

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

ICS 11.100.01

National foreword

This Draft for Development is the UK implementation of CEN ISO/TS 22367:2010. It is identical to ISO/TS 22367:2008, incorporating corrigendum January 2009. It supersedes DD ISO/TS 22367:2008 which is withdrawn.

This publication is not to be regarded as a British Standard.

It is being issued in the Draft for Development series of publications and is of a provisional nature. It should be applied on this provisional basis, so that information and experience of its practical application can be obtained.

Comments arising from the use of this Draft for Development are requested so that UK experience can be reported to the international organization responsible for its conversion to an international standard. A review of this publication will be initiated not later than three years after its publication by the international organization so that a decision can be taken on its status. Notification of the start of the review period will be made in an announcement in the appropriate issue of *Update Standards*.

According to the replies received by the end of the review period, the responsible BSI Committee will decide whether to support the conversion into an international Standard, to extend the life of the Technical Specification or to withdraw it. Comments should be sent to the Secretary of the responsible BSI Technical Committee at British Standards House, 389 Chiswick High Road, London W4 4AL.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Amendments/corrigenda issued since publication

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Date	Comments
31 August 2009	Implementation of ISO corrigendum January 2009, Clause 3.7 deleted
30 April 2010	This corrigendum renumbers DD ISO/TS 22367:2008 as DD CEN ISO/TS 22367:2010

English Version

**Medical laboratories - Reduction of error through risk
management and continual improvement (ISO/TS 22367:2008,
including Cor 1:2009)**

Laboratoires médicaux - Réduction d'erreurs par gestion du
risque et amélioration continue (ISO/TS 22367:2008, Cor
1:2009 inclus)

Medizinische Laboratorien - Fehlerrückführung durch
Risikomanagement und ständige Verbesserung (ISO/TS
22367:2008, einschließlich Cor 1:2009)

This Technical Specification (CEN/TS) was approved by CEN on 4 January 2010 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of ISO 22367:2008, including Cor 1:2009 has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" of the International Organization for Standardization (ISO) and has been taken over as CEN ISO/TS 22367:2010 by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices" the secretariat of which is held by DIN.

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Endorsement notice

The text of ISO 22367:2008, including Cor 1:2009 has been approved by CEN as a CEN ISO/TS 22367:2010 without any modification.

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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.