



CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE®

2nd Edition

QMS12

Developing and Using Quality Indicators for Laboratory Improvement

Sample

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

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

Developing and Using Quality Indicators for Laboratory Improvement

Karen H. Walsh, MS, BS, MT(ASCP), CPHQ, CLSSMBB, FACHE
Lucia M. Berte, MA, MT(ASCP)SBB, DLM, CQA(ASQ), CMQ/OE
Lou Ann Barnett, PhD, MT(ASCP), PMP, CCRP
Michael B. Cohen, MD
Kathryn Connolly, CQA(ASQ), MT(ASCP)
Marilyn S. Hamilton, MD, PhD
Catherine M. Johnson, MA, MT(ASCP)

Bonnie Messinger
Jennifer Nosbisch
Peter L. Perrotta, MD
Hannah Poczter, MPH, DLM(ASCP)
Tawni Reller
Sheryl Thiessen, BSMT, MT(ASCP), MLT(CSMLS),
CLQM(POLQM)

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.

Clinical and Laboratory Standards Institute (CLSI). *Developing and Using Quality Indicators for Laboratory Improvement*. 2nd ed. CLSI guideline QMS12 (ISBN 978-1-68440-037-9 [Print]; ISBN 978-1-68440-038-6 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2019.

The Clinical and Laboratory Standards Institute consensus process, which is the mechanism for moving a document through two or more levels of review by the health care community, is an ongoing process. Users should expect revised editions of any given document. Because rapid changes in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of CLSI documents. Current editions are listed in the CLSI catalog and posted on our website at www.clsi.org.

If you or your organization is not a member and would like to become one, or to request a copy of the catalog, contact us at:

P: +1.610.688.0100 **F:** +1.610.688.0700 **E:** customerservice@clsi.org **W:** www.clsi.org

Copyright ©2019 Clinical and Laboratory Standards Institute. Except as stated below, any reproduction of content from a CLSI copyrighted standard, guideline, derivative product, or other material requires express written consent from CLSI. All rights reserved. Interested parties may send permission requests to permissions@clsi.org.

CLSI hereby grants permission to each individual member or purchaser to make a single reproduction of this publication for use in its laboratory procedures manual at a single site. To request permission to use this publication in any other manner, e-mail permissions@clsi.org.

Suggested Citation

CLSI. *Developing and Using Quality Indicators for Laboratory Improvement*. 2nd ed. CLSI guideline QMS12. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.

Previous Edition:
December 2010

Reaffirmed:
October 2024

Sample

ISBN 978-1-68440-037-9 (Print)

ISBN 978-1-68440-038-6 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 39, Number 3

Acknowledgment

CLSI, the Consensus Council, and the Document Development Committee on Quality Indicators gratefully acknowledge the following volunteers for their important contributions to the development of this guideline:

Marilyn S. Hamilton, MD, PhD
Children's Mercy Hospital
USA

Hannah Poczter, MPH, DLM(ASCP)
North Shore-Long Island Jewish
Health System Laboratories
USA

Sheryl Thiessen, BSMT, MT(ASCP),
MLT(CSMLS), CLQM, CLM
BC's Agency for Pathology and
Laboratory Medicine
Canada

Catherine M. Johnson, MA, MT(ASCP)
Association of Public Health
Laboratories
USA

Tawni Reller
Tawni Reller Consulting, LLC
USA

Sample

Contents

| | |
|--|-----------|
| Abstract | i |
| Committee Membership | iii |
| Foreword | ix |
| Chapter 1: Introduction | 1 |
| 1.1 Scope | 2 |
| 1.2 Background | 3 |
| 1.3 Terminology | 4 |
| Chapter 2: Process to Develop and Use Quality Indicators | 7 |
| 2.1 Need for Quality Indicator Is Determined | 10 |
| 2.2 Appropriate Quality Indicator Is Chosen | 11 |
| 2.3 Quality Indicator Is Defined | 22 |
| 2.4 Preliminary Quality Indicator Target Is Selected | 30 |
| 2.5 Preliminary Evaluation of the Quality Indicator Is Conducted | 35 |
| 2.6 Quality Indicator Is Finalized | 40 |
| 2.7 Quality Indicator Is Implemented | 42 |
| 2.8 Quality Indicator Data Are Analyzed | 42 |
| 2.9 Quality Indicator Report Is Prepared | 55 |
| 2.10 Management Review Process | 63 |
| Chapter 3: Quality System Essentials | 69 |
| 3.1 Quality System Essentials as the Infrastructure for Measuring and Monitoring Laboratory Quality Management Processes | 70 |
| 3.2 Quality System Essential Considerations for a Measuring and Monitoring Program | 70 |
| Chapter 4: Conclusion | 75 |
| Chapter 5: Supplemental Information | 77 |
| References | 78 |
| Appendix A1. Examples of Quality Indicators for the Laboratory's Path of Workflow | 81 |
| Appendix A2. Examples of Laboratory Quality Indicators for the Quality System Essentials | 84 |
| Appendix B1. Example of an Indicator Development Form | 86 |
| Appendix B2. Sample of a Completed Indicator Development Form | 89 |
| Appendix C1. Data Collection Tools | 95 |
| Appendix C2. Investigation and Data Reporting Tools | 96 |
| The Quality Management System Approach | 100 |
| Related CLSI Reference Materials | 102 |

Foreword

Quality system essential (QSE) Assessments is one of the 12 QSEs described in CLSI document QMS01¹ and CLSI product *The Key to Quality*^{™,2} 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.



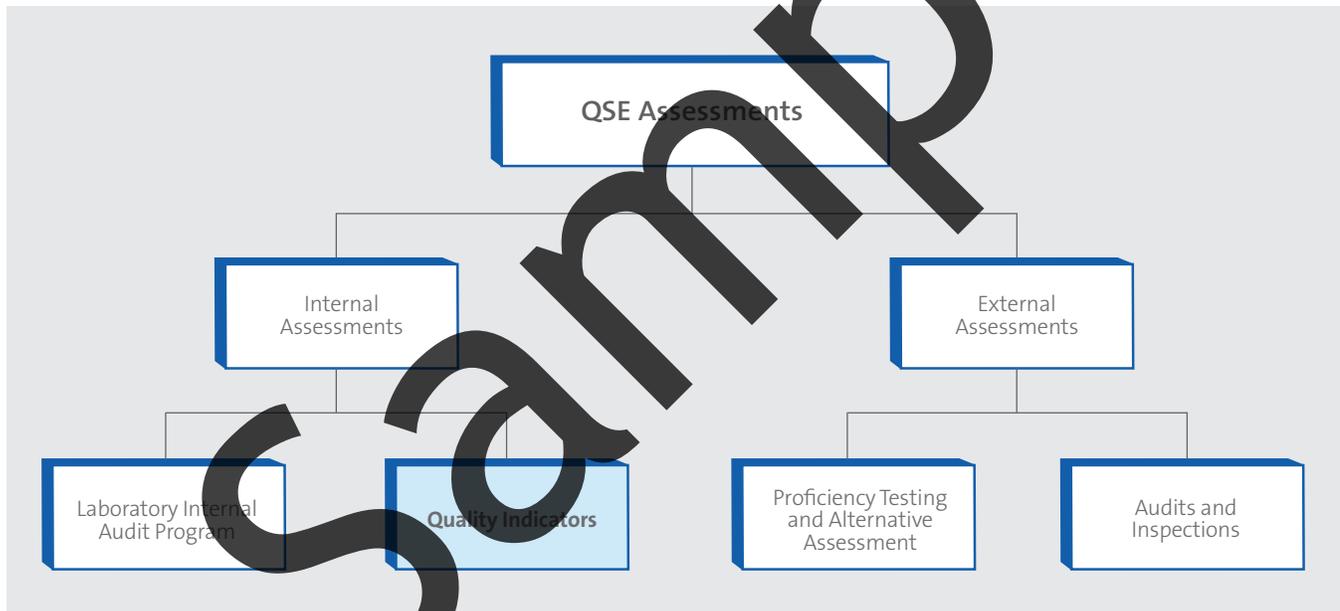
Figure 1. The QMS Model for Laboratory Services (see CLSI document QMS01¹). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

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 QSEs³
- Requirements for both quality management and technical operations of testing and calibration laboratories⁴
- Standards for quality management and technical operations in the medical laboratory environment⁵

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

Properly designed quality indicators stimulate continual improvement and avoid producing confusing and misleading information that could lead to increased work and, consequently, poor decision making. For example, for the laboratory to identify a poor patient identification process practiced by a particular group of personnel or a department, it is important that data associated with the percentage of misidentified specimens be differentiated into groups, such as specimens collected by laboratory personnel vs specimens collected by personnel outside the laboratory (eg, nursing, respiratory services). Some indicators, although well designed and intended, may be impractical because the laboratory does not have the resources to gather the needed information or lacks the capability or resources to follow through with an appropriate action plan. In addition, some laboratories continue to collect data on highly stable processes, rather than shift focus, time, and energy to indicators that provide information that leads to effective change. Laboratories should compare data generated from quality indicators with those of other laboratories, when available, and strive for continual improvement.

Overview of Changes

This guideline replaces the previous edition of the approved guideline, QMS12-A, published in 2010. Several changes were made in this edition, including the addition of:

- Definitions for data, information, and knowledge, with laboratory examples of each
- A flow chart for developing, evaluating, implementing, and monitoring a laboratory quality indicator
- An updated form for constructing an effective quality indicator
- An example of a completed quality indicator development form
- Information about monitoring quality indicators across laboratories within the same health care system

NOTE: The content of this guideline is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

Balanced scorecard

Continual improvement

Corrective action

Goal

Immediate action

Key performance indicators

Management review

Metrics

Objective

Preventive action

Quality indicator

Quality management system

Target

Threshold

Chapter 1

Introduction

This chapter includes:

- Guideline's scope and applicable exclusions
- Background information pertinent to the guideline's content
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the guideline
- Abbreviations and acronyms used in the guideline



Developing and Using Quality Indicators for Laboratory Improvement

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 QMS24⁶)
- QC (see CLSI document EP23^{TM7})
- Personnel competence (see CLSI document QMS03⁸)
- Customer satisfaction (see CLSI document QMS19⁹)

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.

Chapter 2

Process to Develop and Use Quality Indicators

This chapter includes:

- A flow chart for developing and using a laboratory quality indicator
- Background and discussion of each activity in the flow chart



i REMINDER:

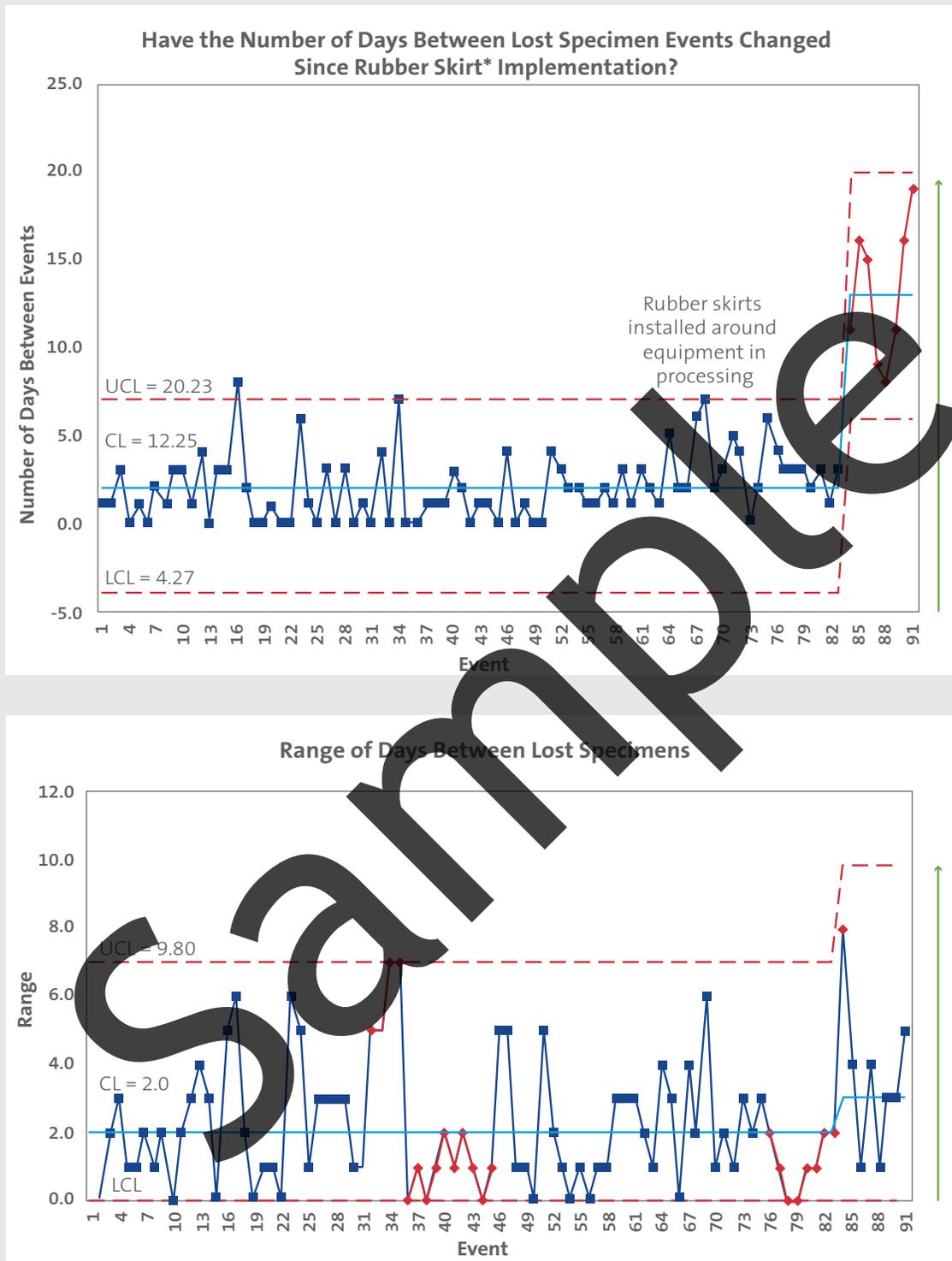
See CLSI document QMS15¹⁸ for information about laboratory internal audit programs.

2 Process to Develop and Use Quality Indicators

A complete laboratory QMS includes the means to systematically measure selected processes, derive information from the data, and identify actions needed for improving the laboratory. In a QMS, quality indicators complement the laboratory's internal audit program to systematically monitor the performance of laboratory processes. See CLSI document QMS15¹⁸ for information about laboratory internal audit programs.

The sequential activities in a well-defined measurement system may be depicted in a flow chart, such as the one shown in Figure 3. Appropriate indicators are chosen, defined, tested for effectiveness, and implemented. Collected data are analyzed at a defined frequency, with information summarized for management or other scheduled reviews in a timely manner. Decisions are made as to whether to continue or discontinue monitoring and whether opportunities for improvement have been identified.

The flow chart shows how the indicator management process is linked to other QMS processes such as management review and continual improvement. The links are important to visualize, so that all laboratory personnel understand the interrelationships between the quality system essentials (QSEs). The flow chart is constructed for an individual indicator. Laboratories can use this flow chart for each indicator selected to monitor.



* A “rubber skirt” is a rectangular piece of rubber that is attached under the bottom of laboratory equipment to keep any dropped specimen tubes from rolling under the equipment and not being visible.

Abbreviations: CL, control limit; LCL, lower control limit; UCL, upper limit.

Figure 12. A Control Chart and Its Related Range Chart

Sample



CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE®

950 West Valley Road, Suite 2500, Wayne, PA 19087 USA

P: +1.610.688.0100 Toll Free (US): 877.447.1888 F: +1.610.688.0700

E: customerservice@clsi.org www.clsi.org

PRINT ISBN 978-1-68440-037-9

ELECTRONIC ISBN 978-1-68440-038-6