AS ISO 22367:2026
ISO 22367:2026

Medical laboratories — Application of risk management to medical laboratories



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- Australasian Association for Clinical Biochemistry and Laboratory Medicine
- Australian Institute of Medical and Clinical Scientists
- Australian Society for Microbiology
- Human Genetics Society of Australasia
- Medical Technology Association of Australia
- National Association of Testing Authorities Australia
- National Pathology Accreditation Advisory Council
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How to read this Standard

This page explains the meaning of the language and structure of this Standard.

Refer to Standards Australia's Standardisation Guide 006 for more details about drafting rules.

Australian and Australian/New Zealand Standards are voluntary unless they are referenced in legislation or called up in contracts.

Requirements

To conform to a Standard, all requirements in the Standard need to be met.

A requirement is any statement in the Standard which uses the word "shall".

Recommendations, permissions and possibilities

The following words are commonly used in Standards, but statements using them do not have to be followed to conform to the Standard:

(a) "should" means that something is recommended.

(b) "may" means that something is permitted.

(c) "can" means that something is possible.

Structure of Standards

A Standard always has the following parts:

(i) The Preface states who developed the Standard, what the Standard is aiming to do, and how it relates to other documents.

(ii) The Scope states what the Standard is about, what it covers and what it does not cover.

(iii) The Normative references clause lists other documents that are referenced in the Standard as part of requirements.

(iv) The Terms and definitions clause defines important terms to help with understanding the Standard.

A Standard may also include other parts, such as the following:

(1) A normative appendix sets additional requirements that need to be conformed to.

(2) An informative appendix provides additional information or guidance. They usually do not contain requirements. If an informative appendix does contain requirements, the Standard will explain when those requirements apply.

(3) A Bibliography lists documents referenced in the Standard but not as part of requirements.

Many Standards include notes. Notes provide recommendations and/or guidance only. They never contain requirements.

Preface

This Standard was prepared by the Standards Australia Committee HE-029, Clinical Laboratory Testing and *in vitro* Diagnostic Test Systems to supersede AS ISO 22367:2021.

The objective of this document is to specify 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 and post-examination aspects, examinations, accurate transmission of examination results into the electronic medical record and other technical and management processes described in ISO 15189.

This document is identical to, and has been reproduced from, ISO 22367:2026, *Medical laboratories — Application of risk management to medical laboratories.*

As this document has been reproduced from an international document, a comma is to be read as a full point when referring to a decimal marker.

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

The terms “normative” and “informative” are used in Standards to define the application of the appendices or annexes to which they apply. A “normative” appendix or annex is an integral part of a Standard, whereas an “informative” appendix or annex is only for information and guidance.

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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.

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

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.

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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.

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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”.

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