CLINICAL AND LABORATORY STANDARDS INSTITUTE®

3rd Edition

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.

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Qualifying, Selecting, and Evaluating a Referral Laboratory

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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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Contents

Contents (Continued)

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.

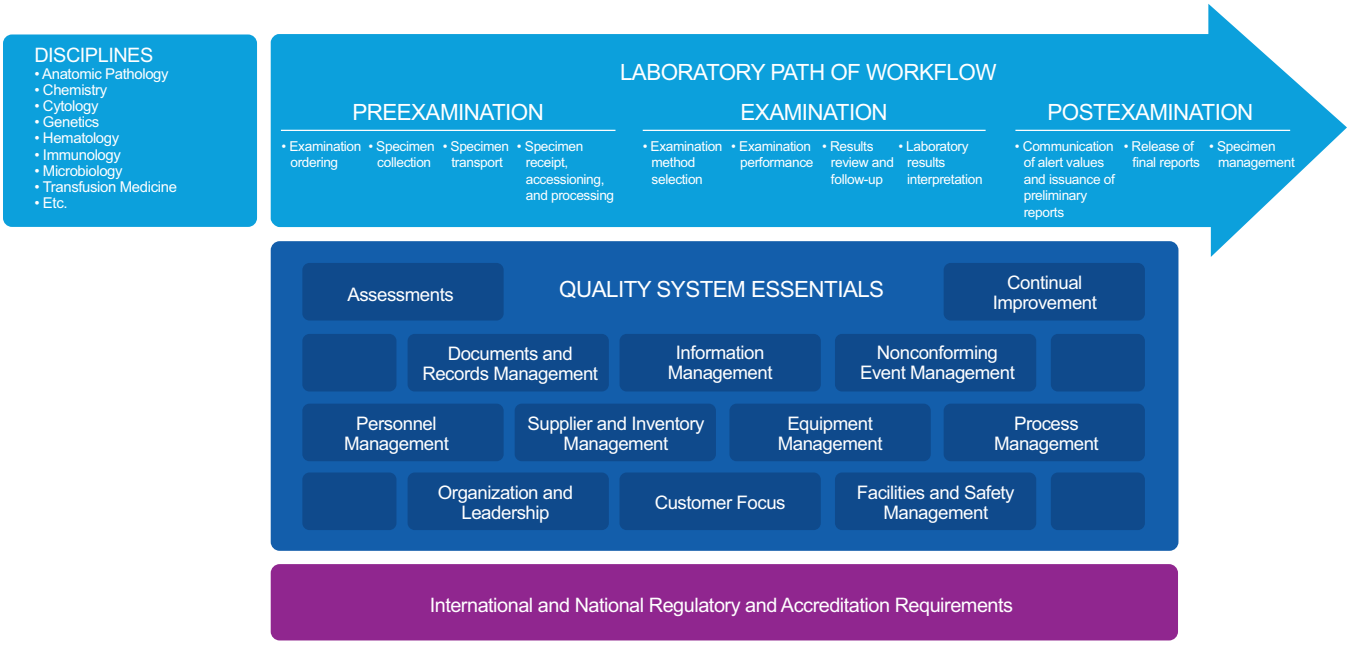

Figure 1. The QMS Model for Laboratory Services (see CLSI document QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. 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 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]

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
Qualification
Referral laboratory
Referring laboratory
Selection

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