SLOVENSKI STANDARD
SIST EN ISO 22367:2026

01-junij-2026

Medicinski laboratoriji - Uporaba obvladovanja tveganja v medicinskih laboratorijih (ISO 22367:2026)

Medical laboratories - Application of risk management to medical laboratories (ISO 22367:2026)

Medizinische Laboratorien - Anwendung des Risikomanagements auf medizinische Laboratorien (ISO 22367:2026)

Laboratoires de biologie médicale - Application de la gestion des risques aux laboratoires de biologie médicale (ISO 22367:2026)

Ta slovenski standard je istoveten z: **EN ISO 22367:2026**

ICS:

03.100.01	Organizacija in vodenje podjetja na splošno	Company organization and management in general
11.100.01	Laboratorijska medicina na splošno	Laboratory medicine in general

SIST EN ISO 22367:2026 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22367

April 2026

ICS 11.100.01

Supersedes EN ISO 22367:2020

English Version

Medical laboratories - Application of risk management to medical laboratories (ISO 22367:2026)

Laboratoires de biologie médicale - Application de la gestion des risques aux laboratoires de biologie médicale (ISO 22367:2026)

Medizinische Laboratorien - Anwendung des Risikomanagements auf medizinische Laboratorien (ISO 22367:2026)

This European Standard was approved by CEN on 4 April 2026.

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 22367:2026 E

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European foreword

This document (EN ISO 22367:2026) has been prepared by Technical Committee ISO/TC 212 "Medical laboratories and in vitro diagnostic systems" in collaboration with Technical Committee CEN/TC 140 “In vitro diagnostic medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2026, and conflicting national standards shall be withdrawn at the latest by April 2029.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 22367:2020.

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Endorsement notice

The text of ISO 22367:2026 has been approved by CEN as EN ISO 22367:2026 without any modification.

International Standard

ISO 22367

Medical laboratories — Application of risk management to medical laboratories

Laboratoires de biologie médicale — Application de la gestion des risques aux laboratoires de biologie médicale

Second edition
2026-04

Reference number
ISO 22367:2026(en)

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Medical laboratories and in vitro diagnostic systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 22367:2020), which has been technically revised.

The main changes are as follows:

— the application of risk management to processes has been emphasized;

— reactive and proactive risk management has been discussed, differentiated, and illustrated;

— the content is as far as possible in agreement the requirements for risk management in ISO 15189:2022;

— the relation with ISO 15189:2022 is indicated in Annex A in which Figure A.1 provides a flow chart for the underlying management system to underpin this document;

— Clause I.5 has been slightly modified to emphasize that risks most often require benefit-risk assessment to determine risk acceptability.

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

Medical laboratories deal with risks as part of their usual activities; these risks affect patients, personnel, caregivers, and the organization as a whole. Risks span the range of services: pre-examination, examination and post-examination processes, including the design and development of laboratory examinations. The intent of this document is not to introduce risk as a concern for the laboratory but to provide a structure for addressing, managing, and documenting risks that are part of the day-to-day and long-term (strategic) activities of the laboratory.

ISO 15189 requires that medical laboratories review all work processes to identify potential failures for risk of harm to patients and opportunities for improvement, modify the processes to reduce or eliminate the identified risks, and document the decisions and actions taken. This document describes a process for managing these risks to the patient, the operator, other persons, equipment and other property, the healthcare enterprise as a whole, and the environment. It does not address business enterprise risks, which are the subject of ISO 31000; however, ISO 31000 is consistent with and can provide further understanding for the concepts in this document.

Medical laboratories span a broad range of activities, some of which rely on the use of in vitro medical devices to achieve their quality objectives. When such devices are involved, risk management is a shared responsibility between the in vitro diagnostic (IVD) manufacturer and the medical laboratory. Since most IVD manufacturers have already implemented ISO 14971, this document has adopted similar concepts, principles and framework to manage the risks associated with the medical laboratory when appropriate. This is especially meaningful for laboratories that implement their own examinations on devices (laboratory developed tests or LDTs); concepts integral to ISO 14971 can be directly applicable. ISO 5649 is a useful reference for identifying and addressing risks in the development, implementation and retirement phases of LDTs.

Activities in a medical laboratory can expose patients, workers or other stakeholders to a variety of hazards, which can lead directly or indirectly to varying degrees of harm. The concept of risk has two components:

a) the probability of occurrence of harm;

b) the consequence of that harm, that is, how severe the harm might be.

Risk management is complex because each stakeholder can place a different value on the risk of harm.

Risk management interfaces with quality management at many points in the medical laboratory. In ISO 15189, as an example, risk management is a component of complaint management, internal audit, corrective action, quality control, management review and external assessment (for both accreditation and proficiency testing). Management of risk also coincides with the management of safety in the medical laboratories, as exemplified by the safety audit checklists in ISO 15190. This document is intended to assist medical laboratories with the integration of risk management into their routine organization, operation and management.

While this document is intended for use throughout the currently recognized medical laboratory disciplines, it can effectively be applied to other healthcare services, such as diagnostic imaging, respiratory therapy, physiological sciences, blood banks and transfusion services.

The use of this document facilitates cooperation between medical laboratories and other healthcare services, assists in the exchange of information, and in the harmonization of methods and procedures.

Medical laboratories — Application of risk management to medical laboratories

1 Scope

This document specifies a process for a medical laboratory to identify and manage the risks to patients, laboratory workers and service providers that are associated with medical laboratory examinations. The process includes identifying, estimating, evaluating, controlling and monitoring the risks.

The requirements of this document are applicable to all aspects of the examinations and services of a medical laboratory, including the pre-examination, examination, and post-examination aspects including accurate transmission of examination results into the electronic medical record, as well as other technical and management processes described in ISO 15189.

This document does not specify acceptable levels of risk.

This document does not apply to risks from post-examination clinical decisions made by healthcare providers.

This document complements the management of risks affecting medical laboratory enterprises that are addressed by ISO 31000, such as business, economic, legal, and regulatory risks.

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 terminology databases for use in standardization at the following addresses:

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

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

3.1
benefit
impact or desirable outcome of a *process* (3.21), *procedure* (3.19) or the use of a medical device on the health of an individual or a positive impact on patient management or public health

Note 1 to entry: Benefits include prolongation of life, reduction of pain, relief of symptoms, improvement in function, or an increased sense of well-being.

3.2
event
occurrence or change of a particular set of circumstances

Note 1 to entry: An event can be one or more occurrences, and can have several causes.

Note 2 to entry: An event can consist of something not happening.

Note 3 to entry: An event can sometimes be referred to as an “incident” or “accident”.

Note 4 to entry: An event without consequences can also be referred to as a “near miss”, “incident”, “near hit” or “close call”.

[SOURCE: ISO 31073:2022, 3.3.11. modified — Note to entry 2 was changed; the original Note 3 to entry was removed, and a new Note 3 to entry and a Note 4 were added.]

3.3
examination
set of operations having the objective of determining the numerical value, text value or characteristics of a property

Note 1 to entry: An examination may be the total of a number of activities, observations or measurements required to determine a value or characteristics.

Note 2 to entry: Laboratory examinations that determine a numerical value of a property are called “quantitative examinations”; those that determine the characteristics of a property are called “qualitative examinations”.

Note 3 to entry: Laboratory examinations are also called “assays” or “tests”.

[SOURCE: ISO 15189:2022, 3.8]

3.4
foreseeable risk
risk (3.25) that is predictable prior to its occurrence

Note 1 to entry: Risk can be known from prior experience, assessment of current circumstances, prior occurrence of an *event* (3.2), or other sources.

Note 2 to entry: Addressing foreseeable risk results in preventive action.

Note 3 to entry: A risk that is foreseeable does not imply that it has been anticipated or addressed.

3.5
frequency
number of *events* (3.2) or outcomes per defined unit of time

Note 1 to entry: Frequency can be applied to past events or to potential future events, where it can be used as a measure of likelihood or *probability* (3.20).

[SOURCE: ISO 31073:2022, 3.3.20]

3.6
harm
injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 51:2014, 3.1]

3.7
hazard
source of potential *harm* (3.6)

[SOURCE: ISO 31073:2022, 3.3.12, modified — Note 1 to entry has been deleted.]

3.8
hazardous situation
circumstance in which people, property, or the environment are exposed to one or more *hazard(s)* (3.7)

[SOURCE: ISO/IEC Guide 51:2014, 3.4]

3.9
healthcare provider
individual authorized to deliver health services to a patient

EXAMPLE Physician, nurse, ambulance attendant, dentist, diabetes educator, laboratory technician, laboratory technologist, biomedical laboratory scientist, medical assistant, medical specialist, respiratory care practitioner.

[SOURCE: ISO 18113-1:2022, 3.1.28, modified — "laboratory technologist" and "biomedical laboratory scientist" were added to the example.]

3.10
in vitro diagnostic manufacturer
IVD manufacturer
natural or legal person with responsibility for the design and/or manufacture of an *IVD medical device* (3.11) with the intention of making the IVD medical device available for use, under his name, whether or not such an IVD medical device is designed and/or manufactured by that person himself or on that person's behalf by another person(s)

[SOURCE: ISO 14971:2019, 3.9, modified — The term "manufacturer" was changed to "in vitro diagnostic manufacturer"; in the definition, "medical device" was changed to "IVD medical device"; Notes to entry were removed.]

3.11
in vitro diagnostic medical device
IVD medical device
medical device, whether used alone or in combination, intended by the manufacturer for the in vitro *examination* (3.3) of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes

Note 1 to entry: The device includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

Note 2 to entry: Adapted from ISO 18113-1:2022, 3.1.53.

3.12
in vitro diagnostic instrument
IVD instrument
equipment or apparatus intended by a manufacturer to be used as an *IVD medical device* (3.11)

[SOURCE: ISO 18113-1:2022, 3.1.32]

3.13
information supplied by the manufacturer
information that is related to identification, technical description, *intended use* (3.15) and proper use of the *IVD medical device* (3.11), but excluding shipping documents

EXAMPLE Labels, instructions for use, manual, written, printed, electronic, or graphic matter.

Note 1 to entry: In IEC standards, documents provided with a medical device and containing important information for the responsible organization or operator, particularly regarding safety, are called "accompanying documents".

Note 2 to entry: Catalogues and material safety data sheets are not considered information supplied by the manufacturer of IVD medical devices.

Note 3 to entry: Adapted from ISO 18113-1:2022, 3.1.35.

3.14
instructions for use
information supplied by the manufacturer (3.13) to enable the safe and proper use of an *IVD medical device* (3.11)

Note 1 to entry: It includes the directions supplied by the manufacturer for the use, maintenance, troubleshooting and disposal of an IVD medical device, as well as warnings and precautions.