



MANAGING RISK

DNV

The Laboratory Biorisk Management Standard: Promoting Cooperation on Disease Surveillance and Research



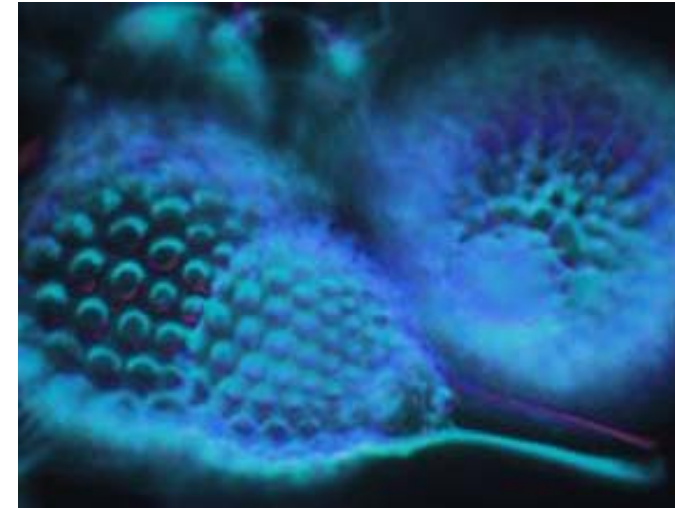
The Biological Weapons Convention Supporting Global Health: Reducing Biological Risk by Building Capacity in Health Security

Dr Stephen McAdam
18th June 2009



“Safeguarding life,
property, and the
environment”

- Biorisk encompasses biosafety and biosecurity, where the hazards are biological agents and their products.
- Laboratory biosafety involves harm to people and other organisms, whereas laboratory biosecurity encompasses the deliberate release of material.
- Biosafety and biosecurity are closely interlinked, and common systems are required to manage both effectively.
- History has shown that failure to address risk management issues can result in potentially drastic consequences for life, property and the environment.



European Biosafety Society • American Biological Safety Association • Det Norske Veritas

International Biosafety and Biosecurity Laboratory Standard Development Initiative



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Public Health
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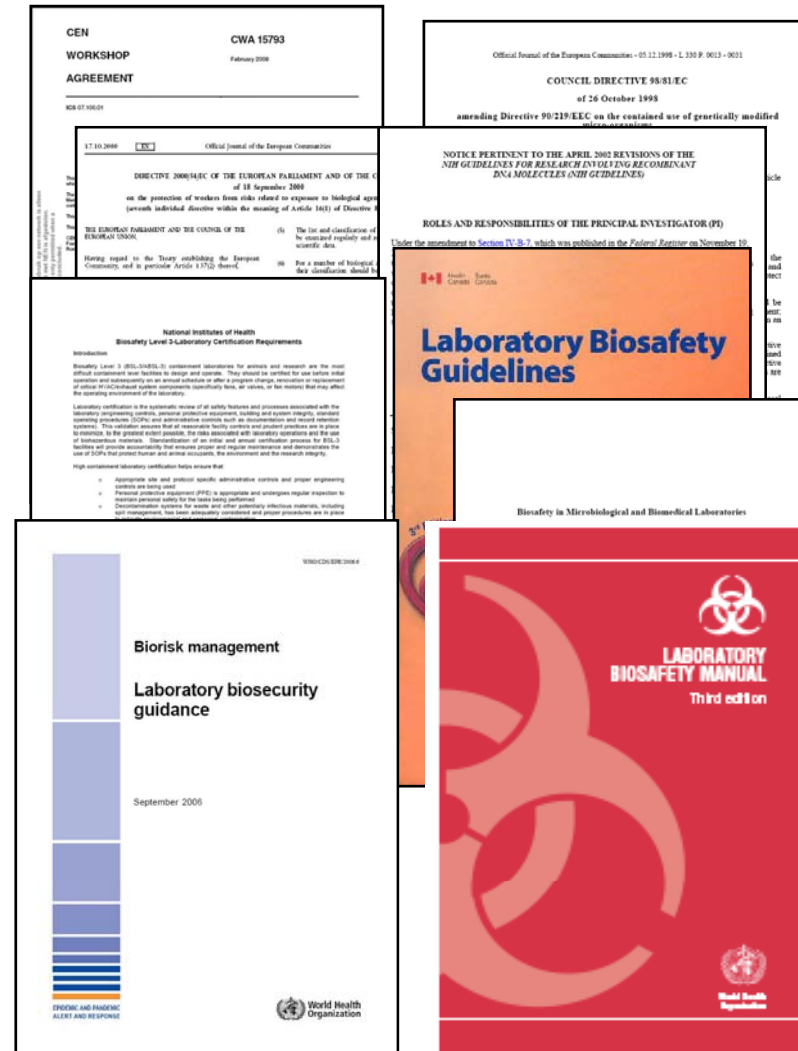


Why develop the Standard?



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- Many reference documents available:
 - Standards
 - Guidelines
 - Codes
- Can be largely technical in nature and often prescriptive
- Often national / regional in nature
- Other major hazard industries already use a management systems approach
- Need to provide assurance to the international community that risk is being managed effectively and proportionately



CWA 15793 - Background

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- CEN Workshop Approach
- Key stakeholders
 - European Commission
 - American, European and Asia Pacific Biosafety Associations
 - Standards organisations
 - WHO
 - Universities
 - Research Institutes
 - Funding agencies
 - Regulators
- 72 participants from 24 countries, including all continents
- Consultation with over 2,000 organisations and individuals
- Published in February 2008

CEN
WORKSHOP
AGREEMENT

CWA 15793
February 2008

ICS 07.100.01

English version

Laboratory biorisk management standard


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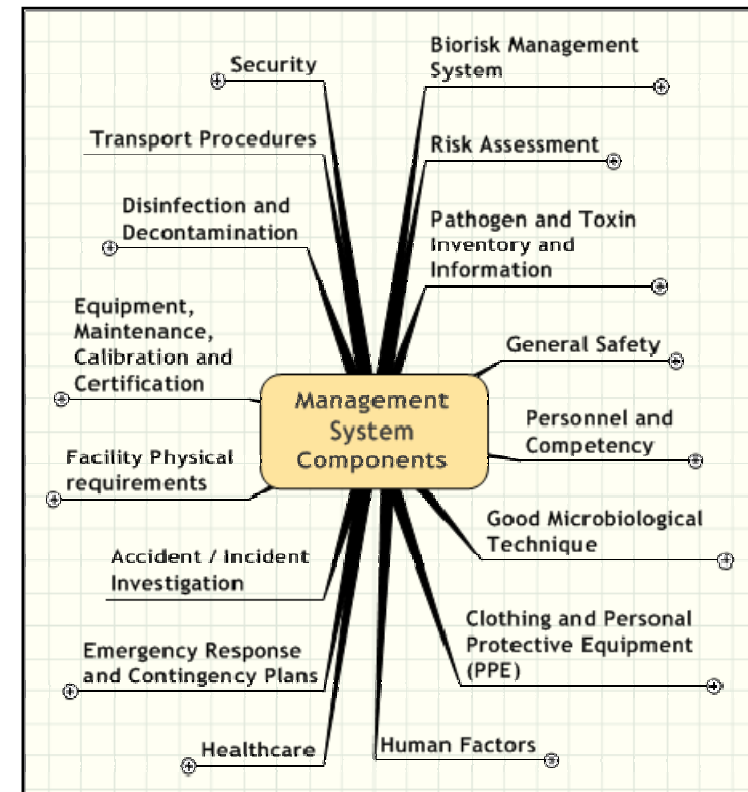
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Laboratory Biorisk Management Standard



- A voluntary standard
- Is performance-orientated and risk-based
- Consistent with other international standards such as ISO 9001 / 14001 and OSHAS18001
- Integrates biosafety and biosecurity under common all hazards approach
- Contains definitions, requirements and notes for guidance
- Objective to be used at a variety of levels and controls will mirror the threat / risk associated with the activity undertaken





- Building sustainable laboratory capacity
 - Designing laboratories appropriate for needs and local conditions
 - Ensuring facilities built meet design needs
 - Developing laboratory management and support services necessary to operate facility

- Need to build trust to facilitate exchange of equipment, materials and technical information
 - Both biosafety and biosecurity concerns
 - Between different industry sectors
 - Between countries/geographies

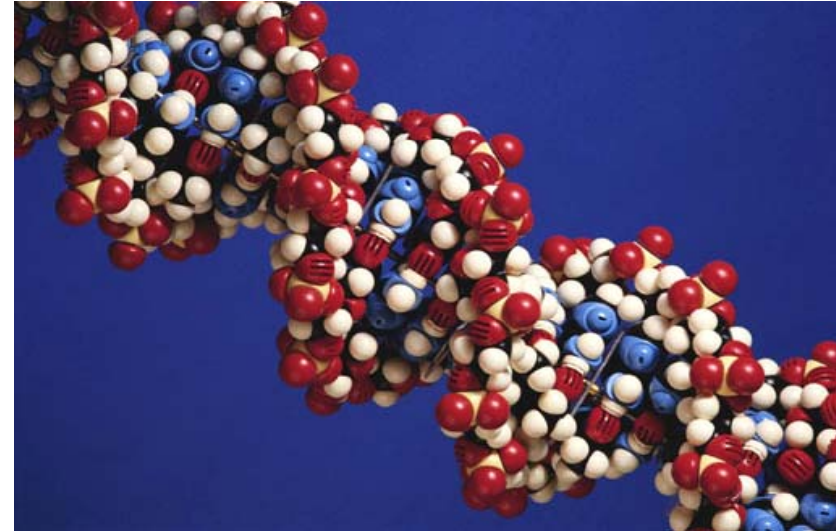
CWA, Capacity building and the BWC

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- Provides a comprehensive framework to guide laboratories:
 - Build laboratory infrastructure;
 - Operate safely and securely given available resources;
 - Identify and provide appropriate training;
 - Prepare for emergencies...

- Provides one mechanism to build trust through:
 - Demonstrating commitment to legal compliance
 - Increasing transparency and improving communication
 - Internal audits and self declaration;
 - Second party audits;
 - Third party audits and certification



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