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Medical laboratories — Application of risk management to medical laboratories

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

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Foreword

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This first edition cancels and replaces (ISO/TS 22367:2008) which has been technically revised. [It also incorporates the Technical corrigendum ISO/TS 22367:2008/Cor.1:2009.]. The main changes compared to the previous edition are as follows:

— Change in title to indicate this document focusses on the complete risk management cycle for all processes in the medical laboratory. The part on continual improvement is left out;

— The numbering of the clauses is in accordance with the formal risk management process as indicated in Figure 1;

— The content is as far as possible in agreement with the approach used in ISO 14971 Medical devices -Application of risk management to medical devices;

— The relation with ISO 15189:2012 is indicated in Annex A in which Figure A.1 provides a flow chart which indicates how to apply risk management in the laboratory;

— Addition of 10 new annexes, all informative, providing valuable information about the different processes in the risk management cycle without demanding more than justified for the specific purpose;

— Annex F. provides an extensive list of aspects which could be considered as source for risks in the different types of medical laboratories.

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

This document provides medical laboratories with a framework within which experience, insight and judgment are applied to manage the risks associated with laboratory examinations. The risk management process spans the complete range of medical laboratory services: pre-examination, examination and post-examination processes, including the design and development of laboratory examinations.

ISO 15189 requires that medical laboratories review their work processes, evaluate the impact of potential failures on examination results, 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 safety risks, primarily to the patient, but also to the operator, other persons, equipment and other property, and the environment. It does not address business enterprise risks, which are the subject of ISO 31000.

Medical laboratories often rely on the use of in vitro medical devices to achieve their quality objectives. Thus, risk management has to be a shared responsibility between the IVD manufacturer and the medical laboratory. Since most IVD manufacturers have already implemented ISO 14971:2007, "Medical devices -Application of risk management to medical devices," this standard has adopted the same concepts, principles and framework to manage the risks associated with the medical laboratory.

Activities in a medical laboratory can expose patients, workers or other stakeholders to a variety of hazards, which can lead directly or indirectly to varying degrees of harm. The concept of risk has two components:

a) the probability of occurrence of harm;

b) the consequence of that harm, that is, how severe the harm might be.

Risk management is complex because each stakeholder may place a different value on the risk of harm. Alignment of this standard with ISO 14971 and the guidance of the Global Harmonization Task Force (GHTF) is intended to improve risk communication and cooperation among laboratories, IVD manufacturers, regulatory authorities, accreditation bodies and other stakeholders for the benefit of patients, laboratories and the public health.

Medical laboratories have traditionally focused on detecting errors, which are often the consequence of use errors during routine activities. Use errors can result from a poorly designed instrument interface, or reliance on inadequate information provided by the manufacturer. They can also result from reasonably foreseeable misuse, such as intentional disregard of an IVD manufacturer's instructions for use, or failure to follow generally accepted medical laboratory practices. These errors can cause or contribute to hazards, which may manifest themselves immediately as a single event, or may be expressed multiple times throughout a system, or may remain latent until other contributory events occur. The emerging field of usability engineering addresses all of these 'human factors' as preventable 'use errors.' In addition, laboratories also have to contend with occasional failures of their IVD medical devices to perform as intended. Regardless of their cause, risks created by device malfunctions and use errors can be actively managed.

Risk management interfaces with quality management at many points in ISO 15189, in particular complaint management, internal audit, corrective action, preventive action, safety checklist, quality control, management review and external assessment, 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.

Risk management is a planned, systematic process that is best implemented through a structured framework. 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 test results into the electronic medical record and 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 does not apply to 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 terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
benefit
impact or desirable outcome of a *process* (3.19), *procedure* (3.17) 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 Guide 73:2009, 3.5.1.3]

3.3
examination
set of operations having the object of determining the value or characteristics of a property

Note 1 to entry: In some disciplines (e.g., microbiology) an examination is the total activity of a number of tests, observations or measurements.

Note 2 to entry: Laboratory examinations that determine a 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 often called assays or tests.

[SOURCE: ISO 15189:2012, 3.7]

3.4
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* (3.18)

[SOURCE: ISO Guide 73:2009, 3.6.1.5]

3.5
harm
injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 51:2014, 3.1]

3.6
hazard
source of potential *harm* (3.5)

[SOURCE: ISO Guide 73:2009, 3.5.1.4, modified – Note 1 to entry has been deleted.]

3.7
hazardous situation
circumstance in which people, property, or the environment are exposed to one or more *hazard(s)* (3.6)

[SOURCE: ISO/IEC Guide 51:2014, 3.4]

3.8
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 18113-1:2009, 3.23]

3.9
in vitro diagnostic manufacturer
IVD manufacturer
natural or legal person with responsibility for the design, manufacture, packaging, or *labelling* (3.12) of an *IVD medical device* (3.10), assembling a system, or adapting an *IVD medical device* (3.10)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, 2.8, modified – "manufacturer" has been changed to "in vitro diagnostic manufacturer"."A medical device" has been changed to "an *IVD medical device*" (3.10). "Attention is drawn to the fact that" has been deleted in Note 1 to entry. In addition, Note 2 to entry has been deleted.]

3.10
in vitro diagnostic medical device
IVD medical device
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 18113-1:2009, 3.27]

3.11
in vitro diagnostic instrument
IVD instrument
equipment or apparatus intended by a manufacturer to be used as an *IVD medical device* (3.10)

[SOURCE: ISO 18113-1:2009, 3.26]

3.12
information supplied by the manufacturer
labelling
written, printed or graphic matter

— affixed to an *IVD medical device* (3.10) or any of its containers or wrappers or

— provided for use with an *IVD medical device* (3.10),

related to identification and use, and giving a technical description, of the *IVD medical device* (3.10), but excluding shipping documents

EXAMPLE Labels, *instructions for use* (3.13).

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* (3.10).

[SOURCE: ISO 18113-1:2009, 3.29]

3.13
instructions for use
information supplied by the manufacturer (3.12) to enable the safe and proper use of an IVD *medical device* (3.10)

Note 1 to entry: Includes the directions supplied by the manufacturer for the use, maintenance, troubleshooting and disposal of an *IVD medical device* (3.10), as well as warnings and precautions.

[SOURCE: ISO 18113-1:2009, 3.30]

3.14
intended use
intended purpose
objective intent of an *IVD manufacturer* (3.9) regarding the use of a product, *process* (3.19) or *service* (3.37) as reflected in the specifications, instructions and information supplied by the *IVD manufacturer* (3.9)

Note 1 to entry: Intended use statements for IVD *labelling* (3.12) can include two components: a description of the functionality of the *IVD medical device* (3.10) (e.g., an immunochemical measurement *procedure* (3.17) 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 18113-1:2009, 3.31, modified — Note 2 has been deleted.]

3.15
laboratory management
person(s) who direct and manage the activities of a laboratory

Note 1 to entry: The term 'laboratory management' is synonymous with the term 'top management' in ISO 9000:2015, 3.1.1.

[SOURCE: ISO 15189:2012, 3.10]

3.16
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* (3.18) or a *frequency* (3.4) 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*" (3.18) is often used. However, in English, "*probability*" (3.18) 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*" (3.18) has in many languages other than English.

[SOURCE: ISO Guide 73:2009, 3.6.1.1]

3.17
procedure
specified way to carry out an activity or a *process* (3.19)

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

[SOURCE: ISO 9000:2015, 3.4.5]

3.18
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* (3.16), Note 2 to entry.

[SOURCE: ISO Guide 73:2009, 3.6.1.4]

3.19
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* (3.37) 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.]

3.20
reasonably foreseeable misuse
use of a product, *process* (3.19) 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* (3.42).

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*" (3.14) and "reasonably foreseeable misuse."

Note 3 to entry: Applies to use of *examination* (3.3) results by a *healthcare provider* (3.8) contrary to the *intended use* (3.14), as well as use of *IVD medical devices* (3.10) by the laboratory contrary to the *instructions for use* (3.13).

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.

Note 6 to entry: Misuse is intended to mean incorrect or improper performance of an *examination* (3.3) *procedure* (3.17) or any *procedure* (3.17) critical for patient safety.

[SOURCE: ISO/IEC Guide 51:2014, 3.7, modified — "a product or system" has been changed to "a product, *process* (3.19) or *service*" (3.37), and "can" has been changed to "may". In addition, "Note 3 to entry to Note 6 to entry" have been added.]

3.21
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]

3.22
residual risk
risk (3.23) remaining after *risk* (3.23) control measures have been taken

[SOURCE: ISO/IEC Guide 63:2012, 2.9]

3.23
risk
combination of the *probability* (3.18) of occurrence of *harm* (3.5) and the *severity* (3.38) of that *harm* (3.5)

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]

3.24
risk analysis
systematic use of available information to identify *hazards* (3.6) and to estimate the *risk* (3.23)

Note 1 to entry: Risk analysis includes *examination* (3.3) of different sequences of *events* (3.2) that can produce *hazardous situations* (3.7) and *harm* (3.5).

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

3.25
risk assessment
overall *process* (3.19) comprising a *risk analysis* (3.24) and a *risk evaluation* (3.28)

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

3.26
risk control
process (3.19) in which decisions are made and measures implemented by which *risks* (3.23) are reduced to, or maintained within, specified levels

[SOURCE: ISO/IEC Guide 63:2012, 2.12]

3.27
risk estimation
process (3.19) used to assign values to the *probability* (3.18) of occurrence of *harm* (3.5) and the *severity* (3.38) of that *harm* (3.5)

[SOURCE: ISO/IEC Guide 63:2012, 2.13]

3.28
risk evaluation
process (3.19) of comparing the estimated *risk* (3.23) against given risk criteria to determine the acceptability of the *risk* (3.23)

[SOURCE: ISO/IEC Guide 63:2012, 2.14]

3.29
risk management
systematic application of management policies, *procedures* (3.17) and practices to the tasks of analysing, evaluating, controlling and monitoring *risk* (3.23)

[SOURCE: ISO/IEC Guide 63:2012, 2.15]

3.30
risk management documentation
set of *records* (3.21) and other documents that are produced by *risk management* (3.29)

[SOURCE: ISO 14971:2007, 2.23]

3.31
risk management plan
scheme specifying the approach, the management components and resources to be applied to the management of *risk* (3.23)

[SOURCE: ISO 31000:2009, 2.6]

3.32
risk management policy
statement of the overall intentions and direction of an organization related to *risk management* (3.29)

[SOURCE: ISO Guide 73:2009, 2.1.2]

3.33
risk matrix
tool for ranking and displaying *risks* (3.23) by defining ranges for consequence and *likelihood* (3.16)

[SOURCE: ISO Guide 73:2009, 3.6.1.7]

3.34
risk monitoring
surveillance
continual checking, critically observing or determining the status in order to identify change from the *risk* (3.23) level required or expected

[SOURCE: ISO Guide 73:2009, 3.8.2.1, modified — "Monitoring" has been changed to "risk monitoring". "Supervising" has been deleted, and "performance" has been changed to"*risk*" (3.23) In addition, Note 1 to entry has been deleted.]

3.35
risk reduction
actions taken to lessen the *probability* (3.18) or negative consequences or both, associated with a *risk* (3.23)

[SOURCE: ISO 22300:2018, 3.210]

3.36
safety
freedom from unacceptable *risk* (3.22)

[SOURCE: ISO/IEC Guide 63:2012, 2.16]

3.37
service
<laboratory medicine> activity performed by a medical laboratory for the *benefit* (3.1) of patients and the *healthcare providers* (3.8) 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 15189:2012, Introduction.

3.38
severity
measure of the possible consequences of a *hazard* (3.6)

[SOURCE: ISO/IEC Guide 63:2012, 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* (3.19) 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 63:2012, 2.19]

3.41
use error
<laboratory medicine> *user* (3.42) action or lack of *user* (3.42) action while performing a laboratory *examination* (3.3) or using an *IVD medical device* (3.10) or performing any task in any *procedure* (3.17) 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* (3.42) to complete a task.

Note 2 to entry: Use errors can result from a mismatch between the characteristics of the *user* (3.42), user interface, task, or use environment.

Note 3 to entry: *Users* (3.42) 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* (3.42) interface or *processes* (3.19), or, inadequate *instructions for use* (3.13).

[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* (3.14) 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* (3.19).

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 a process 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. This process shall include the following elements:

— risk management plan;

— risk analysis;

— risk evaluation;

— risk control;

— risk management review and;

— risk monitoring.

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 24971:2019[2][1)] provides guidance on risk management for in vitro diagnostic medical devices.

NOTE 3 A schematic representation of the risk management process is shown in Figure 1.

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 6.1);

— approve all risk assessments and risk management reports;

— review the suitability of the risk management process 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.

1) Under preparation. Stage at the time of publication: ISO/DTR 24971:2019.