LABORITE JA TEISTE VASTAVATE ORGANISATSIOONIDE BIORISKIHALDUS

Biorisk management for laboratories and other related organisations (ISO 35001:2019, identical + ISO 35001:2019/Amd 1:2024, identical)

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA	NATIONAL FOREWORD
See Eesti standard EVS-ISO 35001:2020+A1:2024 „Laborite ja teiste vastavate organisatsioonide bioriskihaldus“ sisaldab rahvusvahelise standardi ISO 35001:2019 „Biorisk management for laboratories and other related organisations“ ja selle muudatuse A1:2024 identset ingliskeelset teksti.	This Estonian Standard EVS-ISO 35001:2020+A1:2024 consists of the identical English text of the International Standard ISO 35001:2019 „Biorisk management for laboratories and other related organisations“ and its amendment A1:2024.
Ettepaneku rahvusvahelise standardi ümbertrüki meetodil ülevõtuks on esitanud EVS/TK 11, standardi avaldamist on korraldanud Eesti Standardikeskus.	Proposal to adopt the International Standard by reprint method has been presented by EVS/TK 11, the Estonian Standard has been published by the Estonian Centre for Standardisation.
Standard EVS-ISO 35001:2020+A1:2024 on jõustunud sellekohase teate avaldamisega EVS Teatajas.	Standard EVS-ISO 35001:2020+A1:2024 has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega ⟦A1⟩ ⟨A1⟧.	The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags ⟦A1⟩ ⟨A1⟧.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Käsitlusala

See dokument määratleb protsessi, et identifitseerida, kaalutleda, ohjata ja seirata ohtlike bioloogiliste materjalidega seotud riske. See dokument on rakendatav igas laboris või muus organisatsioonis, mis käitleb, säilitab, transpordib ja/või utiliseerib ohtlikke bioloogilisi materjale. See dokument on mõeldud toetama olemasolevaid laborite rahvusvahelisi standardeid.

See dokument ei ole mõeldud laboritele, mis analüüsivad mikroorganismide ja/või toksiinide olemasolu toidus või loomasöödas. Dokument ei ole mõeldud põllumajanduses geneetiliselt muundatud saagi kasutamist puudutavate riskide haldamiseks.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 03.100.70; 07.100.01; 11.100.01

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Amendment A1 Foreword

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This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*, in accordance with Technical Management Board Resolution 75/2023.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The 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 a laboratory or other related organization's overall governance, strategy and planning, management, reporting processes, policies, values, and culture;

— 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 in its activities. As such, this document is intended to define requirements for a biorisk management system that is 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. It can be applied to a biorisk management system, and to each of its individual elements, as follows:

— Plan: establish objectives, programmes, and processes necessary to deliver results in accordance with the organization's biorisk management policy;

— Do: implement the processes as planned;

— Check: monitor and measure activities and processes with regard to the biorisk management policy and objectives, and report the results;

— Act: take actions to continually improve the biorisk management performance to achieve the intended outcomes.

Figure 1 illustrates the PDCA framework and how it relates to other requirements of this document.

NOTE Figure 1 is adapted from ISO 45001 *Occupational health and safety management system — Requirements with guidance for use*.

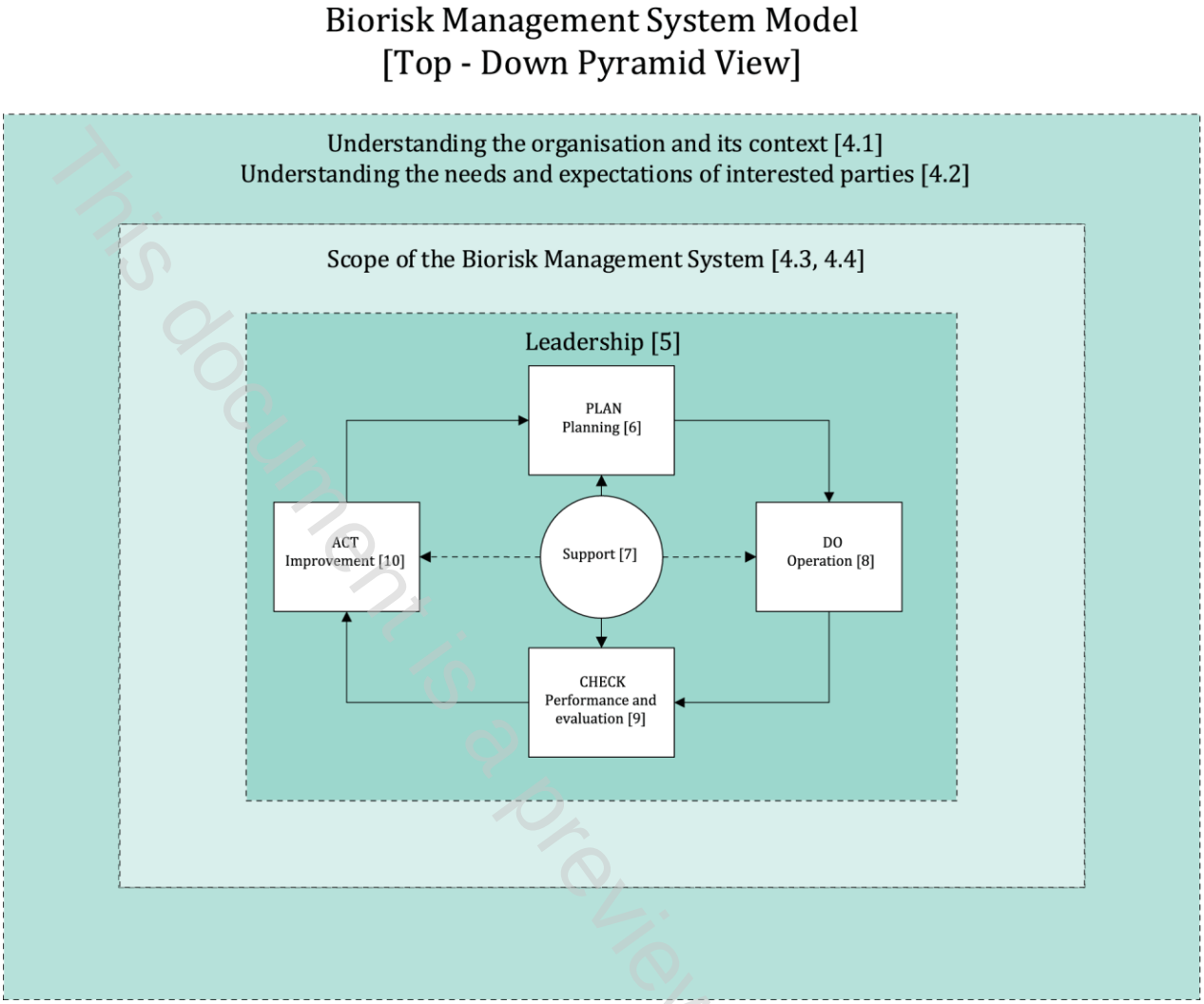

Figure 1 — Top down pyramid view of a biorisk management system model

Improving biorisk management requires attention to and understanding of the causes of nonconformities and incidents. Systematic identification and correction of system deficiencies leads to improved performance and control of biorisks.

Key factors in establishing and implementing a biorisk management system include:

— Commitment by top management to:

  — provide adequate resources;

  — prioritize and communicate biosafety and biosecurity policy;

  — establish performance expectations and integrate biorisk management throughout the organization;

  — determine causes of incidents and nonconformities and prevent recurrence; and

  — identify opportunities for improvement and prevention.

— Focus on continual improvement to:

  — make continual improvement a priority for every individual in the organization;

- use periodic assessment against risk criteria established by the organization to identify areas for potential improvement;
- continually improve the effectiveness and efficiency of processes;
- take corrective action for unsafe or unsecure practices, and promote preventive activities;
- provide workers in the organization with appropriate education and training to support biorisk management, including the methods and tools of continual improvement;
- establish measures and goals for improvement; and
- recognize improvement.

A biorisk management program can assist an organization to fulfill its legal requirements and other requirements.

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Biorisk management for laboratories and other related organizations

1 Scope

This document defines a process to identify, assess, control, and monitor the risks associated with hazardous biological materials. This document is applicable to any laboratory or other organization that works with, stores, transports, and/or disposes of hazardous biological materials. This document is intended to complement existing International Standards for laboratories.

This document is not intended for laboratories that test for the presence of microorganisms and/or toxins in food or feedstuffs. This document is not intended for the management of risks from the use of genetically modified crops in agriculture.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
organization
person or group of people that has its own functions with responsibilities, authorities, and relationships to achieve its *objectives* (3.11)

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, charity, or institution, or part or combination thereof, whether incorporated or not, public or private.

3.2
interested party
stakeholder
person or *organization* (3.1) that can affect, be affected by, or perceive themselves to be affected by a decision or activity

3.3
worker
person performing work or work-related activities under the control of the *organization* (3.1)

Note 1 to entry: Persons performing work or work-related activities under various arrangements, paid or unpaid, such as regularly or temporarily, intermittently or seasonally, casually, or on a part-time basis.

Note 2 to entry: Workers include *top management* (3.8), managerial, and non-managerial persons.