CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

QMS19

Customer Focus in a Quality Management System

This guideline provides useful information for how laboratories can develop and maintain a customer focus and meet the regulatory and accreditation requirements for managing external and internal customers.

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

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QMS19, 1st ed.
September 2017

Customer Focus in a Quality Management System

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Abstract

Clinical and Laboratory Standards Institute guideline QMS19—*Customer Focus in a Quality Management System* defines the laboratory's external and internal customers; outlines the fundamentals of identifying customer expectations, defining shared expectations, and communicating performance outcomes; and provides useful tools to help the laboratory focus on providing quality examination results, products, and services to its customers. The processes described in this guideline will also help laboratories meet regulatory and accreditation requirements related to managing laboratory customers.

Clinical and Laboratory Standards Institute (CLSI). *Customer Focus in a Quality Management System.* 1st ed. CLSI guideline QMS19 (ISBN 1-56238-824-X [Print]; ISBN 1-56238-825-8 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2017.

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Suggested Citation

CLSI. *Customer Focus in a Quality Management System*. 1st ed. CLSI guideline QMS19. Wayne, PA: Clinical and Laboratory Standards Institute; 2017.

ISBN 1-56238-824-X (Print)

ISBN 1-56238-825-8 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 37, Number 12

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Foreword

Quality system essential (QSE) Customer Focus is one of the 12 QSEs described in CLSI document QMS01[1] and CLSI product *The Key to Quality*™,[2] which provide the necessary background information and guidance to develop and maintain a QMS. The QMS model depicted in Figure 1 demonstrates how each QSE, such as Customer Focus, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.

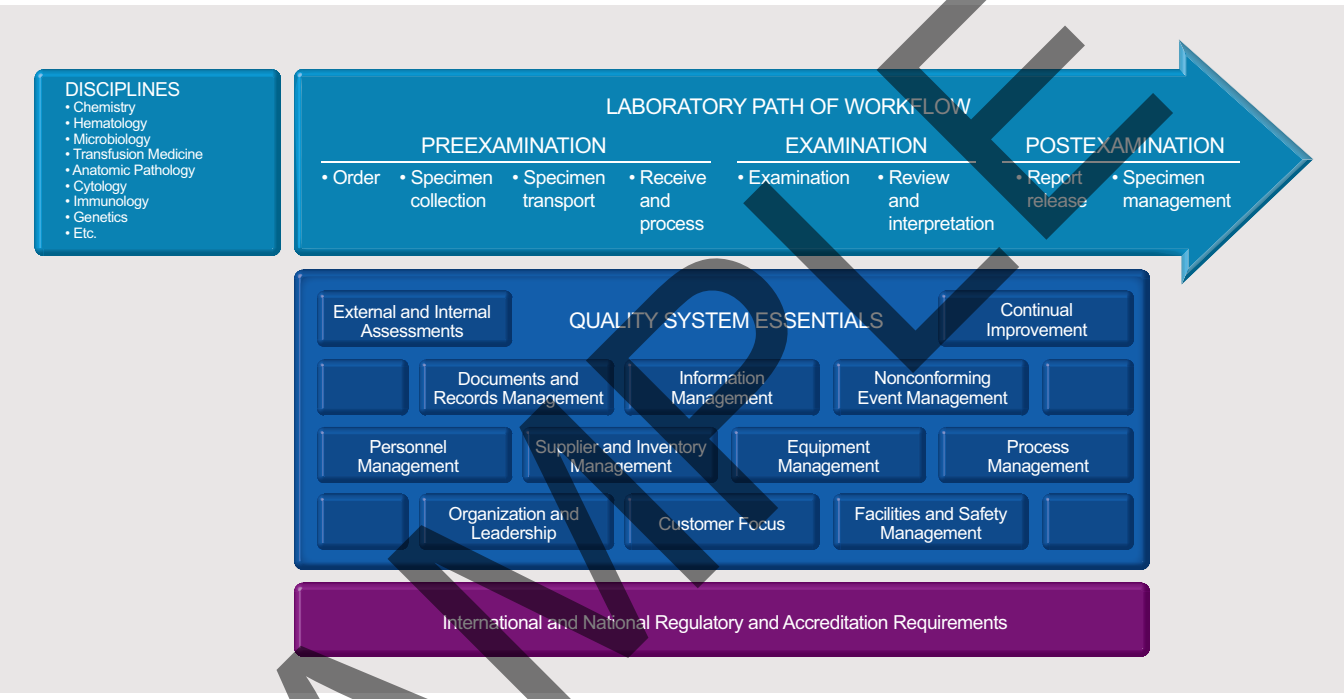

Figure 1. The Quality Management System Model for Laboratory Services (see CLSI document QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow and laboratory disciplines. This example represents how the 12 QSEs support a laboratory's disciplines.

QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. If a QSE is missing or not well implemented, problems will occur in preexamination, examination, and postexamination laboratory processes. For example, when the laboratory lacks defined processes and procedures for properly installing, calibrating, and maintaining its analyzers so they work effectively, problems in examination processes could cause a failure to meet customer expectations.

International guidance related to the QSEs and the laboratory's path of workflow is available. Topics include:

- A process-based model for quality that any business should use to manage its operations, with information relating directly to the QSEs[3]
- Requirements for both quality management and technical operations of testing and calibration laboratories[4]
- Standards for quality management and technical operations in the medical laboratory environment[5]

QMS19 is a **guideline** for how to implement requirements established by customers, regulators, and accreditation organizations.[3-14] **QMS19 is not a standard,** ie, this guideline **does not set requirements** for customer focus. Instead, this guideline describes what laboratories need to do to meet applicable regulatory and accreditation requirements for customer focus and provides suggestions and examples for fulfilling the requirements.

A new paradigm is developing in which the patient is the direct user of laboratory examination results and reports. International standards and recent legislation allow patients to view their own reports without a physician interpretation. This practice creates new opportunities for the laboratory to serve as the patient's educational and informational partner. As a result, when establishing postexamination expectations, the laboratory should evaluate the patient's expectations for reviewing the results.

NOTE: The content of this guideline is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

Customer
Customer satisfaction
External customer
Internal customer
Satisfaction survey
Voice of the customer

Chapter 1

Introduction

This chapter includes:

- Guideline's scope and applicable exclusions
- Background information pertinent to the guideline's content
- "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

Customer Focus in a Quality Management System

NOTE:

This guideline discusses areas in which the laboratory should focus to provide appropriate outputs, products, and customer services.

1 Introduction

1.1 Scope

This guideline is intended to assist laboratories in meeting customer-based requirements for their QMS as represented by quality system essential (QSE) Customer Focus. This guideline does not review the theory of good customer relations or service but instead discusses areas in which the laboratory should focus in order to provide appropriate outputs (such as examination results and reports), products (such as blood and tissue), and customer services (such as courier retrieval of collected specimens from physicians' offices).

This guideline is applicable to medical laboratories of any size, complexity, or specialty, including point-of-care testing. However, because the concepts of customer service and satisfaction are generic, this guideline can be used by other types of laboratories, such as public health, research, food, environmental, and veterinary laboratories. It can be used by all levels of personnel to develop and support a customer-focused laboratory.

This guideline does not apply to patients who use test devices and kits at home, because they are customers of the test kit manufacturer and not the laboratory.

NOTE:

QSE Customer Focus describes the requirements for identifying customer expectations and establishing the capability to meet them, agreeing upon the deliverables, measuring customer satisfaction, and recording and managing complaints.

1.2 Background

QSE Customer Focus describes the requirements for identifying customer expectations, establishing the capability to meet the customer's expectations, agreeing upon the deliverables, measuring customer satisfaction, and recording and managing complaints.

The laboratory's decisions and actions can profoundly affect its internal and external customers. Laboratory decision makers should identify and understand their customers' expectations and impart that knowledge and understanding to personnel through education, communication, and appropriate direction to ensure customer focus is paramount to the operational model. Acquiring and keeping customers is critical to financial success. Increasing competition among laboratory service providers means that, in some situations, customers who feel their expectations are unmet have options to seek these services elsewhere.

Customer focus is ongoing. Once feedback has been received, it is often necessary to cycle through again, identifying current and future customers, determining their current and changing expectations, ensuring those expectations are being met, receiving feedback, and resolving any issues.

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 that 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:

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

QMS19 covers 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.

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										
		GP36									
K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q	K2Q
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01
				QMS05							
											QMS06
									QMS11		
										QMS12	
QMS14											
			QMS16								
						QMS18					

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 their services, namely quality laboratory information.

QMS19 does not cover any of the laboratory path of workflow processes. For a description of the document 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
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01

Related CLSI Reference Materials*

GP36 **Planning for Laboratory Operations During a Disaster. 1st ed., 2014.** This document provides guidance for laboratory and health care leadership for development, implementation, and sustainment of effective emergency preparedness plans (all hazards) supporting nonanalytical components of clinical and public health laboratory services that may pertain to various natural and manmade disasters.

K2Q **The Key to Quality™. 2nd ed., 2013.** This product provides fundamental information for implementing and sustaining a quality management system (QMS). It also includes information on the 12 quality system essentials (QSEs) for building a QMS; the policies, processes, and procedure requirements for each QSE; and, how to apply the 12 QSEs in the laboratory environment.

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.

QMS05 **Quality Management System: Qualifying, Selecting, and Evaluating a Referral Laboratory. 2nd ed., 2012.** This guideline provides recommended criteria and easily implemented processes for qualifying, selecting, and evaluating a referral laboratory.

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.

QMS12 **Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality. 1st ed., 2010.** This document provides guidance on development of quality indicators and their use in the medical laboratory.

QMS14 **Quality Management System: Leadership and Management Roles and Responsibilities. 1st ed., 2012.** This guideline presents concepts and information intended to assist a laboratory in meeting leadership requirements for its quality management system. Guidance is provided for leaders to effectively design, implement, and maintain the cultural, structural, and functional aspects of their laboratory's organization that are critical to managing and sustaining quality.

* 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)

QMS16 **Laboratory Personnel Management. 1st ed., 2015.** This guideline describes the process for meeting the regulatory and accreditation requirements of personnel management in the laboratory environment. This guideline offers suggestions and examples on managing the processes required for laboratory personnel to fully achieve laboratory management's operational and quality goals.

QMS18 **Process Management. 1st ed., 2015.** This guideline describes four requirements for managing laboratory processes and provides suggestions for effectively meeting regulatory and accreditation requirements, optimizing efficient use of resources, and contributing to patient safety and positive outcomes.

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PRINT ISBN 1-56238-824-X

ELECTRONIC ISBN 1-56238-825-8