



International

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Medical laboratories — Application of risk management to medical laboratories

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

ISO 22367

**Second edition
2026-04**



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Published in Switzerland

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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.

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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.