MEETING OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

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Consideration of national, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins

THE LABORATORY BIORISK MANAGEMENT STANDARD AND ITS APPLICABILITY UNDER THE BWC

Submitted by Norway

Introduction

1. Biological containment laboratories are critical for vaccine development, diagnostic work as well as basic research into human, animal and plant pathogens. Different types of live biological materials are handled in these laboratories. Each and every one of them represents safety and security risks.

2. In parallel to the rapid development of biotechnology, the apprehension over bioterrorism increased dramatically following the September 11, 2001 and the subsequent anthrax incidents. Concerns have been further compounded by the emergence of new biological agents and associated disease outbreaks. Consequently, the sensitivity to threats and vulnerabilities has increased – developments that are mirrored in the international interest in biorisk management activities.

3. Biorisks in laboratories encompasses both biosafety and biosecurity, where biosafety relates to harm to e.g. people from accidents or mishaps. Security considerations, resting on the assumption that the pathogens may also be used maliciously, add new dimensions to the traditional safety risk management: biosecurity covers the deliberate unauthorized use of materials. Biosafety and biosecurity are dissimilar yet closely interlinked, and common systems are required to manage both effectively.

Biorisk management and the BWC

4. National, regional and international measures to improve biosafety and biosecurity are all part of the current Work Program of the BWC. Earlier activities (2003) under the auspices of the Convention have dealt with the adoption of national measures to implement the BWC-prohibitions. Efforts encompassed the enactment of penal legislation and national mechanisms to establish and maintain oversight of pathogenic micro-organisms and toxin collections.[1] This approach was found to be highly useful in improving coordination within and between national systems, and the exercise was extended by Member States in subsequent years.

5. International standards also play a vital role in the development of national regulations, guidelines and requirements. External and independent certification may assist containment laboratories in establishing and implementing adequate levels of biosafety and biosecurity. Certified compliance with relevant international standards may, moreover, confirm that appropriate measures are taken with regards to biorisk management.

6. However, until recently there was no internationally recognized management standard for laboratories handling pathogenic micro-organisms. Relevant management systems need not only cover the more traditional technically orientated areas such as facility design or personal protective equipment, but also consider human and organizational factors. This has now been addressed through the development of the Laboratory Biorisk Management Standard.

The Laboratory Biorisk Management Standard

7. In February 2008, the European Committee for Standardization released the **Laboratory Biorisk Management Standard** (CWA 15793).[2] The scope of the Standard is to set requirements necessary to control risks associated with the handling, storage and disposal of biological agents and toxins in laboratories and other facilities. The standard 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.

8. The CEN Laboratory Biorisk Management Standard is based on a management systems approach addressing biosafety and biosecurity in a laboratory setting. The organization's ability to deal with the hazards associated with biological agents and toxins is improved through the identification, understanding and management of a range of interrelated and relevant processes. During the development of the standard, 76 participants from 24 countries[3] worked together. Other contributors included major biosafety associations and a range of internationally recognized institutes and organizations, which included the WHO. As such, the standard represents the only authoritative, consensus-developed biorisk management standard available.

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[1] Presentation by the ISU at the 11th Annual Conference of the European Biosafety Association, Florence, Italy, 3-4 April 2008. www.unog.ch/80256EDD006B8954/(httpAssets)/FAB084DF173EACEBC125747100354C1E/$file/BWC+presentation+EBSA+4+April+08.pdf

[2] The European Committee for Standardization, **Laboratory Biorisk Management Standard**, CWA 15793:2008, www.cen.eu.

[3] 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.

Conclusion

9. Implementing the requirements of the Laboratory Biorisk Management Standard is likely to further biosafety and biosecurity at facilities using, handling or storing hazardous biological materials and toxins. There is also the opportunity for stakeholders to use the Standard and associated monitoring mechanisms (e.g. future certification schemes) to ensure that good practices are being adopted and effective controls maintained. In addition, the Standard should help ensure that facilities are well prepared to respond in the event that biological agents were released.

10. International standards can also play a role in the development of national regulations, guidelines and requirements. The Standard provides a framework for responsible management of risk in laboratories and can contribute directly to meeting objectives associated with preventing direct or indirect exposures to potentially harmful biological agents. As such, the Laboratory Biorisk Management Standard should serve well as a platform for awareness-raising, confidence building, as well as technical cooperation under the BWC.

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