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Title

Medical laboratories - Reduction 1of error through risk management and continual improvement

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Proposed Technical Specification ☐ or *Technical Report* ☒

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Introductory note

This Draft Technical Report is submitted for review and vote by ISO/TC212 in accord with Resolutions 142 an 144 of the Utrecht meeting.

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

Élément introductif — Élément central — Élément complémentaire

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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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In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard (“state of the art”, for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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

This second/third/... edition cancels and replaces the first/second/... edition (), [clause(s) / subclause(s) / table(s) / figure(s) / annex(es)] of which [has / have] been technically revised.

Introduction

It is a requirement of ISO 15189:2003 that laboratories shall have an investigative process to determine aspects that do not conform with their own procedures or agreed upon requirements in the quality management system (4.9.1). The standard specifies that this is to be linked to corrective actions (4.10) and preventive actions (4.11). In addition, the standard specifies that management shall review the suitability and effectiveness of the system and its activities in support of patient care, and to introduce necessary changes (4.15).

Classification of events is a useful for monitoring purposes and allows the laboratory to make determinations for recognizing the criticality of events, setting priorities for addressing the events, and provides a basis for risk management. Classification of events is useful when determining underlying causative factors that contribute to errors.

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

1 Scope

This technical report characterizes the application of ISO 15189:2003 as a system to reduce laboratory error and improve patient safety. The application should have reference to examination and special reference to pre- and post-examination aspects of the cycle of laboratory medical care. The technical report proposes a methodology for finding and characterizing medical laboratory error that would be avoided with 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 9001:2000, Quality management systems -- Fundamentals and vocabulary

ISO 15189:2003, Medical Laboratories – Particular requirements for quality and competence

ISO 14971:2000, Medical Devices – Application of Risk management to medical devices

ISO/IEC Guide 73:2002, Risk Management – Vocabulary – Guidelines for use in standards

Considerations of local, regional, and national regulations shall apply.

3 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 9001, ISO 15189, ISO 14971, ISO/IEC Guide 73, and the following apply.

3.1 active error

an error by a front-end operator; effects are felt immediately

3.2 cognitive error

an error due to miscalculation

3.3 latent error

an error due to underlying factors not under control of the front end operator, such as faulty equipment, poor design, management decision, or organization structure

3.4 non-cognitive error

an error due to fatigue, rushing, non-concentration.

4 Identification of Laboratory non-conformities, errors or incidents

Identification of events may occur through the application of either active or passive processes.

Note: An active process is a planned process to monitor deviations in laboratory practice of outcome measured against a specific requirement. A passive process is one that collects deviations in laboratory practice as they are derived from unsolicited communications including complaints, incident reports, or other recordings.

5 Assessment of risk of deviations from standard

The quality manager should establish and maintain a process for identifying incidents associated with deviations from standards requirements, estimating and evaluating the associated risks to patient care, controlling these risks and monitoring effectiveness of the control. The process should be documented and include the following elements:

a) Incident reporting

b) Evaluation of risk of incident

c) Risk Control and

d) Post evaluation information.

6 Management responsibility in corrective and preventive actions

The management should:

a) Define the policy to identifying non-conformities, errors and incidents

b) Ensure provision of adequate resources

c) Ensure personnel are trained to properly detect non-conformities, errors and incidents.

d) Review the results of non-conformities, errors and incidents analysis.

7 Qualification of Personnel

The laboratory management should ensure that those performing non-conformities, errors and incidents identification and classification include people with knowledge and experience appropriate to the task assigned.

8 Corrective and Prevention Plan

For the particular non-conformity, error or incident, laboratory management should prepare a plan for investigation, correction and prevention. The plan shall include:

a) The scope of the plan

b) A description of the non-conformity, error or incident

c) Allocation of responsibilities

d) Requirement for review

e) Criteria for acceptable resolution.

f) Need for preventive action.

9 Corrective and Prevention Plan File

Each event should be recorded within the Corrective and Prevention Plan File. Records should be maintained within a Corrective and Prevention Plan Master Log.

10 Classification of laboratory non-conformities, errors and incidents.

Identified events can be classified to clarify the character of the event. Points for classification may include, but not limited to:

a) Cycle phase of event:

- pre-examination, such as:
  - — incorrect patient identification
  - — incorrect collection container
  - — incorrect collection timing
  - — incorrect transport conditions or timing
- examination, such as:
  - — discrepant quality control result
  - — procedural non-conformity
  - — equipment or reagent error
  - — delayed time to completion (turnaround time)
- post-examination, such as
  - — incorrect result
  - — ambiguous report
  - — incorrect patient
  - — report sent to incorrect person

b) Recognition of event process:

- internal or external to the laboratory

c) Responsibility for event

- latent or active error
- cognitive or con-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 delay in treatment or diagnosis
- resulted in inappropriate treatment or diagnosis

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

a) At regular intervals, the contents of the corrective plan file should be reviewed to determine commonalities and continuities of events.

b) Events of a consistent and recurrent nature should be subjected to analysis of the underlying causative factors.

c) Each event with either delay or impact on patient care should be subjected to analysis of the underlying causative factors.

12 Continual improvement plan

a) Following the investigation, laboratory management should review information gained about the collected events. The information should be evaluated for possible relevance to patient and laboratory safety, especially the following:

— if previously unrecognized hazards are present

— if original assessments of events is otherwise invalidated.

b) If any of the above is satisfied, the results of the evaluation should be fed back as an input to the evaluation process.

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