EP23-P
Vol. 30 No. 4

Laboratory Quality Control Based on Risk Management; Proposed Guideline

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This proposed document is published for wide and thorough review in the new, accelerated Clinical and Laboratory Standards Institute (CLSI) consensus-review process. The document will undergo concurrent consensus review, Board review, and delegate voting (ie, candidate for advancement) for 90 days.

Please send your comments on scope, approach, and technical and editorial content to CLSI.

Comment period ends

29 April 2010

The subcommittee responsible for this document will assess all comments received by the end of the comment period. Based on this assessment, a new version of the document will be issued. Readers are encouraged to send their comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; Fax: +610.688.0700, or to the following e-mail address: standard@clsi.org.

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COMMENT

This document provides guidance based on risk management for laboratories to develop quality control plans tailored to the particular combination of measuring system, laboratory setting, and clinical application of the test.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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Advancing Quality in Health Care Testing

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- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

Most documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate consensus level.

Proposed A consensus document undergoes the first stage of review by the health care community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Approved An approved standard or guideline has achieved consensus within the health care community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (ie, that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

Our standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following CLSI's established consensus procedures. Provisions in CLSI standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are addressed by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any document. Address comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

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Health care professionals in all specialties are urged to volunteer for participation in CLSI projects. Please contact us at customerservice@clsi.org or +610.688.0100 for additional information on committee participation.

EP23-P
ISBN 1-56238-718-9
Volume 30 Number 4
ISSN 0273-3099

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Abstract

Clinical and Laboratory Standards Institute document EP23-P—*Laboratory Quality Control Based on Risk Management; Proposed Guideline* provides guidance to laboratories on the development of quality control plans for *measuring systems.* Regulatory requirements, information provided by the manufacturer, information pertaining to the laboratory environment, and medical requirements for the test results are evaluated using risk management principles to develop a quality control plan tailored to the particular combination of measuring system, laboratory environment, and clinical application. The effectiveness of the laboratory quality control plan is monitored to detect trends, identify corrective actions, and provide continuous quality improvement. The advantages and limitations of various quality control processes are considered.

Clinical and Laboratory Standards Institute (CLSI). *Laboratory Quality Control Based on Risk Management; Proposed Guideline*. CLSI document EP23-P (ISBN 1-56238-718-9). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2010.

Suggested Citation

CLSI. *Laboratory Quality Control Based on Risk Management; Proposed Guideline*. CLSI document EP23-P. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

Proposed Guideline

January 2010

ISBN 1-56238-718-9
ISSN 0273-3099

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Acknowledgment in Memoriam of our Subcommittee Member and Colleague

CLSI and the Subcommittee on Laboratory Quality Control Based on Risk Management gratefully acknowledge the valuable contributions of the late Dr. Ronald H. Laessig, who was an active participant during the development of this proposed-level document.

Acknowledgment

CLSI and the Subcommittee on Laboratory Quality Control Based on Risk Management extend appreciation to Dr. Donald M. Powers, Powers Consulting Services, and Ms. Christine Diehl for their contributions during the development of this document.

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Foreword

Although the manufacturer is responsible for quality in design of its measuring system and reagents, the laboratory and, ultimately, the laboratory director are accountable for the quality of test results. To establish effective examination quality control (QC), laboratories must process an array of information (regulatory requirements, manufacturer-provided information, the laboratory's environment, and the medical applications of tests performed) through a risk assessment process. This process identifies weaknesses in the measuring system and environment that are weighed against the probability for error, the effectiveness of control processes built into the measuring system, and the laboratory's tolerance for risk in consideration of the clinical use of a laboratory result. This document provides guidance to laboratories for establishing a quality control plan (QCP). Once developed, the QCP is monitored for effectiveness and modified, for example, as unanticipated failure modes or underestimated risks of error are discovered or as particular control procedures are no longer required once sufficient objective data demonstrating reliable performance have been established. The advantages and limitations of a variety of QC measures are discussed to help the laboratory develop a QCP that is appropriate for its particular measuring system, laboratory, and clinical environment.

This document is one in a series of three CLSI documents that address risk assessment and implementation of QC strategies to mitigate risks of error. This series of documents includes EP18,[1] this guideline, and EP22.[2] The interrelationship of the three documents is summarized below and in the table that follows.

Compliance with EP18,[1] EP22,[2] and EP23 may not satisfy the requirements of all regulatory, accreditation, or certification bodies. Laboratories need an awareness of all applicable requirements in the development of their QCPs.

As represented in the table below, the series of CLSI documents is intended to provide guidance to manufacturers of IVD devices and laboratories to assist in identifying potential failure modes and developing a strategy to mitigate the risks.

Intended Audience	Error Prevention	Error Detection
Manufacturer	Risk assessment and risk mitigation for manufacturers References: • International Organization for Standardization (ISO) 14971[3] • CLSI document EP18[1]	Embedded measuring system checks and controls Information regarding key design features intended to mitigate risk of potential measuring system failures that can affect the accuracy of test results Reference: • CLSI document EP22[2]
Laboratory	Techniques (Failure Modes and Effects Analysis [FMEA] and Failure Reporting and Corrective Action System [FRACAS])to identify and control laboratory error sources Reference: • CLSI document EP18[1]	Laboratory implemented QCP References: • CLSI document EP23 • ISO 15189[4]

Invitation for Participation in the Consensus Process

An important aspect of the development of this and all CLSI documents is the consensus process. Within the consensus process, CLSI members and other interested parties (1) have the opportunity to review and comment on CLSI publications in development; and (2) are assured that their comments are given serious consideration. All CLSI documents evolve, as does the technology affecting laboratory and health care procedures, methods, and protocols; and therefore, through the operation of the consensus process, CLSI documents are expected to undergo cycles of evaluation and modification.

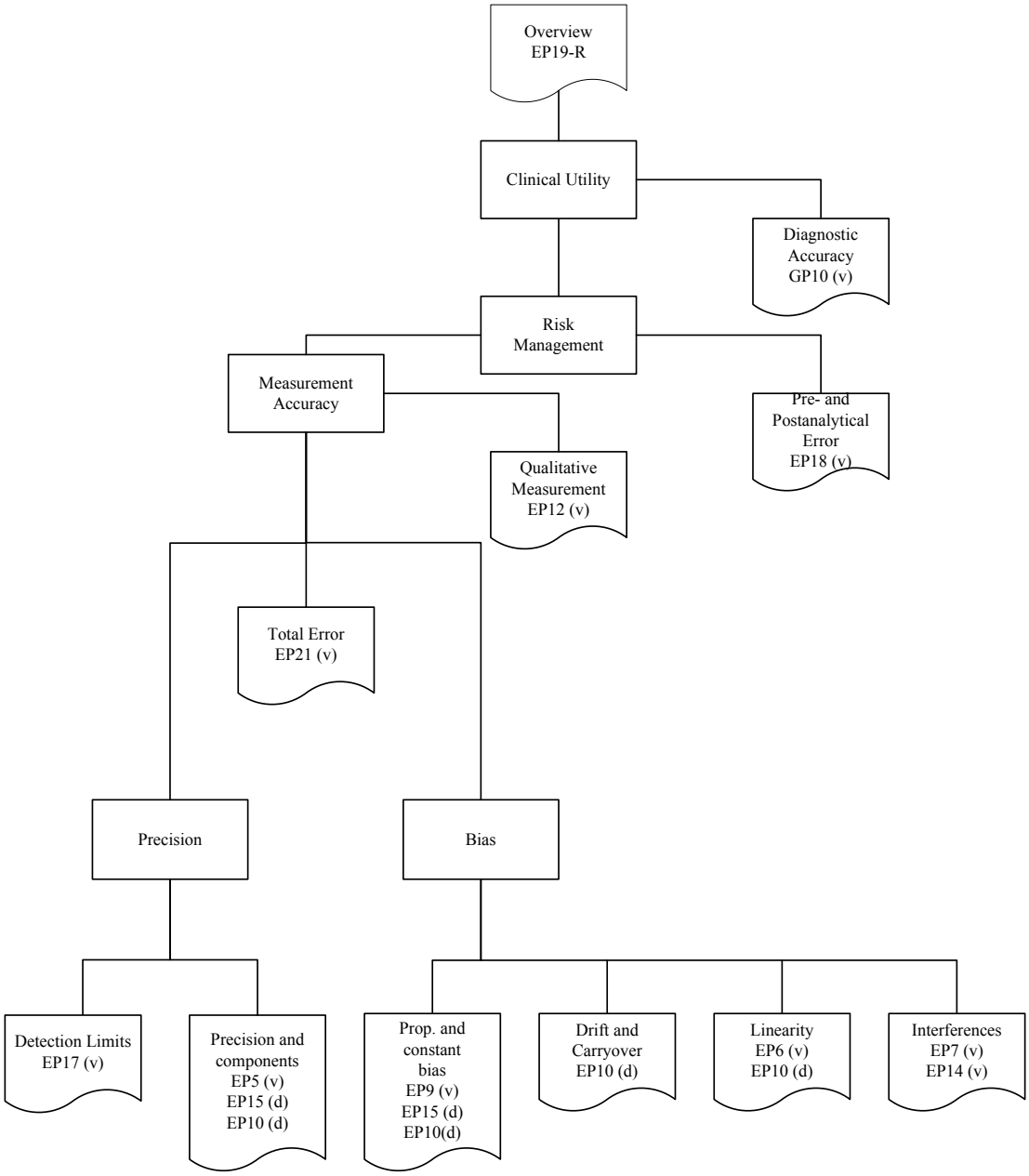
The Area Committee on Evaluation Protocols has attempted to engage the broadest worldwide representation in the committee deliberations to develop this document. Consequently, it is expected that issues may still remain unresolved when the proposed level document is published. Review and comment within the CLSI process is the mechanism for resolving such issues.

The CLSI voluntary consensus process depends on the expertise of worldwide reviewers whose comments add value to the final document. At the end of a 90-day comment period, each subcommittee is obligated to review all comments and to respond in writing to all substantive comments. Where appropriate, modifications will be made to improve the document, and all comments along with the subcommittee's responses will be included in an appendix when the document is published at the next consensus level.

Key Words

Patient safety, quality control, risk assessment, risk management

Laboratory Failure Sources and CLSI Evaluation Protocols Documents



Adapted from Krouwer JS. Estimating total analytical failure and its sources: techniques to improve method evaluation. *Arch Pathol Lab Med.* 1992;116:726-731.[5] Copyright © 1992 American Medical Association. All rights reserved. Reprinted with permission.

Laboratory Failure Sources and CLSI Evaluation Protocols (EP) Documents.[a] This figure illustrates the relationship among parameters estimated by EP documents. Items higher up in the figure are more comprehensive, whereas lower level items are more specific. Overall, the figure is much like a cause-and-effect diagram. Documents marked (d) provide guidance for demonstrating that a source of measurement inaccuracy is within acceptable limits. Documents marked (v) provide guidance for more rigorous evaluation of inaccuracy components.

[a]For a description of each of the documents listed, please see the Related CLSI Reference Materials section at the end of this document.

Laboratory Quality Control Based on Risk Management; Proposed Guideline

1 Scope

This document describes good laboratory practice for developing and maintaining a quality control plan (QCP) using internationally recognized risk management principles. An individual QCP must be established, maintained, and modified as needed for each measuring system. The QCP is based on the performance required for the intended medical application of the test results performed. Risk mitigation information provided by the manufacturer, applicable regulatory and accreditation requirements, and the individual health care and laboratory setting are considered in development of the QCP. This document is intended to guide laboratories in determining QC procedures that are both appropriate and effective for the test being performed. The QCP should be designed to monitor parts of a measuring system that are recognized as high risk and that are not monitored by built-in sensors, checks, and other control processes.

This document may not satisfy the requirements of all regulatory, accreditation, or certification bodies. Laboratories need to be aware of all applicable requirements in the development of their QCPs. This document is not specifically intended to justify reduction in QC testing.

2 Introduction

2.1 Quality Control Plan

Health care providers need test results that are relevant, accurate, and reliable for patient care. A number of factors can adversely affect the quality of test results, from failures of the measuring system to operator errors to environmental conditions. The laboratory establishes QCPs to prevent failures to the greatest extent practicable and to detect any that do occur before incorrect results are reported to health care providers and acted on.

Development of a QCP requires understanding of the allowable error for each test and the consequent risk of harm to a patient should tolerance limits for errors be exceeded and an incorrect result is acted on. Development of the QCP also requires an understanding of the total measuring system (including the premeasurement, measurement, and postmeasurement processes), and identification of the weaknesses in these processes where failures can occur. For laboratory-based testing, the premeasurement phase refers to all steps in the examination that occur before the sample arrives in the laboratory (test ordering, patient preparation, specimen collection, and transport to the laboratory), the measurement phase refers to the steps of the measurement process involved in analyzing the specimen within the laboratory (accessioning, processing, centrifugation, aliquoting, analysis, dilution, and repeat testing), and the postmeasurement phase refers to steps of the measurement after result availability (result reporting, communication to treating caregiver, interpretation, and treatment). Although point-of-care testing eliminates many of these steps (eg, transport, processing, and centrifugation), the total testing process can be similarly broken down into premeasurement, measurement, and postmeasurement phases. To fully understand the potential failure modes of the measuring system, information is needed from the manufacturer that describes its operation and built-in control mechanisms. Any QCP must necessarily consider the entire measuring system because failures occurring in any part of the measuring system can impact the final test result. EP23, however, focuses on the examination phase of the testing process (and premeasurement variables that directly impact the measuring system operation). EP23 emphasizes how to use information provided by the manufacturer about the measuring system (see CLSI document EP22)[2] to develop a QCP.

Risk management begins with a detailed review of each step in the measurement process to identify the potential failure modes so that suitable control measures are put in place. Although it is a desirable goal to have no errors in laboratory testing, in practice, the laboratory will never entirely remove the possibility

