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QMS20-R

Understanding the Cost of Quality in the Laboratory; A Report

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This report provides guidance to a laboratory in understanding and managing the different types of quality costs that affect processes, services, and financial well-being.

A CLSI report for global application.

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Understanding the Cost of Quality in the Laboratory; A Report

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Abstract

Clinical and Laboratory Standards Institute document QMS20-R—*Understanding the Cost of Quality in the Laboratory; A Report* introduces the types of quality costs in laboratory expenditures—prevention, appraisal, internal failure, and external failure—and suggests ways that laboratories can apply this information to continually improve their processes, services, and financial well-being.

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Contents

Abstract	i
Committee Membership	iii
Foreword	vii
Chapter 1: Introduction	1
1.1 Scope	2
1.2 Background	2
1.3 Terminology	3
Chapter 2: The Cost of Quality	9
2.1 The Concept of Quality Costs	10
2.2 Types of Quality Costs	12
2.3 The Effect of Quality Costs on the Laboratory's Budget	24
2.4 Important Relationships Between Quality and Cost	26
2.5 Traditional Approaches to Reducing Failure Costs	29
2.6 A Quality Management System Approach to Quality Costs	31
2.7 Overview of Quality-based Costing Using Laboratory Failure Costs	36
2.8 Quality-based Costing Using Laboratory Failure Costs	37
2.9 Failure Costs in Quality Reports for Management Review	39
2.10 Ways to Eliminate Failure Costs	40
2.11 An Action Plan for Transitioning to a Cost of Quality Culture	44
Chapter 3: Conclusion	49
Chapter 4: Supplemental Information	53
References	54
Additional References	56
Appendix A1. A Detailed Listing of Prevention and Appraisal Costs	57
Appendix A2. A Detailed Listing of Internal and External Failure Costs	59

Contents (Continued)

Appendix B1. Example of a Generic Worksheet to Calculate Failure Cost	60
Appendix B2. Example of a Calculated Failure Cost for a Recollected Blood Sample	61
Appendix B3. Example of a Calculated Failure Cost for a Failed Instrument Examination	62
Appendix B4. Instructions for Use of the Generic Worksheets to Calculate Failure Cost	63
Appendix C. Example of a Quality Report With Calculated Failure Costs	65
The Quality Management System Approach	66
Related CLSI Reference Materials	68

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Foreword

Most laboratories are attentive to the quality of examination results and laboratory services they provide through efforts such as QC of methods, calibration of measuring equipment, and quality assurance measurements of process performance. Yet most nonmanagement laboratory staff is unaware of the quality of the laboratory's financial status, and believe that staying within budget is sufficient. **Every time work is redone, the cost of laboratory services—therefore, the cost of quality—increases.** Consider the cost to the laboratory and to the organization—and the potential adverse effects on patient care—of corrections needed for unacceptable samples, QC failures, lost reports, and erroneous results. These are costs that would not have been expended if laboratory quality were truly perfect, historically referred to as “the cost of poor quality.”¹

A QMS alone is not enough to ensure that all laboratory expenditures support quality. Table 1 was introduced in CLSI document QMS01² and presents a hierarchy defining the stages of quality³ synthesized from the concepts of acknowledged quality experts.^{4,5} CLSI document QMS01² presented this table with the third row, “Quality Management System,” shaded. The topic for this report, however, is one level above QMS, presenting concepts and applications of the “cost of quality.” When a laboratory is committed to quality management and continual improvement, the next logical step up the hierarchy is to understand and apply quality cost concepts.



IMPORTANT NOTE:

Every time work is redone, the cost of laboratory services—therefore, **the cost of quality—increases.**

Table 1. Stages of Quality. The economic aspects of costs that support quality and those resulting from poor quality form the basis for this report.

	Stage	Activities Performed
	Total Quality Management	Management approach centered on sustained high quality, by focusing on long-term success through customer satisfaction
	Quality Cost Management	Measurement system for the economic aspects of the "cost of quality"
	Quality Management System	Systematic process-oriented approach to meeting quality objectives
	Quality Assurance	Planned and systematic activities to provide confidence that an organization fulfills requirements for quality
	Quality Control	Operational process control techniques to fulfill quality requirements for regulatory compliance and accreditation ⁶

 **NOTE:**

Whether or not the laboratory has implemented a **complete QMS**, the concepts and applications presented in this document can still be used to identify and promote the costs of quality management and detect and remove the costs of waste and errors.

Although perfect laboratory processes are generally unattainable, laboratories still have a real need for identifying expenses created by rework and errors and comparing them to the expense of preventing those problems. Around the world, the health care economic environment is such that laboratory funds should be spent only on quality activities that bring about good diagnosis and treatment of patients; redoing work that was not done correctly the first time wastes money.

Whether or not the laboratory has implemented a complete QMS, the concepts and applications presented in this document can still be used to identify and promote the costs of quality management and detect and remove the costs of waste and errors.

KEY WORDS

Appraisal cost

Cost of poor quality

Cost of quality

Failure cost

Quality cost

Prevention cost

Chapter 1

Introduction

This report introduces the types of quality costs in laboratory expenditures:

- ▶ Prevention
- ▶ Appraisal
- ▶ Failure
 - Internal failure
 - External failure

It also suggests ways that laboratories can apply this information to continually **improve their processes, services, and financial performance.**



Understanding the Cost of Quality in the Laboratory; A Report

1 Introduction

QUALITY QUOTE:

“Good things only happen when planned; bad things happen on their own.”

Philip Crosby

1.1 Scope

The concepts of quality costs are generic; therefore, this technical report is applicable to medical laboratories of any size, complexity, or specialty, including point-of-care testing. Other types of laboratories, such as public health, research, food, environmental, and veterinary laboratories, can also use the information in this technical report.

This document presents an initial approach laboratories can take to identify quality costs and remove unnecessary expense from laboratory processes. This report is not meant for laboratories to develop and implement the type of comprehensive quality cost accounting system suggested in the literature for manufacturing and other for-profit industries.^{1,7}

1.2 Background

In the present health care economic environment, laboratories worldwide often have only limited resources to provide their services. 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 being lost to the “cost of poor quality (COPQ).”

Ample evidence exists in the business and manufacturing sectors that when companies adopt a **cost of quality concept**, they are successful in reducing failure cost and improving quality for customers.⁸ Today’s medical laboratories have incoming revenue from charges and reimbursements and outgoing expenses for labor and operations. Laboratories are also businesses; therefore, there is no reason to believe that adopting a cost of quality concept would not also help laboratories reduce waste and improve quality to patients and other customers at a reasonable cost.

Cost of quality concepts are a logical extension of a mature, effective QMS. Wherever they may be in their implementation of a QMS, laboratories will benefit from understanding and applying these concepts in both management and technical operations.

! NOTE:

Wherever a laboratory may be in its QMS implementation, it **will** benefit from understanding and applying quality cost concepts to both management and technical processes.

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

QMS20-R 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, beginning on page 68.

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											
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01
			QMS03				QMS02				
											QMS06
									QMS11		QMS12
										QMS15	

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.

QMS20-R does not address any of the clinical laboratory path of workflow steps. For a description of the document 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
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01

Related CLSI Reference Materials*

- QMS01-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.
- QMS02-A6** **Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition (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-A3** **Training and Competence Assessment; Approved Guideline—Third Edition (2009).** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.
- QMS06-A3** **Quality Management System: Continual Improvement; Approved Guideline—Third Edition (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-A** **Management of Nonconforming Laboratory Events; Approved Guideline (2007).** This guideline provides an outline and the content for developing a program to manage a health care service’s nonconforming events that is based on the principles of quality management and patient safety.
- QMS12-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.
- QMS15-A** **Assessments: Laboratory Internal Audit Program; Approved Guideline (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.

* 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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