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CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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QMS05-A2

Quality Management System: Qualifying, Selecting, and Evaluating a Referral Laboratory; Approved Guideline—Second Edition

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

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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

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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.[1-12] 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.

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