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.

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Clinical and Laboratory Standards Institute
P: +1.610.688.0100
F: +1.610.688.0700
www.clsi.org
standard@clsi.org

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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.

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Committee Membership

Consensus Council

James R. Petisce, PhD
Chairholder
BD Diagnostic Systems
USA

Mary Lou Gantzer, PhD, FACB
Vice-Chairholder
USA

Anne T. Daley, MS, MT(ASCP)DLM, CMQ/OE(ASQ)CSBB
ARUP Laboratories
USA

Avis Danishefsky, PhD
FDA Center for Devices and Radiological Health
USA

Collette Fitzgerald, PhD
Centers for Disease Control and Prevention
USA

Loralie J. Langman, PhD, DABCC, FACB, F-ABFT
Mayo Clinic
USA

Michelle McLean, MS, MT(ASCP), BS
Greiner Bio-One, Inc.
USA

Tania Motschman, MS, MT(ASCP)SBB
Laboratory Corporation of America
USA

M. Laura Parnas, PhD, DABCC
Roche Diagnostics
USA

Robert Rej, PhD
New York State Department of Health – Wadsworth Center
USA

Matthew A. Wikler, MD, FIDSA, MBA
IDTD Consulting
USA

Document Development Committee on Cost of Quality

Lucia M. Berte, MA, MT(ASCP)SBB, DLM, CQA(ASQ)CMQ/OE
Co-Chairholder
Laboratories Made Better!
USA

Anne T. Daley, MS, MT(ASCP)DLM, CMQ/OE(ASQ)CSBB
Co-Chairholder
ARUP Laboratories
USA

Sue Hetzel, MT(ASCP)SBB, CMQ/OE(ASQ)
Committee Secretary
Aurora Health Care/ACL Laboratories
USA

Jennifer Dawson, DLM(ASCP)SLS, QIHC, QLC/LSSBB/CPHQ/MHA
Human Longevity, Inc.
USA

Leonard K. Dunikoski, Jr., PhD, DABCC
BD
USA

Denise Lopez, MS, PHM
Tulare County Public Health Laboratory
USA

Phillip P. Morehouse, MLT, CMQ/OE(ASQ)
LifeLabs
Canada

Mohammed Mustapha, MS
Mayo Clinic
USA

Christina Nickel, MHA, MLS(ASCP)^{CM}, CPHQ
Bryan Medical Center
USA

Andrew Quintenz
Bio-Rad Laboratories, Inc.
USA

Stephanie Shulman, DrPH, MS, MT(ASCP)
New York State Department of Health
USA

Expert Panel on Quality Management Systems

Laura McClannan, MS, MT(ASCP)SBB, CQA(ASQ)
Chairholder
Oklahoma Blood Institute
USA

Debra Kuehl, MS, M(ASCP)
Vice-Chairholder
Centers for Disease Control and Prevention
USA

Lucia M. Berte, MA, MT(ASCP)SBB, DLM, CQA(ASQ)CMQ/OE
Laboratories Made Better!
USA

Julie Coffey, MLT, ART, CMQ/OE(ASQ), CQA
Institute for Quality Management in Healthcare
Canada

Maura Daniels, BS, MT(ASCP)
Sysmex America
USA

Lorie Erikson, MS, MT(ASCP), CQA(ASQ)
FDA Center for Devices and Radiological Health
USA

Sheri L. Hearn, BS, MPH
Oregon State Public Health Laboratory
USA

Karen Heaton, MLT(CMLTA)
Alberta Public Laboratories
Canada

Daniel J. Scungio, MT(ASCP), SLS, CQA(ASQ)
Sentara Healthcare
USA

Jean Tenuta, MS, MBA, MLS(ASCP)^{CM}, DLM, SLS, CQA(ASQ)
BD
USA

Staff

Clinical and Laboratory Standards Institute
USA

Jennifer K. Adams, MT(ASCP), MSHA
Project Manager

Megan L. Tertel, MA, ELS
Editorial Manager

Catherine E.M. Jenkins
Editor

Kristy L. Leirer, MS
Editor

Laura Martin
Editor

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Leonard K. Dunikoski, Jr., PhD, DABCC
BD
USA

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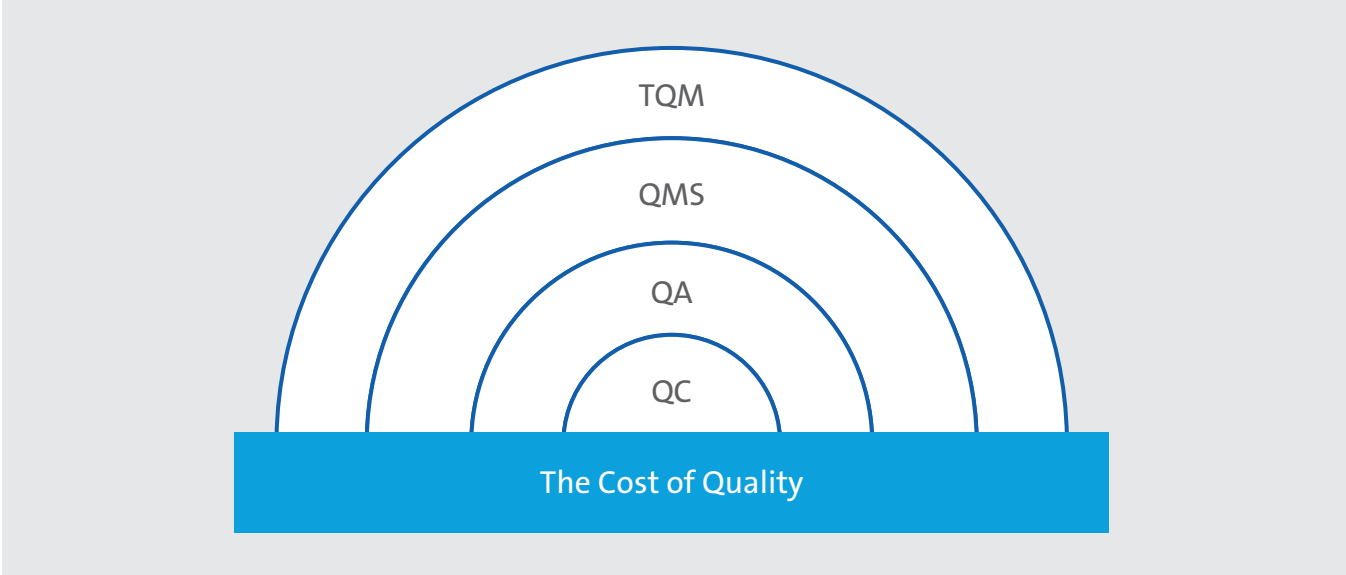
Foreword

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.

Overview of Changes

This guideline replaces the previous edition of the approved report, QMS20-R, published in 2014. Several changes were made in this edition, including:

- Making a clearer distinction between COQ and the different quality cost types
- Separating text into theory (Chapters 1 to 4) and application (Chapters 5 and 6)
- Including additional examples for calculating laboratory quality costs
- Providing a tool for calculating the COPQ

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

Appraisal cost
Cost of poor quality
Cost of quality
Failure cost
Quality cost
Prevention cost

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.