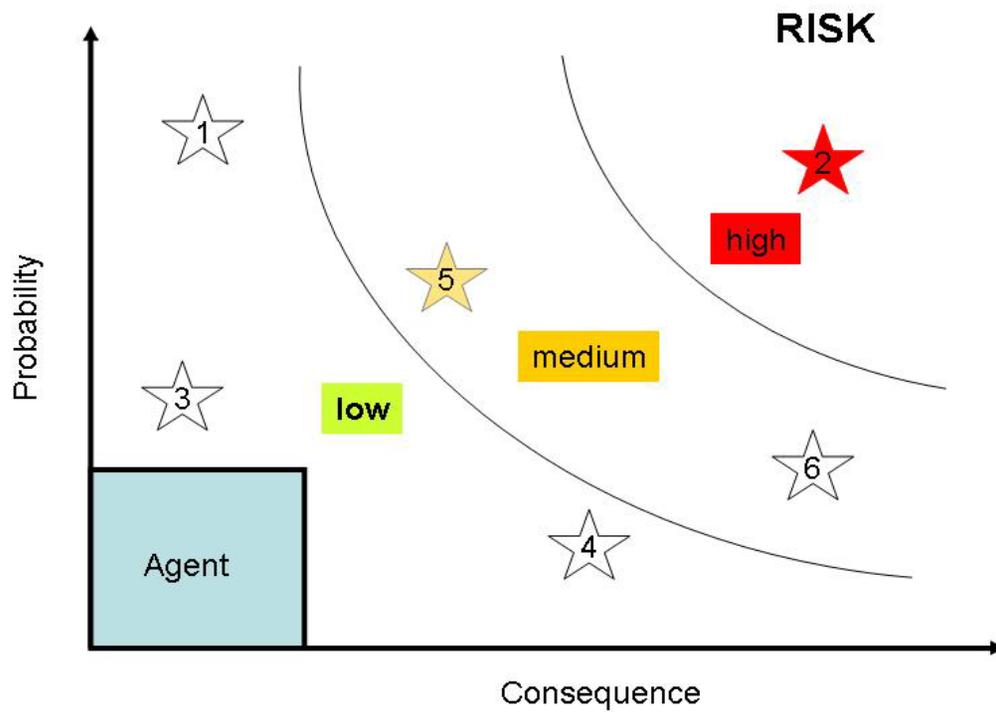
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Risk Assessment



<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.

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Next Steps

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

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Next Steps...

- Document now available on CEN website
- **New 2009 workshop to establish a "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”**
 - Budget ~\$200K (US)
 - 1. Meeting in Europe (September, 2009)
 - 2. Meeting in Africa or South America (January, 2010)
 - 3. Meeting in Asia (April, 2010)
 - Potential sponsorship through Global Partnership, National Biosafety Associations and others



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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*



Laboratory Biorisk Management Standard CWA 15793:2008

Thank you!

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

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