CLINICAL AND LABORATORY STANDARDS INSTITUTE®

2nd Edition

QMS20

The Cost of Quality in Medical Laboratories

This guideline helps laboratories understand, apply, track, and manage the different types of quality costs that affect their processes, services, and financial well-being.

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

QMS20-Ed2
November 2020
Replaces QMS20-R

The Cost of Quality in Medical Laboratories

Lucia M. Berte, MA, MT(ASCP)SBB, DLM, CQA(ASQ) CMQ/OE
Anne T. Daley, MS, MT(ASCP)DLM, CMQ/OE(ASQ)CSBB
Jennifer Dawson, DLM(ASCP)SLS, QIHC, QLC/LSSBB/CPHQ/MHA
Sue Hetzel, MT(ASCP)SBB, CMQ/OE(ASQ)
Denise Lopez, MS, PHM
Phillip P. Morehouse, MLT, CMQ/OE(ASQ)
Mohammed Mustapha, MS
Christina Nickel, MHA, MLS(ASCP)^{CM}, CPHQ
Andrew Quintenz
Stephanie Shulman, DrPH, MS, MT(ASCP)

Abstract

Clinical and Laboratory Standards Institute guideline QMS20—*The Cost of Quality in Medical Laboratories* describes quality costs in laboratory expenditures (including prevention, appraisal, internal failure, and external failure costs) and suggests ways that laboratories can apply this information to continually improve their processes, services, and financial performance.

Clinical and Laboratory Standards Institute (CLSI). *The Cost of Quality in Medical Laboratories*. 2nd ed. CLSI guideline QMS20 (ISBN 978-1-68440-094-2 [Print]; ISBN 978-1-68440-095-9 [Electronic]). Clinical and Laboratory Standards Institute, USA, 2020.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Suggested Citation

CLSI. *The Cost of Quality in Medical Laboratories.* 2nd ed. CLSI guideline QMS20. Clinical and Laboratory Standards Institute; 2020.

Previous Edition:
May 2014

QMS20-Ed2

ISBN 978-1-68440-094-2 (Print)

ISBN 978-1-68440-095-9 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 40, Number 15

Contents

Contents (Continued)

Foreword

Most laboratories use methods such as QC, equipment calibration measurement, QA measurements of process performance, and more recently, implementation of a QMS, to determine the quality of examination results and laboratory services. However, laboratory personnel often are unaware of the laboratory's financial status and believe that staying within budget is sufficient, not considering that every time work is redone, the cost of laboratory services, as well as the cost of quality (COQ), increases. Personnel need to remember that corrections needed for improperly ordered examinations, unacceptable specimens, QC failures, lost reports, erroneous results, etc., increase laboratory and organizational costs and can adversely affect patient care. Historically referred to as the "cost of poor quality" (COPQ), these costs would not have been expended if laboratory quality were perfect.

A QMS alone does not ensure that all laboratory expenditures support quality. Figure 1 depicts a hierarchy of the stages of quality, synthesized from the concepts of acknowledged quality experts. This guideline presents the concepts and applications of COQ as a dimension that is part of every quality level. When a laboratory is committed to quality management and continual improvement, it applies the COQ to all laboratory processes.

Abbreviations: QA, quality assurance; QC, quality control; QMS, quality management system; TQM, total quality management.

Figure 1. COQ Is Part of Every Quality Level. COQ is shown as the base in every level of laboratory quality, from control of individual examination methods (QC); to preexamination, examination, and postexamination process performance (QA); to management of all technical and quality processes (QMS); and to the total satisfaction of personnel and customers (total quality management).

Although perfect laboratory processes are generally unattainable, laboratories still need to identify expenses created by waste, rework, and errors and compare them with the expense of preventing those problems. In the worldwide health care economic environment, laboratory funds should be spent primarily on quality activities that result in accurate diagnosis and proper treatment of patients. Money is wasted when unnecessary work is performed or when work that was not correctly performed is redone.

Regardless of whether a laboratory has implemented a QMS, the concepts and applications presented in this guideline can be used to identify and promote the principles of quality cost management for detecting and removing the costs of waste and errors.

Chapter 1

Introduction

This chapter includes:

- Guideline's scope and applicable exclusions
- Background information pertinent to the guideline's content
- Terminology information, including:
  - Terms and definitions used in the guideline
  - Abbreviations and acronyms used in the guideline

The Cost of Quality in Medical Laboratories

1 Introduction

1.1 Scope

The concept of "cost of quality" (COQ) is generic to all businesses. Therefore, this guideline is applicable to medical laboratories of any size, complexity, or specialty, including point-of-care testing (POCT). Other types of laboratories, such as public health, research, food, environmental, and veterinary laboratories, as well as other health care services, can also use the information in this guideline. QMS20 presents an initial approach that laboratories can take to identify quality costs and remove unnecessary expense from laboratory processes. Several laboratory examples provide tools and guidance for quantifying costs that support good quality and costs that result from poor quality. This guideline does not provide the means for laboratories to develop and implement the type of comprehensive quality cost accounting system recommended in the literature for manufacturing and other for-profit industries.[1,2]

1.2 Background

In many countries, laboratories often have limited resources to provide their services and are increasingly being asked to do more with a smaller budget. Wasting resources has a considerable negative effect on any operating budget, and laboratories rarely have a realistic idea of how much of their limited resources are lost to the cost of poor quality (COPQ). Evidence from the commercial business and manufacturing sectors shows that when companies adopt and apply a COQ concept, they reduce failure cost and improve quality for customers.[3] Today's medical laboratories have incoming revenue from charges and reimbursements and outgoing expenses for labor and operations. Because laboratories are also businesses, adopting a COQ concept helps them reduce waste and improve quality for patients and other customers at a reasonable cost. Application of COQ is a logical extension of a mature, effective QMS. Any laboratory, whether it has long had a complete QMS in place or has just started to implement a QMS, will benefit from understanding and applying these concepts in both management and technical operations.

1.3 Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization whenever 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 different countries and regions and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. CLSI recognizes its important role in these efforts, and its consensus process focuses on harmonization of terms to facilitate the global application of standards and guidelines. Table 1 is provided to clarify the intended interpretations of the following terms.

3 Types of Quality Costs

Quality cost types include costs associated with both attaining and failing to attain the desired level of quality in a service or product.

- **Cost of conformance:** The cost of conforming with industry and customer requirements. These costs include the cost of preventing nonconforming events (NCEs) and the cost of measuring, controlling, and/or inspecting quality levels.
- **Cost of NCEs:** The cost of failing to fulfill applicable requirements or achieve desired quality levels. These costs include the cost of correcting NCEs and any adverse effects on patients from incorrect examination results or misdiagnoses.

Figure 5 depicts common terminology for the quality cost types.

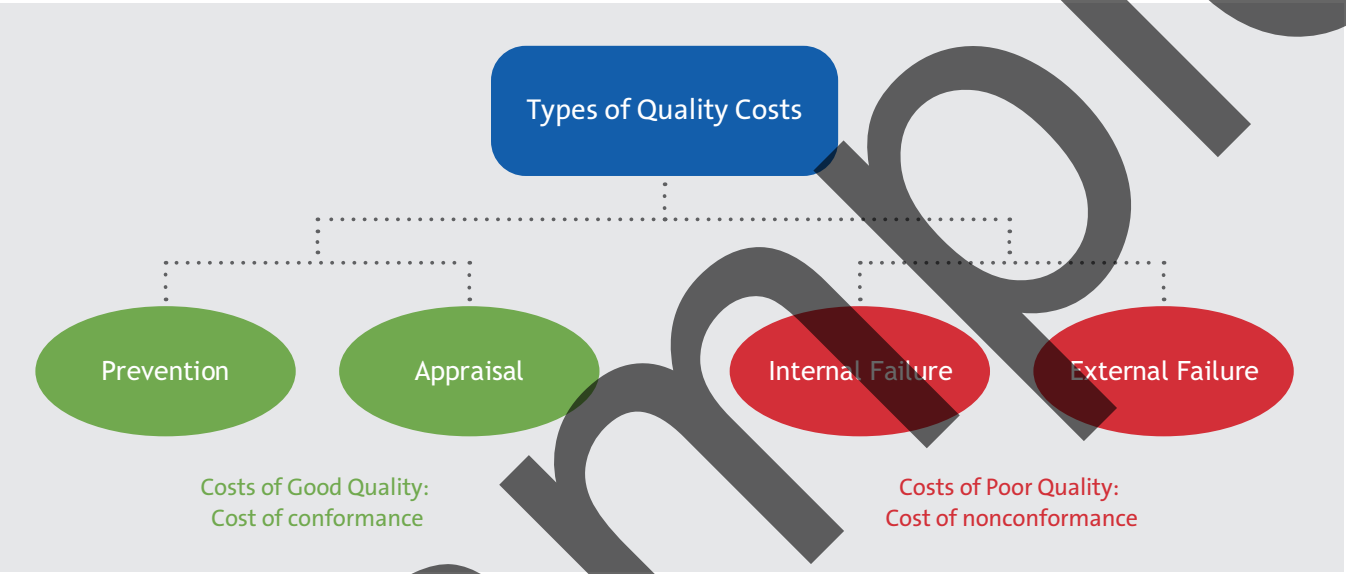

Figure 5. Types of Quality Costs

3.1 Conformance Costs

Conformance costs comprise prevention and appraisal costs.

3.1.1 Prevention Costs

Prevention costs are associated with laboratory activities specifically designed to prevent poor quality in laboratory services. These activities prevent errors or problems from occurring. It is much more expensive to detect and correct problems later in the workflow, when such problems could compromise the accuracy, reliability, and usefulness of examination results and the quality of laboratory services or patient safety.

The term "prevention costs" can be easily misinterpreted. Costs incurred to "prevent" an identified NCE from happening again are not prevention costs. Rather, they are internal failure costs, expended for a correction or corrective action to reduce or eliminate recurrence of an existing NCE. However, when a laboratory indicator shows an unfavorable trend and the laboratory conducts a root cause analysis and develops an improved process that will prevent any potential future NCE, the cost of these preemptive activities is considered a prevention cost. The distinction is one of timing. Costs to fix NCEs after they happen are failure costs, whereas costs to proactively avoid an NCE are prevention costs. Several examples of laboratory prevention costs are described in Subchapters 3.1.1.1 to 3.1.1.8.

3.2.3 Summary of Internal and External Failure Costs

There is an important distinction between the cost of appraisal activities that support laboratory quality and the failure costs of remedying any problems detected by appraisal activities. For example, the expense incurred by the laboratory to set up and maintain an NCE management program is considered an appraisal cost, with the labor time to enter NCEs into the reporting system, analyze the data and information they represent, and prepare the information for management review all being part of the appraisal cost. However, the time and expenses incurred in taking immediate action, investigating, and following up on each NCE, complaint, or inquiry are considered failure costs. The classification of a failure as "internal" or "external" depends on whether the NCE occurred within the laboratory or after examination results and reports were released to the customer. Appendix A2 is an expanded list of internal and external failure costs, derived from an industry model and adapted for the laboratory.[4]

3.3 Effect of Cost of Quality on the Laboratory's Budget

Although the relationship might not be exactly logarithmic, Figure 6 applies the "1:10:100 rule,"[38] showing that the cost of prevention and appraisal efforts is far less than the cost of rectifying failures. Published quantitative data in the manufacturing and commercial business sectors repeatedly demonstrate this relationship.

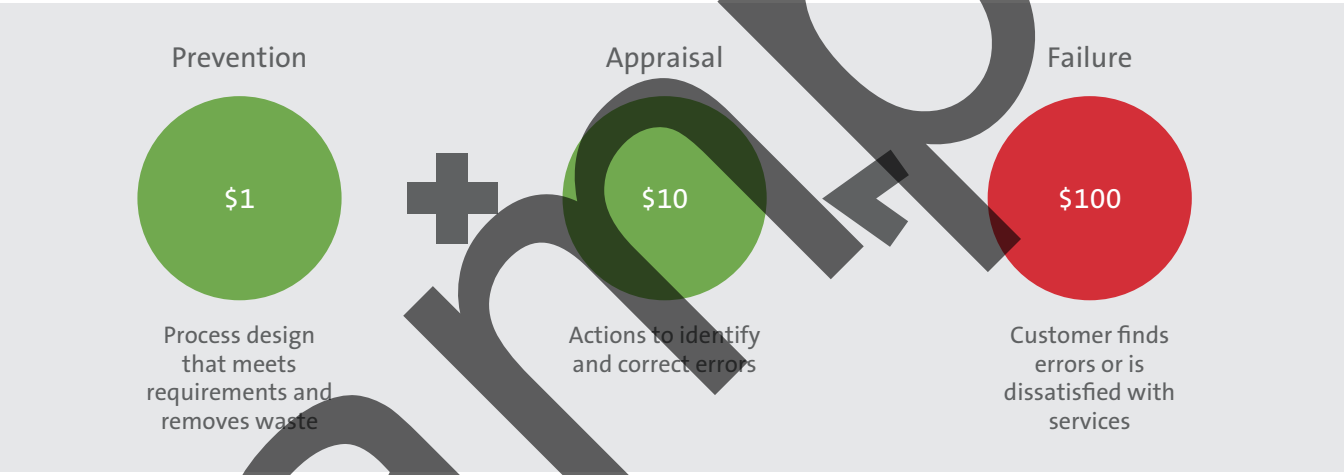

Figure 6. The Combined Cost of Prevention and Appraisal Is Always Less Than the COPQ

The necessary funding to maintain good quality through required prevention and appraisal activities should always be included in the laboratory's annual operating budget. Nonlabor prevention and appraisal costs commonly derive from regulatory and accreditation requirements and are also usually included in the laboratory's budget:

- QC materials
- Calibration materials
- PT program participation
- External assessments
- Equipment maintenance services
- Computer system support

Related CLSI Reference Materials[a]

GP49 **Developing and Managing a Medical Laboratory (Test) Utilization Management Program. 1st ed., 2017.** This report provides guidance for initiating, developing, and maintaining an effective test utilization program.

QMS01 **A Quality Management System Model for Laboratory Services. 5th ed., 2019.** This guideline provides a model for medical laboratories to organize the implementation and maintenance of an effective quality management system.

QMS02 **Quality Management System: Development and Management of Laboratory Documents. 6th ed., 2013.** This document provides guidance on the processes needed for document management, including creating, controlling, changing, and retiring a laboratory's policy, process, procedure, and form documents in both paper and electronic environments.

QMS03 **Training and Competence Assessment. 4th ed., 2016.** This guideline provides a structured approach for developing effective laboratory personnel training and competence assessment programs.

QMS06 **Quality Management System: Continual Improvement. 3rd ed., 2011.** This guideline considers continual improvement as 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.

QMS11 **Nonconforming Event Management. 2nd ed., 2015.** Grounded in the principles of quality management, risk management, and patient safety, this guideline provides an outline and content for developing a program to manage a laboratory's nonconforming events.

QMS12 **Developing and Using Quality Indicators for Laboratory Improvement. 2nd ed., 2019.** This guideline describes how laboratories can develop and use quality indicators to measure and monitor performance of laboratory processes and identify opportunities for improvement.

QMS13 **Quality Management System: Equipment. 1st ed., 2011.** This guideline provides recommendations for establishing equipment management processes from selection through decommission of equipment used in the provision of laboratory services.

QMS14 **Quality Management System: Leadership and Management Roles and Responsibilities. 1st ed., 2012.** 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] CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

Related CLSI Reference Materials (Continued)

QMS15 **Assessments: Laboratory Internal Audit Program. 1st ed., 2013.** This document provides guidance for how a laboratory can establish an internal audit program to enhance the quality of its services through continual improvement. Whereas an audit program defines the "who," "what," "when," "where," and "how" of meeting requirements for internal auditing, the audit process describes the details of how to conduct individual laboratory internal audits.

QMS17 **External Assessments, Audits, and Inspections of the Laboratory. 1st ed., 2017.** This guideline provides recommendations for establishing and maintaining a process to assist the laboratory in achieving a continuous state of readiness for assessment by an external organization. This includes selecting and evaluating an external assessment organization, preparing for and undergoing a successful assessment, and sustaining ongoing readiness for assessment.

QMS18 **Process Management. 1st ed., 2015.** This guideline describes four requirements for managing laboratory processes and provides suggestions for effectively meeting regulatory and accreditation requirements, optimizing efficient use of resources, and contributing to patient safety and positive outcomes.

QMS19 **Customer Focus in a Quality Management System. 1st ed., 2017.** This guideline provides useful information for how laboratories can develop and maintain a customer focus and meet the regulatory and accreditation requirements for managing external and internal customers.

QMS21 **Purchasing and Inventory Management. 1st ed., 2016.** This guideline describes effective purchasing and inventory management processes, which ensure availability of the appropriate equipment, instruments, reagents, consumable materials, other products, and services procured from external sources needed for providing quality laboratory services.

QMS23 **General Laboratory Equipment Performance Qualification, Use, and Maintenance. 2nd ed., 2019.** This guideline reflects requirements and provides recommendations for use in planning, recording, and monitoring performance qualification, function checks, calibration verification, and preventive maintenance activities for general laboratory equipment. Examples are included to provide insight and enhance comprehension.

QMS24 **Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality. 3rd ed., 2016.** This guideline describes an approach for a complete proficiency testing (PT) process and provides assistance to laboratories in using PT as a quality improvement tool.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

PRINT ISBN 978-1-68440-094-2

ELECTRONIC ISBN 978-1-68440-095-9

QMS20-Ed2