CLINICAL AND LABORATORY STANDARDS INSTITUTE®

2nd Edition

CLSI QMS14™

Quality Management System: Leadership and Management Roles and Responsibilities

CLSI QMS14 presents concepts and information to assist a laboratory in meeting leadership requirements for its quality management system. Guidance is provided for leaders to effectively design, implement, and maintain the cultural, structural, and functional aspects of their laboratory that are critical to managing and sustaining quality.

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

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Quality Management System: Leadership and Management Roles and Responsibilities

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Abstract

Clinical and Laboratory Standards Institute QMS14-Ed2—*Quality Management System: Leadership and Management Roles and Responsibilities* assists laboratories in meeting the leadership-based requirements for a QMS, as represented by quality system essential Organization and Leadership. It presents a conceptual framework of three organizational dimensions (ie, cultural, structural, and functional) and provides content for managing laboratory quality.

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Foreword

Quality system essential (QSE) Organization and Leadership is one of the 12 QSEs described in CLSI QMS01,[1] which provides the necessary background information and guidance to develop and maintain a QMS. The QMS model depicted in Figure 1 demonstrates that each QSE, such as Organization and Leadership, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.

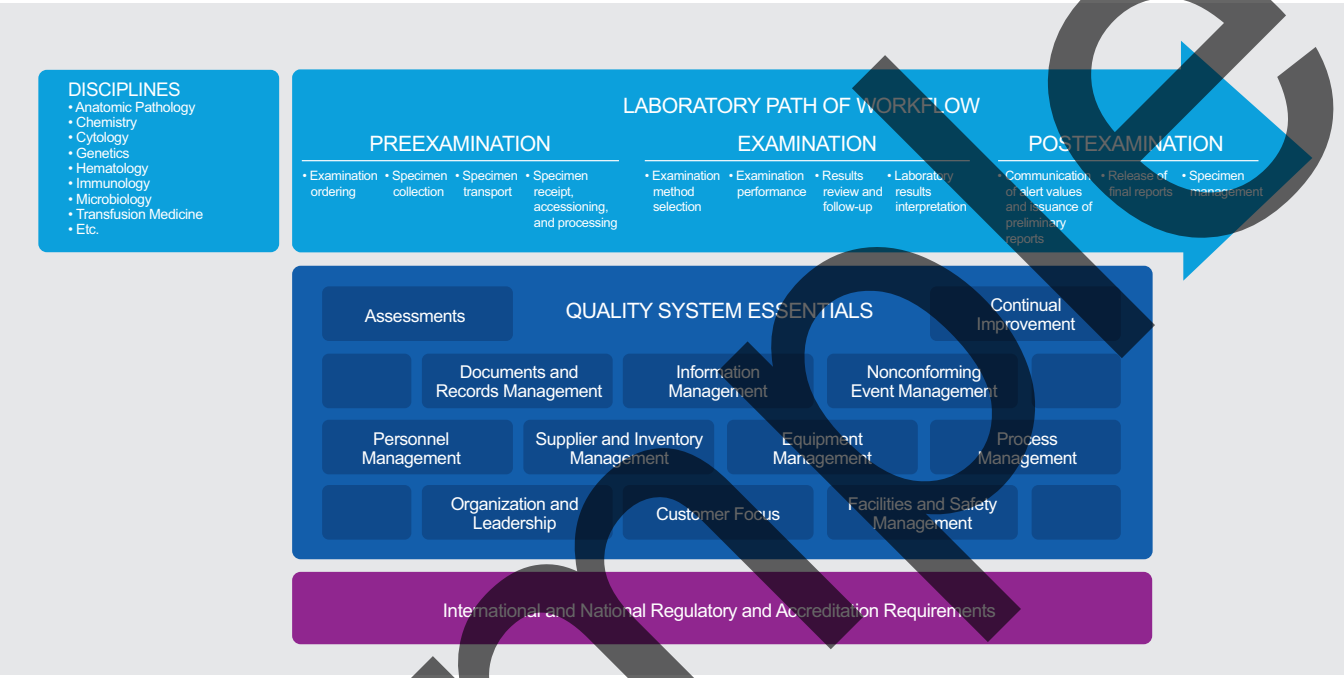

Figure 1. The QMS Model for Laboratory Services (see CLSI QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

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. For example, when the laboratory lacks defined processes for properly installing, calibrating, and maintaining its analyzers so that they are working effectively, there will be problems in examination processes.

International guidance for 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]

Experience has shown that a laboratory's success in implementing and maintaining a QMS depends on laboratory leadership setting the expectation that quality management is the laboratory's "way of doing business" rather than an added activity. Leaders should then foster a culture that supports this expectation and should also actively participate in all aspects of managing quality.

Active and ongoing participation of the laboratory's leadership in defining the laboratory's quality policy, planning for quality, allocating resources to achieve quality goals, seeking customer feedback, and receiving and acting on information derived from quality status reports is essential to an effective QMS. An effective QMS results in the continual improvement of the laboratory's service and enables the laboratory to sustain its performance improvements, thereby more consistently meeting the needs of its customers.

To impress upon laboratory leaders the importance of their role in quality, regulatory and accreditation organizations have specific requirements for laboratory leadership. Leadership requirements can be stated explicitly as leadership standards or can be implicit and integrated with other requirements. When a laboratory documents its intention for leadership in policies and transforms the stated intent into action through its processes and procedures, the requirements (summarized in CLSI QMS01[1]) can be met.

This guideline assists laboratories in meeting leadership requirements for their QMS. A conceptual framework comprising three organizational dimensions (ie, cultural, structural, and functional) is introduced, and content for managing laboratory quality is provided for each dimension. This guideline's content was developed to enhance the effectiveness of leadership at shaping (ie, designing, implementing, and maintaining) the quality-related aspects of each dimension, thereby supporting leaders in fulfilling their QMS roles and responsibilities.

This guideline presents the leadership requirements described in QSE Organization and Leadership, and aspects that enable the successful development, implementation, and/or maintenance of:

- A quality policy
- An appropriate scope of services
- An organizational structure to ensure quality
- Roles and responsibilities to carry out the work processes and activities of the QMS
- An appropriately designed and integrated QMS
- A process for resource management in support of the QMS and provision of laboratory services
- A process for quality planning
- A process for review of performance to assess the effectiveness of the QMS
- A program or plan for ongoing communication of quality-related information

CLSI QMS14 is a **guideline** that can help laboratories implement leadership and management roles and responsibility and meet international standards and regulatory and accreditation requirements.[2-12] **CLSI QMS14 is not a standard;** that is, this guideline **does not set requirements** for organization and leadership. Rather, it provides suggestions and examples for fulfilling the requirements.

Overview of Changes

This guideline was revised in 2024 under the limited revision process and replaces the 1st edition of the guideline, which was published in 2012. Several changes were made in this edition, including:

- Aligning content to the content in the current edition of CLSI QMS01[1]
- Eliminating content now covered in CLSI documents that did not exist when this guideline was published in 2012.
- Aligning CLSI QMS14 to the updated CLSI document template.

KEY WORDS

communication
good professional practice
leadership responsibilities
leadership roles
management review
organization
quality culture
quality manager
quality planning
quality policy
quality report
resource allocation

Chapter 1

Introduction

Quality Management System: Leadership and Management Roles and Responsibilities

1 Introduction

1.1 Scope

This guideline can be used by organizations and individuals involved in managing or operating preexamination, examination, and postexamination laboratory processes. It is applicable to:

- Medical laboratories
- Blood gas laboratories
- Blood donor and pretransfusion testing laboratories
- Public health laboratories
- Clinical research laboratories

This guideline does not describe, in detail, topics and content covered in other CLSI documents. In addition, it does not reference requirements specific to any regulatory agency or accreditation organization. It is suggestive and not prescriptive in approach. It is not a comprehensive instructional manual for applying the concepts discussed, and it does not include detailed instructions or plans for how to design an organizational structure, implement a QMS, allocate resources, or create quality policies, processes, or procedures.

The concepts, descriptions, and examples provided apply to laboratories of any size, functional complexity, scope of service, and organizational structure. This guideline is applicable to any laboratory's QMS, regardless of its comprehensiveness and stage of development. This guideline is also applicable regardless of the regulations or accreditation program followed by a laboratory. Laboratories can use this guideline to assist in justifying the need for a QMS, designing or implementing a QMS, and/or maintaining and improving an established QMS.

1.2 Background

The competence with which laboratory leadership fulfills the role of "quality leader" and the attention paid to leadership responsibilities for the QMS often determines a laboratory's success in realizing the full benefits of a systematic approach to managing quality. The full benefit of a QMS can be visualized as a laboratory that sustains excellence and quality by providing a service that consistently meets or exceeds the needs of internal and external customers, while meeting all applicable regulatory and accreditation requirements. For a medical laboratory that serves patients, an effective QMS enables the laboratory to contribute to safe care and positive patient outcomes.

The occasionally voiced opinion, "Quality begins at the top," acknowledges that the laboratory's leaders have unique roles and responsibilities in shaping the organizational dimensions relevant to managing and sustaining quality. The QMS leadership-based requirements, as represented by QSE Organization and Leadership, reflect the need to attend to organizational dimensions if laboratories are to maintain highly effective and efficient laboratory work processes that consistently meet customers' needs. The organizational dimensions are:

- Cultural
- Structural
- Functional

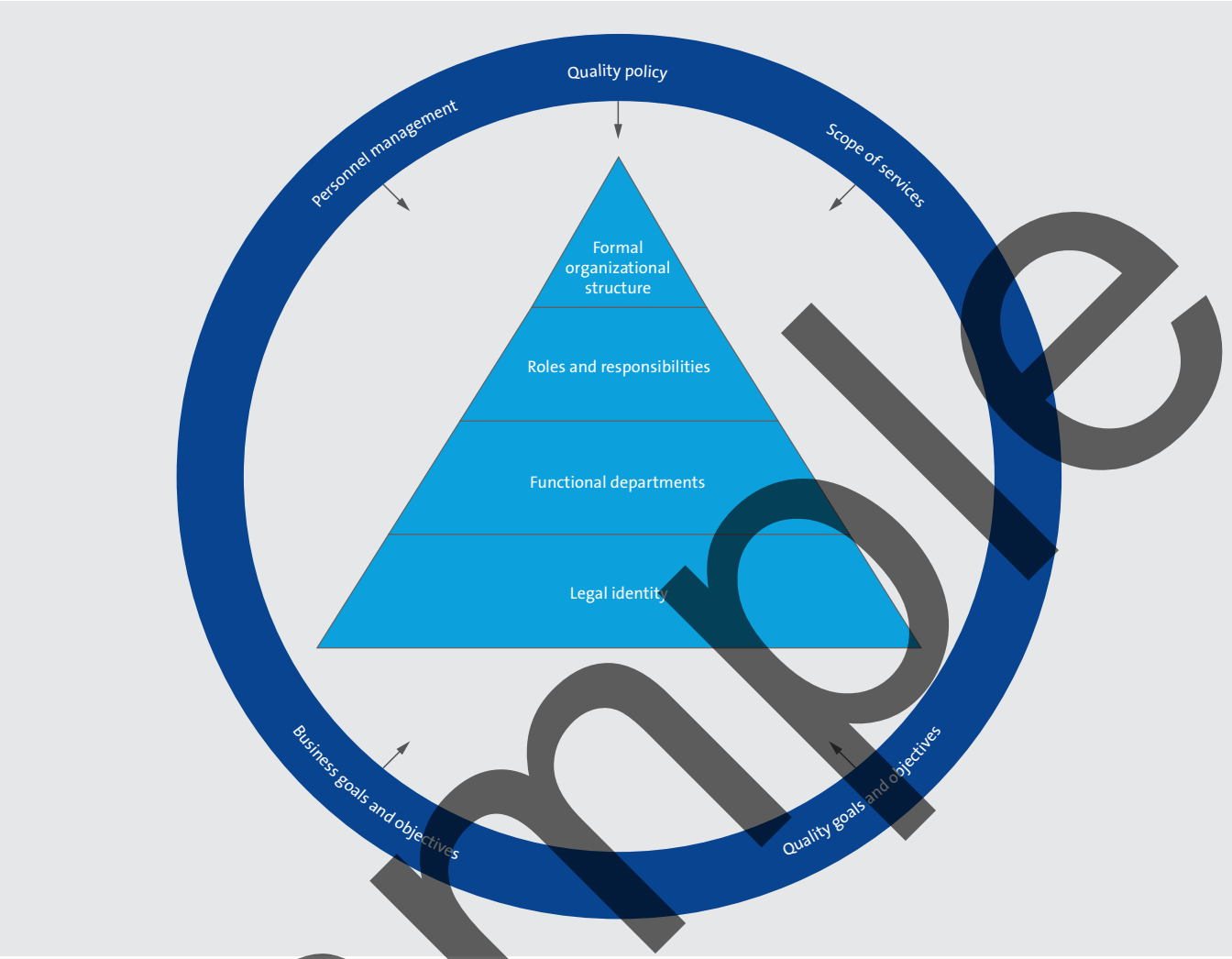

Figure 5. Laboratory Organizational Structure, Process Outputs, and Related Aspects

5.1 Establishing and Maintaining the Laboratory's Legal Identity

The laboratory, or the organization of which the laboratory is a part, needs to be legally identifiable, ie, there needs to be some type of document that verifies the laboratory's existence as a legal entity, as well as its relationship to a larger organization (eg, hospital, commercial laboratory, physician's office) or subsidiaries, where applicable. The document needs to be revised when conditions that affect the laboratory's legal status change.

Leadership is responsible for understanding and adhering to all requirements for establishing and maintaining the laboratory's legal identity. When appropriate, leaders should consider the implications and requirements of the larger organization and ensure that the laboratory meets those requirements. Factors that frequently influence requirements about a laboratory's legal identity include:

- Geographic location (ie, national, state, or local requirements)
- Size
- Type and complexity of examinations
- Scope of services

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