

# Frequently Asked Questions

about the

## ISO 35001:2019 - Biorisk management for laboratories and other related organisations

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This FAQ is based on public information and has no formal status.

This is an informative document that accompanies the working paper “Biorisk management standards and their role in BTWC implementation” (BWC/MSP/2020/MX.2/WP.2) submitted by Belgium to the 2020 session of the Meeting of States Parties to the Biological and Toxin Weapon Convention.

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### 1. What is biorisk, biosafety, biosecurity, according to the 35001 standard?

**Biorisk** encompasses biosafety and biosecurity. Biorisk is the effect of uncertainty expressed by the combination of the consequences of an event (including changes in circumstances) and the associated “likelihood” of occurrence, where biological material is the source of harm. Harm can be the consequence of an unintentional exposure, accidental release, or loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release. **Biosafety** involves practices and controls that reduce the risk of unintentional exposure or release of biological materials (‘protecting people from bad bugs’). **Biosecurity** involves practices and controls that reduce the risk of loss, theft, misuse, diversion of, or intentional unauthorized release of biological materials (‘securing bugs from bad people’).

## **2. What does the ISO 35001 biorisk management system do?**

The ISO 35001 biorisk management system:

- establishes the biorisk management principles that enable laboratories and related facilities to achieve their biosafety and biosecurity objectives;
- defines the essential components of a biorisk management system framework to be integrated into the overall governance, strategy and planning, management, reporting processes, policies, values, and culture of a laboratory or other related facility;
- describes a comprehensive biorisk management process that mitigates biorisks (biosafety and biosecurity risks); and
- provides guidance on the implementation and use of the standard, where appropriate.

The biorisk management system is based on a management system approach, which enables an organization to effectively identify, assess, control, and evaluate the biosafety and biosecurity risks inherent to its activities. As such, the document is intended to define requirements that are appropriate to the nature and scale of any organization. The biorisk management system is 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 its goals. This is known as the Plan-Do-Check-Act (PDCA) principle: The PDCA model is an iterative process used by organizations to achieve continual improvement of processes and products.

## **3. What is the use of the 35001 ISO biorisk management standard?**

Safe and secure handling of biological materials is essential for industry, government and academia. A biorisk management system is a key step to achieve this as it enables an organization to effectively identify, control and manage the biosafety or biosecurity risks related to its activities. The ISO 35001 is the first International Standard for a biorisk management system. It defines the requirements and guidance for laboratories or any other organization that handle biological agents to control and reduce any risks associated with their use. While there are a number of regional or national standards that help organizations manage their risks and meet regulatory requirements, ISO 35001 is the first one that harmonizes them to deliver international best practice.

## **4. Who developed the ISO 35001 standard?**

An ISO standard responds to a need in the market, typically an industry sector. The standard is developed by groups of experts from around the world by means of a multi-stakeholder process, involving industry, professional associations, academia, NGO's and government. Experts gather in a committee, negotiate all aspects of the standard and adopt it in consensus.

The roots of the ISO 35001 go back to 2004 when an international working group of biosafety professionals within the major biosafety professional organizations (e.g. EBSA, ABSA, APAC)<sup>1</sup> recognized the need for biosafety standards and management principles. They first started with setting up a European CEN Workshop Agreement (CWA) 15793, published in 2008. Notwithstanding the international character of a CWA document, the document is often perceived

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<sup>1</sup> EBSA: European Biosafety Association; ABSA: American Biosafety Association; APAC: Asia-Pacific Biosafety Association

as a typical European document. This highlighted the need for a more sustainable and internationally recognized document. Different approaches were explored and it was decided to go for an ISO standard. ISO has extensive experience with setting up management system standards, such as ISO 14001 and ISO 45001. Consequently, when an organisation already has implemented another ISO standard, the ISO 35001 can be easily integrated in the existing management system. ISO 35001 was developed by ISO technical committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*, the secretariat of which is held by the American National Standards Institute, ISO's member for the USA.

#### **5. How does the 35001 standard relate with national and international legislation?**

ISO International Standards are voluntary. They do not include contractual, legal or statutory requirements. Compliance with national and local regulatory standards, regulations and requirements are of primary importance in any biorisk program. Compliance with a standard is not a substitute to compliance with national laws. Where any part of the standard is in conflict with any legal requirement, the conflicting part of the standard may be eligible for exemption if the legal requirement meets or exceeds the intent of the ISO 35001 standard. The biorisk management standard can assist an organization to fulfil its legal requirements and other requirements.

#### **6. How does certification of a standard work and what is accreditation?**

Certification or 'conformity assessment' is the provision by an independent body (a certification body) of written assurance (a certificate) that the product, service or system in question meets the requirements of the standard. Accreditation is the formal recognition by an independent body, generally known as an accreditation body, that a certification body operates according to international standards.

#### **7. Which institutions should use and apply the standard?**

The standard is a voluntary tool that can be applied by all facilities (governmental and non-governmental) that handle hazardous biological materials, such as laboratories and other life science institutions. All institutions can purchase the document and decide to implement it. Institutions can also opt to demonstrate compliance with the requirements of the standard by undergoing a conformity assessment by an independent body and getting a certificate. Typically institutions apply the standard to manage their biological risks, to enter a level playing field that might be required by international partners; to compensate for the absence of sufficient governmental oversight; to demonstrate that they meet risk management requirements; to facilitate international transactions of biological dual-use agents.

#### **8. Where can you get the ISO 35001 standard?**

The full standard document is available for purchase at <https://www.iso.org/standard/71293.html>. A free preview can be downloaded from <https://www.sis.se/api/document/preview/80018014/>.

## **9. Who is applying the ISO 35001 standard?**

Hard to say. Given that it is a voluntary standard, there is no central global measurement that registers how much facilities are applying it. Facilities that are certified according to an ISO standard normally advertise this and currently a query on the internet doesn't reveal any certification – yet. This is probably a consequence of the standard being still quite recent and the corresponding certification guidelines are still under development. But given the global success of the, albeit regional, predecessor biorisk management document (CWA 15793), it seems fair to predict that the ISO standard's outreach will be considerable.

## **10. What is the relevance of the ISO 35001 for the BTWC?**

In 2011 the 7<sup>th</sup> Review Conference of the BTWC<sup>2</sup> 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'*.

Industrial standards fall under the purview of non-governmental actors. They are no substitute for the responsibility of States Parties to implement and comply with 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, through increased mutual confidence regarding precautionary measures in biocontainment laboratories and other relevant facilities and through offering a format for independent conformity assessment of biorisk management requirements .

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<sup>2</sup> BWC/CONF.VII/7 on art. IV §13.