

**LABORITE JA TEISTE VASTAVATE ORGANISATSIOONIDE
BIORISKIHALDUS**

**Biorisk management for laboratories and other related
organisations
(ISO 35001:2019, identical)**

EESTI STANDARDI EESSÕNA**NATIONAL FOREWORD**

| | |
|---|--|
| See Eesti standard EVS-ISO 35001:2020 „Laborite ja teiste vastavate organisatsioonide bioriskihaldus“ sisaldab rahvusvahelise standardi ISO 35001:2019 „Biorisk management for laboratories and other related organisations“ identset ingliskeelset teksti. | This Estonian Standard EVS-ISO 35001:2020 consists of the identical English text of the International Standard ISO 35001:2019 „Biorisk management for laboratories and other related organisations“. |
| 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 on jõustunud sellekohase teate avaldamisega EVS Teataja 2020. aasta juuniku numbris. | Standard EVS-ISO 35001:2020 has been endorsed with a notification published in the June 2020 issue of the official bulletin of the Estonian Centre for Standardisation. |
| Standard on kättesaadav Eesti Standardikeskusest. | The standard is available from the Estonian Centre for Standardisation. |

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

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:

Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact the Estonian Centre for Standardisation:

Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

Contents

Page

| | |
|--|-----------|
| Foreword | v |
| Introduction | vi |
| 1 Scope | 1 |
| 2 Normative references | 1 |
| 3 Terms and definitions | 1 |
| 4 Context of the organization | 7 |
| 4.1 Understanding the organization and its context | 7 |
| 4.2 Understanding the needs and expectations of interested parties | 8 |
| 4.3 Determining the scope of the biorisk management system | 8 |
| 4.4 Biorisk management system | 8 |
| 5 Leadership | 8 |
| 5.1 Leadership and commitment | 8 |
| 5.2 Policy | 9 |
| 5.3 Roles, responsibilities, and authorities | 9 |
| 5.3.1 Top management | 10 |
| 5.3.2 Senior management | 10 |
| 5.3.3 Biorisk management committee | 10 |
| 5.3.4 Biorisk management advisor | 11 |
| 5.3.5 Scientific management | 11 |
| 6 Planning | 12 |
| 6.1 Actions to address risks and opportunities | 12 |
| 6.1.1 Hazard and/or threat identification and analysis | 12 |
| 6.1.2 Risk assessment | 12 |
| 6.1.3 Risk mitigation | 13 |
| 6.1.4 Performance evaluation | 13 |
| 6.2 Biorisk management objectives and planning to achieve them | 13 |
| 7 Support | 14 |
| 7.1 Resources | 14 |
| 7.1.1 Worker health programme | 14 |
| 7.2 Competence | 15 |
| 7.2.1 Behavioural factors and worker management | 15 |
| 7.2.2 Personnel reliability measures | 15 |
| 7.3 Awareness | 16 |
| 7.3.1 Training | 16 |
| 7.4 Communication | 16 |
| 7.5 Documented information | 17 |
| 7.5.1 General | 17 |
| 7.5.2 Creating and updating | 17 |
| 7.5.3 Control of documented information | 17 |
| 7.5.4 Information security | 18 |
| 7.6 Non-employees | 18 |
| 7.7 Personal security | 18 |
| 7.8 Control of suppliers | 18 |
| 8 Operation | 19 |
| 8.1 Operational planning and control | 19 |
| 8.2 Commissioning and decommissioning | 19 |
| 8.3 Maintenance, control, calibration, certification, and validation | 20 |
| 8.4 Physical security | 20 |
| 8.5 Biological materials inventory | 20 |
| 8.6 Good microbiological technique | 20 |
| 8.7 Clothing and personal protective equipment (PPE) | 20 |

| | | |
|-----------|--|-----------|
| 8.8 | Decontamination and waste management..... | 20 |
| 8.9 | Emergency response and contingency planning..... | 21 |
| 8.9.1 | Emergency scenarios..... | 21 |
| 8.9.2 | Emergency plan training..... | 21 |
| 8.9.3 | Emergency exercises and simulations..... | 21 |
| 8.9.4 | Contingency plans..... | 21 |
| 8.10 | Transport of biological materials..... | 21 |
| 8.10.1 | Transport security..... | 22 |
| 9 | Performance evaluation..... | 22 |
| 9.1 | Monitoring, measurement, analysis, and evaluation..... | 22 |
| 9.2 | Internal audit..... | 22 |
| 9.3 | Management review..... | 23 |
| 10 | Improvement..... | 23 |
| 10.1 | General..... | 23 |
| 10.2 | Incident, nonconformity, and corrective action..... | 24 |
| 10.3 | Continual improvement..... | 24 |
| | Bibliography..... | 26 |

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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.

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*.

Biorisk Management System Model [Top - Down Pyramid View]

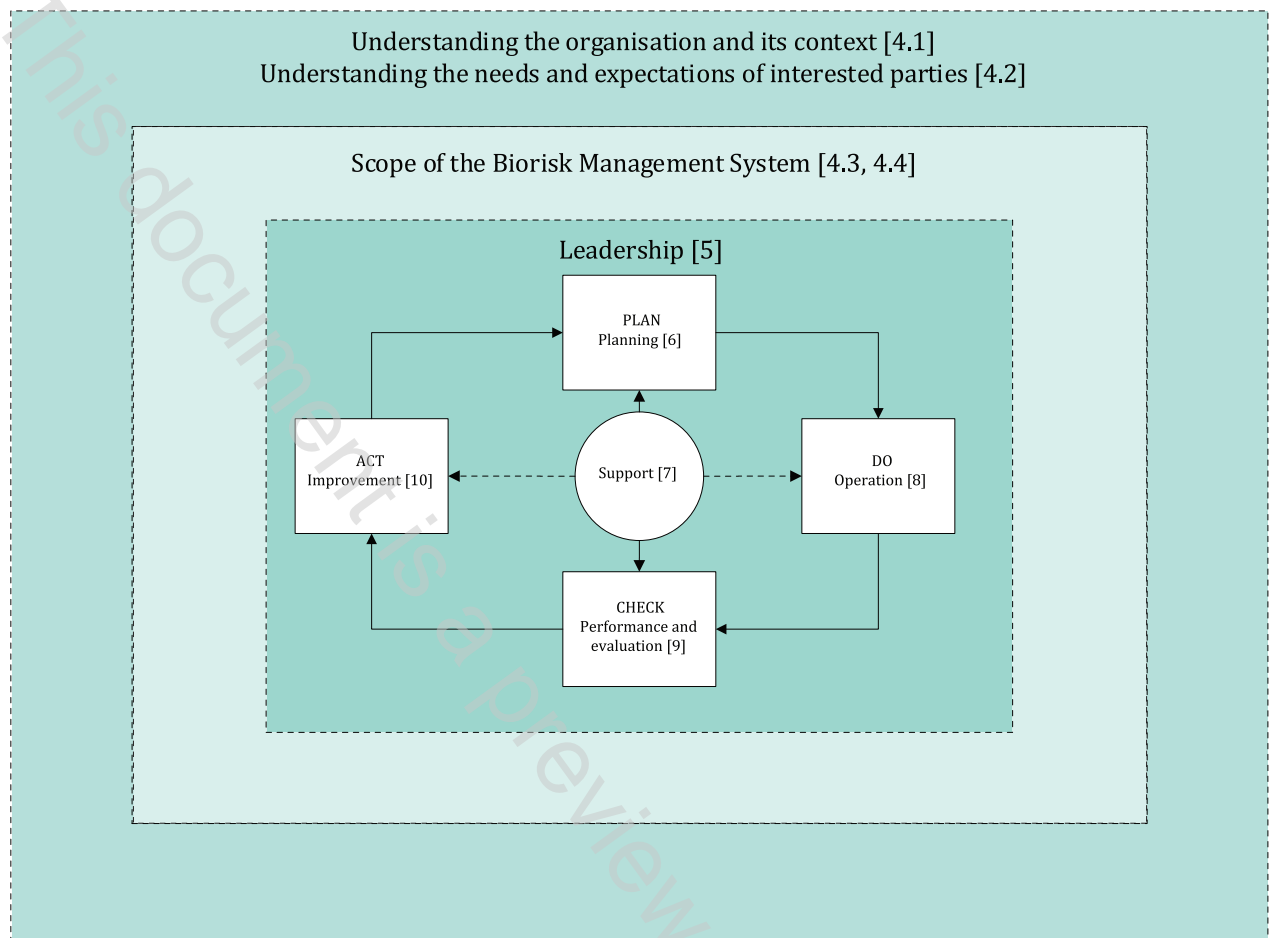


Figure 1 — Top down pyramid view of a biorisk management system model

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.

Biorisk management for laboratories and other related organisations

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.

Note 3 to entry: The work or work-related activities performed under the control of the *organization* (3.1) may be performed by workers employed or contracted by the *organization* (3.1), or by a subcontractor.

[SOURCE: ISO 45001:2018, 3.3]