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.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.
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 clinical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

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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.

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

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Abstract

Clinical and Laboratory Standards Institute document QMS18—Process Management describes published regulatory and accreditation requirements for management of laboratory processes. This document provides guidance, with explanations and examples, for meeting the process management requirements as they apply to preexamination, examination, and postexamination laboratory processes. Because several other CLSI documents contain information about process management for laboratory examinations and for quality management, examples are primarily provided for preexamination and postexamination processes.


The Clinical and Laboratory Standards Institute 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in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of CLSI documents.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 you or your organization is not a member and would like to become one, and to request a copy of the catalog, contact us at:

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Foreword

Developing, documenting, and managing the laboratory’s technical and management processes is critical to optimizing the effectiveness of a QMS and sustaining quality. This guideline encourages using an organized approach for developing, verifying or validating, controlling, and changing laboratory path of workflow processes.

In an environment of process management, work processes are:
- Designed to meet applicable regulatory, accreditation, and customer requirements
- Documented
- Verified or validated as working as intended before implementation
- Monitored to ensure continued acceptable performance
- Changed in a controlled fashion

In the QMS, Process Management is one of the 12 quality system essentials (QSEs) described in CLSI document QMS01, 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 Process Management, is a building block to quality and necessary to support any laboratory’s path of workflow from preexamination to examination to postexamination.

Figure 1. The Quality Management System Model (see CLSI document QMS01)
A laboratory can best reduce errors that can or may cause harm to patients by understanding and documenting its processes, training staff to perform processes competently, identifying problematic processes, and improving processes where problems exist.

Properly developing, implementing, controlling, and changing laboratory work processes positively affects the:

- Ability to reduce or eliminate errors
- Likelihood of meeting customer expectations
- Effectiveness and efficiency of laboratory operations
- Potential for successful governmental and accreditation assessments and customer satisfaction
- Sustainable attainment of quality objectives

**KEY WORDS**

<table>
<thead>
<tr>
<th>Change management</th>
<th>Process analysis</th>
<th>Verification</th>
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<tbody>
<tr>
<td>Flow chart</td>
<td>Process management</td>
<td>Validation</td>
</tr>
</tbody>
</table>
Chapter 1

Introduction

This chapter includes:

- Document scope and applicable exclusions
- Background information pertinent to the document content
- “Note on Terminology” that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the document
- Abbreviations and acronyms used in the document
Process Management

1 Introduction

1.1 Scope

This guideline provides a structured means for laboratory management and staff to develop, implement, monitor, and change laboratory work processes, with suggestions for how laboratories can meet the related regulatory and accreditation requirements. This guideline can be used for managing and delivering preexamination, examination, and/or postexamination phases of workflow in laboratories of any size and functional complexity worldwide, including laboratories and other health care providers that perform point-of-care testing. Such laboratories include, but are not limited to, medical laboratories and public health laboratories. This guideline can also be used for developing and delivering quality management processes.

This document does not provide details about information covered in other CLSI documents or available in published literature. Instead, this guideline provides a high-level overview in which to apply the detailed information.

QMS18 is a guideline for how to implement requirements established in international standards, and by regulatory and accrediting organizations for managing laboratory work processes. QMS18 is not a standard; that is, this guideline does not set requirements for implementing and controlling laboratory processes and procedures. Instead, this guideline describes what laboratories need to do to meet published regulations, accreditation requirements, and international standards for process management and control, and provides suggestions and examples for fulfilling the requirements.

NOTE:
This guideline can be used for developing, implementing, monitoring, and changing laboratory operations and management processes.

QMS18 is intended for use by the following:

- Administrative and technical personnel who develop, perform, and supervise laboratory processes and procedures
- Pathologists and laboratory medical directors
- Regulatory and accreditation organizations
- Educators
- Manufacturers

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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:

<table>
<thead>
<tr>
<th>Organization</th>
<th>Personnel</th>
<th>Process Management</th>
<th>Nonconforming Event Management</th>
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<tr>
<td>Customer Focus</td>
<td>Purchasing and Inventory</td>
<td>Documents and Records</td>
<td>Assessments</td>
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<tr>
<td>Facilities and Safety</td>
<td>Equipment</td>
<td>Information Management</td>
<td>Continual Improvement</td>
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QMS18 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 page 108.
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.

QMS18 does not address any of the clinical laboratory path of workflow steps. For a description of the document listed in the grid, please refer to the Related CLSI Reference Materials section, on page 108.

<table>
<thead>
<tr>
<th>Preexamination</th>
<th>Examination</th>
<th>Postexamination</th>
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<td>Examination ordering</td>
<td>Sample collection</td>
<td>Sample transport</td>
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<tr>
<td>Sample receipt/processing</td>
<td>Examination</td>
<td>Results review and follow-up</td>
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<td>Interpretation</td>
<td>Results reporting and archiving</td>
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Related CLSI Reference Materials

GP27 Using Proficiency Testing to Improve the Clinical Laboratory. 2nd ed., 2007. This guideline provides assistance to laboratories in using proficiency testing as a quality improvement tool.

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.

QMS02 Quality Management System: Development and Management of Laboratory Documents. 6th ed., 2013. This document provides guidance on the processes needed for document management, including creating, controlling, changing, and retiring a laboratory’s policy, process, procedure, and form documents in both paper and electronic environments.

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.

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 Management of Nonconforming Laboratory Events. 1st ed., 2007. This guideline provides an outline and the content for developing a program to manage a health care service’s nonconforming events that is based on the principles of quality management and patient safety.

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.

QMS15 Assessments: Laboratory Internal Audit Program. 1st ed., 2013. This document provides guidance for how a laboratory can establish an internal audit program to enhance the quality of its services through continual improvement. Whereas an audit program defines the “who,” “what,” “when,” “where,” and “how” of meeting requirements for internal auditing, the audit process describes the details of how to conduct individual laboratory internal audits.

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