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)

**COPYRIGHT PROTECTED DOCUMENT**



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

# Contents

Page

# 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.

# 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.

Note 2 to entry: Instructions for use can also be referred to as “package insert” or manual for instruments.

Note 3 to entry: Adapted from ISO 18113-1:2022, 3.1.36.

**3.15**
**intended use**
**intended purpose**
objective intent of an *IVD manufacturer* (3.10) regarding the use of a product, *process* (3.21) or *service* (3.38) as reflected in the specifications, instructions and information supplied by the IVD manufacturer

Note 1 to entry: Intended use statements for IVD *information supplied by the manufacturer* (3.13) can include two components: a description of the functionality of the *IVD medical device* (3.11) (e.g. an immunochemical measurement *procedure* (3.19) for the detection of analyte “x” in serum or plasma), and a statement of the intended medical use of the *examination* (3.3) results.

[SOURCE: ISO 18113-1:2022, 3.1.37, modified — In Note 1 to entry, “labelling” was changed to “information supplied by the manufacturer”; Note 2 was removed.]

**3.16**
**laboratory management**
person(s) with responsibility for, and authority over, a laboratory

Note 1 to entry: Laboratory management has the power to delegate authority and provide resources within the laboratory.

Note 2 to entry: The laboratory management includes the laboratory director(s) and delegates together with individuals specifically assigned to ensure the quality of the activities of the laboratory.

[SOURCE: ISO 15189:2022, 3.15]



**3.17**
**likelihood**
chance of something happening

Note 1 to entry: In risk management terminology, the word “likelihood” is used to refer to the chance of something happening, whether defined, measured or determined objectively or subjectively, qualitatively or quantitatively, and described using general terms or mathematically (such as a *probability* (3.20) or a *frequency* (3.5) over a given time period).

Note 2 to entry: The English language term “likelihood” does not have a direct equivalent in some languages; instead, the equivalent of the term “probability” is often used. However, in English, “probability” is often narrowly interpreted as a mathematical term. Therefore, in risk management terminology, “likelihood” is used with the intent that it should have the same broad interpretation as the term “probability” has in many languages other than English.

[SOURCE: ISO 31073:2022, 3.3.16]

**3.18**
**medical laboratory**
laboratory
entity for the *examination* (3.8) of materials derived from the human body for the purpose of providing information for the diagnosis, monitoring, management, prevention and treatment of disease, or assessment of health

Note 1 to entry: The laboratory can also provide advice covering all aspects of examinations including appropriate selection, the interpretation of results and advice on further examinations.

Note 2 to entry: Laboratory activities include pre-examination, examination and post-examination *processes* (3.21).

Note 3 to entry: Materials for examination include but are not limited to, microbiological, immunological, biochemical, immunohaematological, haematological, biophysical, cytological, tissue and cells, and genetic material.

[SOURCE: ISO 15189:2022, 3.20]

**3.19**
**procedure**
specified way to carry out an activity or a *process* (3.21)

Note 1 to entry: Procedures can be documented or not.

[SOURCE: ISO 9000:2015, 3.4.5]

**3.20**
**probability**
measure of the chance of occurrence expressed as a number between 0 and 1, where 0 is impossibility and 1 is absolute certainty

Note 1 to entry: See definition of *likelihood* (3.17), Note 2 to entry.

[SOURCE: ISO 31073:2022, 3.3.19]

**3.21**
**process**
set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: Whether the "intended result" of a process is called output, product or *service* (3.38) depends on the context of the reference.

[SOURCE: ISO 9000:2015, 3.4.1, modified — Notes 2 to 6 have been removed.]

**3.22**
**reasonably foreseeable misuse**
use of a product, *process* (3.21) or *service* (3.38) in a way not intended by the supplier, but which can result from readily predictable human behaviour



Note 1 to entry: Readily predictable human behaviour includes the behaviour of all types of intended *users* (3.43).

Note 2 to entry: In the context of consumer safety, the term "reasonably foreseeable use" is increasingly used as a synonym for both *"intended use"* (3.15) and "reasonably foreseeable misuse".



Note 3 to entry: Applies to use of *examination* (3.3) results by a *healthcare provider* (3.9) contrary to the intended use, as well as use of *IVD medical devices* (3.11) by the laboratory contrary to the *instructions for use* (3.14).

Note 4 to entry: Misuse includes abnormal use, i.e. intentional use of the device in a way not intended by the manufacturer.

Note 5 to entry: Misuse is intended to mean incorrect or improper performance of an examination *procedure* (3.19) or any procedure critical for patient safety.

[SOURCE: ISO/IEC Guide 51:2014, 3.7 modified — In the definition, "system" was changed to "process or service"; examples were removed from Note 1; Notes 3 to 5 were added.]

**3.23**
**record**
document stating results achieved or providing evidence of activities performed

Note 1 to entry: Records can be used, for example, to formalize traceability and to provide evidence of *verification* (3.45), preventive action and corrective action.

Note 2 to entry: Generally, records need not be under revision control.

[SOURCE: ISO 9000:2015, 3.8.10]

**3.24**
**residual risk**
*risk* (3.25) remaining after *risk control* (3.28) measures have been taken

[SOURCE: ISO/IEC Guide 63:2019, 3.9]

**3.25**
**risk**
combination of the *probability* (3.19) of occurrence of *harm* (3.6) and the *severity* (3.39) of that harm

Note 1 to entry: This definition focuses on risks to the safety of patients and other persons. Other documents that emphasize risk to a business enterprise will have alternative definitions.

[SOURCE: ISO/IEC Guide 51:2014, 3.9, modified — The original Note 1 to entry was removed and a new note was added.]

**3.26**
**risk analysis**
systematic use of available information to identify *hazards* (3.7) and to estimate the *risk* (3.25)

Note 1 to entry: Risk analysis includes examination of different sequences of *events* (3.2) that can produce *hazardous situations* (3.8) and *harm* (3.6).

[SOURCE: ISO/IEC Guide 51:2014, 3.10, modified — Note 1 to entry was added.]

**3.27**
**risk assessment**
overall *process* (3.21) comprising a *risk analysis* (3.26) and a *risk evaluation* (3.30)

[SOURCE: ISO/IEC Guide 51:2014, 3.11]

**3.28**
**risk control**
*process* (3.21) in which decisions are made and measures implemented by which *risks* (3.25) are reduced to, or maintained within, specified levels

[SOURCE: ISO/IEC Guide 63:2019, 3.12]



**3.29**
**risk estimation**
*process* (3.21) used to assign values to the *probability* (3.19) of occurrence of *harm* (3.6) and the *severity* (3.39) of that harm



[SOURCE: ISO/IEC Guide 63:2019, 3.13]

**3.30**
**risk evaluation**
*process* (3.21) of comparing the estimated *risk* (3.25) against given risk criteria to determine the acceptability of the *risk*

[SOURCE: ISO/IEC Guide 63:2019, 3.14]

**3.31**
**risk management**
systematic application of management policies, *procedures* (3.19) and practices to the tasks of analysing, evaluating, controlling and monitoring *risk* (3.25)

[SOURCE: ISO/IEC Guide 63:2019, 3.15]

**3.32**
**risk management documentation**
set of *records* (3.23) and other documents that are produced by *risk management* (3.31)

[SOURCE: ISO 14971:2019, 3.25, modified — The term “risk management file” was changed to “risk management documentation”.]

**3.33**
**risk management plan**
scheme specifying the approach, the management components and resources to be applied to the management of *risk* (3.25)

[SOURCE: ISO 31073:2022, 3.2.3, modified — "scheme within the risk management framework" was changed to "scheme"; the Notes to entry were removed.]

**3.34**
**risk management policy**
statement of the overall intentions and direction of an organization related to *risk management* (3.31)

[SOURCE: ISO 31073:2022, 3.2.2]

**3.35**
**risk monitoring**
**surveillance**
continual checking, critically observing or determining the status in order to identify change from the *risk* (3.25) level required or expected

[SOURCE: ISO 31073:2022, 3.3.40, modified — The term "monitoring" has been changed to "risk monitoring", and surveillance was added as a preferred term; in the definition, "supervising" was deleted, and "performance level" was changed to "risk level"; Note 1 to entry was deleted.]

**3.36**
**risk reduction**
actions taken to lessen the *probability* (3.19) or negative consequences, or both, associated with a *risk* (3.25)

[SOURCE: ISO 22300:2025, 3.2.20]



**3.37**
**safety**
freedom from unacceptable *risk* (3.25)



[SOURCE: ISO/IEC Guide 63:2019, 3.16]

**3.38**
**service**
laboratory medicine activity performed by a medical laboratory for the *benefit* (3.1) of patients, the *healthcare providers* (3.9) responsible for the care of those patients, or screened populations

Note 1 to entry: Medical laboratory services include arrangements for *examination* (3.3) requests, patient preparation, patient identification, collection, transportation, storage, processing and examination of clinical samples, together with subsequent interpretation, reporting and advice, in addition to the considerations of *safety* (3.36) and ethics in medical laboratory work.

**3.39**
**severity**
measure of the possible consequences of a *hazard* (3.7)

[SOURCE: ISO/IEC Guide 63:2019, 3.17]

**3.40**
**stakeholder**
person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity

[SOURCE: ISO 31073:2022, 3.3.2, modified — The preferred term "interested party" was removed.]

**3.41**
**state of the art**
developed stage of technical capability at a given time as regards products, *processes* (3.21) and *services* (3.38), based on the relevant consolidated findings of science, technology and experience

Note 1 to entry: The state of the art embodies what is currently and generally accepted as good practice. The state of the art does not necessarily imply the most technologically advanced solution. The state of the art described here is sometimes referred to as the "generally acknowledged state of the art".

[SOURCE: ISO/IEC Guide 63:2019, 3.18]

**3.42**
**use error**
laboratory medicine *user* (3.43) action or lack of user action while performing a laboratory *examination* (3.3) or using an *IVD medical device* (3.11) or performing any task in any *procedure* (3.19) that leads to a different result than that intended by the laboratory or manufacturer or expected by the user

Note 1 to entry: Use error includes the inability of the user to complete a task.

Note 2 to entry: Use errors can result from a mismatch between the characteristics of the user, user interface, task, or use environment.

Note 3 to entry: Users might be aware or unaware that the use error has occurred.

Note 4 to entry: An unexpected physiological response of the patient is not by itself considered use error.

Note 5 to entry: A malfunction of an IVD medical device that causes an unexpected result is not considered a use error.

Note 6 to entry: Use error includes the use of an examination result for an unintended target group or for an unintended diagnostic or patient management purpose.

Note 7 to entry: The term was chosen over "user error", "human error" or "laboratory error" because not all causes of error are partially or solely due to the user. Use errors are often the result of poorly designed user interface or *processes* (3.21), or, inadequate *instructions for use* (3.14).



[SOURCE: IEC 62366-1:2015, 3.21 modified — In the definition, "user" was changed to "laboratory medicine user", and "performing a laboratory examination" and "performing any task in any procedure" were added; the original Note 6 to entry was removed and a new Note 6 to entry and a Note 7 were added.]

**3.43**
**user**
individual responsible for an action that is intended to lead to a desired outcome

Note 1 to entry: Although such individuals are often laboratory personnel that are expected to be trained and competent to perform the action, this term is not limited to such personnel and can include the patient.

Note 2 to entry: The use of this term is not intended to imply that a device is utilized for the action; it is used as a general term to include any individual that has a role in producing the desired outcome.

**3.44**
**validation**
confirmation, through the provision of objective evidence, that the requirements for a specific *intended use* (3.15) or application have been fulfilled

Note 1 to entry: The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word "validated" is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13]

**3.45**
**verification**
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for verification are sometimes called a qualification *process* (3.21).

Note 3 to entry: The word "verified" is used to designate the corresponding status.

[SOURCE: ISO 9000:2015, 3.8.12]

# 4 Risk management

## 4.1 Risk management process

The medical laboratory shall establish, document, implement and maintain processes for identifying hazards associated with its examinations and services, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the controls. The scope of specific risk management processes may be broad (e.g. for the development of a new examination with which a laboratory has little or no experience), or the scope may be limited (e.g. for resolving the risks associated with either anticipated or unanticipated nonconformities).

NOTE 1 The activities of the laboratory have an underlying concern with risk, especially risks to the patient. The considerations that occur in developing and implementing such activities involve understanding and approaching such risks; this can be referred to as "risk-based thinking". To be an effective part of the quality management system, such risk management activities require a structured approach.



Where a documented management system exists, such as that described in ISO 15189, it shall incorporate risk management into the appropriate parts.

A master plan as described in Clause B.2 should be in place when multiple individual risk management plans are present



NOTE 2 Annex A provides additional guidance for using a documented management system, such as is required in ISO 15189, to address patient safety in a systematic manner, in particular to enable the early identification of hazards and hazardous situations in order to implement appropriate risk control measures.

NOTE 3 ISO/TR 24971:2020, Annex H provides guidance on risk management for in vitro diagnostic medical devices.

## 4.2 Management responsibilities

The medical laboratory management shall show evidence of its commitment to the risk management process by providing adequate resources and qualified personnel for risk management to ensure conformance to this document (see 4.3).

The laboratory management shall:

— define and document the laboratory's risk management policy, including the policy for determining risk acceptability (see 7.3.1);

— approve all risk assessments and risk management reports;

— review the suitability of risk management processes at planned intervals to ensure their continuing effectiveness, and document any decisions and actions taken during the review. This review may be part of the management system review.