SLOVENSKI STANDARD
oSIST prEN ISO 22367:2019

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Medicinski laboratoriji - Uporaba obvladovanja tveganja pri medicinskih laboratorijih (ISO/DIS 22367:2019)

Medical laboratories - Application of risk management to medical laboratories (ISO/DIS 22367:2019)

Medizinische Laboratorien - Fehlerverringerung durch Risikomanagement und ständige Verbesserung (ISO/DIS 22367:2019)

Laboratoires médicaux - Réduction d'erreurs par gestion du risque et amélioration continue (ISO/DIS 22367:2019)

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Medical laboratories — Application of risk management to medical laboratories

Laboratoires médicaux — Réduction d'erreurs par gestion du risque et amélioration continue

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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).

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).

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

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 standard cancels and replaces ISO/TS 22367:2008, which has been technically revised.

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 standard 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 must 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 ISO15189.

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 the medical laboratory enterprise that are addressed by ISO 31000, such as business, economic, legal, and regulatory risks.

NOTE International, national, or regional regulations or requirements may also apply to specific topics covered in this international standard

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:

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

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

3.1
benefit
impact or desirable outcome of a process, procedure 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 of 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 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

[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

[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)

[SOURCE: ISO/IEC Guide 51:2014, 3.2]

3.8
healthcare provider
individual authorized to deliver health services to a patient

EXAMPLES 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 of an IVD medical device, assembling a system, or adapting an IVD medical device 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". "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 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

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

3.12
in vitro diagnostic reagent
IVD reagent
chemical, biological or immunological components, solutions or preparations intended by the manufacturer to be used as an IVD medical device

[SOURCE: ISO 18113-1:2009, 3.28]

3.13
information supplied by the manufacturer
labelling
written, printed or graphic matter

– affixed to an IVD medical device or any of its containers or wrappers or

– provided for use with an IVD medical device,

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

EXAMPLES Labels, instructions for use.

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.

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

3.14
instructions for use
information supplied by the manufacturer to enable the safe and proper use of an IVD medical device

Note 1 to entry: 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.

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

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

Note 1 to entry: Intended use statements for IVD labelling can include two components: a description of the functionality of the IVD medical device (e.g., an immunochemical measurement procedure for the detection of analyte "x" in serum or plasma), and a statement of the intended medical use of the examination results.

[SOURCE: ISO 18113-1:2009, 3.31]

3.16
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]

3.17
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 or a frequency 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 Guide 73:2009, 3.6.1.1]

3.18
procedure
specified way to carry out an activity or a process

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 Guide 73:2009, 3.6.1.4]

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 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 or service 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.

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" and "reasonably foreseeable misuse."

Note 3 to entry: Applies to use of examination results by a healthcare provider contrary to the intended use, as well as use of IVD medical devices by the laboratory contrary to the instructions for use.

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 or service", and "can" has been changed to "may". In addition, "Note 3 to entry to Note 5 to entry" have been added.]

Note 6: Misuse is intended to mean incorrect or improper performance of an examination procedure or any procedure critical for patient safety

[SOURCE: ISO/IEC Guide 51:2014, 3.14]

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, 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 remaining after risk control measures have been taken

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

3.24
risk
combination of the probability of occurrence of harm and the severity of that harm

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, 3.2]

3.25
risk analysis
systematic use of available information to identify hazards and to estimate the risk

Note 1 to entry: Risk analysis includes examination of different sequences of events that can produce hazardous situations and harm.

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

3.26
risk assessment
overall process comprising a risk analysis and a risk evaluation

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

3.27
risk control
process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels

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

3.28
risk estimation
process used to assign values to the probability of occurrence of harm and the severity of that harm

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

3.29
risk evaluation
process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk

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

3.30
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk

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

3.31
risk management documentation
set of records and other documents that are produced by risk management

[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

[SOURCE: ISO 3100:2009, 2.6]

3.33
risk management policy
statement of the overall intentions and direction of an organization related to risk management

[SOURCE: ISO Guide 73:2009, 2.1.2]

3.34
risk matrix
tool for ranking and displaying risks by defining ranges for consequence and likelihood

[SOURCE: ISO Guide 73:2009, 3.6.1.7]