CLINICAL AND LABORATORY STANDARDS INSTITUTE®

2nd Edition

QMS15

Laboratory Internal Audit Program

This guideline provides recommendations for establishing a laboratory internal audit program to enhance the quality of laboratory services through continual improvement. An audit program defines the "who," "what," "when," "where," and "how" of meeting requirements for internal auditing, and the audit process describes the details of conducting individual laboratory internal audits.

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

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Laboratory Internal Audit Program

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Abstract

Clinical and Laboratory Standards Institute guideline QMS15—*Laboratory Internal Audit Program* 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 meeting requirements for internal auditing, and the audit process describes the details of conducting an audit. Committed laboratory leadership and individuals willing to share their expertise and experience enable a successful internal audit program.

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Foreword

Quality system essential (QSE) Assessments is one of the 12 QSEs described in CLSI document QMS01,[1] which provides the necessary background information and guidance to develop and maintain a QMS. The QMS model depicted in Figure 1 demonstrates that each QSE, such as Assessments, 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 QMS Model for Laboratory Services (see CLSI document QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

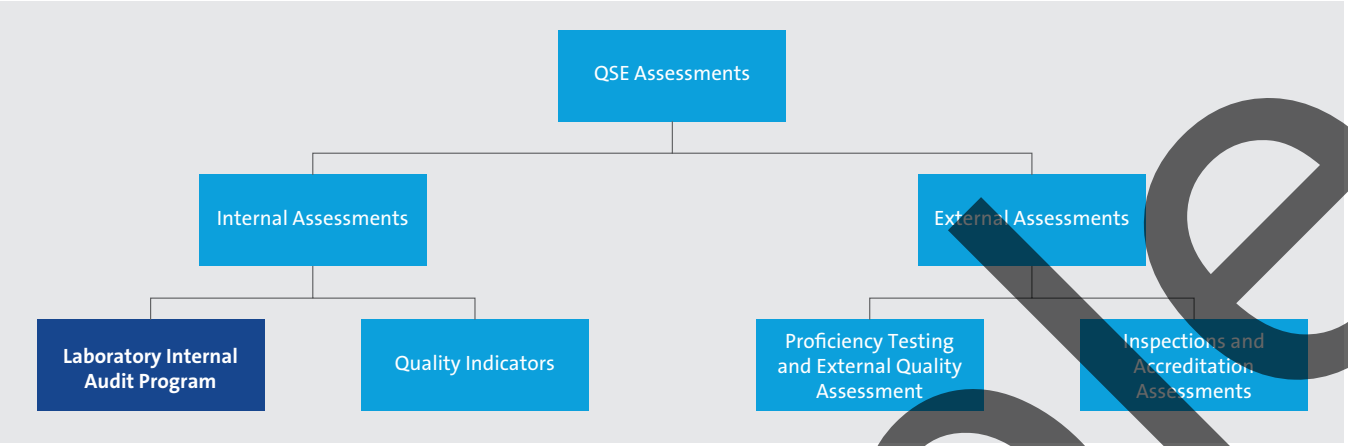
QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. When a QSE is missing or poorly implemented, problems will occur in preexamination, examination, and postexamination processes. For example, when the laboratory does not perform internal audits of its preexamination, examination, and postexamination processes, laboratory leadership does not know whether personnel are consistently following approved procedures. This knowledge is sometimes gained only when a nonconforming event occurs or a complaint is received, and personnel are found to be making unapproved deviations (also known as "workarounds") they believe will save time.

International guidance for 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[2]
- Requirements for both quality management and technical operations of testing and calibration laboratories[3]
- Standards for quality management and technical operations in the medical laboratory environment[4]

The internal audit program gathers information on the effectiveness of the laboratory's QMS. The purpose of internal audits is to monitor current practices and document the findings for review and action when indicated. The audit program enables the laboratory to monitor and maintain an effective QMS, improve patient and personnel safety,

reduce risk, and increase personnel engagement. 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). QMS15 provides guidance for implementing an internal audit program.



Abbreviation: QSE, quality system essential.

Figure 2. Components of QSE Assessments

QMS15 is a **guideline** that can help laboratories implement an internal audit program and meet international standards and regulatory and accreditation requirements.[2-13] **QMS15 is not a standard;** that is, this guideline **does not set requirements** for internal audit programs. Rather, it provides suggestions and examples for fulfilling the requirements.

Overview of Changes

This guideline replaces the previous edition of the approved guideline, QMS15-A, published in 2013. Several changes were made in this edition, including:

- Reorganizing the justification for the internal audit program
- Adding a subchapter on auditor training and competence assessment
- Revising the responsibilities of the functional roles
- Revising the audit process flow chart
- Adding a subchapter on audit criteria
- Reorganizing the audit process chapter
- Adding more appendixes

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

Assessment
Audit
Audit program
Inspection
Internal audit
Quality management system

Chapter 1

Introduction

Laboratory Internal Audit Program

1 Introduction

1.1 Scope

This guideline is intended for use by laboratory leaders, such as directors, managers, and supervisors, as well as other laboratorians who perform laboratory testing. This guideline focuses on using an internal audit program to actualize the laboratory's commitment to quality, good professional practice, and continual improvement by identifying problematic processes. The audit program described in this guideline can be used in laboratories worldwide. This guideline is intended for use primarily by:

- Medical laboratories
- Blood gas laboratories
- Blood donor and pretransfusion testing laboratories
- Public health laboratories
- Research laboratories

The examples provided are applicable to laboratories of any size and functional complexity. This guideline is not intended for use by laboratories involved in examinations for clinical trials, because the requirements applied to those laboratories are more stringent. This guideline does not include audit program details available in published materials on auditing.

1.2 Background

Internal auditing of work practices is an important QMS tool that helps a laboratory meet regulatory, accreditation, and customer requirements. Audits of laboratory processes, documents, and records provide objective evidence of noncompliances and risks that can affect the quality of laboratory services and patient safety. The identification of noncompliances enables a laboratory to improve its services through corrective actions, while the identification of risks provides opportunities for improvement. Audit programs can also identify positive practices that can be replicated within the laboratory environment and affirm compliance with requirements.

This guideline describes the use of an audit program and related processes to enhance quality and continually improve the laboratory. An audit program and related processes are scalable to any size laboratory and necessitate that laboratory leadership and personnel be willing to compare current practice with regulatory and accreditation requirements and with the laboratory's approved policies, processes, and procedures.

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

4.2 Audit Preparation Is Performed

The audit program coordinator is responsible for initiating the audit process. Table 5 outlines the items to consider before the auditor(s) performs the audit. The sequence of events can vary depending on the audit type.

Table 5. Items to Prepare and Plan for an Audit

Activity	Responsible Role	Purposes
Audit objective, scope, and type are determined.	Audit program coordinator	Identifies specific nature of the audit
Audit criteria are identified.	Audit program coordinator	Identifies the criteria against which the laboratory will be audited
Audit plan is initiated.	Audit program coordinator	Provides guidance for performing the audit
Auditor(s) is selected.	Audit program coordinator	• Ensures auditor resources are provided for the audit • Ensures auditor(s) with the appropriate experience level for the audit scope is chosen • Provides for as much auditor objectivity as feasible
Audit schedule is communicated (unless it is an unannounced audit).	Lead or sole auditor	Allows time for the auditor(s) and auditees to prepare
Documents and records are collected.[a]	Auditee at auditor's request	Provides information for auditor(s)
Documents and records are reviewed (ie, desk audit).	Auditor(s)	• Identifies needed objective evidence • Establishes understanding of workflow processes • Ensures the auditor has sufficient knowledge to perform the audit
Reports from previous internal and external audits are reviewed.	Auditor(s)	• Provides an opportunity to review previous audit findings and responses • Provides an opportunity to review previous reports for documentation of root cause analysis, if applicable • Identifies corrective actions whose implementation and effectiveness should be reviewed, when applicable
Audit tools are prepared (eg, audit questions, checklists, direct observation forms).	Auditor(s)	Enables assessment of key areas in a complete and efficient manner

[a] Documents and records include but are not limited to system audit reports, external proficiency testing (PT) data, blind PT data, operating procedures, process flow charts, manufacturer inserts that are incorporated into procedures, instrument and equipment records, reference and/or QC performance data, software validation materials, test validation documents, laboratory and bench worksheets, training and competence assessment files, job descriptions, report samples, reference sheets, budget and financial statements, contracts, licenses, personnel qualifications, complaint files, nonconforming event files, corrective action records, change control documents, and other audit reports (eg, from supplier audits).

4.3.4 Preliminary Findings Are Drafted

Audit teams should convene to review their respective observations and objective evidence and to prepare preliminary findings that will be presented at the closing meeting. **Single items of objective evidence are not separate audit findings.** Single pieces of objective evidence collected by an auditor during the audit need to be organized in a manner that points to a problem in the system or process being audited. Only then is the problem represented by the objective evidence written as an audit finding. Figure 5 depicts this concept.

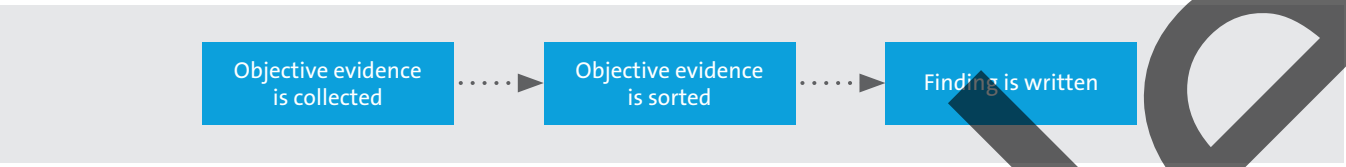


Figure 5. Transforming Objective Evidence Into an Audit Finding

Sorting objective evidence based on risk to the laboratory, patient safety, or QSE requirement helps the auditor draw conclusions from the evidence and communicate the noncompliance clearly to the auditee. Objective evidence can apply to more than one noncompliance. Table 7 provides a short procedure for drafting an audit finding from the collected objective evidence. The preliminary finding can be drafted and delivered as a verbal informal statement. Alternatively, the auditor can draft a formal statement of the finding that will be included in the final report.

Appendix I1 provides an example of a finding drafted using the procedure in Table 7. It is a laboratory example of seemingly random pieces of objective evidence that point to a specific problematic laboratory process.

Table 7. Procedure for Drafting Audit Findings

Step	Action
1	Ensure each piece of objective evidence is clearly stated and can be traced back to a specific place, person, document, or record. **NOTE:** During the audit, each piece of objective evidence should be written as a statement of what was observed or discovered.
2	Review all the objective evidence and look for underlying common elements or themes. **NOTE:** It is useful to sort objective evidence by QSE or processes within a given QSE, such as training, competence, equipment maintenance, document control, inventory management, safety, and information systems.
3	Group objective evidence into the common themes discovered.
4	For each grouping of objective evidence, record the requirement(s) that has or has not been satisfied. **NOTE:** The requirements include clauses or items specified in regulatory or accreditation requirements or in the laboratory's approved policies, processes, and procedures.
5	Draft a finding that identifies the condition that is having an adverse effect on the quality of the system, process, product, or service being audited.

Abbreviation: QSE, quality system essential.

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