

## Standard for biorisk management: from idea to an ISO standard



Interview with Toon De Kesel, manager of Febris Biorisk Consult and associate partner of Perseus. Since 2004, Toon De Kesel has been closely involved in setting up the CEN Workshop Agreement and subsequently the ISO 35001:2019 standard for biorisk management

### What is management of biorisks? Why is it important?

Biosafety in a laboratory, either for R&D, QC or production activities, is of crucial importance to avoid exposure of staff to hazardous biological agents and to prevent the release into the environment. Therefore, biosafety officers assist companies and institutes in developing and implementing biosafety programs and practices. However, our understanding of potential hazards and risks, as well as the technologies to cope with them keep evolving. Consequently, biosafety solutions need to evolve. This leads to a more risk-based approach of biosafety, meaning that facilities, equipment and work practices have to be subject to a continuous and balanced assessment and can be adapted whenever deemed necessary. This will allow for a flexible laboratory design and will emphasize human factors and education of employees. The need for a risk-based approach is clearly illustrated in the current days, when many laboratories seek to support the diagnosis and/or the research of SARS-CoV-2.

### What is an ISO standard?

Standards are documents that are agreed upon by a group of experts and according to a specific process and rules for representation. They can cover a wide range of topics such as a product, managing a process, delivering a service or supplying materials. Standards can be developed within a company or organization, within a consortium of organizations or by a recognized (inter)national standards organization. ISO, an abbreviation for 'International Organization for Standardization', is such an international standards organization that develops and publishes standards. It is an independent, non-governmental organization with a membership of 164 national standards bodies. The standards generated by ISO are called ISO standards. Also other document types can be generated, such as ISO technical specifications, ISO guides and international workshop agreements.

In view of biorisk management, ISO recently developed and published the standard ISO 35001. This standard defines a process to identify, assess, control, and monitor the risks associated with hazardous biological materials. The document is applicable to any laboratory or other organization that works with, stores, transports, and/or disposes of hazardous biological materials. It is not intended for laboratories that test for the presence of microorganisms and/or toxins in food or feedstuffs, nor for the management of risks from the use of genetically modified crops in agriculture.

### How was ISO 35001 developed?

In 2004, 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 the CEN Workshop Agreement (CWA) 15793, published in 2008. Notwithstanding the international character of a CWA document, the document is often perceived as a typical European document. Moreover, CWA documents expire 6 years after publishing. This highlighted the need for a more sustainable and internationally recognized document. Different approaches were explored such as converting the document into a WHO guideline or an ANSI standard. Converting into an ISO standard was the preferred option, as ISO is acknowledged worldwide and not linked to a specific national or regional organization. Furthermore, 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.

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

## How can ISO 35001 help biorisk management?

The ISO standard on biorisk management has preserved the content and the principles outlined in CWA 15793. In brief, it will help companies and organizations to set up a management system in order to identify, assess, control, and monitor the risks associated with hazardous biological materials. Such is reflected in the need for e.g. a continuous hazard and threat identification, evaluation of emergency planning, ongoing risk assessment and subsequent mitigation plans within the biosafety program.

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. This is known as the Plan-Do-Check-Act (PDCA) principle.

Finally, taking into account the broad experience with ISO in management systems, ISO 35001 can be easily integrated with existing or future ISO management system standards a company or organization has implemented.

## Which organizations can use ISO 35001?

ISO 35001 is a performance-based standard and can be implemented applying a so-called 'elements-based' approach. This means the ISO describes biorisk-related elements that can be implemented, but these elements are not outlined in great detail. For example, it mentions that an organization needs an inventory, but it does not describe in detail the requirements for the inventory. This less descriptive approach allows implementation tailored to the needs and possibilities of each organization, independent of its size or maturity. In any case, implementing a biorisk management system requires commitment of higher management, to ensure sufficient time and resources are made available to set up and maintain the system.

## Does ISO 35001 replace legal obligations?

Compliance with national and local regulatory standards, regulations and requirements are of primary importance in any biorisk program. 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.

## How can I get ISO 35001?

ISO standards are generally not for free. If you are looking to buy an ISO Standard, then you can contact the ISO or a national standardization organization (e.g. NBN, NEN, BSI, AFNOR, ANSI, etc.).

ISO can be contacted via <https://www.iso.org/standard/71293.html>



Founded in 2003, Perseus BV is a service company dedicated to biosafety and biotechnology regulatory services. With science based assessment of safety at the core of its activities, Perseus' services extend to biorisk management in all project phases (contained use, confined trials, commercial applications, movement of materials, imports and stewardship) and cover biotechnology applications in the agrifood chain, food industry, industrial deployment, as well as clinical & medical developments.

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