CWA 15793: 2008
Laboratory Biorisk Management Standard

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Gary Burns  
Biosafety Manager  
AstraZeneca Pharmaceuticals

Patrick Seechurn  
Biosafety Advisor  
University of Manchester
Summary

• How the standard arose

• Content

• How it is used/should be used in practice

• Application in HE sector

• Future developments
Why develop the Standard?

• Many reference documents available:
  – Standards
  – Guidelines
  – Codes
• Can be largely technical in nature and often prescriptive
• Often national/regional in nature
• Management systems successful in other areas (Safety/Quality/Environment)
• Assurance to the international community
Development of the Standard

- Oslo February 2005 –concept discussion
- Attended by representatives from EBSA, ABSA, DNV, WHO and others
- Reviewed existing Standards/ Guidelines/Codes
  - Can be largely technical in nature and often prescriptive
  - Often national / regional in nature
- Recognition that management systems successful in other areas (Safety/Quality/Environment)
- Agreement that a performance-oriented international standard would drive improvement in standards especially in regions with less well-developed regulatory framework
- Steering Group set up to look at options
Options considered

• ANSI/EN/ISO Standard
  – Slow process, long timescale
  – Expensive
  – ANSI perceived as US-focused?

• CEN Workshop Agreement – quicker and cheaper. Despite European flavour in the title, CWA’s can be developed with an international basis
European Biosafety Society • American Biological Safety Association • Det Norske Veritas

International Biosafety and Biosecurity Laboratory Standard Development Initiative

CEN WORKSHOP AGREEMENT CWA 15793
February 2008

This CEN Workshop Agreement has been drafted and approved by a Working Group consisting of a number of experts and the text is intended to serve as the basis for a future European standard.

The European Committee for Standardization (CEN) is a voluntary association established for the purpose of working for the standardization of the products and services which are traded in the European Community.

The CEN Workshop Agreement is one of the methods used by CEN for the development of Standards. It is based on the principle of mutual recognition and is intended to facilitate the harmonization of technical standards.

The CEN Workshop Agreement is a voluntary agreement between the parties involved in the development of a European Standard. It is based on the principle of mutual recognition and is intended to facilitate the harmonization of technical standards.
Key stakeholders

- European Commission
- American, European and Asia Pacific Biosafety Associations
- Standards organisations
- WHO
- Universities
- Research Institutes
- Funding agencies
- Regulators
Funding & Stakeholder Engagement

- Business plan/budget developed by Steering Group
- Funding application to European Commission (European Programme for Critical Infrastructure Protection)
- Approval 2006
- ~75% of budget from EC, remainder from other sources including participant registration fees
- Steering group develop initial draft
- 2000 organisations/individuals contacted
- 3 workshops scheduled in 2007 (Brussels/Boston).
- Public consultation between 2nd and final meetings.
- Consensus reached on a final draft at last meeting (Nov 07)
- CWA 15793 published Feb 08
Participation in development

72 participants from 24 countries
The CEN Workshop Agreement (CWA 15793:2008) and its consequences on science and research

Dr Christine Rohde
DSMZ, Braunschweig, Germany
E-mail: chr@dsMZ.de


Article by Christine Rohde from the German Collection of Microorganisms and Cell Cultures

• Apprehension that smaller institutions or universities cannot implement the CWA because of lack of financial resources.
• The CWA does not need to be fully implemented in every laboratory - individual labs should determine to what extent the CWA is applicable for them.
• Implementation of the document should help discover weaknesses in an institution’s practices and prevent misuse of biological resources, data and know-how.
• CWA is certainly an additional helpful tool for culture collections.
• The pros and cons of the CWA should be carefully weighed and comments on the document should be directed to the CEN management centre or CEN Workshop 31 Secretariat.
Laboratory Biorisk Management Standard

• Addresses both biosafety and biosecurity – “Biorisk”
• 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
Application

• Voluntary

• Applicable to all organizations handling biological agents and/or toxins, regardless of type, size and biological agents handled.

• Does not employ biological agent risk classification or laboratory safety containment levels, although such approaches can be entirely compatible with this standard.

• If any part of the standard is in conflict with any national legal requirement or local regulatory standards, the conflicting part of the standard may be eligible for exemption.
Overview of requirements

CWA 15793 Requirements

- Biorisk management policy
  - Planning for hazard identification, risk assessment and risk control
    - Conformity and compliance
    - Objectives, targets and programme
  - Roles, responsibilities and authorities
  - Personnel training, awareness and competence
  - Consultation and communication
  - Operational control
  - Emergency response and contingency plans

- Review
  - Biorisk management review

- Implementation and operation
  - Checking and corrective action

- Performance measurement and analysis of data
  - Records, document and data control
  - Inventory monitoring and control
  - Accident and incident investigation, non-conformity, corrective and preventive actions
  - Inspection and audit
Key elements/outcomes

• Management is responsible and ensures risk is managed responsibly
• Activities are proactively planned, conducted and reviewed
• Risks are identified, assessed and managed in a structured way using recognised approaches and the controls are reasonable and proportionate to the risk
• Appropriate standards and norms must be identified, used and complied with (e.g. laws, codes, BWC, WHO LBM3, WHO LBG)
Elements/Outcomes cont’d……

• Roles, responsibilities and authorities are clearly defined – helps understanding of required competencies
• Combines controls related to engineering, instructions and people
• Links between related and dependent activities – i.e. a systematic approach
• Workers understand and can comply with requirements
• Proactive approach leading to continuous improvement
Biosecurity concerns addressed

- Polices and management controls
- Defining and approving projects
- Selection and vetting of workers
- Control of inventories
- General security controls
Potential applications

- Framework for biorisk management systems
- Internal or external audits and inspections
- Customised protocols and other tools
- Certification and accreditation activities – assurance to stakeholders
- Demonstration of compliance as a prerequisite for funding projects?
- Could facilitate international collaboration
Future…

• Review in 2011
  – Retain/Promote to EN/ISO Standard
  – Revise
  – Withdraw

• Development of Guidance on implementation

• Development of an Accreditation/Certification process
Conclusions

• The Laboratory Biorisk Management Standard has been developed by the user community for the user community
• Addresses biorisk holistically and is directly applicable to control measures for hazardous biological agents and toxins
• Can be used a basis to demonstrate responsible management of biorisk
Breakdown of Topics Covered
Planning

Planning for hazard identification, risk assessment and risk control

Conformity and compliance

Objectives, targets and programme

Planning and resources
- Risk assessment timing and scope
- Hazard identification
- Risk assessment
- Risk management

Biorisk control objectives and targets

Monitoring controls
Implementation and Operation

Roles, responsibilities and authorities

- Top management
  - Senior management
- Biorisk management committee
- Biorisk management advisor
- Scientific management
- Occupational health
- Facility management
- Security management
- Animal handling

Personnel training, awareness and competence

- Recruitment
  - Competence
  - Continuity and succession planning
  - Training

Consultation and communication

- General safety
  - Biological agents and toxin inventory and information
- Work programme, planning and capacity
- Change management
- Work practices, decontamination and personnel protection

Operational control

- Worker health programme
- Personnel reliability
- Infrastructure and operational management
- Personal security
- Transport of biological agents and toxins

Emergency response and contingency plans

- Emergency scenarios
  - Emergency plans
  - Emergency exercises and simulations
  - Contingency plans
Emergency Response and Contingency Plans

- Emergency scenarios
- Emergency plans
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- Contingency plans
Checking and Corrective Action

- Performance measurement and analysis of data
- Records, document and data control
- Inventory monitoring and control
- Accident / incident investigation
- Control of nonconformities
- Corrective action
- Preventive action
- Accident and incident investigation, non-conformity, corrective and preventive actions
- Inspection and audit