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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Biological risk assessment and management

Biorisk management standards and their role in BTWC implementation

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I. Overview

1. This working paper provides an overview of recent developments in industrial management standards and demonstrates the complementary and supportive role these standards can play with regard to the implementation of the BTWC. It describes the genesis and establishment of ISO 35001 (Biorisk management for laboratories and other related organisations), adopted in 2019. The paper explains how industrial standards, while not in any way substituting for a governmental compliance regime, can help States Parties implement the obligations set out in the BTWC and how they can enhance biosafety and biosecurity, aka biorisk management. Finally, it proposes a way forward for States Parties, including through a dialogue with biosafety associations, the life sciences industry and international standards organizations.

II. Implementing the BTWC by biosafety and biosecurity measures

2. Article IV of the BTWC obliges States Parties to "take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere". Compliance with this Article necessitates *inter alia* the enactment of biosafety and biosecurity measures aimed at preventing the accidental release of, or unintentional exposure to, biological agents and toxins, and preventing the loss, theft, unauthorized possession or transfer, and misuse of biological dual-use agents. While Governments have the responsibility to set up the appropriate legislative and regulatory framework to ensure biosafety and biosecurity, this policy can be enhanced by measures taken by the life science institutions and industry. Internationally accepted, verifiable and certifiable standards play a pivotal role in this regard.

3. Industrial standards are developed by the business community, in order to manage risk, create a level playing field, facilitate communication and trade, and ease implementation of legislation. They are developed with the help of national, regional and international standardization institutes, such as the European Committee for Standardization (CEN) and the International Organisation for Standardisation (ISO). These institutions can be public, private or mixed. The standards are more than mere declarations of intent or codes of conduct. They can include a system of validation: a company can be "certified" according to a certain standard, after an audit/inspection by an accredited "conformity assessment body". By granting a certificate, a standard organization guarantees that the certified organization is complying and functioning according to the management standard.

4. For laboratories, businesses and other organisations handling 'hazardous' biological materials, biorisk management standards can be useful, because it helps them to:

(a) Manage physical security, personnel security (vetting), material control and accountability, information and transport security;

(b) Facilitate implementation and ensure compliance with current national, regional and international legal requirements;

(c) Prevent intentional and unintentional release of and exposure to biological materials;

(d) Implement, maintain and improve biorisk management;

(e) Assure itself of conformity with its stated biorisk policy;

(f) Demonstrate such conformance to others;

(g) Seek internationally recognized third party certification of its biorisk management system.

5. Examples of widely used industrial standards are ISO 9001 on quality management and ISO 14001 on environmental management. With regard to biosafety and biosecurity, the European Committee for Standardization (CEN) developed the Laboratory Biorisk Management document: CEN Workshop Agreement (CWA) 15793:2008. The term "Biorisk" encompasses both biosecurity and biosafety. CEN also developed a CWA, describing the tasks and competence areas of a biosafety professional in CWA 16335:2011 on Biosafety Professional Competence.

6. The most significant recent development is the adoption in 2019 of ISO 35001 - Biorisk management for laboratories and other related organisations. This standard defines a process to identify, assess, control, and monitor the risks associated with hazardous biological materials. It is applicable to any laboratory or other organization that works with, stores, transports, and/or disposes of hazardous biological materials. ISO 35001 harmonizes existing national and regional standards and thus establishes a uniform set of best practices for biorisk management that can be applied and certified on a global scale.

7. This development within the life sciences industry strengthens the international capacity to reach the goals of the BTWC in several ways:

(a) it provides a tool for awareness raising in the scientific community regarding the risks related to biological dual-use items;

(b) it reduces the risk of unauthorized access to biological agents and materials;

(c) it provides an increased level of assurance that life science institutions are complying with the prohibitions and obligations of the BTWC;

(d) it guarantees responsible biorisk management in certified facilities, even in cases where national legislation and regulation fall short of requirements;

(e) it can facilitate international transactions relevant for Article X assistance.

(f) it will enhance responsible research of hazardous biological materials, including engineered and synthetically derived materials.

III. Improving BTWC implementation through harmonized biorisk management practices

8. SARS, pandemic viruses and threats of the malicious use of pathogens illustrate the risks that biological agents and materials pose and the need to reinforce safety and security precautions. The productive results of the auto-regulatory initiatives of the life sciences community offer the opportunity to increase safety and security and thus can ameliorate the implementation of the BTWC. The Seventh Review Conference of the BTWC in 2011[1] noted 'the value of national implementation measures, as appropriate, in accordance with the constitutional process of each State Party, to implement voluntary management standards on biosafety and biosecurity; encourage the consideration of development of appropriate arrangements to promote awareness among relevant professionals in the private and public sectors and throughout relevant scientific and administrative activities'. In preparation of this Conference a working paper[2] on Biorisk management standards and their role in BTWC implementation was submitted.

9. It is therefore proposed that the States Parties of the BTWC:

(a) Welcome the development and encourage the implementation of biorisk management standards within the life sciences community;

(b) Recognise that biorisk management standards can play a complementary and supportive role in the implementation of the obligations of the BTWC;

(c) Call on the life sciences community to adhere to international biorisk management standards;

(d) Encourage States Parties to provide assistance, where appropriate, for the implementation of biorisk management standards in life science institutions in accordance with Article X;

(e) Within the intersessional programme of work, enter into dialogue with representatives from biosafety associations, the life sciences community and international standards organizations in order to discuss means and methods to raise awareness regarding international biorisk management standards and to facilitate their application.

10. Industrial standards fall under the purview of non-governmental actors. They are no substitute for the responsibility of States Parties to implement the BTWC through policy, legislation and enforcement. They do not provide fail proof guarantees against unlawful use of biological agents and materials. They do however have the potential of strengthening the global implementation of the BTWC through reinforced biosafety and biosecurity, and through increased mutual confidence regarding precautionary measures in biocontainment laboratories and other relevant facilities. The States Parties of the BTWC should therefore seize this opportunity.

[1] BWC/CONF.VII/7 on art. IV §13.
[2] BWC/CONF.VII/WP.7.