This guideline provides recommended criteria and easily implemented processes for qualifying, selecting, and evaluating a referral laboratory.

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

Clinical and Laboratory Standards Institute document QMS05-A2—Quality Management System: Qualifying, Selecting, and Evaluating a Referral Laboratory; Approved Guideline—Second Edition provides recommended criteria and easily implemented processes for qualifying, selecting, and evaluating a referral laboratory.

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Foreword

Clinical laboratories, whether associated directly with a provider of medical services or free standing, are often asked to identify and forward test specimens to a referral laboratory or laboratories. The director of the referring laboratory bears the final responsibility for qualifying and recommending or selecting the referral laboratory and for evaluating its ongoing performance after the selection process.

This guideline presents a set of criteria and the requirements to consider when evaluating candidates for selection as a referral laboratory. Emphasis is placed on objective criteria that are measureable and readily evaluated by the referring laboratory. The criteria proposed in this guideline relate directly to the quality of services provided by a referral laboratory.

The authors of this guideline believe that quality is best assessed from the perspective of patient care outcomes, and those criteria that influence favorable patient care outcomes are emphasized. Users of the guideline are strongly encouraged to focus particular attention on criteria that relate most directly to patient care at their own institutions. For example, the referring laboratory at a tertiary care provider may require detailed information about the clinical application of a set of esoteric laboratory tests and may need active support from interpretive consultative services offered by the referral laboratory. These criteria may be less important for an institution that mainly provides primary care services. The selection criteria discussed in the guideline are also helpful for referral laboratories as they seek to anticipate and meet the needs of their customers.

Overview of Changes From GP09-A

This edition of the guideline includes alignment with any new or changed international, national, or accreditation requirements for laboratories since the last version. In addition, this version of QMS05 has been more closely aligned with the CLSI Quality Management System Model—specifically, Quality System Essential (QSE) Purchasing and Inventory, which includes international, regulatory, and accreditation requirements for purchasing materials and services from suppliers. With regard to referral laboratory services, the referring laboratory is purchasing laboratory services from a qualified referral laboratory.

Key Words

Purchasing laboratory services, referral laboratory, referring laboratory
Quality Management System: Qualifying, Selecting, and Evaluating a Referral Laboratory; Approved Guideline—Second Edition

1 Scope

The guideline can be used by referring laboratories seeking a broad spectrum of services, a limited number of esoteric examinations, or a possible backup service provider for examinations provided by the referring laboratory. This guideline is not meant as the only way to qualify, select, and evaluate referral laboratories; referring laboratories are free to modify the suggested criteria with the caveat not to delete criteria that reflect international, national, regional, local, or organizational requirements.

2 Introduction

This guideline contains specific recommendations for referring laboratories engaged in qualifying, selecting, and evaluating a referral laboratory. The suggested qualifying criteria can be used by staff at a referring laboratory to gather data and to evaluate and compare candidate referral laboratories. These criteria can be easily adapted as a request for information (RFI) or a request for proposal (RFP) by the referring laboratory. In preparing an RFP, the referring laboratory may elect to omit certain criteria that are not considered essential in the decision making process. This guideline also makes suggestions for how to periodically evaluate referral laboratory services. The recommendations in this guideline include activities necessary to meet international and national published requirements for referral laboratories.

3 Terminology

3.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever 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 the United States, Europe, and elsewhere; that these differences are reflected in CLSI, International Organization for Standardization (ISO), and European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. In light of this, CLSI's consensus process for development and revision of standards and guidelines focuses on harmonization of terms to facilitate the global application of standards and guidelines.

While the term “reference laboratory” is a common term of use, the internationally accepted terminology is “referral laboratory.” In order to align the terminology used in this document with that of ISO, the phrase “referral laboratory” was adopted throughout the document. For the sake of introduction and to avoid confusion, the alternate term (ie, “reference laboratory”) is indicated with the definition of “referral laboratory.”

Additional important note:

Throughout this guideline, the phrase “the laboratory needs to” explains an action directly related to fulfilling requirements of international, national, and accreditation organizations. By taking the actions described in this guideline, the laboratory will fulfill requirements; means by which the requirements are met are left to the discretion of the laboratory unless otherwise specified.
The phrase “the laboratory should” describes a recommendation provided in laboratory literature, a statement of good laboratory practice, or a suggestion for how to meet a requirement.

3.2 Definitions

**accreditation** – procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks [modified from ISO/IEC 17000].

**conflict of interest** – situation that has the potential to undermine the impartiality of a person because of the possibility of differences between the person’s self-interest and professional interest or public interest.

**consultative services** – organized program supported by dedicated staff at a referral laboratory, designed to provide specific information to referring laboratory clients to facilitate the ordering and performance of examinations or the interpretation of examination results; **NOTE**: A consultation may involve technical information or medical interpretive information.

**courier service** – provider that facilitates the transport of specimens from a referring laboratory to a referral laboratory; **NOTE**: A courier service may be provided by the referral laboratory or may be offered through a third party as part of a separate fee-for-service arrangement between the referring laboratory and referral laboratory.

**evaluation** – process by which the referring laboratory assesses the quality of service received from the referral laboratory, during the agreement and as part of periodic review.

**licensure** – process by which a laboratory is recognized as qualified to provide particular examination services.

**proficiency testing** – evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO 17043).

**qualification** – process by which one provider of laboratory services investigates and determines the capabilities and quality of services offered by another provider; **NOTE**: As used in this document, the term applies to the process of due diligence by which a referring laboratory assesses the capabilities of prospective referral laboratories.

**quality management system (QMS)** – management system to direct and control an organization with regard to quality (ISO 9000 [3.2.3]).

**referral laboratory//reference laboratory** – external laboratory to which a sample is submitted for an examination procedure; **NOTE**: Referral/reference laboratories can include laboratories that are considered internal because they are a subsidiary of the parent laboratory, but are truly external because they operate under a different QMS.

**referring laboratory** – laboratory that submits samples for a supplementary or confirmatory examination procedure and receives the report from the referral laboratory.

**sample** – one or more parts taken from a system, and intended to provide information on the system, often to serve as a basis for decision on the system or its production (ISO 15189 [3.16]); **NOTE**: For example, a volume of serum taken from a larger volume of serum (ISO 15189 [3.16]).

**specimen (patient)** – discrete portion of a body fluid or tissue taken for examination, study, or analysis of one or more quantities or characteristics, to determine the character of the whole (ISO 18113-1).
The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The quality management system approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any health care service’s path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The QSEs are as follows:

- Organization
- Personnel
- Process Management
- Nonconforming Event Management
- Customer Focus
- Purchasing and Inventory
- Documents and Records
- Assessments
- Facilities and Safety
- Equipment
- Information Management
- Continual Improvement

QMS05-A2 addresses the QSE indicated by an “X.” For a description of the document listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Path of Workflow

A path of workflow is the description of the necessary processes to deliver the particular product or service that the organization or entity provides. A laboratory path of workflow consists of the sequential processes: preexamination, examination, and postexamination and their respective sequential subprocesses. All laboratories follow these processes to deliver the laboratory’s services, namely quality laboratory information.

QMS05-A2 does not address any of the clinical laboratory path of workflow steps. For a description of the document listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.
Related CLSI Reference Materials*

GP26-A4  Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition (2011). This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.

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