



CLINICAL AND  
LABORATORY  
STANDARDS  
INSTITUTE®

3rd Edition

# QMS24

## Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality

This guideline describes an approach for a complete proficiency testing (PT) process and provides assistance to laboratories in using PT as a quality improvement tool.

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

# Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality

Teresa Darcy, MD, MMM  
Gary L. Horowitz, MD  
Deirdre Astin, MS, MT(ASCP)  
Lucia M. Berte, MA, MT(ASCP)SBB,  
DLM, CQA(ASQ)CMQ/OE  
Joanne Brisbois  
Shilo Caulfield, BS, CQIA (ASQ)  
Kathryn Connolly, CQA(ASQ), MT(ASCP)  
Gulderen Yanikkaya Demirel, MD, PhD

Bruce Jones, MD  
Bob Kaplanis, PBT, MT(ASCP)  
Christopher Lyle, MS, MBA  
Penny Petinos, BS, MBus  
Alan T. Remaley, MD, PhD  
Heather Stang, MS  
Daniel W. Tholen, MS  
Nico Vandepoele  
Min Xu, MD, PhD

## Abstract

Clinical and Laboratory Standards Institute guideline QMS24—*Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality* provides laboratories with a detailed description of important activities in the proficiency testing (PT) process and includes suggestions for how to improve this process from a quality management perspective. It includes a suggested classification of unacceptable PT results and specific examples of investigations of unacceptable results.

Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality*. CLSI guideline QMS24 (ISBN 1-56238-944-0 [Print]; ISBN 1-56238-945-9 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2016.

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## Suggested Citation

CLSI. *Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality*. 3rd ed. CLSI guideline QMS24. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

### Previous Editions:

GP27: April 1997, August 1999, February 2007  
GP29: July 2001, December 2002, August 2008

### Reaffirmed:

May 2021

ISBN 1-56238-944-0 (Print)

ISBN 1-56238-945-9 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 36, Number 11

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## Foreword

Proficiency testing (PT) is a valuable tool in the quality improvement process. PT provides one measure of objective evidence of laboratory competence to customers and regulatory and accreditation organizations. It serves as a unique source of information not obtainable by other methods. QMS24 provides guidance to laboratories on designing a PT process and using PT results, whether acceptable or unacceptable, to improve the quality of laboratory testing. PT cannot be used as the sole means for evaluating the quality of a laboratory, as PT is only one component of laboratory quality management. Current accreditation requirements include integration of PT into the laboratory's quality improvement program, and this guideline describes how that can be accomplished.

### Overview of Changes

This guideline replaces the second edition of GP27, published in 2007, and has been recoded as QMS24. Several changes were made in this edition, including:

- ▶ The terminology and definitions were updated and clarified.
- ▶ The scope of the guideline was expanded to include information published in CLSI document GP29, and to eliminate redundancy with that document.
- ▶ The entire guideline was reorganized and updated to be consistent with CLSI's quality system essentials, with a focus on using a process workflow for the PT process.
- ▶ A process flow chart was added that outlines development, implementation, and monitoring of the PT process.
- ▶ Additional information on opportunities for improvement for laboratories in longitudinal review of successful PT events was included.
- ▶ Additional information to assist laboratories in using PT to assess and improve laboratory quality was included.
- ▶ Chapters were added to provide an in-depth discussion of PT in specialized areas of the laboratory, such as molecular and gynecological cytology.

#### KEY WORDS

Alternative assessment procedure

Corrective action

External quality assessment

Proficiency testing

Quality assurance

Quality improvement

# Chapter 1

## Introduction

### This chapter includes:

- ▶ Guideline’s scope and applicable exclusions
- ▶ Background information pertinent to the guideline’s content
- ▶ Standard precautions information
- ▶ “Note on Terminology” that highlights particular use and/or variation in use of terms and/or definitions
- ▶ Terms and definitions used in the guideline
- ▶ Abbreviations and acronyms used in the guideline

QUALITY

# Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality

## 1 Introduction

### 1.1 Scope

#### **IMPORTANT NOTE:**

Regulatory and accreditation organizations may have additional requirements extending beyond the guidance in QMS24.

#### **REMINDER:**

See CLSI document QMS11<sup>7</sup> for information on how to conduct a root cause analysis.

#### **NOTE:**

PT serves as an external verification of a laboratory's results, and also as a valuable self-monitoring tool.

The purpose of this guideline is to help medical laboratories use proficiency testing (PT) as a quality improvement tool.<sup>1-6</sup> This guideline presents a systematic approach for designing the PT process as a component of the laboratory QMS.

QMS24 is intended for clinical laboratory managers and analysts in both the public and private sectors, and is applicable to any setting in which clinical laboratory testing is performed, from bedside testing to large multispecialty laboratories. This guideline applies to both qualitative and quantitative laboratory testing, including detection and quantification of blood and fluid measurands and blood and tissue typing. Some discussions apply only to examinations with quantitative results, whereas other discussions apply to examinations with qualitative results.

The processes described in this guideline can help laboratories design a PT process, monitor PT results, and investigate and respond to unacceptable PT results. Part of this response may include preparation of information for submission to regulatory or accreditation organizations. Laboratories are cautioned, however, that regulatory and accreditation organizations may have additional requirements not supported by the guidance in QMS24.

QMS24 also provides guidance for how to use PT as a tool to prevent problems through analysis of acceptable results, education of laboratory personnel, and monitoring of internal processes.

This guideline does not recommend specific corrective actions for specific root causes (see CLSI document QMS11<sup>7</sup>).

### 1.2 Background

PT evaluates a laboratory's performance on various types of testing and examinations in comparison to peer group performance or a reference standard or method. Alternative assessment procedures (AAPs) may evaluate testing and examination performance against a reference laboratory or against clinical information. PT serves as an external verification of a laboratory's results, and also as a valuable self-monitoring tool. PT directly benefits the laboratory and, indirectly, its customers and regulatory and accreditation organizations.

The use of PT to improve the quality of laboratory performance is not limited to the investigation of unacceptable results. Monitoring



# The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system (QMS) approach in the development of standards and guidelines, which facilitates project management; defines a document structure using a template; and provides a process to identify needed documents. The QMS 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

QMS24 covers the QSEs indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section.

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				X	X
						EP07					
						EP09					
						EP14					
					EP21	EP21					
EP31		EP31			EP31	EP31					
		M29									
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01
			QMS03								
											QMS06
									QMS11		

## 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.

QMS24 does not cover any of the medical laboratory path of workflow processes. For a description of the documents listed in the grid, please refer to the Related CLSI Reference Materials section.

Preexamination				Examination			Postexamination	
Examination ordering	Sample collection	Sample transport	Sample receipt and processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
				EP21				
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01

## Related CLSI Reference Materials\*

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- EP07**     **Interference Testing in Clinical Chemistry. 2nd ed., 2005.** This document provides background information, guidance, and experimental procedures for investigating, identifying, and characterizing the effects of interfering substances on clinical chemistry test results.
- EP09**     **Measurement Procedure Comparison and Bias Estimation Using Patient Samples. 3rd ed., 2013.** This document addresses the design of measurement procedure comparison experiments using patient samples and subsequent data analysis techniques used to determine the bias between two *in vitro* diagnostic measurement procedures.
- EP14**     **Evaluation of Commutability of Processed Samples. 3rd ed., 2014.** This document provides guidance for evaluating the commutability of processed samples by determining if they behave differently than unprocessed patient samples when two quantitative measurement procedures are compared.
- EP21**     **Evaluation of Total Analytical Error for Quantitative Medical Laboratory Measurement Procedures. 2nd ed., 2016.** This guideline provides manufacturers and end users with an understanding of concepts related to total analytical error (TAE) for quantitative measurement procedures. An experimental protocol and data analysis method are provided to estimate TAE based upon a comparison of methods experiment with patient specimens, and to assess it relative to a pre-established goal for clinical acceptability.
- EP31**     **Verification of Comparability of Patient Results Within One Health Care System. 1st ed., 2012.** This document provides guidance on how to verify comparability of quantitative laboratory results for individual patients within a health care system.
- M29**     **Protection of Laboratory Workers From Occupationally Acquired Infections. 4th ed., 2014.** 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.
- QMS01**    **Quality Management System: A Model for Laboratory Services. 4th ed., 2011.** This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.
- QMS03**    **Training and Competence Assessment. 3rd ed., 2009.** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.

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

## Related CLSI Reference Materials (Continued)

- QMS06**    **Quality Management System: Continual Improvement. 3rd ed., 2011.** This guideline considers continual improvement as an ongoing, systematic effort that is an essential component of a quality management system. A continual improvement program may consist of fundamental processes and common supporting elements described in this guideline.
- QMS11**    **Nonconforming Event Management. 2nd ed., 2015.** Grounded in the principles of quality management, risk management, and patient safety, this guideline provides an outline and content for developing a program to manage a laboratory's nonconforming events.

Sample

# Sample



950 West Valley Road, Suite 2500, Wayne, PA 19087 USA  
P: +1.610.688.0100 Toll Free (US): 877.447.1888 F: +1.610.688.0700  
E: [customerservice@clsi.org](mailto:customerservice@clsi.org) [www.clsi.org](http://www.clsi.org)

PRINT ISBN 1-56238-944-0  
ELECTRONIC ISBN 1-56238-945-9