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

Setting the standard for quality in medical laboratory testing around the world.

The Clinical and Laboratory Standards Institute (CLSI) is a not-for-profit membership organization that brings together the varied perspectives and expertise of the worldwide laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine by developing and implementing medical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

Consensus Process

Consensus—the substantial agreement by materially affected, competent, and interested parties—is core to the development of all CLSI documents. It does not always connote unanimous agreement, but does mean that the participants in the development of a consensus document have considered and resolved all relevant objections and accept the resulting agreement.

Commenting on Documents

CLSI documents undergo periodic evaluation and modification to keep pace with advancements in technologies, procedures, methods, and protocols affecting the laboratory or health care.

CLSI’s consensus process depends on experts who volunteer to serve as contributing authors and/or as participants in the reviewing and commenting process. At the end of each comment period, the committee that developed the document is obligated to review all comments, respond in writing to all substantive comments, and revise the draft document as appropriate.

Comments on published CLSI documents are equally essential, and may be submitted by anyone, at any time, on any document. All comments are managed according to the consensus process by a committee of experts.

Appeals Process

When it is believed that an objection has not been adequately considered and responded to, the process for appeals, documented in the CLSI Standards Development Policies and Processes, is followed.

All comments and responses submitted on draft and published documents are retained on file at CLSI and are available upon request.

Get Involved—Volunteer!

Do you use CLSI documents in your workplace? Do you see room for improvement? Would you like to get involved in the revision process? Or maybe you see a need to develop a new document for an emerging technology? CLSI wants to hear from you. We are always looking for volunteers. By donating your time and talents to improve the standards that affect your own work, you will play an active role in improving public health across the globe.

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

Clinical and Laboratory Standards Institute
950 West Valley Road, Suite 2500
Wayne, PA 19087 USA
P: +1.610.688.0100
F: +1.610.688.0700
www.clsi.org
standard@clsi.org
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.

The Clinical and Laboratory Standards Institute (CLSI) consensus process, which is the mechanism for moving a document through two or more levels of review by the health care community, is an ongoing process. Users should expect revised editions of any given document. Because rapid changes in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of CLSI documents. Current editions are listed in the CLSI catalog and posted on our website at www.clsi.org.

If your organization is not a member and would like to become one, and to request a copy of the catalog, contact us at:

P: 610.688.0100    F: 610.688.0700    E: customerservice@clsi.org    W: www.clsi.org
Suggested Citation


Previous Edition:
January 2010

Reaffirmed:
April 2016

ISBN 1-56238-767-7 (Print)
ISBN 1-56238-768-5 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)
# Contents

## Abstract

### Volume 31  
© Clinical and Laboratory Standards Institute. All rights reserved.

## Committee Membership

### Volume 31  
© Clinical and Laboratory Standards Institute. All rights reserved.

## Foreword

### Volume 31  
© Clinical and Laboratory Standards Institute. All rights reserved.

## Chapter 1: Introduction

1. **Scope**
2. **Introduction**
   2.1 Quality Control Plan
   2.2 Risk Management
3. **Standard Precautions**
4. **Terminology**
   4.1 A Note on Terminology
   4.2 Definitions
   4.3 Abbreviations and Acronyms

## Chapter 2: Path of Workflow

5. **Process Flow Chart**
6. **EP23 Path of Workflow**
   6.1 Information Gathering for Risk Assessment
   6.2 Process Mapping
   6.3 Developing the Quality Control Plan
   6.4 Postimplementation Monitoring of the Quality Control Plan

## Chapter 3: Quality System Essentials

7. **Quality System Essentials**
   7.1 Organization
   7.2 Documents and Records
   7.3 Nonconforming Event Management
   7.4 Assessments
   7.5 Continual Improvement

## Chapter 4: Conclusion

## Chapter 5: Supplemental Information

### References

### Appendix A. The Quality Control Toolbox

### Appendix B. Quick Guide Checklist for Establishing a Quality Control Plan Based on Risk Management

### Appendix C. The Laboratory Risk Assessment: Example Glucose Measurement Using an Automated Measuring System

### Appendix D. Summary of Laboratory Risk Assessment Table. Example: Glucose Measurement on an Automated Measuring System

### Appendix E. The Quality Control Plan Developed From the Individual Components of the Quality Control Strategies From Appendixes C and D. Example: Glucose Measurement on an Automated Measuring System

### Appendix F. Example of Failure Investigation and Corrective Action for Glucose Measurement on an Automated Measuring System

## The Quality Management System Approach

## Related CLSI Reference Materials
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

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 healthcare 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 (i.e., 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:

<table>
<thead>
<tr>
<th>Organization</th>
<th>Customer Focus</th>
<th>Personnel</th>
<th>Process Management</th>
<th>Nonconforming Event Management</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

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.
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.


**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.
Explore the Latest Offerings From CLSI!

As we continue to set the global standard for quality in laboratory testing, we are adding products and programs to bring even more value to our members and customers.

By becoming a CLSI member, your laboratory will join 1,600+ other influential organizations all working together to further CLSI’s efforts to improve health care outcomes. You can play an active role in raising global laboratory testing standards—in your laboratory, and around the world.

Find out which membership option is best for you at www.clsi.org/membership.

Find what your laboratory needs to succeed! CLSI U provides convenient, cost-effective continuing education and training resources to help you advance your professional development. We have a variety of easy-to-use, online educational resources that make eLearning stress-free and convenient for you and your staff.

See our current educational offerings at www.clsi.org/education.

When laboratory testing quality is critical, standards are needed and there is no time to waste. eCLIPSE™ Ultimate Access, our cloud-based online portal of the complete library of CLSI standards, makes it easy to quickly find the CLSI resources you need.

Learn more and purchase eCLIPSE at clsi.org/eCLIPSE.

For more information, visit www.clsi.org today.