TECHNICAL SPECIFICATION

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Medical laboratories — Reduction of error through risk management and continual improvement

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

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/TS 22367 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

Introduction

It is a requirement of ISO 15189 that laboratories have an investigative process to identify aspects that do not conform with their own procedures or with predetermined requirements in the quality management system. ISO 15189 specifies that this be linked both to corrective actions and to preventive actions. In addition, it specifies that management review the suitability and effectiveness of the system and its activities in support of patient care, and that they introduce necessary changes. This can best be done by considering potential risks introduced at each step of each process.

Preventive actions are planned and appropriate anticipatory processes, based upon verifiable information, are undertaken to prevent a potential action from occurring. Corrective actions are similarly planned together with appropriate reactive processes; however, these are undertaken to amend identified problems and to avoid their recurrence. Risk management is a planned process that is part of preventive actions and corrective actions.

Preventive actions and corrective actions can be more effectively directed when they are based upon information that is well-organized; classification systems and risk management analysis are two processes that provide well-organized information.

In the context of organizational management, risk has been described as a multidimensional concern about stability and predictability of outcome. Organizational risk involves components that affect the operational, technical, liability and business aspects of the laboratory. In the context of continual improvement, the risk elements of potential for loss are considered with higher priority than the elements of gain. Consideration of risk necessarily includes the linked but different elements of likelihood of occurrence and severity of impact. Factors that impact upon risk can act either directly or indirectly.

The framework of risk management can be described as consisting of the following steps:

a) planning for risk,

b) identifying risk and its impacts,

c) developing risk-handling strategies, and

d) monitoring for risk control.

These steps are consistent with the management requirements described in ISO 15189, including:

— identifying and controlling non-conformities,

— establishing preventive actions and corrective actions,

— carrying out internal audits and management reviews, and

— implementing continual improvement.

This Technical Specification is intended to provide the first steps to introduce risk management into the structure, organization, operation and quality management system of the medical laboratory.

Classification of laboratory non-conformities, errors and incidents is useful for monitoring purposes and allows the laboratory to determine their criticality, to set priorities in addressing them and to identify underlying causative factors that contribute to errors.

Considerations contained within local, regional and national regulations normally apply.

Medical laboratories — Reduction of error through risk management and continual improvement

1 Scope

This Technical Specification characterizes the application of ISO 15189 as a system for reducing laboratory error and improving patient safety by applying the principles of risk management, with reference to examination aspects, especially to pre- and post-examination aspects, of the cycle of laboratory medical care. This Technical Specification proposes a methodology for finding and characterizing medical laboratory error that would be avoided with the application of ISO 15189.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15189, *Medical laboratories — Particular requirements for quality and competence*

ISO/IEC Guide 73, *Risk management — Vocabulary — Guidelines for use*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, ISO 14971, ISO 15189, ISO/IEC Guide 73 and the following apply.

3.1
laboratory error
failure of a planned action to be completed as intended, or use of a wrong plan to achieve an aim, occurring at any part of the laboratory cycle, from ordering examinations to reporting results and appropriately interpreting and reacting to them

3.2
active error
error by a front-line operator

NOTE See Reference [2].

3.3
cognitive error
error of incorrect choices, owing to insufficient knowledge, misinterpretation of available information, or application of the wrong cognitive rule

NOTE 1 See Reference [1].

NOTE 2 A cognitive error is also referred to as an “attentional error” or a “mistake” (see Reference [9]).

3.4
failure modes and effects analysis
FMEA
systematic review of a system or product involving identification of potential failures and assessing the impact on total system/product performance of that failure

NOTE 1 This analysis also includes (a) review(s) of the steps taken to guard against failure, or to mitigate its effect.

NOTE 2 The procedure is sometimes referred to as a “bottom-up” analysis.

3.5
latent error
error due to underlying structural factors not under control of the front end operator

EXAMPLE Faulty equipment, poor design, management decision, or organization structure (see Reference [2]).

3.6
non-cognitive error
error due to inadvertent or unconscious lapse in expected automatic behaviour

NOTE 1 See Reference [1].

NOTE 2 A non-cognitive error is also referred to as a “schematic error” or a “slip” (see Reference [9]).

3.7
failure mode and effects analysis
prospective risk analysis process of high risk processes to identify needed improvements that will reduce the chance of an unintended adverse event

4 Management responsibility in preventive and corrective actions, and continual improvement

4.1 General

Management should ensure the provision of adequate resources to ensure that both preventive and corrective actions can be identified and enacted.

4.2 Management responsibility in preventive actions

The management should:

— define the policy and processes for collecting data about process performance across the testing cycle,

— analyse the data for trends and patterns that suggest the potential for problems or errors to occur, and

— formulate and implement preventive actions through process improvement to eliminate the causes of potential non-conformities to prevent occurrence.

4.3 Management responsibility in corrective actions

The management should:

— define the policy and processes for identifying and reporting non-conformities, errors, and incidents,

— ensure all personnel are trained to properly identify and report non-conformities, errors, and incidents,

— review the results of the analysis of non-conformities, errors, and incidents, and

— formulate remedial and corrective actions to eliminate or reduce recurrence of the non-conformity, error, or incident.

4.4 Management responsibility in continuous improvement

Management should ensure that the results of risk management, preventive actions and corrective actions are incorporated into a continual improvement process.

5 Identification of potential and actual laboratory non-conformities, errors and incidents

5.1 Potential and actual laboratory non-conformities, errors and incidents should be identified by means of the following processes:

— a review of internal audits,

— incident reports,

— opportunities for improvement, or

— a prospective risk analysis process.

5.2 A map of the total analytical process can be used to identify potential and actual causes for erroneous results. Every step of the process should be analyzed to determine an estimation of probability for each hazard (see Annex A).

6 Classification of laboratory non-conformities, errors and incidents

Identified laboratory non-conformities, errors, and incidents can be classified. Points for classification may include, but are not limited to, those listed below.

a) Cycle phase of event:

— pre-examination:

— incorrect patient identification;

— incorrect or missing diagnostic information;

— incorrect interpretation of medical order;

— incorrect patient preparation;

— incorrect collection container or preservative;

— incorrect collection container labelling;

— incorrect mixing of sample;

— incorrect collection timing;

— incorrect transport conditions or timing;

— examination:

— discrepant quality control result;