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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.

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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:

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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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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;

- procedural non-conformity;
- equipment or reagent error;
- delayed time to completion (turnaround time);

NOTE Time delays can occur throughout the total laboratory cycle.

- post-examination:
  - incorrect result;
  - incorrect transcription of result;
  - ambiguous report;
  - result ascribed to incorrect patient;
  - report sent to incorrect person;
  - missing information about restrictions on interpretations of result.

b) Recognition of laboratory non-conformity, error, or incident process:

- internal or external to the laboratory.

c) Responsibility for event:

- latent or active error;
- cognitive or non-cognitive error;
- internal or external to the laboratory, or unable to determine.

d) Preventability:

- not preventable to highly preventable.

e) Impact on patient care:

- none or minimal;
- resulted in delayed treatment or diagnosis;
- resulted in inappropriate treatment or diagnosis.

7 Preventive action and corrective actions

7.1 The identification of potential errors and laboratory non-conformities through planned review of processes and identification of the impact of changes is highly effective in preventing errors from occurring. Laboratory non-conformities, errors and incidents can be identified by means of a review of internal audits, incident reports, opportunities for improvement or a prospective risk analysis process.

7.2 Corrective actions that ensue when a laboratory non-conformity is identified should lead to a reduction of repeat occurrences of the non-conformity or of the development of a related non-conformity, if the investigation phase of the corrective action includes an analysis of root causes that contributed to the non-conformity.

NOTE It is advisable that a thorough root cause analysis address not only the likely cause of error, but also the factors that could have contributed to the occurrence of the cause. It is advisable that the corrective action plan address all contributing factors.

8 Assessment of risk arising from actual and potential laboratory non-conformities

The quality manager should establish and maintain processes for:

a) identifying high risk processes where the potential for error could lead to a safety risk for patients,

b) identifying actual incidents associated with deviations from standards requirements,

c) estimating and evaluating the associated risks to patient safety,

d) controlling these risks, and

e) monitoring effectiveness of the control.

The process should consider a risk model (see Annex B) and include a method for assessing the risk of process failures (see Annex C).

NOTE 1 A prospective risk analysis can be an FMEA, or other tools to determine the potential for errors, problems or safety risks to patients, e.g. Process Hazard Analysis (PHA), Failure Modes Effects and Criticality Analysis [FME(C)A], Fault Tree Analysis (FTA), Hazard and Operability Analysis (HAZOP) and Hazard Analysis and Critical Control Points (HACCP). ISO 14971:2007, Annex G, provides a discussion of these tools and their applicability. See also References [13], [14], [15], [16], [17] and [18].

The process should also include assessment of potentially high-risk processes, on the basis of previous audits, surveys, experience or evidence-based literature on procedures where a failure may lead to a significant safety risk to patients.

The quality manager should identify a team of people to study the selected process.

NOTE 2 It is advisable that the team members have personal knowledge of the process and the effects of failures.

NOTE 3 It is advisable that the team be comprised of people with appropriate levels and types of knowledge.

The team should organize a thorough analysis of the process to include:

— each activity of the process,

— how each activity of the process may fail,

— how each failure at each activity of the process may affect patient safety,

— the severity and probability of each failure mode effect,

— the most critical failure mode effects,

— potential root causes of the most critical failure mode effects, and

— actions to address the root causes.

NOTE 4 Severity ranking can be classified as negligible, minor, serious, critical and catastrophic. Probability can be classified as improbable, remote, occasional, probable and frequent.

The analysis of an FMEA should form the basis of a preventive action plan for potential problems, or a corrective action plan for problems that have already occurred.

9 Review of collected laboratory non-conformities, errors and incidents

At regular intervals, the contents of the corrective action plan file should be reviewed to determine common factors and continuing problems relating to laboratory non-conformities, errors and incidents.

The underlying causative factors of laboratory non-conformities, errors and incidents should be analysed appropriately (see Annex C).

The analysis should be incorporated into the appropriate preventive action, corrective action and continual improvement plans.

10 Preventive action and corrective action plans

Laboratory management should prepare a plan for investigation and prevention/correction of any non-conformity, error or incident identified in an FMEA or observed in another way. Such plans should include:

— the scope of the plan,

— a description of the specific failure mode effect, non-conformity, error or incident,

— the identification of potential risks associated with the potential error or non-conformity,

— allocation of responsibilities to address the changes required,

— requirement for review,

— criteria for acceptable resolution, and

— the need for preventive action or corrective action.

11 Preventive action and corrective action plan files

All laboratory preventive actions, corrective actions, non-conformities, errors and incidents should be recorded within the preventive action and corrective action plan file. Records should be maintained within a preventive action and corrective action plan master log.

The compiled files should be reviewed regularly as part of the management review.

12 Continual improvement plan

Once the investigation has been completed, laboratory management should review information gained about the collected laboratory non-conformities, errors and incidents. This information should be evaluated for possible relevance to patient and laboratory safety, especially with regard to the following:

— whether previously unrecognized hazards are present;

— whether original assessments of laboratory non-conformities, errors and incidents are invalidated as a result.

If either of the above applies, the results of the evaluation should be fed back as an input into the evaluation process.

In addition, an in-depth investigation into the root cause of high-risk laboratory non-conformities, errors and incidents should be carried out immediately, in order to prevent their recurrence.

Annex A
(informative)

Failure modes and effects analysis

Failure modes and effects analysis (FMEA) is a methodology for identifying potential points of failure within a process, determining their effects, and identifying actions to mitigate the failures. FMEA is particularly useful when deciding whether to introduce a new process within the laboratory.

While it is not possible to anticipate every failure mode, the team of laboratory participants can formulate as extensive a list of potential failure modes as possible.

A block diagram of the product/process indicating the major process steps should be developed. The major process steps should be linked together by lines that indicate how the components or steps are related. The diagram shows the logical relationships of components and establishes a structure around which the FMEA can be developed.

Figure A.1 gives a typical process map in a medical laboratory, which includes pre-analytic, analytic and post-analytic handling of the sample, reagents, equipment, instruments, calibrators, controls, result presentation and result documentation.

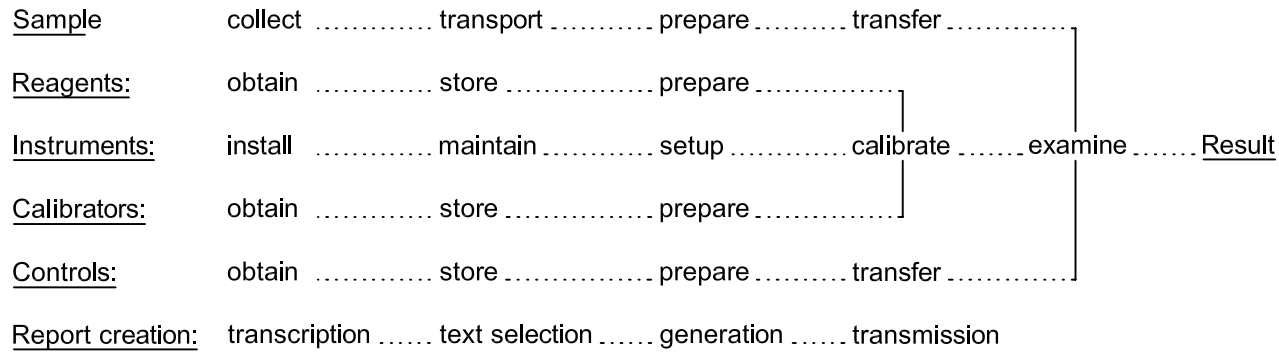

Figure A.1 — Example of process map in a medical laboratory

A failure mode, defined as the manner in which the process could potentially fail, should be identified in a manner that could determine what the ultimate effect will be. A failure effect is defined as the result of a failure mode on the process, as perceived by a test error. It can be described in terms of what the patient might experience should the identified failure mode occur, such as inconvenience or harm resulting from delayed or inaccurate examination results, diagnosis or therapy.

One failure mode in one component can serve as the cause of another failure mode in another activity within the process.

For each failure mode identified, the team should determine what the ultimate effect will be and establish a numerical ranking for the severity of the effect, in order to help determine which failures to address first.

The team then identifies controls and other potential monitoring procedures that can prevent the cause of the failure mode from occurring. Each procedure can be assessed to determine how well it is expected to detect a failure mode.

Once the new process has been in use, previously undetected or unidentified failure modes may appear. The FMEA should then be updated and plans made to address those failures to eliminate them from the product/process.

Annex B
(informative)

Model for assessing risk of harm

Figure B.1 illustrates how the risk model needs to be taken into account in order to assess the risk of harm posed to a patient from erroneous results.

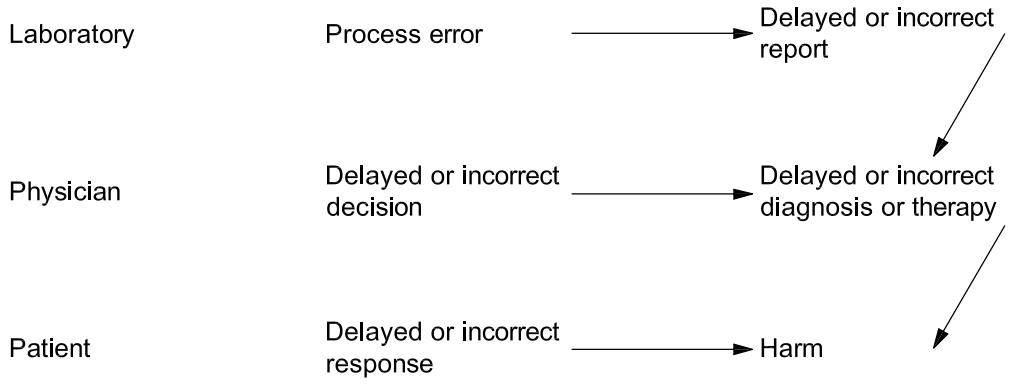

Figure B.1 — Example of model for assessing risk of harm

According to this model, the consequences of delivering an erroneous result to a physician will depend on the action of the physician and the medical significance of the respective laboratory process. Physicians use laboratory examination results together with other available medical information to evaluate a patient and reach a decision. In some cases, the laboratory result may be the only basis for the medical decision. The probability of a patient being harmed is a combination of the probabilities that each event illustrated in the model would occur. Each individual probability is partially offset by a probability that the fault, hazard or hazardous situation will be recognized by the laboratory or the physician, thus allowing intervention and avoiding harm. The actual chain of events will depend on the particular laboratory process, and the risk from each combination of events should be assessed independently, using this scheme as a guide.

Annex C
(informative)

Ranking of severity levels

The response to laboratory error should be appropriate to both the likelihood of recurrence and the potential severity of its outcome. The risk of errors that are negligible or of minor consequence may be tolerable, unless they are likely to recur frequently. On the other hand, the risk of errors that are potentially life threatening, even if their likelihood of occurrence is remote, would always be unacceptable. Where an elimination or sufficient reduction of the hazard is not possible, the information of the recipients of the result of the residual hazard may be considered as a measure to reduce the risk. Table C.1 illustrates one example for linking frequency of risk and outcome.

Table C.1 — Example of ranking of severity levels linking frequency of risk and outcome

Probability	Severity ranking				
	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	Unacceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Probable	Acceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Occasional	Acceptable	Acceptable	Acceptable	Unacceptable	Unacceptable
Remote	Acceptable	Acceptable	Acceptable	Unacceptable	Unacceptable
Improbable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

Bibliography

[1] ASTION, ML, SHOJANIA, KG, HAMILL, TR, KIM, S and NG, VL, "Classifying laboratory incident reports to identify problems that jeopardize patient safety", *American Journal of Clinical Pathology* (2003), 120 (1), pp. 18-26

[2] KOHN, LT, CORRIGAN, JM and DONALDSON, MS, eds. *To Err is Human: Building a Safer Health System*, Institute of Medicine, Washington DC: National Academy Press (2000), (3)

[3] SPATH, PL, "Using failure mode and effects analysis to improve patient safety", *Association of Operating Room Nurses (AORN) Journal* (2003), 78 (2), pp. 16-37

[4] BONINI, PA, PLEBANI, M, CERIOTTI, F and RUBBOLI, T, "Errors in laboratory medicine", *Clin Chem*. (2002), 48, pp. 691-698

[5] CLSI/NCCLS, *A Quality Management System Model for Health Care; Approved Guideline* (2nd Edition), NCCLS document HS1-A3, Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA (2004)

[6] CLSI/NCCLS, *Continuous Quality Improvement: Integrating Five Key Quality System Essentials; Approved Guideline* (2nd Edition), NCCLS document GP22-A2, Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA (2004)

[7] CLSI/NCCLS, *A Quality Management System Model for Health Care; Approved Guideline* (2nd Edition), NCCLS document HS1-A3, Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA (2004)

[8] CLSI/NCCLS, *Quality Management for Unit-Use Testing; Approved Guideline*, NCCLS document EP18-A, Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA (2002)

[9] REASON, JT, *Human Error*, New York, NY: Cambridge University Press (1990)

[10] DAVIDSON FRAME, J, *Managing Risk in Organizations: A Guide for Managers*, San Francisco CA: Jossey-Bass (2003)

[11] ROBITAILLE, D, *The Preventive Action Handbook*, Chico, CA: Paton Press (2003)

[12] *Guidelines for Hazard Evaluation Procedures — With Worked Examples* (2nd Edition), Center for Chemical Process Safety/AIChE (1992), ISBN 0-8169-0491-X

[13] MIKE, W. Schmidt, *The Use and Misuse of FMEA in Risk Analysis*, (MDDI March 2004)

[14] STAMATIS, D.H., *Failure Mode and Effect Analysis: FMEA From Theory to Execution* (2nd Edition, 2003), ISBN 0873895983

[15] MIL-STD-1629A, *Military Standard Procedures for Performing a Failure Mode, Effects and Criticality Analysis*, United States Department of Defense, Washington, DC 20301 (1980)

[16] IEC 60812, *Analysis techniques for system reliability — Procedure for failure mode and effects analysis (FMEA)*

[17] IEC 61025, *Fault tree analysis (FTA)*

[18] IEC 61882, *Hazard and operability studies (HAZOP studies) — Application guide*

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