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WORKSHOP

AGREEMENT

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Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008

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Foreword

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties on 2011-11-25, the constitution of which was supported by CEN following the public call for participation made on 2010-01-13. NEN, the Netherlands Standardization Institute, provided the secretariat of the Workshop.

A list of the individuals and organizations which supported the technical consensus represented by the CEN Workshop Agreement is available to purchasers from the CEN-CENELEC Management Centre. These organizations were drawn from the following organisations: Aga Khan University, PK, American Biological Safety Association (ABSA), Animal Health Research Centre, ES, Asia-Pacific Biosafety Association (A-PBA), SG, Azerbaijan Medical University, AZ, Bayer CropScience, BE, Biological Threat Reduction Program, US, Biosecurity Institute, DK, Boston University and Boston Medical Center, US, Centers for Disease Control and Prevention, KR, Deakin University, AU, Defense Threat Reduction Agency, US, Det Norske Veritas (DNV), NO, E.R. Griffin Research Foundation, US, Eliava Institute, GE, Emory University, US, European Biosafety Association (EBSA), Friedrich-Loeffler-Institut, Federal Research Institute for Animal Health, DE, GlaxoSmithKline Biologicals, BE, Global Partnership Program, CA, Hannover Medical School, DE, Institute for Animal Health, GB, Institute for Medical Research Ministry of Health, MY, International Centre for Infectious Diseases, CA, Kazakhstan Scientific Center of Quarantine and Zoonotic Diseases, KZ, Kenya Medical Research Institute (KEMRI), KE, KESC Medical, PK, Laboratory of Ministry of Agriculture (LMA), GE, Medical Biological Safety Association, MX, Medical Research Council (MRC), GB, Merck Sharp & Dohme, US, Ministry of Health, AZ, Ministry of Health, PH, National Center for Disease Control and Public Health (NCDC&PH), GE, National Institute for Public Health and the Environment, NL, National Institute of Health Research and Development, ID, National Institute of Public Health, RO, National Institutes of Health, US, National Veterinary Laboratory, PK, Novartis International AG, CH, Pfizer, IE, Plas-Labs, US, Public Health Agency of Canada, CA, Regional Public Health Department, GE, Republican Veterinary Laboratory, AZ, Research Institute for Biological Safety Problems, KZ, San Lazaro Hospital, PH, Sandia National Laboratories, US, SES, UA, Société Général de Surveillance (SGS), CH, Spiez laboratory, CH, Statens Serum Institut, DK, Telstar Projects (Tpro), ES, U.S. Government Accountability Office, US, Universidad Autónoma de Madrid, ES, US Department of State, US, US Naval Medical Research Unit, US, WHO collaborating Center for Biosafety in Microbiology, AU, World BioHazTec Corporation, US, Xibios, BE.

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The final review/endorsement round for this CWA was started on 2011-11-07 and was successfully closed on 2011-11-25.The final text of this CWA was submitted to CEN for publication on 2011-12-02.

Background

CWA 15793:2008 - Laboratory Biorisk Management Standard - was developed as a voluntary standard by an international consortium of biosafety and biosecurity experts through a CEN Workshop (WS 31) to describe the required components of an effective biorisk management system. To facilitate implementation of CWA 15793, this guidance document has been developed to build on and expand the guidance notes already provided.

Because CWA 15793:2008 is compatible with management guidance documents, such as ISO 9000 series (Quality), ISO 14000 series (Environmental), OHSAS 18000 series (Health and Safety) and BSI PAS 99 integrated management series, it can be integrated with them.

Format

The document quotes the specific requirements from CWA 15793:2008 in a framed text box accompanied in many cases with informative guidance notes to aid interpretation. Guidance notes from CWA 15793:2008 are in italics; if notes have been expanded for clarification or to remove redundancies, the text is not in italics. The clause numbering of the document is aligned with that of CWA 15793:2008. In the event the output is identical to the intent, only the intent will be stated.

Generic guidance is provided on the application and implementation of CWA 15793:2008. The underlying principles of CWA 15793:2008 are explained against each requirement. This document does not create additional requirements to those specified in CWA 15793:2008 nor does it prescribe mandatory approaches to the implementation of CWA 15793:2008. To be consistent with other management systems, where appropriate, the text will address intent, typical input and output without explicitly referring to these terms.

The new guidance document should not conflict with the notes provided in CWA 15793:2008; however, if there are areas where different interpretation is possible, the text provided by CWA 15793:2008 will take precedence.

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

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Introduction

Organizations of all kinds are increasingly concerned with achieving and demonstrating robust biosafety and biosecurity practices controlling their biorisks consistent with their own biorisk policy and objectives. They do so in the context of increasing concern expressed by a variety of stakeholders and, in many countries, by a regulatory system that is becoming increasingly stringent.

Many organizations have undertaken biorisk “reviews” or “audits” to assess their biorisk performance. On their own, however, these “reviews” and “audits” may not be sufficient to provide an organization with the assurance that its performance not only meets, but also will continue to meet, its legal and policy requirements. To be effective, they need to be conducted within a structured systematic approach integrated throughout the organization.

CWA 15793:2008 specifies requirements for a biorisk management system that will enable an organization to develop and implement a biorisk policy, establish objectives and processes to achieve the policy commitments and improve its performance. It follows a risk based approach taking in legal requirements and current knowledge and is intended to apply to all types and sizes of organizations and to accommodate diverse geographical, cultural and social conditions. The success of the system depends on commitment from all levels and functions within the organization, and especially from top management. The overall aim of CWA 15793:2008 is to support and promote good biorisk practices, including self regulation.

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 15793:2008 would be expected to consider all recommendations where the term “should” is used.

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.

This document was written as a guide to the CWA 15793:2008 Laboratory biorisk management standard, wich aims to support organizations and biosafety professionals to implement a biorisk management system that is both practicable and robust.

1 Scope

For the purposes of this document, the scope given in the CWA 15793:2008 Laboratory biorisk management standard, applies to this guidance document.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

CWA 15793:2008, *Laboratory biorisk management standard*

NOTE 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. Therefore, the application of this guidance document is relevant to CWA 15793:2011 as well.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in CWA 15793:2008 apply.

4 Biorisk management system

4.1 General requirements

4.1.1 Biorisk management system

The organization shall establish, document, implement and maintain a biorisk management system in accordance with the requirements of this laboratory biorisk management standard.

This CWA 15793:2008 requirement is a general statement concerning the establishment and maintenance of a biorisk management system within an organization. “Establish” implies a level of permanency, and the system should not be considered established until all its elements have been demonstrably implemented. “Maintain” implies that, once established, the system continues to operate. This requires active effort on the part of the organization. The elements of CWA 15793:2008 (such as self-audit programme and corrective action and management review) aim to ensure proactive maintenance of the system.

The priority should be on protecting employees, their community and environment from accidental or unauthorized intentional release of biological materials from the facility.

The level of detail and complexity of the biorisk management system, the extent of documentation and the resources devoted to it will be dependent on the nature (size, structure, complexity) of an organization and its activities.

An organization may choose to implement CWA 15793:2008 for its entire facility or specific units or laboratories as long as any boundaries set do not exclude specific activities that have an impact on biorisk management for those units or laboratories implementing CWA 15793:2008.

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