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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.



Clinical and Laboratory Standards Institute

Advancing Quality in Health Care Testing

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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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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

Laboratory Quality Control Based on Risk Management; Approved Guideline

1 Scope

This document describes good laboratory practice for developing and maintaining a quality control plan (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 quality control (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 of analyzing, evaluating, controlling, and monitoring risk. QC in this document is defined as the set of operations, processes, and procedures designed to monitor the measuring system to ensure the results are reliable for the intended clinical use. QC in this context is broader than, although not necessarily exclusive of, the measurement of QC samples intended to simulate clinical patient samples.

A QCP is a documented strategy to mitigate and prevent errors in testing that describes the practices, resources, and sequences of specified activities to control the quality of a particular measuring system or measurement process to ensure intended purposes are met. The laboratory establishes QCPs to prevent failures and to detect nonconformities that may occur before incorrect results are reported to health care providers and clinical action is taken.

Development of a QCP requires an understanding of the preexamination (preanalytical), examination (analytical), and postexamination (postanalytical) processes, and identification of the weaknesses (potential failure modes) in these processes where failures can impact a given measuring system and potentially cause patient harm. Although this guideline addresses the examination phase, it is important to recognize that preexamination (preanalytical) and postexamination (postanalytical) processes are also important and may directly influence the acceptability of a measurement result. For example, sample collection, transport, and handling may contribute to the acceptability of a reported result.

The laboratory should manage risk by implementing QCPs that serve to ensure test result quality is appropriate for clinical use of the information by:

- 1) Monitoring the testing process for the occurrence of errors
- 2) Introducing control procedures to mitigate the occurrence of errors

Given the variety of testing performed in a typical health care facility, with particular measuring systems, examination (analytical) procedures, laboratory environments, and clinical applications, laboratories need guidance to determine effective combinations of control strategies to achieve reliable test results. This document discusses some of the QC tools available to the laboratory and summarizes their advantages and limitations. It describes an approach to develop a QCP that involves 1) collecting the necessary information from manufacturers, literature, regulatory and accreditation agencies, the laboratory's particular environment, and the clinical application of test results; 2) conducting a risk assessment; and 3) identifying effective control measures to reduce risk.

In the risk management process, attempts are first made to identify and eliminate the causes of potential process and system failures before implementing measures to detect failures and/or their effects (eg, incorrect test results). Activities to monitor ongoing performance are directed toward the identification of unpredicted events that cause risks, modification of the QCP, and continual improvement (CI). Figure 1 depicts schematically the inputs needed to develop and continually improve a QCP.

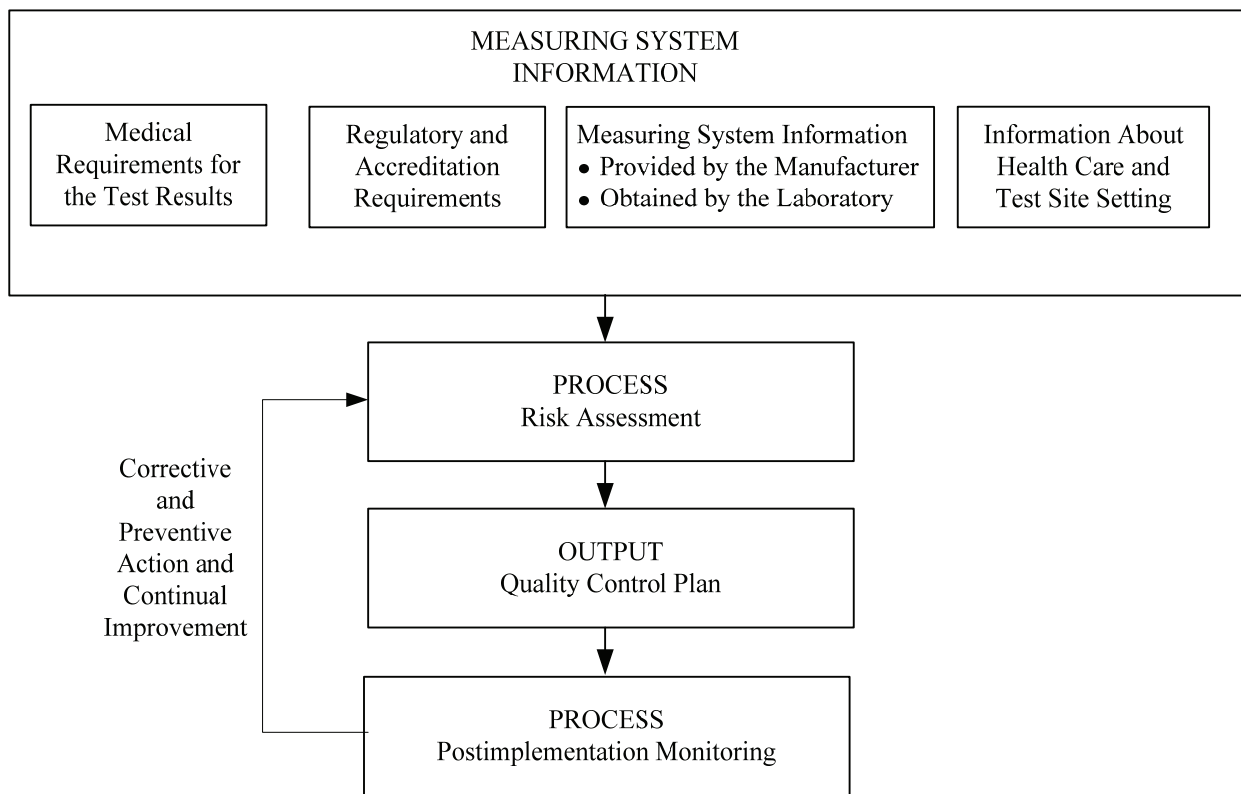


Figure 1. Process to Develop and Continually Improve a QCP. (The terms *corrective and preventive action* and *continual improvement* are referred to as CAPA and CI, respectively, in risk management literature.)

2.2 Risk Management

Application of risk management to the entire life cycle of a laboratory measuring system is described for manufacturers in ISO 14971.¹ The principles described are adapted in this document for use by laboratories to develop a QCP for measuring systems currently in use or introduced in a health care setting.

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
						X C24 EP18					
GP26	GP26	GP26 M29	GP21 GP26	GP26	GP26	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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