

# QMS15-A

## Assessments: Laboratory Internal Audit Program; Approved Guideline

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

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# Assessments: Laboratory Internal Audit Program; Approved Guideline

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## Abstract

Clinical and Laboratory Standards Institute document QMS15-A—*Assessments: Laboratory Internal Audit Program; Approved Guideline* provides recommendations for establishing an internal audit program and related processes for enhanced quality and continual improvement in the laboratory. The audit program defines the “who,” “what,” “when,” “where,” and “how” of the laboratory’s intent to audit its work, whereas the audit process describes how the act of tracing samples and records through laboratory workflow processes can identify areas of noncompliance and opportunities for improvement. Committed laboratory leadership and individuals willing to share their expertise and experience will enable a successful internal audit program.

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# Foreword

## NOTE:

The word **“audit”** should not be used interchangeably with the terms assessment, inspection, or survey, as they are **not the same thing!**

In the QMS, Assessments is one of the 12 quality system essentials (QSEs) described in CLSI document QMS01,<sup>1</sup> 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 Assessments, is a building block to quality and necessary to support any laboratory’s path of workflow from preexamination to examination to postexamination.

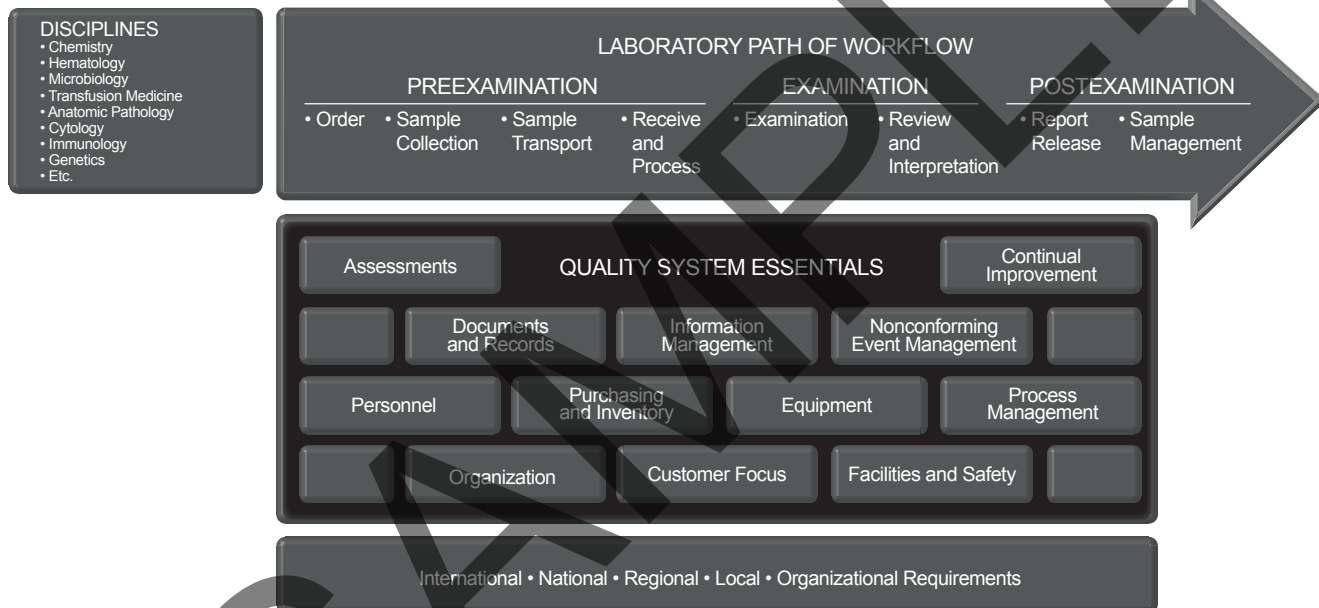


Figure 1. The Quality Management System Model (see CLSI document QMS01)<sup>1</sup>

A laboratory audit program is critical to ensuring the laboratory meets applicable requirements. QSE Assessments encompasses both internal and external assessments, with separate elements for each (see Figure 2). This document provides guidance for implementing an internal audit program.

**KEY WORDS**

- Assessment
- Audit
- Audit program
- Inspection
- Internal audit
- Quality management system

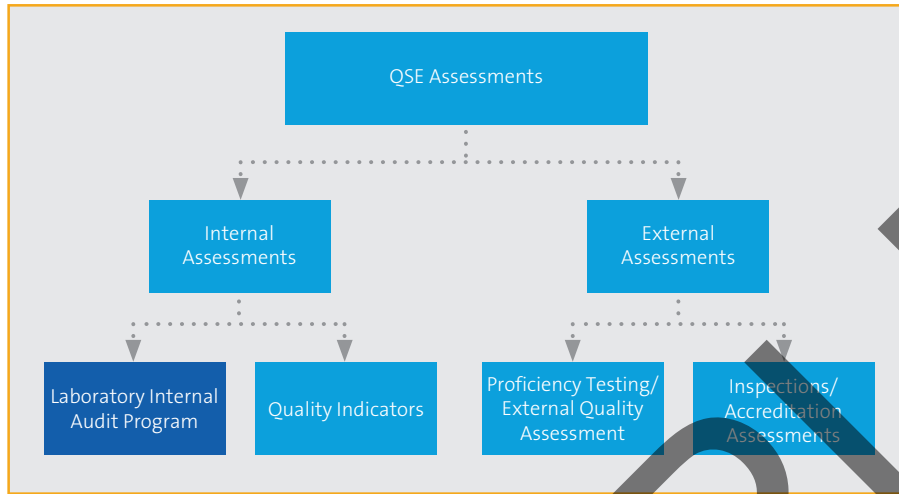


Figure 2. Components of QSE Assessments

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# Chapter 1

## Introduction

This chapter includes:

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



# Assessments: Laboratory Internal Audit Program; Approved Guideline

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## NOTE:

Internal audits of laboratory processes **provide objective evidence of nonconformances and risks** that can affect the quality of laboratory services and patient safety.

## IMPORTANT NOTE:

The laboratory internal audit **program** described in this guideline is **scalable to any size laboratory**.

## 1 Introduction

### 1.1 Scope

This guideline is intended for use by laboratory leaders such as directors, managers, and supervisors, and other individuals associated with laboratories that perform medical testing. This document focuses on using a laboratory internal audit program to actualize the laboratory's commitment to quality, good professional practice, and continual improvement, by identifying problematic processes.

The examples provided are applicable to laboratories of any size and functional complexity. Some examples provided in both the text and the appendixes are not intended to be complete, but rather are abbreviated to clarify the material being presented.

### 1.2 Background

Internal auditing of work practices is an important QMS tool that helps a laboratory meet regulatory, accreditation, and customer requirements. Internal audits of laboratory samples, documents, and records provide objective evidence of nonconformances and risks that can affect the quality of laboratory services and patient safety. The identified nonconformances improve laboratory services through corrective actions while the identified risks provide opportunities for improvement. Internal audit programs can also identify positive practices that can be replicated within the laboratory environment and affirm compliance with requirements.

This guideline has adapted successful models used in business and industry and made them applicable to medical laboratories. It describes the use of an internal audit program and related processes for achieving enhanced quality and continual improvement in the clinical laboratory. An internal audit program and related processes are scalable to any size laboratory and require only the laboratory leadership's and staff's willingness to compare current practice to expectations.

The audit **program** defines the "who," "what," "when," "where," and "how" of meeting requirements for internal auditing, and the audit **process** describes the details of how to conduct individual laboratory internal audits. Committed laboratory leadership and individuals willing to share their expertise and experience will enable a successful internal audit program.

# 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:

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

QMS15-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, beginning on page 80.

Organization	Customer Focus	Facilities and Safety	Personnel	Purchasing and Inventory	Equipment	Process Management	Documents and Records	Information Management	Nonconforming Event Management	Assessments	Continual Improvement
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	X QMS01	QMS01
			QMS03				QMS02				
									QMS11		
QMS14											

## 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.

QMS15-A 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 the following page.

Preexamination				Examination			Postexamination	
Examination ordering	Sample collection	Sample transport	Sample receipt/ 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\*

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- QMS01-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.
- QMS02-A6** **Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition (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-A3** **Training and Competence Assessment; Approved Guideline—Third Edition (2009).** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.
- QMS11-A** **Management of Nonconforming Laboratory Events; Approved Guideline (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.
- QMS14-A** **Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline (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.

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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.

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