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

S.R. CWA 16393:2012

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English version

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

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-CENELEC 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

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.

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 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.

This CEN Workshop Agreement is publicly available as a reference document from the National Members of CEN: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

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.