CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

QMS21

Purchasing and Inventory Management

This guideline describes effective purchasing and inventory management processes, which ensure availability of the appropriate equipment, instruments, reagents, consumable materials, other products, and services procured from external sources needed for providing quality laboratory services.

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

QMS21, 1st ed.
November 2016

Purchasing and Inventory Management

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Abstract

Clinical and Laboratory Standards Institute guideline QMS21—*Purchasing and Inventory Management* provides laboratories with guidance on developing processes for qualifying and selecting suppliers of laboratory equipment, instruments, reagents, consumable materials, other products, and services obtained from external sources; procuring, receiving, and managing inventory; and monitoring supplier performance. Laboratories need efficient and effective purchasing and inventory management processes to provide timely and high-quality services to their customers and meet regulatory, accreditation, and customer requirements.

Clinical and Laboratory Standards Institute (CLSI). *Purchasing and Inventory Management*. 1st ed. CLSI guideline QMS21 (ISBN 1-56238-800-2 [Print]; ISBN 1-56238-801-0 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2016.

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Suggested Citation

CLSI. *Purchasing and Inventory Management*. 1st ed. CLSI guideline QMS21. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

Reaffirmed:

June 2021

ISBN 1-56238-800-2 (Print)

ISBN 1-56238-801-0 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 36, Number 15

Contents

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Foreword

Developing or participating in the processes for procuring equipment, instruments, reagents, consumable materials, other products, and services from external sources needed for the laboratory's scope of operations and managing the laboratory's inventory of reagents and materials are critical to optimizing the effectiveness of a QMS and sustaining quality. This guideline encourages an organized approach for procuring laboratory equipment, instruments, reagents, consumable materials, other products, and services from external sources in a manner that meets regulatory, accreditation, and business requirements.

In the QMS, Purchasing and Inventory is one of the 12 quality system essentials (QSEs) described in CLSI document QMS01,[1] which defines a structured approach to organizing, creating, and maintaining the necessary information for the QSEs. The QMS model depicted in Figure 1 demonstrates how each QSE, including Purchasing and Inventory, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.

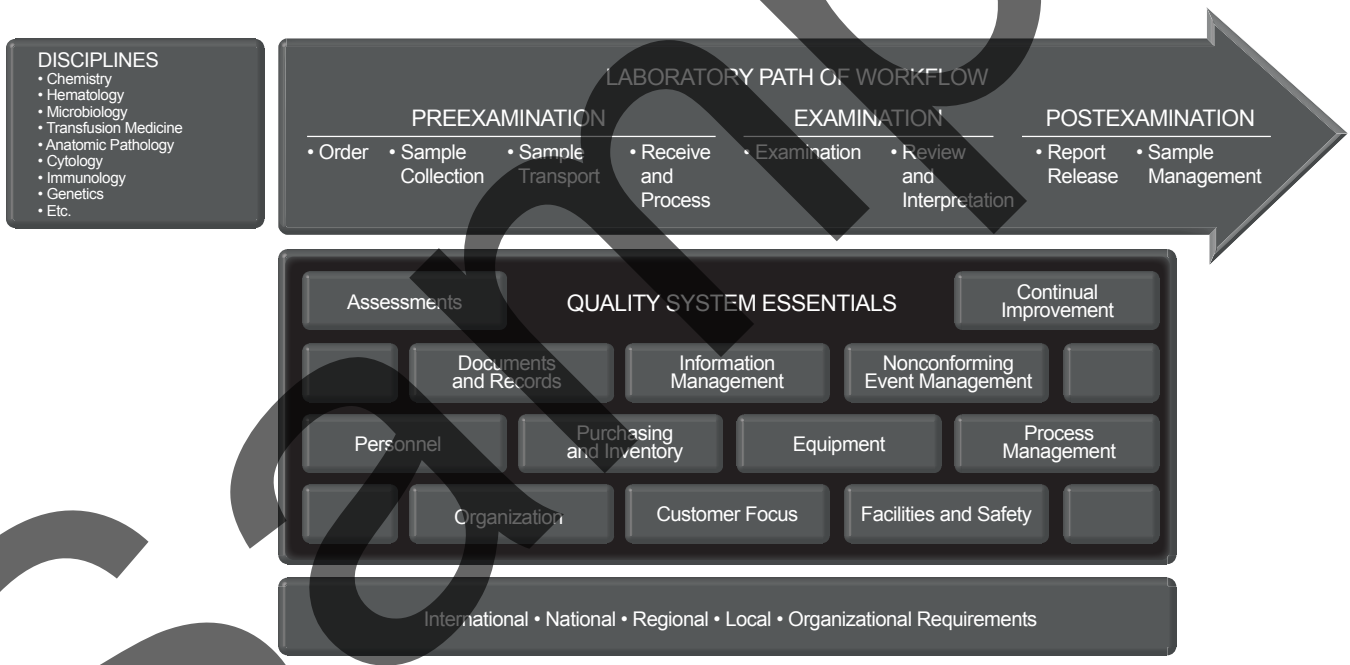

Figure 1. The Quality Management System Model for Laboratory Services (see CLSI document QMS01[1])

Properly developing or participating in purchasing and inventory management processes positively affects the:

- Effectiveness and efficiency of these processes
- Ability to reduce or eliminate costly procurement or inventory problems
- Likelihood of meeting organizational expectations
- Potential for successful regulatory and accreditation assessments
- Assurance of customer satisfaction
- Sustainable attainment of quality objectives

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

Consumable materials

Electronic inventory management

Equipment

Instruments

Inventory management

Materials management

Procurement

Purchasing

Qualification

Quotes

Reagents

Services

Specifications

Suppliers

Supplies

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

Purchasing and Inventory Management

1 Introduction

1.1 Scope

NOTE:

This guideline provides information for procuring equipment, instruments, reagents, consumable materials, other products, and services from external sources and also provides information about inventory management processes.

This guideline is applicable to medical laboratories of any size, complexity, or specialty, including point-of-care testing (POCT). However, because the concepts behind purchasing and inventory requirements are generic, other types of laboratories, such as public health, research, food, environmental, and veterinary laboratories, can also use this guideline.

This guideline provides information for procuring equipment, instruments, reagents, consumable materials, other products, and services from external sources and also provides information about inventory management processes for externally procured or internally prepared items. Chapter 5 presents key features of electronic inventory management systems.

This guideline references procurement and inventory management of blood components and cellular therapy products but does not provide technical details. However, the purchasing and inventory management concepts presented in this guideline can be used by laboratories that support provision of these products.

QMS21 is a guideline for how to implement requirements established in international standards, and by regulatory and accrediting organizations for managing laboratory work processes. QMS21 is not a standard; that is, this guideline does not set requirements for purchasing and inventory management processes and procedures. Instead, this guideline describes what laboratories need to do to meet published regulations, accreditation requirements, and international standards[2-13] for purchasing and inventory management, and provides suggestions and examples for fulfilling the requirements.

This guideline does not provide detailed information on how to make a business case for the purchase of expensive capital items such as equipment, instruments, test systems, or information systems. It does not discuss the purchase of other business units.

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

QMS21 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							
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01
				QMS05							
									QMS11		
					QMS13						

Related CLSI Reference Materials*

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.

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 the content for developing a program to manage a laboratory's nonconforming events.

QMS13 **Quality Management System: Equipment. 1st ed., 2011.** This guideline provides recommendations for establishing equipment management processes from selection through decommission of equipment used in the provision of laboratory services.

* 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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PRINT ISBN 1-56238-800-2

ELECTRONIC ISBN 1-56238-801-0