

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.

Clinical and Laboratory Standards Institute

Setting the standard for quality in medical laboratory testing around the world.

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 medical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

Consensus Process

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.

Commenting on Documents

CLSI documents undergo periodic evaluation and modification to keep pace with advances in technologies, procedures, methods, and protocols affecting the laboratory or health care.

CLSI's consensus process depends on experts who volunteer to serve as contributing authors and/or as participants in the reviewing and commenting process. At the end of each comment period, the committee that developed the document is obligated to review all comments, respond in writing to all substantive comments, and revise the draft document as appropriate.

Comments on published CLSI documents are equally essential and may be submitted by anyone, at any time, on any document. All comments are managed according to the consensus process by a committee of experts.

Appeal Process

When it is believed that an objection has not been adequately considered and responded to, the process for appeal, documented in the CLSI *Standards Development Policies and Processes*, is followed.

All comments and responses submitted on draft and published documents are retained on file at CLSI and are available upon request.

Get Involved—Volunteer!

Do you use CLSI documents in your workplace? Do you see room for improvement? Would you like to get involved in the revision process? Or maybe you see a need to develop a new document for an emerging technology? CLSI wants to hear from you. We are always looking for volunteers. By donating your time and talents to improve the standards that affect your own work, you will play an active role in improving public health across the globe.

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

Clinical and Laboratory Standards Institute

P: +1.610.688.0100

F: +1.610.688.0700

www.clsi.org

standard@clsi.org

Laboratory Internal Audit Program

Laura McClannan, MT(ASCP)SBB, CQA(ASQ)
E. Jayne Scoggin, BA, CT, CG, MB(ASCP), CQA(ASQ)
Lisa Ballou, MS, MLS(ASCP)DLM, PMP
Lucia M. Berte, MA, MT(ASCP)SBB, DLM, CQA(ASQ)CMQ/OE
Kathryn Connolly, MT(ASCP), CQA(ASQ)
Jennifer S. DeBow, MT(ASCP), MAOL

Bereneice M. Madison, PhD, MT(ASCP)
Dawn Maghakian, MS, MB(ASCP)^{CM}, CGMBS
Kyle Nevins, MT(ASCP)^{CM}
Chantel G. Runnels, MBA, CQIA(ASQ)
Christina White, MPH, HT

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.

Clinical and Laboratory Standards Institute (CLSI). *Laboratory Internal Audit Program*. 2nd ed. CLSI guideline QMS15 (ISBN 978-1-68440-150-5 [Print]; ISBN 978-1-68440-151-2 [Electronic]). Clinical and Laboratory Standards Institute, USA, 2022.

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, or to request a copy of the catalog, contact us at:

P: +1.610.688.0100 **F:** +1.610.688.0700 **E:** customerservice@clsi.org **W:** www.clsi.org

Copyright ©2022 Clinical and Laboratory Standards Institute. Except as stated below, any reproduction of content from a CLSI copyrighted standard, guideline, derivative product, or other material requires express written consent from CLSI. All rights reserved. Interested parties may send permission requests to permissions@clsi.org.

CLSI hereby grants permission to each individual member or purchaser to make a single reproduction of this publication for use in its laboratory procedures manual at a single site. To request permission to use this publication in any other manner, e-mail permissions@clsi.org.

Suggested Citation

CLSI. *Laboratory Internal Audit Program*. 2nd ed. CLSI guideline QMS15. Clinical and Laboratory Standards Institute; 2022.

Previous Edition:

December 2013

QMS15-Ed2

ISBN 978-1-68440-150-5 (Print)

ISBN 978-1-68440-151-2 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 42, Number 14

.....

Committee Membership

Consensus Council

The Consensus Council sets priorities for CLSI standards development and votes on Final Draft documents to confirm that process requirements have been met. Consensus Council members are listed on the CLSI website: <https://clsi.org/standards-development/consensus-council>

Document Development Committee on Laboratory Internal Audit

**Laura McClannan, MT(ASCP)SBB,
CQA(ASQ)
Chairholder
Oklahoma Blood Institute
USA**

Kathryn Connolly, MT(ASCP),
CQA(ASQ)
COLA
USA

Bereneice M. Madison, PhD, MT(ASCP)
Centers for Disease Control and
Prevention
USA

**E. Jayne Scoggin, BA, CT, CG,
MB(ASCP), CQA(ASQ)
Vice-Chairholder
ResearchDX
USA**

Jennifer S. DeBow, MT(ASCP), MAOL
ACL Laboratories - Advocate Aurora
Health Care
USA

Dawn Maghakian, MS, MB(ASCP)^{CM},
CGMBS
USA

Lisa Ballou, MS, MLS(ASCP)DLM, PMP
Beckman Coulter
USA

Gillian Rose Edwards, MS, CQA,
SM(NRCM), PHM
Centers for Medicare & Medicaid
Services
USA

Kathleen Maher, MT(ASCP)
Northwell Health
USA

Lucia M. Berte, MA, MT(ASCP)SBB,
DLM, CQA(ASQ)CMQ/OE
Laboratories Made Better!
USA

Lauren Farnsworth, MS, CMQOE ASQ
Dartmouth Hitchcock
USA

Shafqat Tahir
St. Michael's Hospital – Unity Health
Toronto
Canada

Expert Panel on Quality Management Systems

Expert Panel volunteers support the development of CLSI documents by providing technical expertise in specialty areas. Expert Panel members are listed by area of expertise on the CLSI website: <https://clsi.org/standards-development/expert-panels>

Staff

Clinical and Laboratory Standards
Institute
USA

Laura Martin
Editorial Manager

Kristy L. Leirer, MS
Editor

Jennifer K. Adams, MT(ASCP), MSHA
Project Manager

Catherine E.M. Jenkins, ELS
Editor

Lisa M.W. Walker, MS, ELS
Editor

Acknowledgment

CLSI, the Consensus Council, and the Document Development Committee on Laboratory Internal Audit gratefully acknowledge the following volunteers for their important contributions to the revision of this guideline:

Samira Ahmed, BSc, MLT, SCYM(SCP)
Halton Healthcare
USA

Kyle Nevins, MT(ASCP)^{CM}
NYU Winthrop
USA

Christina White
Memorial Sloan Kettering Cancer
Center
USA

Lauren Forbes, MB(ASCP)
University of Florida
USA

Eric Nyirenda, BSc, ASQ-CMQ/OE,
CSSBB, CQA
Nchanga North General Hospital
Zambia

Xin Yi, PhD, DABCC, FAACC
Houston Methodist Weill Cornell
Medical College
USA

Karrie Hovis, MHS, MLS(ASCP)^{CM},
CQIA(ASQ)
Ochsner Health System
USA

Ahmad Omar, BS, CQA(ASQ)
ARUP Laboratories
USA

Cleofe Lanez, MS, MLS(ASCP)^{CM}
Memorial Sloan Kettering Cancer
Center
USA

Chantel G. Runnels, MBA, CQIA(ASQ)
Centers for Disease Control and
Prevention
USA

Contents

Abstract	i
Committee Membership	iii
Foreword	vii
Chapter 1: Introduction	1
1.1 Scope	2
1.2 Background	2
1.3 Terminology	3
Chapter 2: Rationale for a Laboratory Internal Audit Program	5
2.1 Purpose and Goals of the Laboratory Internal Audit Program	6
2.2 Benefits of the Laboratory Internal Audit Program	6
2.3 Justification for an Internal Audit Program	7
Chapter 3: Development of the Laboratory Internal Audit Program	11
3.1 Designing the Audit Program	12
3.2 Defining Roles and Responsibilities	15
3.3 Developing Auditor Training and Competence Assessment	20
Chapter 4: Structure of the Internal Audit Process	25
4.1 The Audit Process	26
4.2 Audit Preparation Is Performed	27
4.3 Audit Is Conducted	31
4.4 Final Audit Report Is Written	37
4.5 Audit Follow-up Is Performed	38
Chapter 5: Evaluating the Effectiveness of the Audit Program	41
5.1 Trending and Analyzing Information From All Audits	42
5.2 Compiling Audit Program Feedback	43
5.3 Preparing a Report of Audit Findings for Quality Report and Management Review	43
5.4 Management Review	43
Chapter 6: Quality System Essentials	45
6.1 Organization and Leadership	46
6.2 Customer Focus	46
6.3 Facilities and Safety Management	46
6.4 Personnel Management	46
6.5 Supplier and Inventory Management	46
6.6 Equipment Management	46

Contents (Continued)

6.7 Process Management.....	46
6.8 Documents and Records Management	47
6.9 Information Management.....	47
6.10 Nonconforming Event Management	47
6.11 Assessments	47
6.12 Continual Improvement.....	47
Chapter 7: Conclusion	49
Chapter 8: Supplemental Information	51
References	52
Additional Resource	54
Appendix A. Annual Audit Schedule Example	55
Appendix B1. Laboratory Internal Auditor Training Guide	56
Appendix B2. Laboratory Internal Auditor Trainer Responsibilities	57
Appendix B3. Laboratory Internal Auditor Learner Responsibilities	58
Appendix B4. Training Checklist for the Laboratory Internal Audit Process	59
Appendix C. Audit Process Comparison for Small-Site vs Large-Site Audits	60
Appendix D. Laboratory Internal Audit Plan Template.....	61
Appendix E. Internal Audit Checklist Example.....	62
Appendix F. Laboratory Supply Management Audit Questions Example.....	63
Appendix G. Audit Questions Form	64
Appendix H. Audit Tool for Verifying Effectiveness of Document Control Process	65
Appendix I1. Audit Finding Drafted From Objective Evidence Example	68
Appendix I2. Audit Findings Report Template – Sample 1	69
Appendix I3. Audit Findings Report Template – Sample 2	71
Appendix I4. Quality Assessment Audit Findings Report Template	73
Appendix I5. Audit Findings and Quality Action Form	76
Appendix J. Audit Evaluation Template	77
Appendix K. Internal Auditor Performance Evaluation Template	78
The Quality Management System Approach.....	79

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.

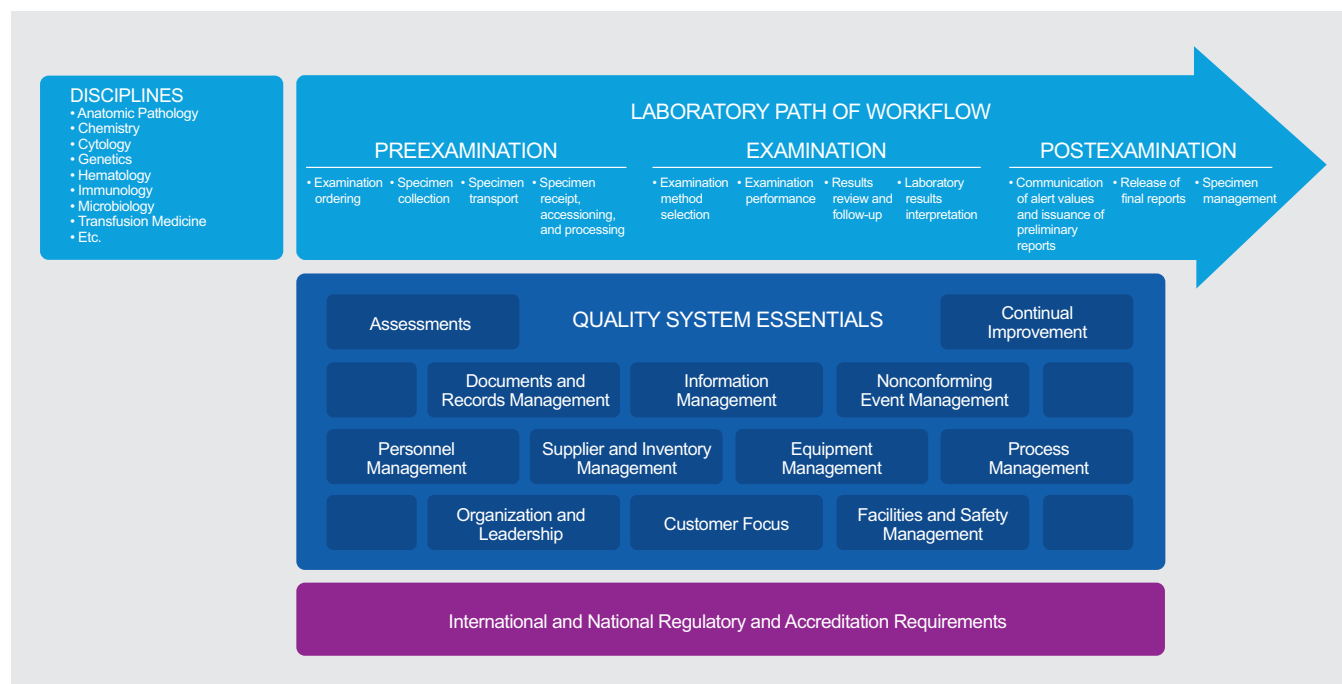


Figure 1. The QMS Model for Laboratory Services (see CLSI document QMS01¹). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

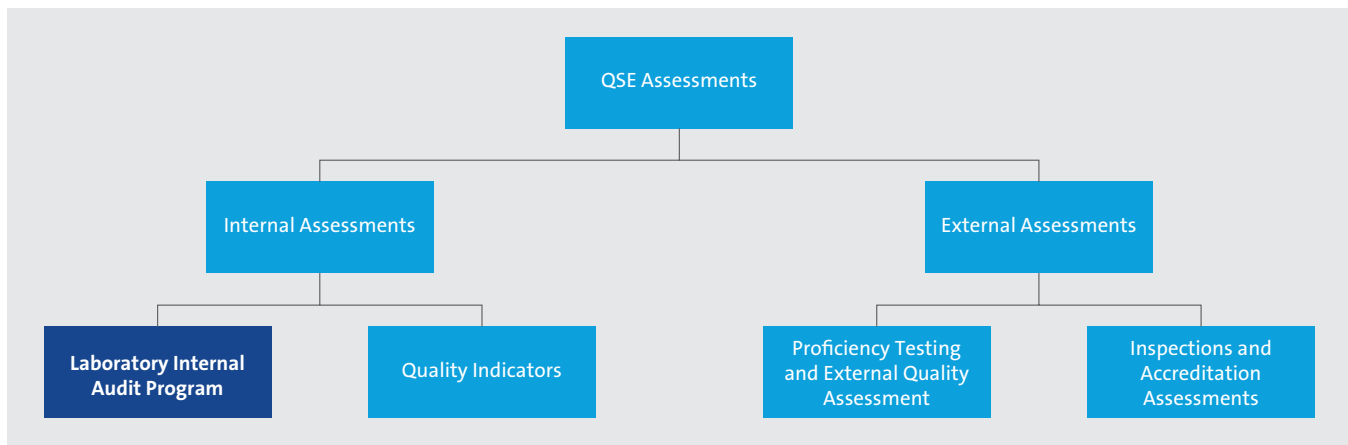
QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. When a QSE is missing or poorly implemented, problems will occur in preexamination, examination, and postexamination processes. For example, when the laboratory does not perform internal 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 QSEs²
- Requirements for both quality management and technical operations of testing and calibration laboratories³
- Standards for quality management and technical operations in the medical laboratory environment⁴

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 program

Internal audit

Audit

Inspection

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.