NSAI Standards

Standard Recommendation
S.R. CWA 15793:2011

Laboratory biorisk management

S.R. CWA 15793:2011

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S.R. CWA 15793:2011

CEN WORKSHOP AGREEMENT

CWA 15793

September 2011

ICS 07.100.01

Supersedes CWA 15793:2008

English version

Laboratory biorisk management

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

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Foreword

CWA 15793:2011 was prepared by CEN Workshop 31 - Laboratory biosafety and biosecurity.

This document supersedes CWA 15793:2008.

The CEN Workshop offers a mechanism whereby stakeholders can bring their standardization and specification requirements and develop a result by consensus, validated in an open process.

In a CEN Workshop all the decision-making powers rest with the interested parties themselves, the members of the Workshop. These include all stakeholders (for example industry representatives, service providers, administrators, users) and can come from any part of the globe. They are responsible for the funding and direction of the Workshop and for the approval of the deliverables.

The main activity of a CEN Workshop is the development and publication of the CEN Workshop Agreement (CWA). This CWA applies internationally. It does not have the force of regulation and conformity is voluntary.

For the development of this CWA, there were 76 participants from the following countries:

Argentina, Australia, Belgium, Canada, China, Denmark, Germany, Ghana, Hong Kong, Hungary, Ireland, Japan, Kazakhstan, Kyrgyzstan, Latvia, the Netherlands, Norway, Russia, Singapore, Spain, Sweden, Switzerland, the United Kingdom and the United States. A list of organizations participating in this Workshop and in support of this CWA is available from the CEN-CENELEC Management Centre. The WHO also participated in the Workshop.

There was also a public comment phase that brought comments from an additional 33 stakeholders from Argentina, Canada, Europe, Russia, Taiwan and the United States. More information on CEN and the CEN Workshops can be found at: www.cen.eu

NEN, the Dutch Standardization Institute, provided the secretariat of the Workshop.

The formal process followed by the Workshop in the development of the CEN Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN-CENELEC Management Centre can be held accountable for the technical content of the CEN Workshop Agreement or possible conflict with standards or legislation. This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its members

The final review/endorsement round for this CWA was successfully closed on 2011-02-28.The final text of this CWA was submitted to CEN for publication on 2011-08-03.

This CEN Workshop Agreement is publicly available as a reference document from the National Members of CEN: AENOR, AFNOR, ASRO, BDS, BSI, CSNI, CYS, DIN, DS, ELOT, EVS, IBN, IPQ, IST, LVS, LST, MSA, MSZT, NEN, NSAI, ON, PKN, SEE, SIS, SIST, SFS, SN, SNV, SUTN and UNI.

Comments or suggestions from the users of the CEN Workshop Agreement are welcome and should be addressed to the CEN-CENELEC Management Centre.

In 2011, the workshop 31 participants renewed the CWA 15793:2008 for another three years without any technical changes. The only editorial changes implemented involved the replacement of the word “standard” in the original document with the words “CWA” or “Agreement” wherever appropriate, based on a request to CEN by the CEN National Members.

Introduction

Management systems approach - Introduction

This laboratory biorisk management CWA is based on a management system approach. This implies that identifying, understanding and managing a system of interrelated processes for a given objective, improves the organization's effectiveness and efficiency.

Application of the management systems approach principle leads to the following actions:

a) defining the system by identifying or developing the processes that affect a given objective;
b) structuring the system to achieve the objective in the most effective manner;
c) understanding the interdependencies among the processes of the system;
d) continually improving the system through measurement and evaluation, and;
e) establishing resource constraints prior to action.

The systems approach outlined above has been successfully adopted by the International Organization for Standardization (ISO). Organizations which have already implemented systems for quality, environmental and/or occupational health and safety management, will find significant synergy between these systems and the one for biorisk management.

The management system approach enables an organization to effectively identify, monitor and control the laboratory biosafety and biosecurity aspects of its activities.

An effective management system approach should be built on the concept of continual improvement through a cycle of planning, implementing, reviewing and improving the processes and actions that an organization undertakes to meet goals. This is known as the PDCA (Plan-Do-Check-Act) principle:

Plan: Planning, including identification of hazard and risk and establishing goals,

Do: Implementing, including training and operational issues,

Check: Checking, including monitoring and corrective action,

Act: Reviewing, including process innovation and acting to make needed changes to the management system.

In order to improve biorisk management the organization needs to focus on the causes of non-conformities and undesirable events. Systematic identification and correction of system deficiencies leads to improved performance and control of biorisk.

Keys to a successful biorisk management system

Some of the key factors in establishing and implementing a successful biorisk management system include:

- Commitment by top management:
  - providing adequate resources, prioritization and communication of biosafety and biosecurity policy;
  - integrating of biorisk management throughout the organization;
  - identifying opportunities for improvement and prevention, determining root causes and preventing recurrence.

- Focus on continual improvement:
  - making continual improvement an objective for every individual in the organization;
  - using periodic assessment against established risk-criteria to identify areas for potential improvement;
  - continually improving the effectiveness and efficiency of processes;
  - promoting prevention activities;
  - providing personnel in the organization with appropriate education and training including the methods and tools of continual improvement;
  - establishing measures and goals for improvement;
  - recognizing improvement.

Management system integration

This laboratory biorisk management CWA is compatible with the ISO 9001:2000 (Quality), ISO 14001:2004 (Environmental) and OHSAS 18001:2007 (Occupational Health and Safety) management systems standards, in order to facilitate the integration of all such management systems of an organization.

Application

The requirements of this agreement are generic and are intended to be applicable to all organizations handling biological agents and/or toxins, regardless of type, size and biological agents handled. This agreement takes a risk-based approach but it does not employ biological agent risk classification or laboratory safety / containment levels, although such approaches can be entirely compatible with this agreement.

Where any requirements of this agreement cannot be applied due to the nature of the organization and its processes, this can be considered for exclusion. Where exclusions are made, claims of conformity to this agreement are not acceptable, unless such exclusions do not affect the organization’s ability or responsibility to control biorisk in the manner required by this agreement. Any claims of exclusion shall be detailed and justification provided.

Compliance with national and local regulatory standards, regulations and requirements are of primary importance in any programme. Where any part of this agreement is in conflict with any legal requirement, the conflicting part of the agreement may be eligible for exemption if the legal requirement meets or exceeds the intent of this agreement.

All organizations face challenges in putting the management system requirements of this agreement in place. For small organizations the challenges are potentially greater due to minimal available resources, costs involved and difficulty in understanding and applying the agreement. Small organizations are typically ones in which only a few people are involved, there is a simple communication flow and individuals undertake a wide variety of tasks. Decisions are made by just a few people. Small organizations should analyse each requirement clause of the agreement and determine in which manner they can interpret and comply with it to suit the objective of the agreement in identification and control of risk.

The more challenging requirement clauses in this respect may be the ones related to continual improvement. The organization should regard this as a recurring, step-by-step activity. When opportunities for improvement are identified, and justified, the organization needs to decide how they are to be implemented based on the available resources. The justification should be founded on an analysis of the potential gains in terms of improved control of risk. Improvements may typically address issues like:

- training and awareness programmes;
- internal communications;
- effectiveness of reviews;
- preventive actions;
- effectiveness of follow-up activities;
- documented procedures and instructions.

1 Scope

The scope of this laboratory biorisk management system agreement is to set requirements necessary to control risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities.

This CWA will enable organizations to:

a) establish and maintain a biorisk management system to control or minimize risk to acceptable levels in relation to employees, the community and others as well as the environment which could be directly or indirectly exposed to biological agents or toxins;
b) provide assurance that the requirements are in place and implemented effectively;
c) seek and achieve certification or verification of the biorisk management system by an independent third party;
d) provide a framework that can be used as the basis for training and raising awareness of laboratory biosafety and laboratory biosecurity guidelines and best practices within the scientific community.

This CWA is performance-based and sets out requirements for and places responsibility on organizations to demonstrate that appropriate and validated risk reduction procedures have been established and implemented.

This agreement is structured in a manner where the specific requirements pertaining to each individual clause are defined and stated in a frame-box. Informative guidance has been provided as an aid in interpreting the requirements where considered appropriate. This guidance is in the form of notes in association with the pertaining requirements clause and uses the terms “should” (recommendation), “may” (allowance) and “can” (possibility). Organizations wishing to implement this CWA would be expected to consider all recommendations where the term “should” is used.

Contents of the notes shall not in any way be construed as being requirements.

2 Informative references

Two central guidance documents for biorisk management and the development of this CWA are:

– WHO Laboratory biosafety manual, third edition, 2004, WHO/CDS/CSR/LYO/2004.11

– WHO Biorisk Management: Laboratory Biosecurity Guidance, 2006, WHO/CDS/EPR/2006.6

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
accident
unintended event giving rise to harm

NOTE An accident is an incident which has resulted in harm.