

QMS05

Qualifying, Selecting, and Evaluating a Referral Laboratory

Sample

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.

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.

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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.

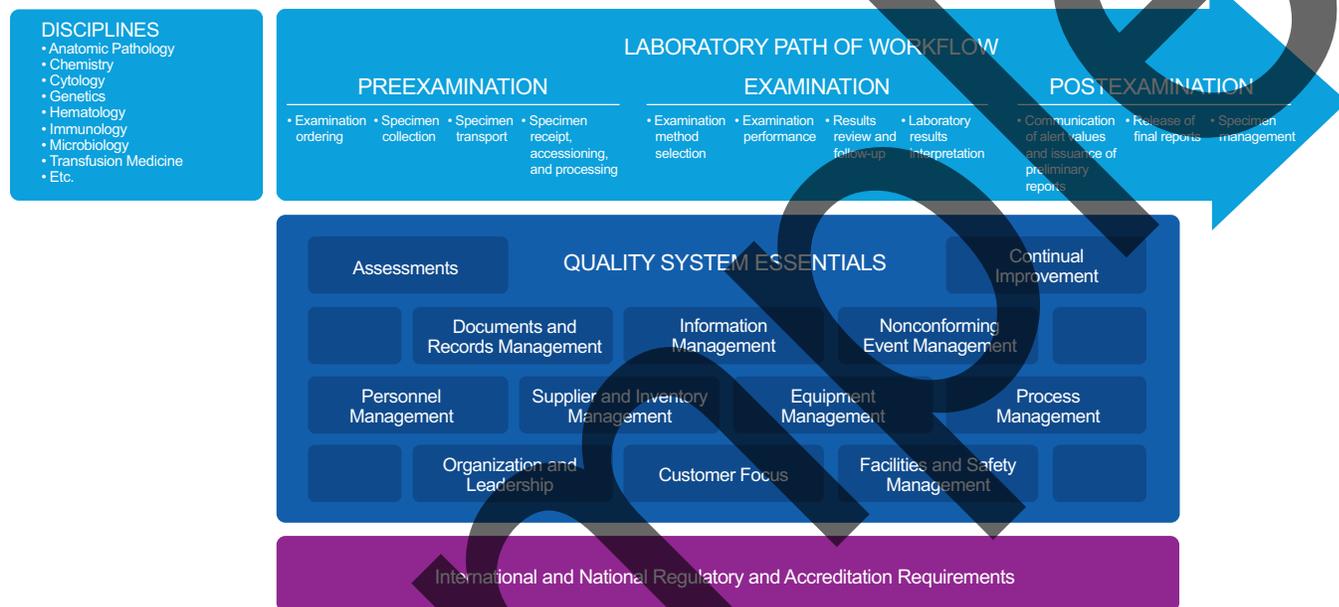


Figure 1. The QMS Model for Laboratory Services (see CLSI document QMS01¹). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

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

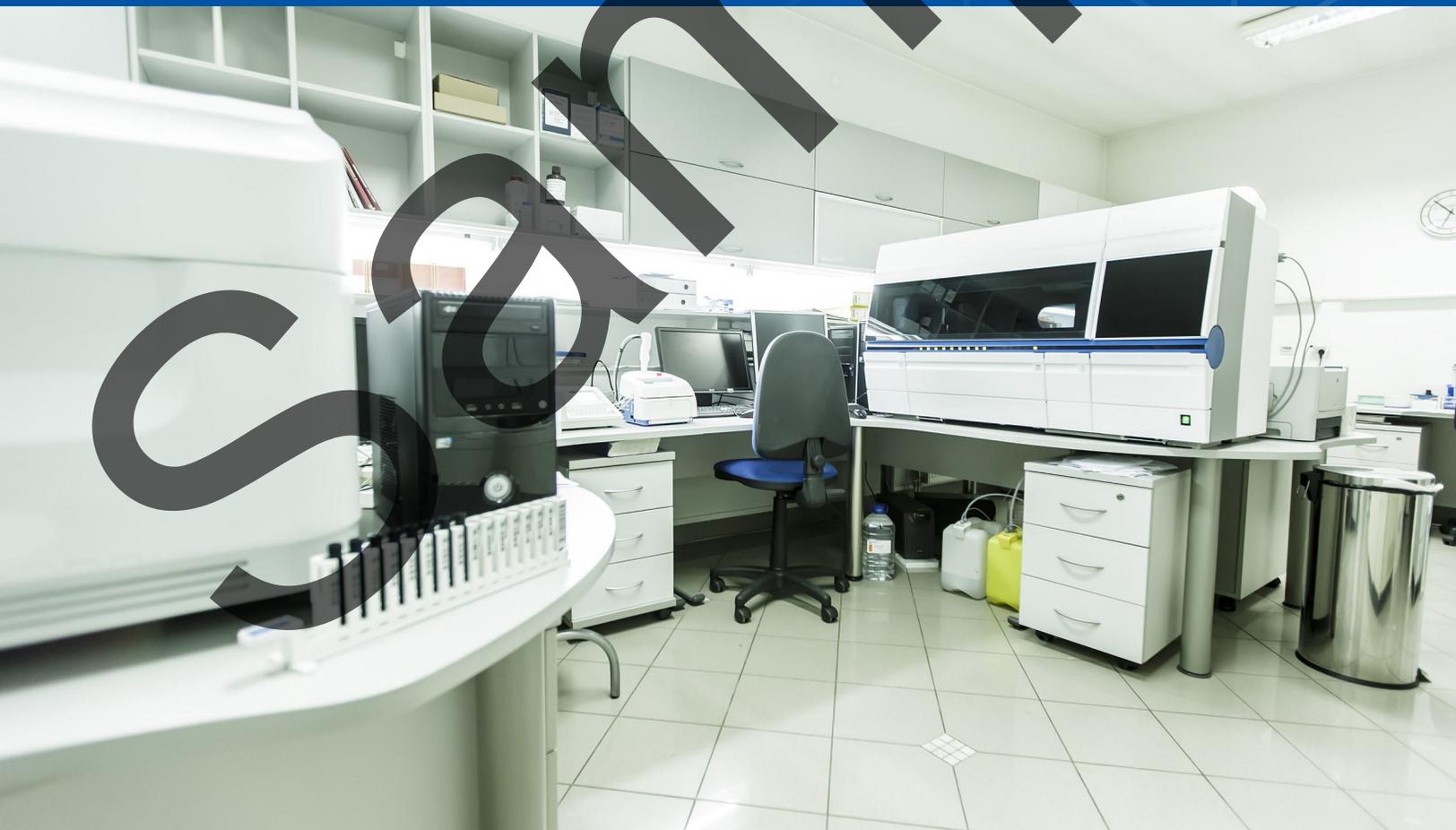
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Chapter 1

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

3.8 Service Metrics Are Applied

The referring laboratory should develop metrics that enable monitoring of the referral laboratory's performance. Metrics that align with the criteria used in the original referral laboratory selection process should be defined. Additional metrics can be defined as needed to monitor any new examinations or services or to monitor the effectiveness of corrective actions. The referring laboratory process to define metrics about a referral laboratory is similar to the process to develop internal quality indicators for laboratory operations. See CLSI document QMS12¹⁶ for information the laboratory should consider when selecting and developing metrics. The metrics and thresholds will vary based on examinations and services provided and should be outlined within the agreement. See Appendix D for suggested metrics.

3.8.1 Data and Information Are Collected

Representative examples of data and information that can be collected for the evaluation criteria in Subchapter 3.2.1 are included in Table 3.

Table 3. Examples of Representative Data and Information Used in Evaluating a Referral Laboratory

Evaluation Criteria	Data and/or Information for Review
Licensure and accreditation status	<ul style="list-style-type: none"> • Review of current licenses and accreditation certificates for expiry dates • Review of sanctions or limitations from licensing and/or accrediting organizations
Quality	<ul style="list-style-type: none"> • Review of PT data • Review of alternative assessment data
Customer service	<ul style="list-style-type: none"> • Number and type of complaints • Percent of complaints resolved within a specified time • Response time to inquiries and complaints
Connectivity	<ul style="list-style-type: none"> • Audits of data transmission to determine if there is a loss or corruption of the data • Number of times the interface was not operational
Specimen transport and logistics	<ul style="list-style-type: none"> • Audit of pickup and delivery times to determine transport times • Number of specimens deemed unacceptable by the referral laboratory • Number of specimens lost by the courier and the referral laboratory
Examination capabilities	<ul style="list-style-type: none"> • Examination performance with a documented order • Availability of examinations as established within the agreement
Reporting	<ul style="list-style-type: none"> • Acceptable TATs • Regulatory- and/or accreditation-compliant reporting formats • Rate of corrected and amended reports • Time interval for reporting critical (imminently life-threatening) values
Consultation and interpretation services	<ul style="list-style-type: none"> • Response time for inquiries about examination selection • Response time for inquiries about results interpretation
Billing and costs	<ul style="list-style-type: none"> • Consistency of charges for referral laboratory services with those stated in the agreement • Application of charges to only those services performed • Appropriate application of credits (eg, for lost specimens)

Abbreviations: PT, proficiency testing; TAT, turnaround time.

4.6 Equipment Management

- Is additional equipment needed to process specimens being sent to the referral laboratory?

4.7 Process Management

- How are changes in specimen processing, packaging, and shipment validated?
- Is there a process to track specimens in transit to the referral laboratory?
- How does the referral laboratory return examination results to the referring laboratory?
- Does the referring laboratory have a process to manage examination results returned from the referral laboratory?

4.8 Documents and Records Management

- Are there written procedures that provide instructions for specimen processing and packaging for transport?
- Are there written procedures that provide instructions for receiving examination results and consultation reports?
- How is specimen tracking information maintained?
- Are finalized examination results maintained according to regulatory and accreditation requirements?
- Are documents and records created during the referral laboratory processes maintained according to the records retention schedule?

4.9 Information Management

- Does a software interface need to be established and validated for the transmission of specimen information and examination results and reports?
- Is information transmitted securely and in a manner that maintains confidentiality?
- What is the process to order examinations and receive results when the software interface is not operational?

4.10 Nonconforming Event Management

- How are complaints and problems with the referral laboratory services recorded, investigated, and tracked?
- How are recalls from the referral laboratory managed?

4.11 Assessments

- What is the process to evaluate the referral laboratory's or consultant's services?
- What metrics need to be established to determine whether the referral laboratory or consultant meets the needs of the referring laboratory and its customers?

4.12 Continual Improvement

- How will information collected to assess referral laboratory or consultant services be used to improve identified defects?
- What information should the referring laboratory request from the referral laboratory that provides objective evidence of the referral laboratory's continual improvement?

Related CLSI Reference Materials*

- QMS01** **A Quality Management System Model for Laboratory Services. 5th ed., 2019.** This guideline provides a model for medical laboratories to organize the implementation and maintenance of an effective quality management system.
- QMS11** **Nonconforming Event Management. 2nd ed., 2015.** Grounded in the principles of quality management, risk management, and patient safety, this guideline provides an outline and content for developing a program to manage a laboratory's nonconforming events.
- QMS12** **Developing and Using Quality Indicators for Laboratory Improvement. 2nd ed., 2019.** This guideline describes how laboratories can develop and use quality indicators to measure and monitor performance of laboratory processes and identify opportunities for improvement.
- QMS21** **Purchasing and Inventory Management. 1st ed., 2016.** This guideline describes effective purchasing and inventory management processes, which ensure availability of the appropriate equipment, instruments, reagents, consumable materials, other products, and services procured from external sources needed for providing quality laboratory services.

* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

Sample



950 West Valley Road, Suite 2500, Wayne, PA 19087 USA

P: +1.610.688.0100 Toll Free (US): 877.447.1888 F: +1.610.688.0700

E: customerservice@clsi.org www.clsi.org

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