

# QMS12

## Developing and Using Quality Indicators for Laboratory Improvement

This guideline describes how laboratories can develop and use quality indicators to measure and monitor performance of laboratory processes and identify opportunities for improvement.

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

# Developing and Using Quality Indicators for Laboratory Improvement

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## Abstract

Clinical and Laboratory Standards Institute guideline QMS12—*Developing and Using Quality Indicators for Laboratory Improvement* provides recommendations on developing meaningful quality indicators for single and multiple laboratory organizations. This guideline includes criteria for selecting quantitative and qualitative indicators. It also includes procedures for gathering data and using the information to present and interpret results, monitor performance over time, and communicate laboratory indicator performance to internal and external laboratory customers.

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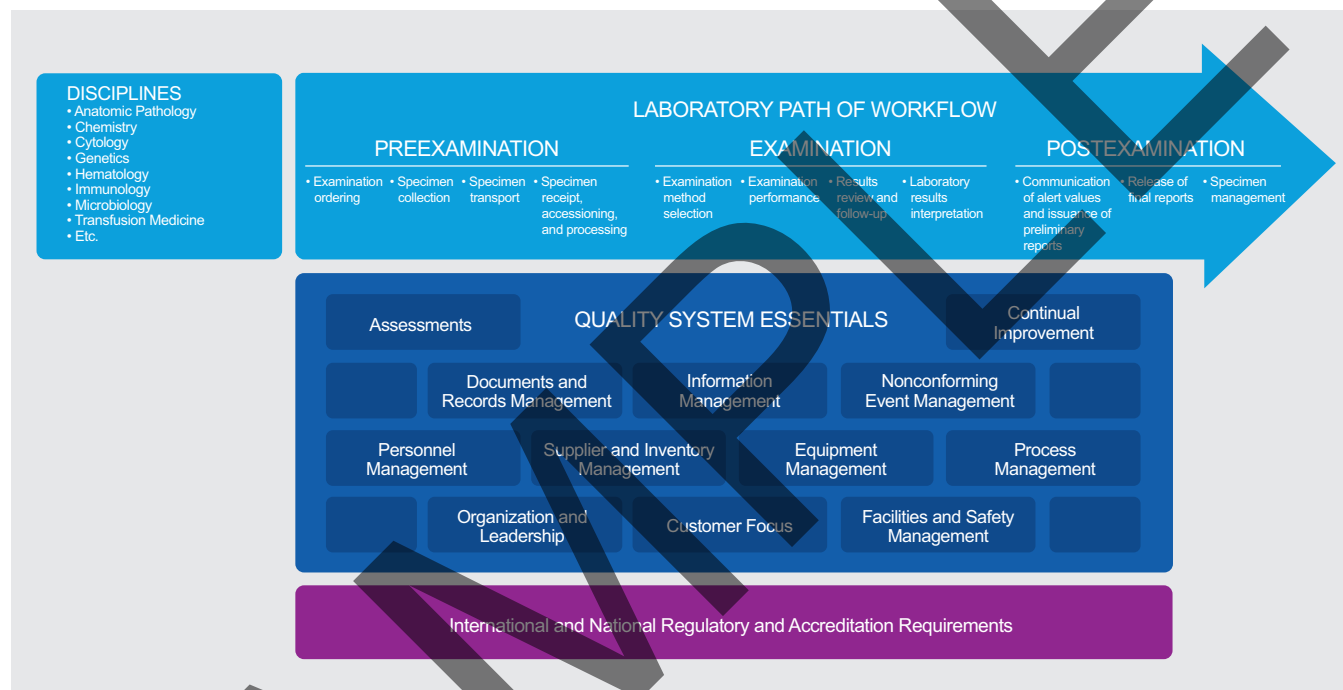
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## Foreword

Quality system essential (QSE) Assessments is one of the 12 QSEs described in CLSI document QMS01<sup>1</sup> and CLSI product *The Key to Quality*<sup>™,2</sup> which provide 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 Assessments, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.



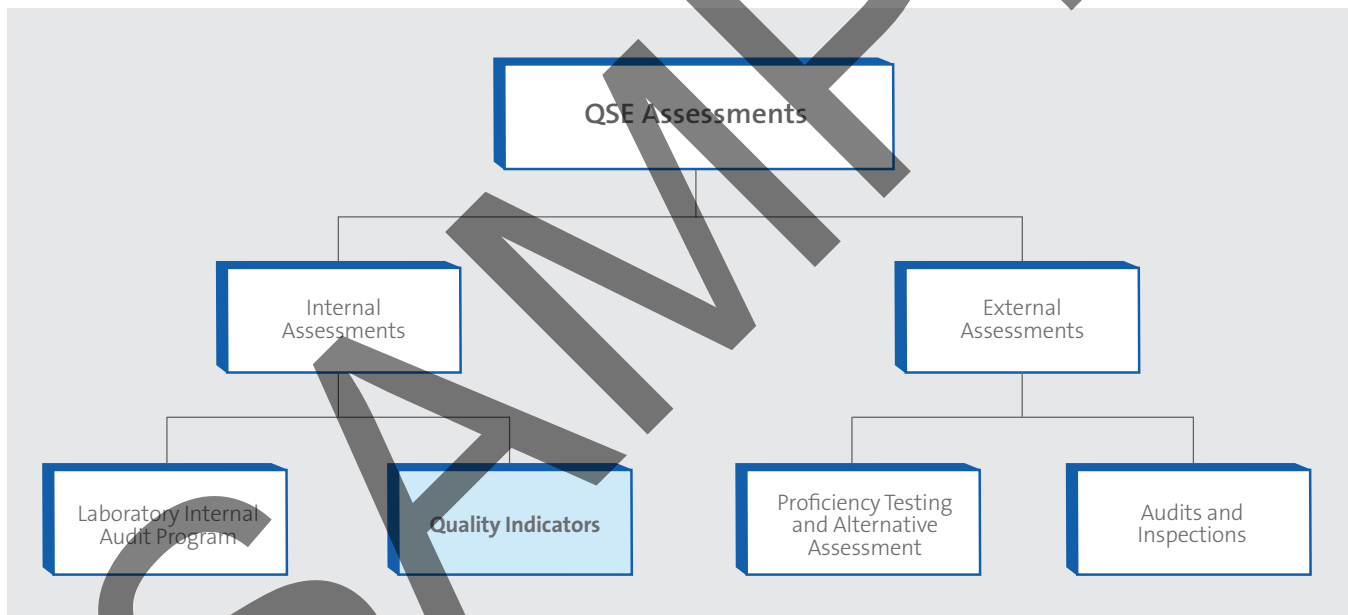
**Figure 1. The QMS Model for Laboratory Services (see CLSI document QMS01<sup>1</sup>).** The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

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, if a laboratory does not measure the turnaround time for specific examinations to key laboratory customers, it cannot know whether it is meeting customer expectations for the timeliness of examination results.

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<sup>3</sup>
- Requirements for both quality management and technical operations of testing and calibration laboratories<sup>4</sup>
- Standards for quality management and technical operations in the medical laboratory environment<sup>5</sup>

QSE Assessments encompasses both internal and external laboratory assessments, shown as separate elements in Figure 2. One program for internal assessment is the development and use of laboratory quality indicators, which provide appropriate, measurable, interpretable information about laboratory processes and outputs that is used to make decisions about laboratory quality and opportunities for improvement. Quality indicators help ensure the laboratory meets applicable regulatory, accreditation, and organizational requirements and customer expectations. QMS12 provides guidance for developing and implementing laboratory quality indicators.



Abbreviation: QSE, quality system essential.

**Figure 2. Components of QSE Assessments**

# Developing and Using Quality Indicators for Laboratory Improvement

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## 1 Introduction

### 1.1 Scope

This guideline describes how to develop and use quality indicators in the medical laboratory. These indicators include measures developed within a single laboratory for local use, as well as indicators developed or required by regulatory and accreditation organizations. This guideline also provides criteria for developing quantitative and qualitative indicators. In addition, it includes procedures for gathering data, presenting and interpreting results, monitoring performance over time, and comparing performance with that of other laboratories or national norms.

This guideline's main focus is quality indicators for preexamination, examination, and postexamination processes, because these are specifically required by regulatory and accreditation organizations. However, the process flow, concepts, and indicator development form presented in this guideline can also be used to create indicators to measure the effectiveness of the laboratory's QMS (ie, management) processes, if desired.

This guideline is intended for use by laboratory directors, managers, supervisors, and the quality manager as a means to ensure laboratories implement an effective approach to selecting, developing, interpreting, and using information derived from well-designed quality indicators.

Although laboratories can study these areas as a reflection of laboratory quality, this guideline does not cover monitoring of:

- Proficiency testing (PT) (see CLSI document QMS24<sup>6</sup>)
- QC (see CLSI document EP23<sup>TM7</sup>)
- Personnel competence (see CLSI document QMS03<sup>8</sup>)
- Customer satisfaction (see CLSI document QMS19<sup>9</sup>)

This guideline is also integrated into and consistent with the other CLSI quality management documents that provide a complete approach to implementing a laboratory QMS.

achieving the laboratory goals. Information derived from quality indicator data also provides objective evidence that demonstrates the laboratory's contribution to the organization's goals and mission as well as fulfillment of regulatory and accreditation requirements.



**Figure 4. Graphical Representation of a Performance Monitoring Approach.** A relationship exists between the organization's mission (as applicable), the laboratory's mission, and laboratory goals and objectives. Monitoring performance based on laboratory quality indicators should lead to continual improvement that helps the laboratory meet its goals, fulfilling the laboratory's and, as applicable, the organization's missions.

**NOTE:** The overall perspective of “Goal → Objective → Indicator → Target → Threshold” is applied throughout the remainder of this guideline as a logical approach for developing quality indicators and evaluating data and information about laboratory performance.



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