CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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EP23-A™

Laboratory Quality Control Based on Risk Management; Approved Guideline

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.

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For additional information on committee participation or to submit comments, contact CLSI.

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Abstract

Clinical and Laboratory Standards Institute document EP23-A—*Laboratory Quality Control Based on Risk Management; Approved 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.

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Contents

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 quality control (QC), laboratories should 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 potential 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 assessment of 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 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.

Compliance with EP23 may not satisfy the requirements of all regulatory, accreditation, or certification bodies. Laboratories need to comply with all applicable requirements in the development of their QCPs.

KEY WORDS

Quality Control
Risk Assessment
Risk Management

Chapter 1
Introduction

In this document, you will learn how to **create a quality control plan (QCP) that is customized for your institution, facility, and laboratory,** so that you can **run your tests in an effective and efficient manner,** improving patient care.

You will learn:

- How to compile information into a QCP
- The many types of tools in the QC toolbox, and which are most effective for your situation
- How to detect potential errors
- How to determine if potential errors can cause harm
- How to help prevent errors from occurring
- How to ensure your QCP is effective

Laboratory Quality Control Based on Risk Management; Approved Guideline

1 Scope

NOTE:

This document may not satisfy the requirements of all regulatory, accreditation, or certification bodies. **LABORATORIES NEED TO COMPLY WITH ALL APPLICABLE REQUIREMENTS** in the development of their QCPs.

This document describes good laboratory practice for developing and maintaining a QCP for medical laboratory testing using internationally recognized risk management principles. An individual QCP should 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. Risk mitigation information obtained from the manufacturer and identified by the laboratory, 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.

This document may not satisfy the requirements of all regulatory, accreditation, or certification bodies. Laboratories need to comply with all applicable requirements in the development of their QCPs.

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 and present a risk of harm to the patient, from failures of the measuring system, to operator errors, to environmental conditions. Failure is used in this document in the context of risk management and means, in the broadest sense, a case when the system does not meet the user's expectation. Failure includes the inability of a measurement process to perform its intended functions satisfactorily or within specified performance limits, errors of a measuring system that may produce an incorrect result, and incorrect use of a measuring system that may cause an incorrect result. Risk management is the systematic application of management policies, procedures, and practices to the tasks

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The quality management system approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any health care service's path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The QSEs are as follows:

Organization	Personnel	Process Management	Nonconforming Event Management
Customer Focus	Purchasing and Inventory	Documents and Records	Assessments
Facilities and Safety	Equipment	Information Management	Continual Improvement

EP23-A addresses the QSE indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Organization	Customer Focus	Facilities and Safety	Personnel	Purchasing and Inventory	Equipment	Process Management	Documents and Records	Information Management	Nonconforming Event Management	Assessments	Continual Improvement
GP26	GP26	GP26 M29	GP21 GP26	GP26	GP26	X C24 EP18 GP26	GP02 GP26	GP02 GP26	EP18 GP26	EP18 GP26	EP18 GP26

Path of Workflow

A path of workflow is the description of the necessary processes to deliver the particular product or service that the organization or entity provides. A laboratory path of workflow consists of the sequential processes: preexamination, examination, and postexamination and their respective sequential subprocesses. All laboratories follow these processes to deliver the laboratory's services; namely, quality laboratory information.

EP23-A addresses the clinical laboratory path of workflow steps indicated by an "X." For a description of the document listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Preexamination				Examination			Postexamination	
Examination ordering	Sample collection	Sample transport	Sample receipt/ processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
GP26	GP26	GP26	GP26	X GP26	X GP26	X GP26	GP26	GP26

Related CLSI Reference Materials*

C24-A3 **Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition (2006).** This guideline provides definitions of analytical intervals, planning of quality control procedures, and guidance for quality control applications.

EP18-A2 **Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition (2009).** This guideline describes risk management techniques that will aid in identifying, understanding, and managing sources of failure (potential failure modes) and help to ensure correct results. Although intended primarily for *in vitro* diagnostics, this document will also serve as a reference for clinical laboratory managers and supervisors who wish to learn about risk management techniques and processes.

GP02-A5 **Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition (2006).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the medical laboratory community.

GP21-A3 **Training and Competence Assessment; Approved Guideline—Third Edition (2009).** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.

GP26-A4 **Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition (2011).** This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.

M29-A3 **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** Based on US regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

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