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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 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*

ICS: 11.100.01

ISO/TC 212

Secretariat: **ANSI**

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This document is circulated as received from the committee secretariat.

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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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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*.

This second edition cancels and replaces (ISO 22367:2020), which has been technically revised. The main changes compared to the previous edition 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 quality management system to underpin this standard;
- Annex [I.5](#) has been slightly modified to emphasize that risks most often require benefit-risk assessment to determine risk acceptability.

Recognizing the effort required for translation, only [Annex A](#) and [Annex I](#) as mentioned above and Annex [sections F.1, F.6.1 and F.8](#) have been modified. The remaining annexes have been retained unchanged after review from the prior edition.

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 has to be a shared responsibility between the IVD manufacturer and the medical laboratory. Since most IVD manufacturers have already implemented ISO 14971:2019, “Medical devices Application of risk management to medical devices,” this standard 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); concepts integral to ISO 14971:2019 can be directly applicable. ISO 5649:202X is a useful reference for identifying and addressing risks in the development, implementation and retirement phases of LDT.

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 may 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 standard is intended to assist medical laboratories with the integration of risk management into their routine organization, operation and management.

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 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.

The primary reason for risk management in medical laboratories is to reduce risk of harm to patients and identify opportunities for improved patient care.

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

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* (3.20), *procedure* (3.18) 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]

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

a *risk* (3.24) that is predictable prior to its occurrence.

Note 1 to entry: *Risk* (3.24) can be known from prior experience, assessment of current circumstances, prior occurrence of an *event* (3.2), or other sources.

Note 2 to entry: A *risk* (3.24) 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* (3.2) or to potential future *events* (3.2), where it can be used as a measure of likelihood or *probability* (3.19)

[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 have 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]

3.10**in vitro diagnostic manufacturer
IVD manufacturer**

natural or legal person with responsibility for the design, manufacture, packaging, or *labelling* (3.13) of an *IVD medical device* (3.11), assembling a system, or adapting an *IVD medical device* (3.11) before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

Note 1 to entry: Provisions of national or regional regulations can apply to the definition of manufacturer.

[SOURCE: ISO 14971:2007, definition 2.8, modified – “manufacturer” has been changed to “in vitro diagnostic manufacturer”. “A medical device” has been changed to “an *IVD medical device*” (3.11). “Attention is drawn to the fact that” has been deleted in Note 1 to entry. In addition, Note 2 to entry has been deleted.]

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 and including reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

[SOURCE: ISO 18113-1:2022, 3.1.33, Note 1 merged into body, Note 2 deleted]

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
labelling**

written, printed or graphic matter

- affixed to an *IVD medical device* (3.11) or any of its containers or wrappers or
- provided for use with an *IVD medical device* (3.11),

related to identification and use, and giving a technical description, of the *IVD medical device* (3.11), but excluding shipping documents

EXAMPLE Labels, *instructions for use* (3.14).

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 labelling of *IVD medical devices* (3.11).

[SOURCE: ISO 18113-1:2022, 31.35, modified]

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: Includes the directions supplied by the manufacturer for the use, maintenance, troubleshooting and disposal of an *IVD medical device* (3.11), as well as warnings and precautions.

[SOURCE: ISO 18113-1:2022, 3.1.6, modified]

3.15

intended use

intended purpose

objective intent of an *IVD manufacturer* (3.10) regarding the use of a product, *process* (3.20) or *service* (3.37) as reflected in the specifications, instructions and information supplied by the *IVD manufacturer* (3.10)

Note 1 to entry: Intended use statements for *IVD labelling* (3.13) can include two components: a description of the functionality of the *IVD medical device* (3.11) (e.g., an immunochemical measurement *procedure* (3.18) 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, 3.1.7, Note 2 deleted]

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* (3.19) 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*” (3.19) is often used. However, in English, “*probability*” (3.19) 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*” (3.19) has in many languages other than English.

[SOURCE: ISO 31073:2022, 3.3.16]

3.18

procedure

specified way to carry out an activity or a *process* (3.20) Note 1 to entry: Procedures can be documented or not.

[SOURCE: ISO 9000:2015, 3.4.5]

3.19

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]

3.20

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– Note 2 to entry to Note 6 to entry have been deleted.]

3.21

reasonably foreseeable misuse

use of a product, *process* (3.20) or *service* (3.37) in a way not intended by the supplier, but which may 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* (3.15), 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: Adapted from ISO Guide 63:2012, 2.8, to apply to medical laboratories. [SOURCE: ISO/IEC Guide 51:2014, 3.7, modified- “a product or system” has been changed to “a product, *process* (3.20) or *service*” (3.38), and “can” has been changed to “may”. In addition, “Note 3 to entry to Note 5 to entry” have been added.]

Note 6 to entry: Misuse is intended to mean incorrect or improper performance of an *examination* (3.3) *procedure* (3.18) or any *procedure* (3.18) critical for patient safety

[SOURCE: ISO/IEC Guide 51:2014, 3.7 modified-Note 1 examples were removed]

3.22

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* (3.44), preventive action and corrective action.

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

[SOURCE: ISO 9000:2015, 3.8.10]

3.23

residual risk

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

[SOURCE: ISO/IEC Guide 63:2019, 2.9]

3.24

risk

combination of the *probability* (3.19) of occurrence of *harm* (3.6) and the *severity* (3.38) of that *harm* (3.6)

Note 1 to entry: In standards that focus on management of risks to a business enterprise, such as ISO 31000, risk is defined as “the effect of uncertainty on objectives.” ISO 14971 and this document have retained the definition from ISO/IEC Guide 51:1999 because they are externally focused on risks to the safety of patients and other persons.

[SOURCE: ISO/IEC Guide 51:2014, 3.9]

3.25

risk analysis

systematic use of available information to identify *hazards* (3.7) and to estimate the *risk* (3.24)

Note 1 to entry: Risk analysis includes *examination* (3.3) 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 has been added.]

3.26

risk assessment

overall *process* (3.20) comprising a *risk analysis* (3.25) and a *risk evaluation* (3.29)

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

3.27

risk control

process (3.20) in which decisions are made and measures implemented by which *risks* (3.24) are reduced to, or maintained within, specified levels

[SOURCE: ISO/IEC Guide 63:2019, 2.12]

3.28

risk estimation

process (3.20) used to assign values to the *probability* (3.19) of occurrence of *harm* (3.6) and the *severity* (3.39) of that *harm* (3.6)

[SOURCE: ISO/IEC Guide 63:2019, 2.13]

3.29

risk evaluation

process (3.20) of comparing the estimated *risk* (3.24) against given *risk* (3.24) criteria to determine the acceptability of the *risk* (3.24)

[SOURCE: ISO/IEC Guide 63:2019, 2.14]

3.30

risk management

systematic application of management policies, *procedures* (3.18) and practices to the tasks of analysing, evaluating, controlling and monitoring *risk* (3.24)

[SOURCE: ISO/IEC Guide 63:2019, 2.15]

3.31

risk management documentation

set of *records* (3.22) and other documents that are produced by *risk management* (3.30)

[SOURCE: ISO 14971:2007, 2.23]

3.32

risk management plan

scheme specifying the approach, the management components and resources to be applied to the management of *risk* (3.24)

[SOURCE: ISO 31000:2009, 2.6]

3.33

risk management policy

statement of the overall intentions and direction of an organization related to *risk management* (3.30)

[SOURCE: ISO 31073:2022, 3.2.2]

3.34

risk monitoring

surveillance

continual checking, critically observing or determining the status in order to identify change from the *risk* (3.24) level required or expected

[SOURCE: ISO 31073:2022, definition 3.3.40, modified – “Monitoring” has been changed to “risk monitoring”. “Supervising” has been deleted, and “performance” has been changed to “*risk*” (3.24) In addition, Note 1 to entry has been deleted.]

3.35

risk reduction

actions taken to lessen the *probability* ([3.19](#)) or negative consequences or both, associated with a *risk* ([3.24](#))

[SOURCE: ISO 22300:2018, 3.210]

3.36

safety

freedom from unacceptable *risk* ([3.24](#))

[SOURCE: ISO/IEC Guide 63:2019, 2.16]

3.37

service

laboratory medicine activity performed by a medical laboratory for the *benefit* ([3.1](#)) of patients and the *healthcare providers* ([3.9](#)) responsible for the care of those patients

Note 1 to entry: Medical laboratory services include arrangements for *examination* ([3.3](#)) requests, patient preparation, patient identification, collection of samples, transportation, storage, processing and *examination* ([3.3](#)) 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.

Note 2 to entry: Adapted from ISO 15189:2022, Introduction

3.38

severity

measure of the possible consequences of a *hazard* ([3.7](#))

[SOURCE: ISO/IEC Guide 63:2019, 2.17]

3.39

stakeholder

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

Note 1 to entry: A decision maker can be a stakeholder.

[SOURCE: ISO Guide 73:2009, 3.2.1.1]

3.40

state of the art

developed stage of technical capability at a given time as regards products, *processes* ([3.20](#)) and *services* ([3.37](#)), 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, 2.19]

3.41

use error

laboratory medicine *user* ([3.43](#)) action or lack of *user* ([3.43](#)) action while performing a laboratory *examination* ([3.3](#)) or using an *IVD medical device* ([3.11](#)) or performing any task in any *procedure* ([3.18](#)) that leads to a different result than that intended by the laboratory or manufacturer or expected by the *user* ([3.42](#))

Note 1 to entry: Use error includes the inability of the *user* ([3.43](#)) to complete a task.

Note 2 to entry: Use errors can result from a mismatch between the characteristics of the *user* ([3.43](#)), user interface, task, or use environment.

Note 3 to entry: *Users* ([3.43](#)) 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* (3.3) 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* (3.42). Use errors are often the result of poorly designed *user* (3.43) interface or *processes* (3.20), or, inadequate *instructions for use* (3.14).

[SOURCE: ISO/IEC 62366-1:2015, 3.21 modified – “(laboratory medicine)” has been added. “Performing a laboratory *examination* (3.3) or”, “an IVD” and “laboratory or” have also been added. Note 6 to entry was deleted. A new Note 6 to entry and a Note 7 to entry were added.]

3.42

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

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.

3.43

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]

3.44

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* (3.20).

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

NOTE 1 [Annex A](#) provides additional guidance for using a documented quality 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 2 Annex H of ISO/TR 24971:2020^[2] provides guidance on risk management for in vitro diagnostic medical devices.

NOTE 3 A master plan as described in Annex B2 should be in place when multiple individual risk management plans are present.

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 its continuing effectiveness, and document any decisions and actions taken during the review. This review may be part of the quality management system review.

The laboratory shall retain records for each activity required in this standard. The records shall be retrievable and available for review as needed.

NOTE The required documentation and records can be incorporated within the documentation produced by the laboratory’s quality management system.

4.3 Qualification of personnel

Persons performing risk management tasks shall have the knowledge and experience for the tasks assigned to them. This knowledge and experience shall include, where appropriate, the process and procedures to be assessed; the medical uses of the results that are produced; and the techniques used to assess the risks.

Such persons may be qualified by training, competence, and through the provision of sufficient instruction for managing instances of risk.

NOTE An example of a foreseeable risk ([4.4.1](#)) may be the authorization of routine personnel who receive specimens to assess whether collection tubes for functional coagulation studies are sufficiently full, given that underfilled tubes can lead to artificially prolonged measurement times. By training and use of visual aids, such personnel may assess, reject an underfilled specimen, document this action in the patient record, and contact the provider for a valid specimen prior to submission for testing. Should the provider request that the specimen be processed regardless, this could be beyond the training and competence of the individual originally handling the specimen and would then be handled as a reactive risk ([7.1.1](#)).

Risk management tasks may be performed by a team of representatives of several functions of the laboratory, each contributing their specific knowledge and expertise. Alternatively, risk management task

may be sufficiently covered by a subset of the laboratory management, such as a section manager and the laboratory director. The necessary personnel shall be based on the required knowledge and expertise for the specific task.

Records shall be maintained to document personnel involved in risk management tasks and their qualifications.

4.4 Risk management activities

The activities necessary to manage a given risk shall be defined and followed, consistent with the quality management system of the laboratory.

The risk management process shall be appropriate for the nature of the risk. The following elements shall be considered:

- risk management plan;
- risk analysis;
- risk evaluation;
- risk control;
- risk management review and;
- risk monitoring.

The extent of risk management for each process shall be determined and implemented for each identified risk that is commensurate with the nature of the risk. Risks may arise

- in the implementation of new activities;
- as known risk to be managed as they arise; or
- as nonconformities with defined processes or from complaints
- Risk management may be classified as either proactive or reactive.

Management of proactive risks shall entail all six of the above elements as described in [Clauses 5-11](#). These risks include implementation of new activities and process design to manage known risks.

Reactive risk management shall include at a minimum risk evaluation through risk monitoring, [Clauses 7-10](#), as appropriate. These risks include those that arise from nonconformities or complaints as well as addressing specific instances when known risks arise. These risks are specific to the situation in which they arise and often require decision-making that are not amenable to a formal, structured approach.

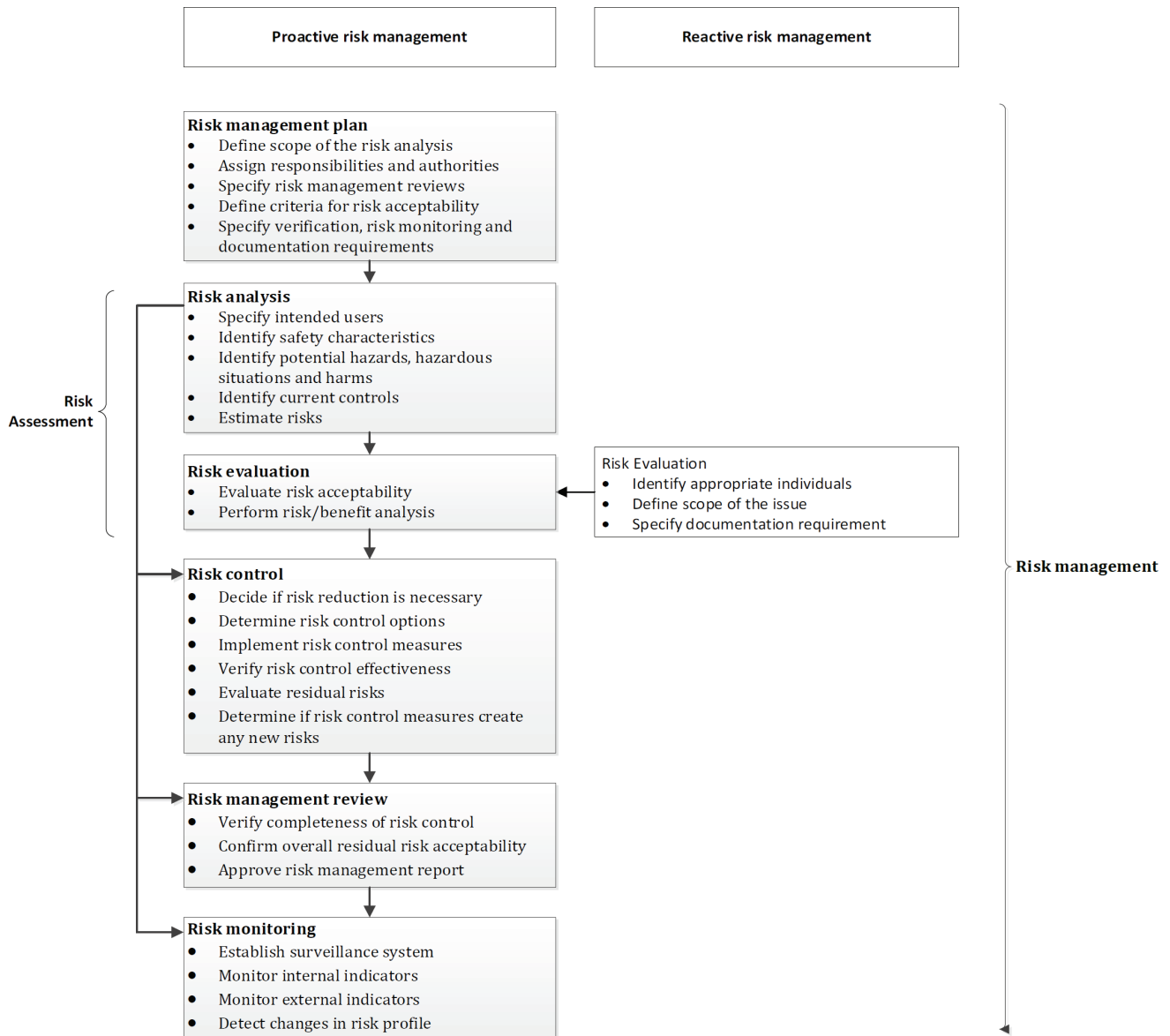


Figure 1 — Schematic representation of the risk management process

The risk management process, whether proactive or reactive, shall identify the individuals responsible for the activities, define their qualifications, and specify the documentation of outcome, review, and monitoring.

4.4.1 Foreseeable risk

The laboratory shall identify and address such risks that are foreseeable. Management of such risks, when deemed necessary, shall be proactive but may allow for reactive response to specific issues as they arise.

Foreseeable risks can be identified through:

- known risks from the literature;
- prior experience;
- nonconformities and complaints;

as well as other approaches.

4.4.2 Opportunity

The laboratory shall consider opportunities for improvement beyond the risk being addressed when appropriate. Such opportunities for improvement recognize that risks and hazards do not happen in isolation but may represent specific instances of a broader area of concern.

An example of such an opportunity can be addressing the foreseeable risk of haemolysed specimens from new external personnel, if responsible for collecting samples, with limited experience in phlebotomy. Participation in the initial training sessions for such personnel on phlebotomy techniques also is an opportunity for introduction to other aspects of laboratory usage, such as proper sampling labeling, resources for information and questions, and other details that affect laboratory activities and risk to patients.

4.4.3 Information provided to users

The laboratory shall assess the information to be communicated to users to mitigate risks that the users themselves can affect.

Examples of such risks include:

- submission of inappropriate specimens (preanalytical risk);
- limitations of an examination that do not serve the needs of the user (analytical risk);
- misleading reporting of results or interpretations (postanalytical risk);

Changes in laboratory processes shall be communicated to users when necessary to allow the users to adjust their expectations for the laboratory services

5 Management of proactive risks

5.1 Proactive risk management plan

For risk management that is proactive in nature, such as new activities where the laboratory has no prior experience, a formal plan shall be developed to address expected and theoretical risks

When addressing foreseeable risks as they arise, the risk management plan shall provide appropriate guidance. The initial assessment shall be proactive with the intent to implement foreseeable risk mitigation to the extent possible. These residual risks (8.4) are expected to occur and the plan shall include guidance for addressing individual instances where issues arise. Such guidance shall specify the responsibilities for assessing and addressing these risks as they occur and may be incorporated into the process for the activities where such risks will arise.

NOTE 1 For new and complex activities, such as the development of a new area of service, providing service to a new client, or development of an in-house developed laboratory examinations (laboratory developed tests), a structured, documented process for risk management may be helpful. The following process is proactive in nature but is not intended to be the approach for developing a risk management plan for all proactive risks.

NOTE 2 Foreseeable risks represent issues that have the potential to happen under certain circumstances. These issues may include exceptions to sample acceptance criteria for critical or irreplaceable clinical samples (see ISO 15189:2022 clause 7.2.6.2), internal quality control failure (see ISO 15189:2022 clause 7.3.7.2) and emergency release of uncrossmatched blood to a patient presenting with uncontrolled hemorrhage. Development of a process to address such known risks may benefit from past experience with such issues, information gleaned from other sources, and adapting processes that address similar risks.

NOTE 3 There may be considerable overlap in any given instance between circumstances representing a foreseeable risk and a nonconformity. As an example, the handling of an internal quality control failure may well have a defined overall process. However, the specific examination and the severity of the underlying issue causing the failure may need to be considered in addressing the risk to patient care. The effect of potential delay in turnaround time, the specific clinical services that may be affected, and alternate examinations that may be available may all be factors that affect how a given nonconforming event is handled.

5.2 Scope of the plan

The scope of the plan or plans shall be determined by laboratory management. The scope of the plan and the extent of the risk management activities required shall be proportional to the risks associated with the processes being considered.

A risk management plan may be created, for example, for technical and management processes, for specific pre- and post-examination aspects, for one or more examinations performed by a particular IVD system, for a particular examination developed by the laboratory, or for all of the examinations performed by the laboratory in which risks could be identified and assessed.

The scope of the plan and the extent of the risk management activities should be proportional to the risks associated with the processes (4.4). Factors that should be considered include but are not limited to:

- a) relevant quality specifications;
- b) medical decision levels and critical values;
- c) patient populations;
- d) reliability of the measurement system and measurement uncertainty;
- e) performance characteristics (precision, bias, specificity, etc.);
- f) pre-examination contact with the patient (e.g., phlebotomy);
- g) clinical use of the examination results (e.g., screening, diagnostic, confirmatory tests); and
- h) opportunities for improvement beyond directly addressing the specific risk.

5.3 Contents of the plan

Each risk management plan shall address at least the following:

- a) assignment of responsibilities and authorities;
- b) actions to be taken for immediate response to risks (Clause 11);
- c) requirements for review of risk management activities;
- d) description of the processes, examinations and services, covered by the plan, any IVD medical devices involved, and all relevant pre- and post-examination aspects within the scope of the plan;
- e) criteria for individual and overall risk acceptability, based on the laboratory's policy for determining acceptable risk; and
- f) risk control verification and monitoring activities.

NOTE Refer to [Annex C](#) for guidance on risk acceptability considerations, and [Annex B](#) for guidance on establishing risk acceptability criteria.

5.4 Revisions to the plan

The plan shall be updated if significant changes occur that could affect the risk assessment. A record of changes to the plan shall be maintained.

NOTE Examples of significant changes that could affect the risk assessment include:

- a) modification of laboratory facilities or utilities;
- b) introduction of new policies, procedures or work instructions;
- c) acquisition, purchase or introduction of new equipment, including laboratory information systems;

- d) introduction of new examinations or services, or change in service delivery level;
- e) change to a different vendor;
- f) development of in-house examinations;
- g) modification of existing examination procedures;
- h) nonconformities inappropriately or incompletely addressed;
- i) any other changes that could affect characteristics related to user or patient safety.

5.5 Documentation of the risk management plan

There shall be documentation of the risks that are identified and addressed and the management approach that is taken.

For a formal, proactive risk management plan, such risks shall be enumerated in the plan together with the defined mitigation that is taken.

6 Proactive risk analysis

Risk analysis shall consider, as appropriate,

- the users at risk,
- safety characteristics that are present,
- hazards, both potential and existing, and existing harms, and
- existing controls that may mitigate hazards and harms.

Estimate of risks shall be based on these risk analysis considerations.

6.1 General

Risk analysis shall follow the risk management plan (5.1). Appropriate individuals shall be identified with the qualifications to perform the risk analysis. (4.3)

Qualification may be based on experience, training, knowledge, or recognized skill and shall be in accord with the risk management plan.

If an examination procedure involves an IVD medical device, and if the IVD manufacturer followed a risk management process in conformance with ISO 14971, the laboratory's risk analysis may start, but should not be limited to, the residual risks disclosed by the IVD manufacturer.

If a risk analysis, or other relevant information, is available for a similar examination procedure or service, that analysis or information may be used as a starting point for the new analysis. The degree of relevance depends on the differences between the examinations or services. The extent that an existing risk analysis can be used should be based on a systematic evaluation of whether these differences could:

- significantly affect the outputs, characteristics, performance or results;
- cause the introduction of new hazards;
- lead to the development of new hazardous situations.

NOTE 1 Some risks which can occur in medical laboratory examinations are described in [Annexes D, E and F](#).

NOTE 2 Some risk analysis techniques are described in [Annex G](#) and [H](#).

6.2 Risk analysis process

Risk analysis shall

- a) Define the scope
- b) Identify persons who carried out the risk analysis, including their expertise
- c) Record the date of the analysis, and
- d) Document approval.

The responsibility for review and approval of the risk analysis shall be defined by the laboratory, preferably in the quality management system of the laboratory.

6.3 Documentation of the risk analysis process

When the risk analysis is proactive in nature (see [5.1](#)), the documentation of the risk analysis process shall include the items in [6.2](#) and:

- a) intended medical laboratory use and reasonably foreseeable misuses;
- b) characteristics that affect patient safety;
- c) known and foreseeable hazards;
- d) known or foreseeable situations that may be hazardous;
- e) foreseeable patient harms associated with identified hazards; and
- f) estimated risks for each identified hazard.

NOTE 1 Misuse is intended to mean incorrect or improper performance of a process.

NOTE 2 The most common hazards to patients from medical laboratory examinations are incorrect results, misidentified results and delayed results. The examples of possible hazards in [Annex E](#) can be used as guidance when identifying hazards to laboratory workers, service personnel and other persons.

6.3.1 Intended medical laboratory use and reasonably foreseeable misuses

The intended laboratory use determines the risks to be assessed together with consideration of foreseeable misuse

6.3.2 Identification of characteristics related to safety

For the particular process being considered, identifying and documenting qualitative and quantitative characteristics that could affect the safety of the patient, and where appropriate, their defined limits should be considered.

For in vitro examinations, such considerations include diagnostic specificity, diagnostic sensitivity, measurement specificity, measurement precision, measurement bias, analytical interference, reagent stability, analyte stability, sterility (for phlebotomy services), biological reference intervals.

NOTE [Annex D](#), contains a series of questions that can serve as a guide in identifying the characteristics of the examination and any IVD medical devices involved that could have an impact on safety.

6.3.3 Identification of hazards

Identifying and documenting known and foreseeable hazards associated with a given process and their causes (e.g., potential failure modes and use errors) can be an integral part of risk analysis. Hazards in both normal use (i.e., correct use and use errors), reasonably foreseeable misuse and fault conditions are all considerations in risk analysis.

For examinations involving the use of an IVD medical device, the laboratory may obtain information from the IVD manufacturer about potential hazards that were identified but not fully eliminated during the manufacturer's risk management process.

7 Risk evaluation

The evaluation of a given risk will differ if the risk management process is proactive or reactive in nature as described in [4.4](#).

Management of reactive risk begins with this clause. Management of proactive risk continues from [Clauses 5](#) and [6](#).

7.1 General

Personnel involved in the risk evaluation shall be qualified ([4.3](#)). Qualification may be through training and experience; qualification does not imply a level of education or responsibility.

7.1.1 Evaluation of reactive risks

The laboratory shall have a process for management of risks that are reactive in nature, such as the immediate handling of nonconformities and complaints as they present risks to patients or personnel, with defined review and monitoring. Such reactive activities are dependent on the specific nature of the event and sufficient flexibility should be present in the process to allow the laboratory to adapt as necessary, though the review and monitoring of these events may benefit from a structured approach.

At a minimum the process shall address who is authorized to evaluate the risk, what credentials or qualifications are required to develop and implement the plan, and where the details of the plan shall be documented.

Although the management of known risks ([5.1](#) Note 1) is proactive in nature, when the issue arises, each instance often must be managed as a reactive risk. Analysis of instances of known and accepted risks shall be performed by the appropriate individuals within the limits determined by the defined process. If the risk is determined to exceed that expected by the defined process, it shall be handled as a nonconformity.

Nonconformities and complaints often present rare circumstances specific to a certain patient or clinical need. These situations typically require both an immediate response to ensure that the risk posed by the events have been mitigated to the extent possible as well as a review process for adequacy. The plan for addressing such issues should designate such personnel with the qualifications to determine a reasonable immediate action and a review process to determine the adequacy of the immediate response and likelihood of recurrence. Analysis of nonconformities shall include determination of root cause to the extent necessary to define the event.

Reactive risk management shall be documented as appropriate for each event.

Examples of reactive risk management documentation include incorporating the laboratory decision regarding exceptions to sample acceptance criteria within the patient record and handling of internal quality control failures within the IQC record itself. When these reactive issues are addressed according to a predetermined protocol, the protocol itself may be sufficient to document the management approach that was taken.

7.1.2 Evaluation of proactive risks

The laboratory shall evaluate risks identified in the risk analysis and potential actions to be taken. This evaluation may be part of risk analysis or be a subsequent defined step in the risk management process.

The laboratory shall have criteria for individuals involved in risk evaluation defined in the risk management plan ([5.1](#)). These individuals may be the same approved individuals that performed the risk analysis ([6.1](#)) or may be different, as defined by the plan.

The laboratory shall consider whether outside participants have a role in evaluating identified risks.

NOTE Outside participants may include care providers, patient representatives, individuals from other areas of the healthcare organization, among others.

The laboratory shall communicate as appropriate with outside providers when a risk is associated with the material or services from these providers.

Outside providers may include equipment and device manufacturers, suppliers, referral laboratories, among others.

Such communication should be based on risk analysis demonstrating a likelihood that the risk may not be controlled ([Clause 8](#)) without involvement of the outside provider. This may be necessary whether the risk is proactive or reactive.

7.2 Benefit-Risk analysis

The medical laboratory may perform an analysis of relevant clinical evidence to determine if the medical benefits of the intended activity outweigh the risk. This analysis may be performed as part of the initial evaluation of risk, at the level of an individual residual risk or for the overall residual risk ([8.4](#)).

NOTE Clinical evidence is obtained from sources such as the medical literature, clinical studies, performance evaluations, adverse event experience, and expert medical opinion. Refer to [Annex K](#) for further guidance for performing a benefit-risk analysis.

If the risk is demonstrated to be outweighed by the benefits, then the risk may be considered acceptable. The laboratory shall determine which information is necessary to disclose the risk.

If the evidence does not support the conclusion that the medical benefits outweigh the risk, then the laboratory shall evaluate risk controls ([clause 8](#)) against the benefits.

The results of the benefit-risk-benefit analysis and the information to be disclosed to intended recipients shall be recorded.

7.3 Proactive risk evaluation

When the risk to be managed is proactive in nature ([5.1](#)), the risk evaluation process shall include a benefit-risk analysis against a defined risk acceptability criteria.

7.3.1 Risk acceptability criteria

Established criteria for risk acceptability shall be incorporated into risk management plans where appropriate. This is especially useful when individual risks can be reasonably and completely defined and some assessment of overall residual risk can be determined.

Consideration for risk acceptability criteria include:

- applicable national or regional regulations, applicable safety standards, and relevant medical practice standards;
- the generally accepted state of the art; and
- known stakeholder concerns.

NOTE It is not necessary to apply the same risk acceptability criteria for all examinations or services performed by the laboratory. The criteria can differ based on the intended use or other factors.

For each identified hazardous situation, the approved risk acceptability criteria shall be applied to decide if risk reduction is required. Generally, if the risk is considered negligible, then the risk is acceptable and no further risk reduction is necessary.

Evaluating the overall risk including residual risk after controls are implemented shall be based on determined and documented acceptability criteria.

NOTE [Annex J](#) describes three criteria that can be the basis for evaluating acceptability of the overall risk: a) The risk associated with an examination procedure or laboratory service compares favourably to similar examination procedures or laboratory processes already in use. B) The medical benefits of the examination procedure or laboratory service outweigh the overall residual risk. C) The overall residual risk has been reduced as far as reasonably feasible and verification of the risk control measures demonstrates that they are effective.

For individual risks, acceptability may be documented in a matrix to indicate the combinations of probability of occurrence and severity of harm that are acceptable or unacceptable.

NOTE See examples in [Annex C](#).

Such a matrix may be further subdivided into zones that indicate which risks are considered negligible and which risks are acceptable if the risks are minimized (i.e., the risks are first reduced as far as reasonably possible).

NOTE See guidance and examples in Annexes [B.5](#) and C for determining endpoints for risk reduction.

Considerations in establishing overall residual risk acceptability criteria may include:

- compliance with required national or regional regulations;
- laboratory accreditation to standards of quality and competence;
- participation in recognized proficiency testing schemes;
- whether informed consent is required.

7.3.2 Risk reduction

If risk reduction is required, then risk control activities, such as described in [clause 8](#), shall be performed.

If the level of risk is considered unacceptable, and cannot be reduced to an acceptable level, laboratory management shall decide whether the examination or service in question may be commenced or continued based on a documented risk – benefit analysis as described in [Clause 7.2](#).

If risk reduction is not required, then the risk control requirements in [Clause 8](#) do not apply for the particular hazardous situation being evaluated, and the laboratory may proceed to [Clause 9](#), risk management review.

8 Risk control

Risk control is proactive in nature, intended to decrease either the incidence or severity of anticipated risk.

Management of risks that are reactive in nature is limited to the issue (e.g., nonconformance, complaint) that is being addressed. A process for risk monitoring and analysis ([Clause 10](#)) of such reactive risks shall be documented and available. The process as defined need not require that all reactive risks be monitored nor need it explicitly state criteria for monitoring. The participants that address such reactive risks ([7.1.2](#)) shall have the option to refer the circumstance for risk monitoring and analysis.

An instance of a risk that is managed reactively shall be considered as a foreseeable risk in that it can recur. Whether a formal assessment and development of proactive risk management control is necessary should be part of the risk evaluation process ([7.1.1](#)).

If the outcome of risk management review ([Clause 9](#)) or surveillance ([Clause 10](#)) indicates that the risk has not been adequately managed, the laboratory shall undertake risk control as outlined in this clause.

The remainder of this clause shall apply to proactive risk control except as stated above for reactive control of risks.

8.1 Risk control options

The laboratory shall identify, implement and verify risk control measure(s) that reduce the risk(s) to an acceptable level.

NOTE Risk control measures can reduce the severity of the harm, reduce the probability of occurrence of the harm, or both.

The preferred order for consideration of the risk control options is:

- a) inherent safety by process design (e.g., potential for failure is reduced or eliminated);
- b) protective measures in the examination, pre-examination, post-examination and quality assurance procedures (e.g., review of actions or results as a step in the process, calibration, quality control activities, including new control activities added by the laboratory to reduce residual risk);

NOTE If an IVD medical device is a part of the risk to be managed and controlled, protective measures in the device (e.g., alarms, failure detection, fail-safe mechanisms serve as risk control considerations.

- c) information for staff on safety;
- d) training.

When implementing option b) or c), the laboratory should select risk control measures that will reduce the risk as far as reasonably possible before determining whether the residual risk is acceptable.

Increase or alternation in staffing as well as reassignment of the process to another section of the laboratory may also be options. In the case of reassignment, this may affect other risks present in the other laboratory [section \(8.3\)](#) and shall be considered if this option is taken.

The laboratory may also consider whether use of an examination for a specific patient population should be contraindicated based on risk evaluation ([Clause 7](#)) including benefit-risk analysis.

8.1.1 Role of standards in risk control

Conformance to relevant standards should be considered as part of the risk control option analysis.

Application of relevant standards during the design and development of an examination or another procedure might constitute a risk control activity, and may meet the requirements given in this clause. It is up to the laboratory to determine whether application of the standard meets all of the requirements.

8.1.2 Role of IVD medical devices in risk control

If the process involves an IVD medical device that was designed, developed, validated and manufactured in conformance to a recognized risk management standard such as ISO 14971, the laboratory should follow the manufacturer's instructions regarding any risk control measures incorporated in or provided with the device. Exceptions shall be justified.

NOTE This recommendation is intended to enable laboratories to rely on risk management activities performed by the IVD manufacturer, thus avoiding unnecessary duplication of efforts. This promotes effective risk communication between stakeholders.

Risk control measures incorporated in or provided with an IVD medical device may not require further verification if:

- the IVD manufacturer certifies that the device was designed, developed, validated and manufactured in conformance to ISO 14971, and;
- the information provided by the manufacturer in the device labelling shows that the risk control measures are effective.