CLINICAL AND LABORATORY STANDARDS INSTITUTE®

December 2012

QMS14-A

Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline

This guideline presents concepts and information intended 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's organization 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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ISBN 1-56238-861-4 (Print)
ISBN 1-56238-862-2 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)

QMS14-A
Vol. 32 No. 16
Formerly GP38-A
Vol. 32 No. 16

Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline

Volume 32 Number 16

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Abstract

Clinical and Laboratory Standards Institute document QMS14-A—*Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline* is intended to assist laboratories in meeting the leadership-based requirements for a QMS, as represented by quality system essential (QSE) Organization. It presents a conceptual framework comprising three organizational dimensions (ie, cultural, structural, and functional) and provides content relevant to the management of laboratory quality in the form of descriptions, examples, and sample templates. This guideline is intended for use by all organizations and individuals involved in the management or operation of preexamination, examination, and postexamination phases of the medical laboratory. This document may be applicable to other types of laboratories, as well as nonlaboratory settings.

Clinical and Laboratory Standards Institute (CLSI). *Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline*. CLSI document QMS14-A (ISBN 1-56238-861-4 [Print]; ISBN 1-56238-862-2 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.

Suggested Citation

CLSI. *Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline.* CLSI document QMS14-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2012.

Reaffirmed:
June 2017

ISBN 1-56238-861-4 (Print)
ISBN 1-56238-862-2 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)

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Foreword

Quality system essential (QSE) Organization is one of the 12 QSEs described in CLSI document GP26,[1] which provides the necessary background information and guidance to develop and maintain a QMS. The QMS model depicted in Figure 1 demonstrates how each QSE, such as Organization, 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 Quality Management System Model for Laboratory Services (see CLSI document GP26).[1] The 12 QSEs function as building blocks that are necessary to support any laboratory's path of workflow and laboratory disciplines. This example represents how the 12 QSEs support a clinical laboratory's disciplines.

QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. If a QSE is missing or not well implemented, problems will occur in preexamination, examination, and postexamination laboratory activities. 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 related to the QSEs and the laboratory's path of workflow is described in selected International Organization for Standardization (ISO) standards. ISO 9001[2] defines a process-based model for quality that any business should use to manage its operations—the information relates directly to the QSEs. ISO 17025[3] specifies requirements for both quality management and technical operations of testing and calibration laboratories. ISO 15189[4] defines standards for quality management and technical operations in the medical laboratory environment.

Experience has shown that for a laboratory to be successful in implementing and maintaining a QMS, the laboratory's leadership should set 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 its quality policy, planning for quality, allocating resources to achieve quality goals, seeking customer feedback, and receiving and acting upon information derived from quality status reports is essential to the effectiveness of the QMS. An effective QMS will result in the continual improvement of the laboratory's service and enable 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 may be stated explicitly as leadership standards or may be implicit and integrated with other requirements. Either way, the leadership requirements summarized in CLSI document GP26[1] apply. If 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 document GP26[1]) will 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 relevant to managing laboratory quality is provided for each dimension. This guideline's content was developed with the aim of enhancing the effectiveness of leadership at shaping (ie, designing, implementing, and maintaining) the quality-related aspects of each dimension, thereby supporting leaders in the fulfillment of their QMS roles and responsibilities.

This guideline addresses the leadership requirements as described by QSE Organization, and aspects to be considered to 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 quality manual
- 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

Key Words

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

Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline

1 Scope

This guideline is intended to assist laboratories in meeting the leadership-based requirements for their QMS, as represented by quality system essential (QSE) Organization. A conceptual framework comprising three organizational dimensions (ie, cultural, structural, and functional) is presented, and content is provided to illustrate relevance to managing laboratory quality. This guideline's content was developed with the aim of enhancing leadership's effectiveness at shaping these dimensions, and thereby supports leaders in the fulfillment of their roles and QMS responsibilities.

This guideline is intended for use by all organizations and individuals involved in the management or operation of preexamination, examination, and postexamination phases of the medical laboratory. This document may be applicable to other types of laboratories, as well as nonlaboratory settings.

This guideline does not address, in detail, topics and content covered in other CLSI documents. In addition, this document does not reference requirements specific to any regulation or accrediting body. It is not meant to be prescriptive, but rather suggestive in approach. It is not a comprehensive instructional manual for application of the concepts discussed, and does not include detailed instructions or plans for how to design an organizational structure, implement a QMS, allocate resources (eg, budgeting, staffing), or create a quality manual.

2 Introduction

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 sustaining 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 the provision of 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, reflect the necessity for attending to organizational dimensions if laboratories are to maintain highly effective and efficient laboratory work processes that consistently meet the needs of customers. The organizational dimensions are:

- Cultural
- Structural
- Functional

Guidance is provided to leadership to realize its commitment to quality and good professional practice, ultimately achieving:

- A culture that supports and sustains quality
- An organizational structure that ensures quality
- A functional and sustainable QMS

- Optimally allocated resources
- Ongoing planning for quality
- Ongoing review to ensure the effectiveness of the QMS
- Ongoing communication of quality-related information

The guideline sections, which are organized along these dimensions, address the fundamental responsibilities of leadership related to the requirements of QSE Organization. The fundamental responsibilities are categorized by organizational dimension, correlated with the guideline sections, and summarized in Table 1.

Table 1. QSE Organization – Fundamental Leadership Responsibilities

Dimension	Section(s)	Section Heading	Responsibility
Cultural	4 5	Vision for Quality Making the Case for a QMS	Formulating and articulating a vision for quality
	6	Committing to Quality and Good Professional Practice	• Maintaining a quality policy as a formal statement of commitment • Conducting business ethically and professionally • Fostering a culture that supports the vision for quality
Structural	6	Committing to Quality and Good Professional Practice	Maintaining an appropriate scope of services
	7	Creating and Maintaining an Organizational Structure to Ensure Quality	• Maintaining the legal identity of the laboratory • Maintaining an appropriate organization structure with defined roles and responsibilities
	8	Effectively Implementing the QMS	Designing and implementing a QMS
Functional	9	Managing Resources	Managing and allocating resources sufficient for scope of services and quality goals
	10	Planning for Quality	Planning for quality
	11	Management Review	Assessing the effectiveness of the QMS
	12	Communicating Quality-Related Information	Communicating quality-related information

Abbreviation: QMS, quality management system.

The concepts, descriptions, and examples provided are applicable 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 its stage of development. The 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 new QMS, and/or maintaining and improving an established QMS.

For a laboratory leader who has clearly articulated a compelling vision of quality, the first priority may be to act on his or her personal commitment to quality and good professional practice. Leaders, by way of authority, formal position, and/or influence, are uniquely placed in the organization to *realize* their

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

QMS14-A addresses the QSE indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Organization	Customer Focus	Facilities and Safety	Personnel	Purchasing and Inventory	Equipment	Process Management	Documents and Records	Information Management	Nonconforming Event Management	Assessments	Continual Improvement
X GP26 K2Q	GP26 K2Q	GP26 K2Q	GP26 K2Q	GP26 K2Q	GP26 GP37 K2Q	GP26 K2Q	GP02 GP26 K2Q	GP26 K2Q	GP26 K2Q	GP26 K2Q	GP22 GP26 GP35 K2Q

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.

QMS14-A does not address any of the clinical laboratory path of workflow steps. For a description of the documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Preexamination				**Examination**			**Postexamination**	
Examination ordering	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
GP26 K2Q	GP26 K2Q	GP26 K2Q	GP26 K2Q	GP26 K2Q	GP26 K2Q	GP26 K2Q	GP26 K2Q	GP26 K2Q

Related CLSI Reference Materials*

GP02-A5 **Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition (2006).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the medical laboratory community.

GP22-A3 **Quality Management System: Continual Improvement; Approved Guideline—Third Edition (2011).** This guideline considers continual improvement to be an ongoing, systematic effort that is an essential component of a quality management system. A continual improvement program may consist of fundamental processes and common supporting elements described in this guideline.

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.

GP35-A **Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline (2010).** This document provides guidance on development of quality indicators and their use in the medical laboratory.

GP37-A **Quality Management System: Equipment; Approved Guideline (2011).** This guideline provides recommendations for establishing equipment management processes from selection through decommission of equipment used in the provision of laboratory services.

K2Q **The Key to Quality (2007).** This comprehensive specialty portfolio, with tabs for quick references, showcases the implementation of all 12 quality system essentials. The portfolio includes essentials, examples, flow charts, cross-references, evaluations, and a CD-ROM based on the widely used QMS documents.

* 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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PRINT ISBN 1-56238-861-4

ELECTRONIC ISBN 1-56238-862-2