

# INTERNATIONAL STANDARD

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## **Biorisk management for laboratories and other related organisations**

*Système de management des biorisques en laboratoires et autres  
organismes associés*



Reference number  
ISO 35001:2019(E)

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## ISO 35001:2019(E)



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## 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](http://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](http://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](http://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](http://www.iso.org/members.html).

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### 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:

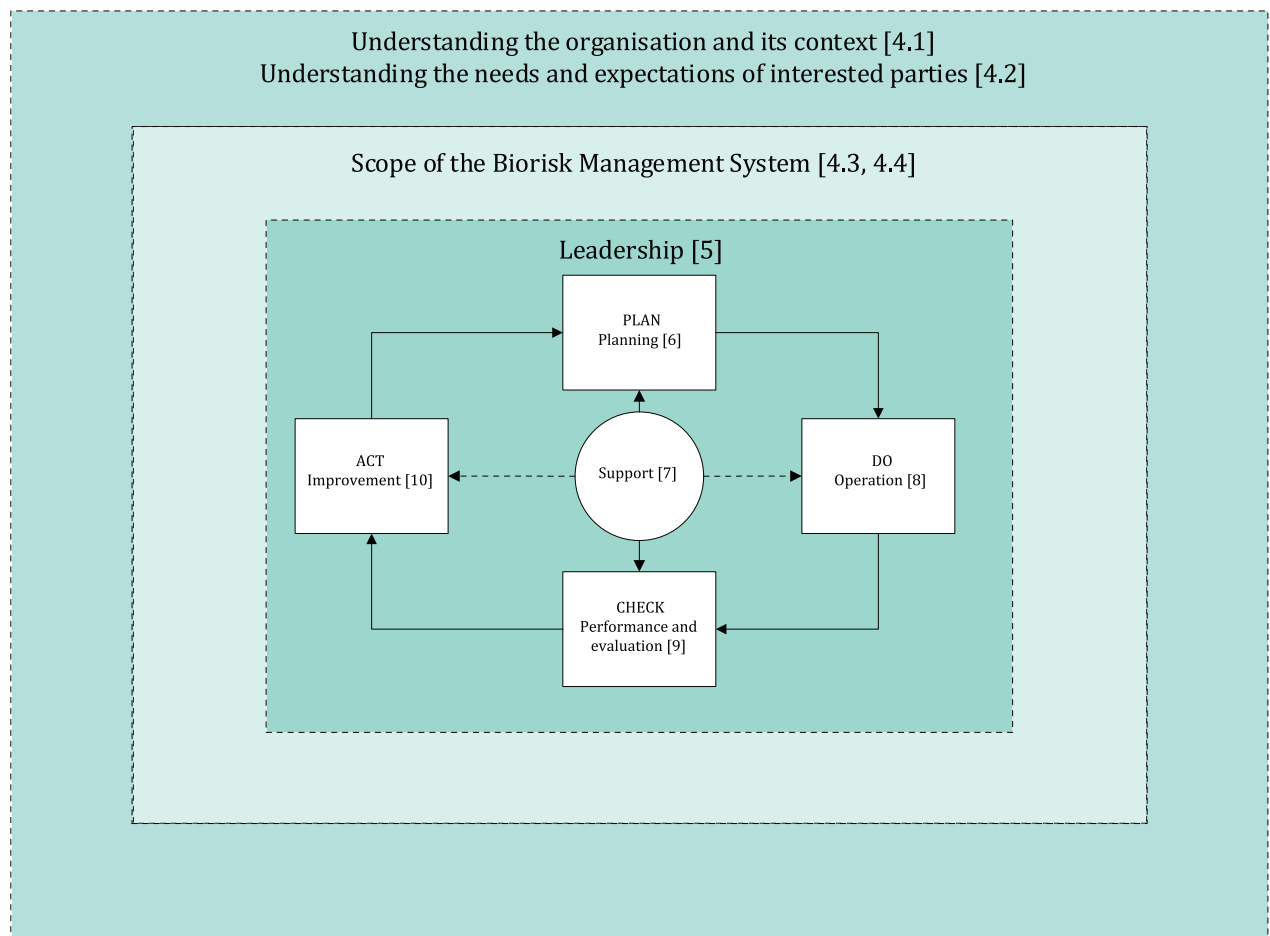
The PDCA model is an iterative process used by organizations to achieve continual improvement of processes and products. It can be applied to a biorisk management system, and to each of its individual elements, as follows:

- 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;

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- 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]

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### 3.4 requirement

need or expectation that is stated, generally implied, or obligatory

Note 1 to entry: “Generally implied” means that it is custom or common practice for the *organization* (3.1) and *interested parties* (3.2) that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, for example in *documented information* (3.30).

### 3.5 management system

set of interrelated or interacting elements of an *organization* (3.1) to establish *policies* (3.10), *objectives* (3.11), and *processes* (3.31) to achieve those *objectives* (3.11)

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The system elements include the *organization's* (3.1) structure, roles and responsibilities, planning and operation.

Note 3 to entry: The scope of a management system may include the whole of the *organization* (3.1), specific and identified functions of the *organization* (3.1), specific and identified sections of the *organization* (3.1), or one or more functions across a group of organizations.

### 3.6 biorisk management

coordinated activities to direct and control an *organization* (3.1) with regard to *biorisk* (3.17)

[SOURCE: ISO Guide 73:2009, definition 2.1, modified — “risk” has been replaced by “biorisk.”]

### 3.7 biorisk management system

*management system* (3.5) or part of a *management system* (3.5) used to establish *biorisk management* (3.6) *policies* (3.10), *objectives* (3.11), and *processes* (3.31) to achieve those *objectives* (3.11)

Note 1 to entry: A biorisk management system addresses the control of *biorisk(s)* (3.17).

### 3.8 top management

person or group of people who directs and controls an *organization* (3.1) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the *organization* (3.1).

Note 2 to entry: If the scope of the *biorisk management system* (3.7) covers only part of an *organization* (3.1), then top management refers to those who direct and control that part of the *organization* (3.1).

### 3.9 effectiveness

extent to which planned activities are realized and planned results achieved

### 3.10 policy

intentions and direction of an *organization* (3.1) as formally expressed by its *top management* (3.8)

### 3.11 objective

result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels [such as strategic, organization-wide, project, product and *process* (3.31)].

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of *biorisk management systems* (3.7), objectives are set by the *organization* (3.1), consistent with the organization's *policy* (3.10), to achieve specific results.

### 3.12 environment

surroundings in which an *organization* (3.1) operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelationships

Note 1 to entry: Surroundings can extend from within an organization to the local, regional, and global system.

Note 2 to entry: Surroundings can be described in terms of biodiversity, ecosystems, climate, or other characteristics.

[SOURCE: ISO 14001:2015, 3.2.1]

### 3.13 biological agent

any microbiological entity, cellular or non-cellular, naturally occurring or engineered, capable of replication or of transferring genetic material that may be able to provoke infection, allergy, toxicity or other adverse effects in humans, animals, or plants

EXAMPLE Bacteria, fungi, viruses, viroids, endo-, and ectoparasites.

Note 1 to entry: The definition of biological agents covers commonly used terms, such as pathogens, quarantine microorganisms, microorganisms of dual-use potential.

Note 2 to entry: For the purpose of this document, prions are regarded as biological agents.

Note 3 to entry: The term “engineered” includes biological agents that are synthetically derived.

### 3.14 biological materials

any material comprised of, containing, or that may contain *biological agents* (3.13) and/or their harmful products, such as *toxins* (3.15) and allergens

Note 1 to entry: Biological materials may be blood, secretions, or tissues of human or animal origin. Other biological materials include debris or organic material from nature, culture, or preservation media, and/or cell cultures from human, animal, and plants.

Note 2 to entry: Animals and plants or parts thereof handled in relevant laboratories that may contain *biological agents* (3.13) or *toxins* (3.15) or biological agent vectors, such as arthropods, nematodes, and mites, are considered biological materials.

### 3.15 toxin

substance, produced by plants, animals, protists, fungi, bacteria, or viruses, which in small or moderate amounts produces an adverse effect in humans, animals, or plants

Note 1 to entry: This definition includes substances and materials, natural or as a result of biotechnology, that may contain toxins (see also *biohazard* (3.20)), any poisonous substance or any poisonous isomer, homologue, or derivative of such a substance.

[SOURCE: CEN Workshop Agreement 15793:2011, Laboratory biorisk management, 3.46, modified — clarified biological sources of toxins and added Note 1 to entry.]

### 3.16 risk

effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected — positive or negative.