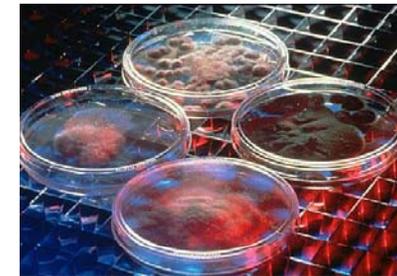


What is Program Management?

- A laboratory program which seeks to effectively and efficiently manage an institution's laboratory biorisks
- Effective program management is central to the success of implementing biosafety and biosecurity in any laboratory!
- Laboratory biorisk management programs need:
 - Resources
 - Institutional guidelines and operating procedures
 - Training
 - Oversight



Common Concerns with Implementing Program Management

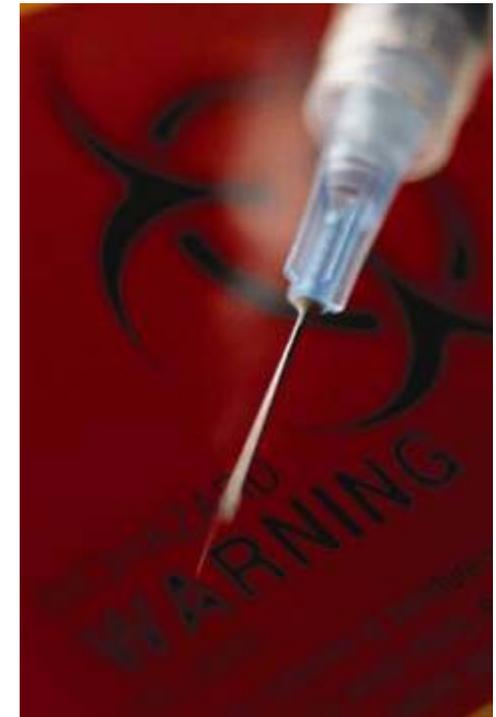
- How do you allocate scarce resources?
- What do you address in operating procedures?
- Which training is required and for whom?
- What level of oversight is appropriate?

It Depends on the Risk Assessment!!



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- 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



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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



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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

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CEN	CWA 15793
WORKSHOP	February 2008
AGREEMENT	

ICS 07.100.01

English version

Laboratory biorisk management standard

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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 of biosafety and biosecurity risk
- 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



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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

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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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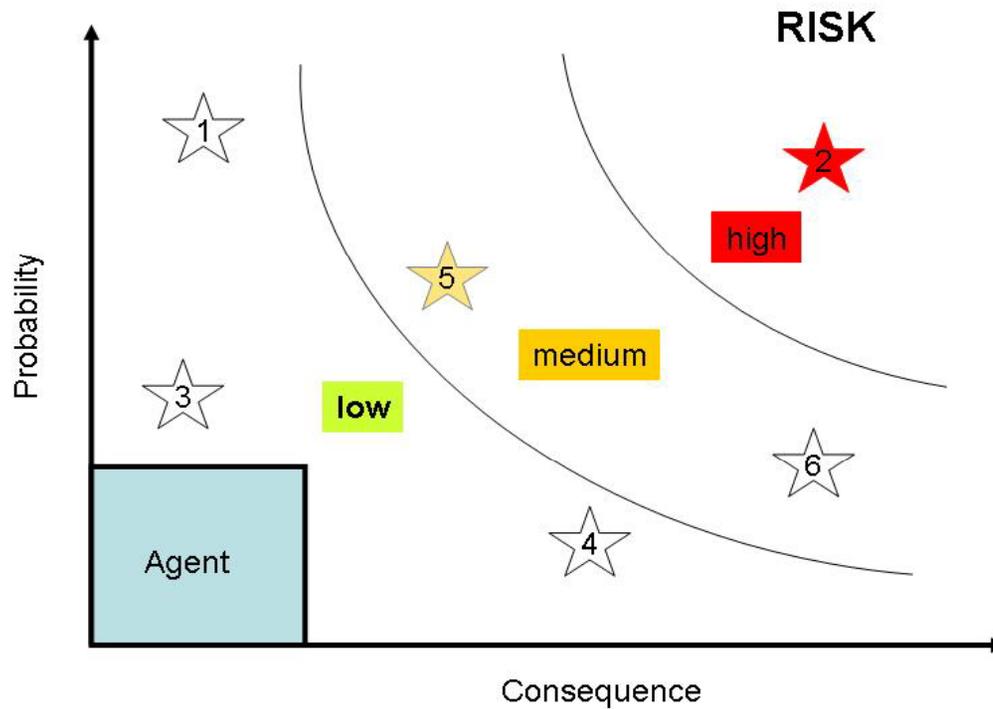
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Risk Assessment



<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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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

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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 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 (2009)
 2. Meeting in Africa (2010)
 3. Meeting in North America (2010)

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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*



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