

**Medical laboratories - Application to risk
management to medical laboratories**

DSS Stage

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Published in Seychelles

National Foreword

This Seychelles Standard is an adoption *ISO 22367:2026 Medical laboratories — Application of risk management to medical laboratories*, published by the International Organization for Standardization (ISO).

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

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*.

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.

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.

The adoption of this international standard was proposed by Technical Committee for Management Systems Standards (TC8), and approved by the Seychelles Bureau of Standards to be published as a Seychelles Standard without technical deviation or language editing.

Whenever the words “International Standard” appear, referring to this standard, they should be read as “Seychelles Standard”.

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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).

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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.

1 Scope

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 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.

