

QMS05

Qualifying, Selecting, and Evaluating a Referral Laboratory

This guideline provides recommended criteria and easily implemented processes to qualify, select, and evaluate a referral laboratory.

.....

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
950 West Valley Road, Suite 2500
Wayne, PA 19087 USA
P: +1.610.688.0100
F: +1.610.688.0700
www.clsi.org
standard@clsi.org

Qualifying, Selecting, and Evaluating a Referral Laboratory

Laura McClannan, MS, MT(ASCP)SBB, CQA(ASQ)
Marie C. Earley, PhD
Deirdre Astin, MS, MT(ASCP)
Jennifer Daley-Bernier
Chakshu Gupta, MD

Sherri Hawkins
Dawn Maghakian, MS, MB(ASCP)^{CM}, CGMBS
Megan Phillips, PhD
R. Ross Reichard, MD
Stephanie Whitehead, MBA, MPH, BS, MLS(ASCP)

Abstract

Clinical and Laboratory Standards Institute guideline QMS05—*Qualifying, Selecting, and Evaluating a Referral Laboratory* provides laboratories with a defined process to identify candidate referral laboratories and consultants and qualify them for additional consideration. Important criteria that the laboratory should consider when selecting a referral laboratory or consultant are also provided. These criteria are the basis on which agreements for service are prepared and the referral laboratory's or consultant's performance in service delivery can later be evaluated.

Clinical and Laboratory Standards Institute (CLSI). *Qualifying, Selecting, and Evaluating a Referral Laboratory*. 3rd ed. CLSI guideline QMS05 (ISBN 978-1-68440-077-5 [Print]; ISBN 978-1-68440-078-2 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2020.

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 ©2020 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. *Qualifying, Selecting, and Evaluating a Referral Laboratory*. 3rd ed. CLSI guideline QMS05. Wayne, PA: Clinical and Laboratory Standards Institute; 2020.

Previous Editions:

November 1985, December 1991, November 1998, September 2012

ISBN 978-1-68440-077-5 (Print)

ISBN 978-1-68440-078-2 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 40, Number 5

Committee Membership

Consensus Council

James R. Petisce, PhD
Chairholder
BD Diagnostic Systems
 USA

Collette Fitzgerald, PhD
 Centers for Disease Control and
 Prevention
 USA

M. Laura Parnas, PhD, DABCC
 Roche Diagnostics
 USA

Mary Lou Gantzer, PhD, FACB
Vice-Chairholder
 USA

Loralie J. Langman, PhD, DABCC, FACB,
 F-ABFT
 Mayo Clinic
 USA

Robert Rej, PhD
 New York State Department
 of Health – Wadsworth Center
 USA

Anne T. Daley, MS, MT(ASCP)DLM,
 CMQ/OE(ASQ)CSBB
 ARUP Laboratories
 USA

Michelle McLean, MS, MT(ASCP), BS
 Greiner Bio-One, Inc.
 USA

Matthew A. Wikler, MD, FIDSA, MBA
 IDTD Consulting
 USA

Avis Danishefsky, PhD
 FDA Center for Devices and
 Radiological Health
 USA

Tania Motschman, MS, MT(ASCP)SBB
 Laboratory Corporation of America
 USA

Document Development Committee on Referral Laboratories

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

Jennifer Daley-Bernier
 Northwest Territories Health and
 Social Services – Stanton Territorial
 Hospital
 Canada

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

Marie C. Earley, PhD
Vice-Chairholder
Centers for Disease Control and
Prevention
 USA

Chakshu Gupta, MD
 North Kansas City Hospital Laboratory
 and MAWD Pathology Group
 USA

Megan Phillips, PhD
 Physicians Premier Emergency Rooms
 USA

Deirdre Astin, MS, MT(ASCP)
 New York State Department of Health
 USA

Sherri Hawkins
 Mayo Clinic
 USA

Stephanie Whitehead, MBA, MPH, BS,
 MLS(ASCP)
 University Health System
 USA

Expert Panel on Quality Management Systems

**Anne T. Daley, MS, MT(ASCP)DLM,
CSBB(ASQ)CMQ/OE
Chairholder
ARUP Laboratories
USA**

Maura Daniels, BS, MT(ASCP)
Sysmex America
USA

Sheri L. Hearn, BS, MPH
Oregon State Public Health Laboratory
USA

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

Jennifer Dawson, DLM(ASCP)SLS,
QIHC, QLC/LSSBB/CPHQ/MHA
Human Longevity, Inc.
USA

Karen Heaton, MLT(CMLTA)
Alberta Precision Laboratories
Canada

Glenda G. Abbott, BS, MS,
CMQ/OE(ASQ)
Abbott Laboratories
USA

Gillian Rose Edwards, MS, CQA,
PHM, SM(NRCM)
California Department of
Public Health
USA

Debra Kuehl, MS, M(ASCP)
Centers for Disease Control and
Prevention
USA

Julie Coffey, MLT, ART, CMQ/OE(ASQ),
CQA
Institute for Quality Management in
Healthcare
Canada

Staff

Clinical and Laboratory Standards
Institute
USA

Megan L. Tertel, MA, ELS
Editorial Manager

Kristy L. Leirer, MS
Editor

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

Catherine E.M. Jenkins
Editor

Laura Martin
Editor

Acknowledgment

CLSI, the Consensus Council, and the Document Development Committee on Referral Laboratories gratefully acknowledge the following volunteer for his important contributions to the revision of this guideline:

R. Ross Reichard, MD
Mayo Clinic
USA

Contents

Abstract	i
Committee Membership	iii
Foreword	vii
Chapter 1: Introduction	1
1.1 Scope	2
1.2 Background	2
1.3 Terminology	2
Chapter 2: Path of Workflow	5
Chapter 3: Referral Laboratory Qualification, Selection, and Evaluation	9
3.1 Laboratory's Expectations for Service Are Identified	10
3.2 Referral Laboratory Is Qualified	11
3.3 Selection Process Is Defined	16
3.4 Referral Laboratory Is Selected	17
3.5 Agreement Is Developed	17
3.6 Agreement Is Documented and Maintained	19
3.7 Services Are Initiated	20
3.8 Service Metrics Are Applied	22
3.9 Referral Laboratory Performance Is Evaluated	24
Chapter 4: Quality System Essentials	25
4.1 Organization and Leadership	26
4.2 Customer Focus	26
4.3 Facilities and Safety Management	26
4.4 Personnel Management	26
4.5 Supplier and Inventory Management	26
4.6 Equipment Management	27
4.7 Process Management	27
4.8 Documents and Records Management	27
4.9 Information Management	27
4.10 Nonconforming Event Management	27
4.11 Assessments	27
4.12 Continual Improvement	27

Contents (Continued)

.....

Chapter 5: Conclusion	29
Chapter 6: Supplemental Information	31
References	32
Appendix A. Questions for Qualifying and Selecting a Referral Laboratory	34
Appendix B. Example of Selection Criteria Scoring and Worksheet	40
Appendix C. Approved Referral Laboratory List.....	47
Appendix D. Metrics for Assessing a Referral Laboratory	48
The Quality Management System Approach.....	52
Related CLSI Reference Materials	54

Foreword

Quality system essential (QSE) Supplier and Inventory Management 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. A referral laboratory is considered a supplier of a purchased laboratory service because laboratories that cannot perform specified examinations pay for examinations to be performed on specimens sent to a referral laboratory. The QMS model depicted in Figure 1 demonstrates that each QSE, such as Supplier and Inventory Management, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.

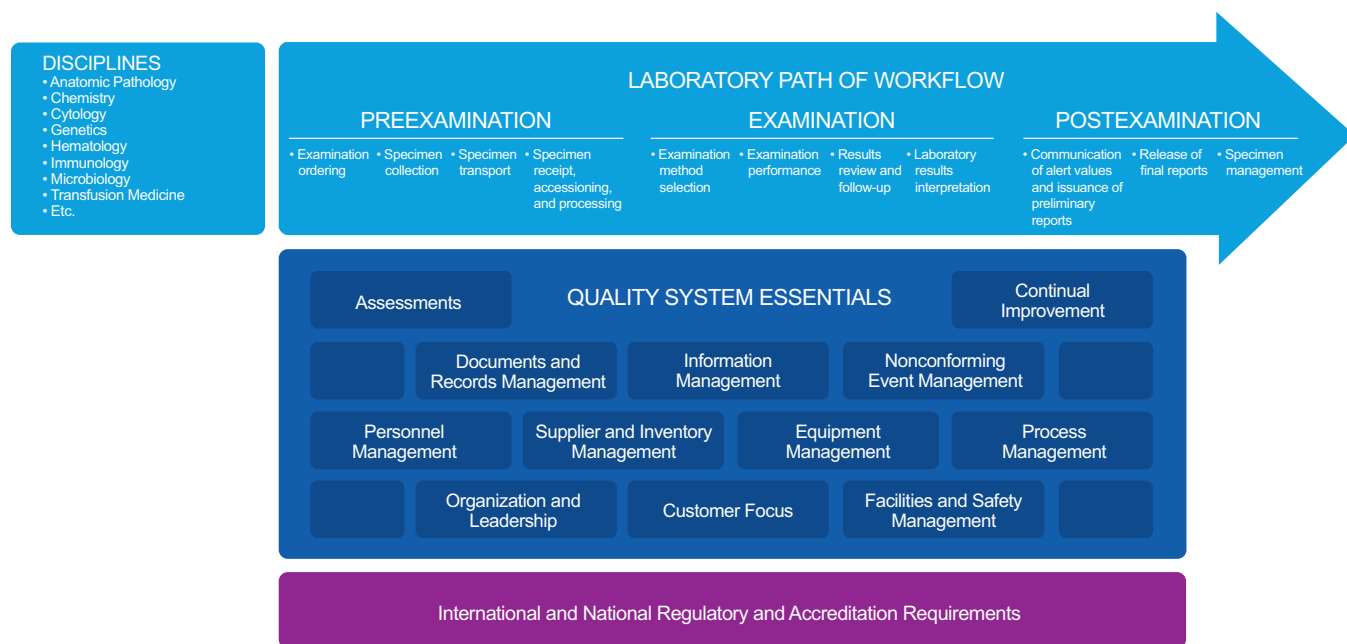


Figure 1. The QMS Model for Laboratory Services (see CLSI document QMS01¹). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. If a QSE is missing or poorly implemented, problems will occur in preexamination, examination, and postexamination processes. International guidance related to 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

QMS05 is a **guideline** that can help laboratories qualify, select, and evaluate a referral laboratory and meet international standards and regulatory and accreditation requirements.²⁻¹³ **QMS05 is not a standard**; that is, this guideline **does not set requirements** for qualifying, selecting, or evaluating a referral laboratory. Rather, it provides suggestions and examples for fulfilling the requirements.

Overview of Changes

This guideline replaces the previous edition of the approved guideline, QMS05-A2, published in 2012. Several changes were made in this edition, including:

- Added a flow chart outlining the process to qualify, select, and evaluate a referral laboratory
- Expanded content on qualifying and selecting a referral laboratory
- Added new information on evaluating a referral laboratory
- Included additional information in the 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

Evaluation

Referral laboratory

Selection

Qualification

Referring laboratory

Chapter 1

Introduction

This chapter includes:

- Guideline's scope
- Background information pertinent to the guideline's content
- Terminology information, including:
 - Terms and definitions used in the guideline
 - Abbreviations and acronyms used in the guideline



Qualifying, Selecting, and Evaluating a Referral Laboratory

1 Introduction

1.1 Scope

This guideline is intended for use by referring laboratories seeking a broad spectrum of services, a limited number of esoteric examinations, consultative services, or a backup service provider for examinations performed by the referring laboratory. This guideline provides recommendations for periodically evaluating the services provided by the referral laboratory. This guideline can also be used by referral laboratories to assist in understanding the qualification, selection, and evaluation process and what might be expected by them from a referring laboratory. The recommendations in this guideline include activities necessary to meet international and national published requirements for referral laboratories.

The recommendations in this guideline are not meant as the only way to qualify, select, and evaluate referral laboratories. Referring laboratories can modify the suggested criteria, with the caveat not to delete criteria that reflect applicable regulatory and accreditation requirements for medical laboratories.²⁻¹³

1.2 Background

This guideline contains specific recommendations for referring laboratories engaged in qualifying, selecting, and evaluating a referral laboratory. Referring laboratory personnel can use the suggested qualifying criteria to gather data and to evaluate and compare candidate referral laboratories.

1.3 Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization whenever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in different countries and regions and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. CLSI recognizes its important role in these efforts, and its consensus process focuses on harmonization of terms to facilitate the global application of standards and guidelines. Table 1 is provided to clarify the intended interpretations of the following terms.

Table 1. Common Terms or Phrases With Intended Interpretations

Term or Phrase	Intended Interpretation
“Needs to” or “must”	Explains an action directly related to fulfilling a regulatory and/or accreditation requirement or is indicative of a necessary step to ensure patient safety or proper fulfillment of a procedure
“Require”	Represents a statement that directly reflects a regulatory, accreditation, performance, product, or organizational requirement or a requirement or specification identified in an approved documentary standard
“Should”	Describes a recommendation provided in laboratory literature, a statement of good laboratory practice, or a suggestion for how to meet a requirement