SLOVENSKI STANDARD
SIST EN ISO 22367:2020

01-maj-2020

Nadomešča:
SIST-TS CEN ISO/TS 22367:2010

Medicinski laboratoriji - Uporaba obvladovanja tveganja v medicinskih laboratorijih (ISO 22367:2020)

Medical laboratories - Application of risk management to medical laboratories (ISO 22367:2020)

Medizinische Laboratorien - Fehlerverringerung durch Risikomanagement und ständige Verbesserung (ISO 22367:2020)

Laboratoires de biologie médicale - Application de la gestion des risques aux laboratoires de biologie médicale (ISO 22367:2020)

Ta slovenski standard je istoveten z: **EN ISO 22367:2020**

ICS:

03.100.01	Organizacija in vodenje podjetja na splošno	Company organization and management in general
11.100.01	Laboratorijska medicina na splošno	Laboratory medicine in general

SIST EN ISO 22367:2020 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22367

March 2020

ICS 11.100.01

Supersedes CEN ISO/TS 22367:2010

English Version

Medical laboratories - Application of risk management to medical laboratories (ISO 22367:2020)

Laboratoires de biologie médicale - Application de la gestion des risques aux laboratoires de biologie médicale (ISO 22367:2020)

Medizinische Laboratorien - Fehlerverringerung durch Risikomanagement und ständige Verbesserung (ISO 22367:2020)

This European Standard was approved by CEN on 7 February 2020.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents

Page

European foreword

This document (EN ISO 22367:2020) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 “In vitro diagnostic medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2020, and conflicting national standards shall be withdrawn at the latest by March 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes CEN ISO/TS 22367:2010.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 22367:2020 has been approved by CEN as EN ISO 22367:2020 without any modification.

INTERNATIONAL STANDARD

ISO 22367

First edition
2020-02

Medical laboratories — Application of risk management to medical laboratories

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

Reference number
ISO 22367:2020(E)

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

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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 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.