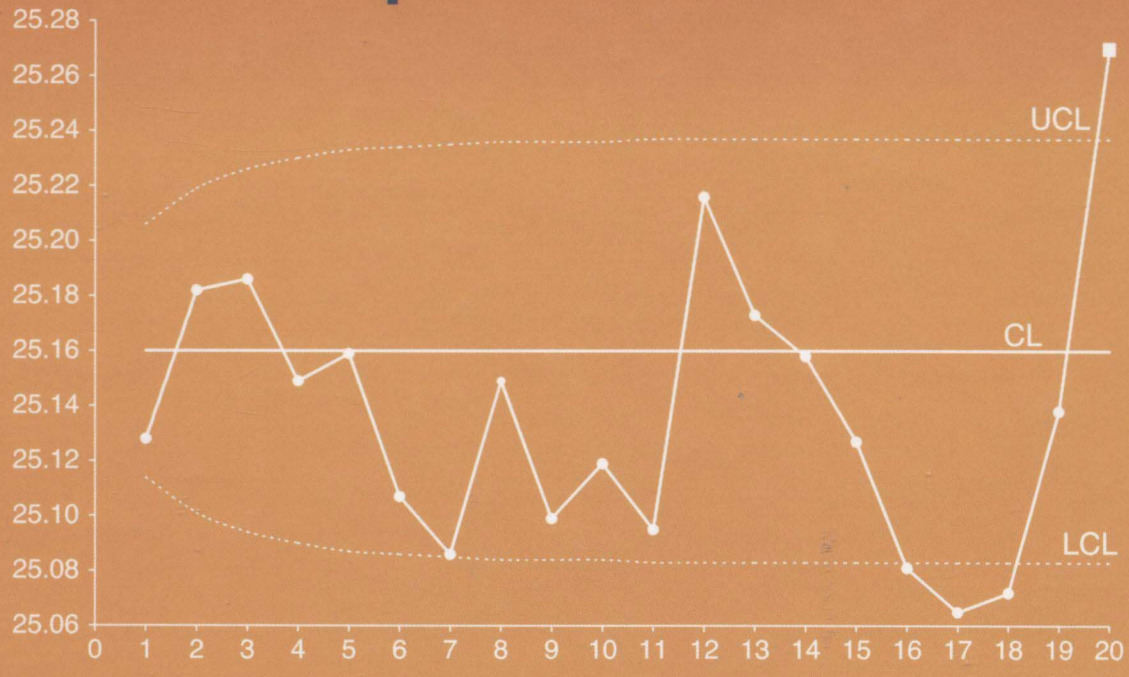
Fundamentals of Quality Control and Improvement



FOURTH EDITION

Amitava Mitra

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FUNDAMENTALS OF QUALITY CONTROL AND IMPROVEMENT

Fourth Edition

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To the memory of my parents,
who instilled the importance of
an incessant inquiry for knowledge —
and whose inspiration transcends mortality

PREFACE

This book covers the foundations of modern methods of quality conrol and improvement that are used in the manufacturing and service industries. Quality is key to surviving tough competition. Consequently, business needs technically competent people who are well-versed in statistical quality control and improvement. This book should serve the needs of students in business and management and students in engineering, technology, and related disciplines. Professionals will find this book to be a valuable reference in the field.

An outgrowth of many years of teaching, research, and consulting in the field of quality assurance and statistical process control, the methods discussed in this book apply statistical foundations to real-world situations. Mathematical derivations and proofs are kept to a minimum to allow a better flow of material. Although an introductory course in statistics would be useful to a reader, the foundations of statistical tools and techniques discussed in Chapter 4 should enable students without a statistical background to understand the material.

Prominently featured are many real-world examples. For each major concept, at least one example demonstrates its application. The field of health care within the service sector is of immense importance. From an individual or a population perspective, creating processes that provide quality health care are desirable. Additionally, the growing escalation of the cost of providing quality care raises the question of improving the effectiveness and efficiency of all processes associated with the delivery of such services. For this reason, issues related to health care quality have been addressed in several chapters, for example, Chapters 3, 5, 7, 8, 11, and 13.

The book is divided into five parts. Part I, which deals with the philosophy and fundamentals of quality control, consists of three chapters. Chapter 1 is an introduction to quality control and the total quality system. In addition to introducing the reader to the nomenclature associated with quality control and improvement, it provides a framework for the systems approach to quality. Discussions of quality costs and their measurement, along with activity-based costing, are presented. In Chapter 2 we examine philosophies of such leading experts as Deming, Crosby, and Juran. Deming's 14 points for management are analyzed, and the three philosophies are compared. Features of quality in the service sector are introduced. Chapter 3 covers quality management practices, tools, and standards. Topics such as total quality management, balanced scorecard, quality function deployment, benchmarking, failure mode and effects criticality analysis, and tools for quality improvement are presented. Concepts of health care analytics and its associated challenges are discussed.

Part II deals with the statistical foundations of quality control and consists of two chapters. Chapter 4 offers a detailed coverage of statistical concepts and techniques in quality control and improvement. It present a thorough treatment of inferential statistics. Depending on the student's background, only selected sections of this chapter will need to be covered.

Chapter 5 covers some graphical methods of analyzing empirical distributions. Identification of the population distribution using probability plotting along with the several transformations to achieve normality are presented. Analysis of count data, including contingency table analysis and measures of association, are discussed. Strategic and operational decision making, through analyses of survey data from customers, is included. Finally, some common sampling designs and determination of an appropriate sample size are features of this chapter.

The field of statistical quality control consists of two areas: statistical process control and acceptance sampling. Part III deals with statistical process control and consists of four chapters. Chapter 6 provides an overview of the principles and use of control charts. A variety of control charts for variables are discussed in detail in Chapter 7. In additon to charts for the mean and range, those for the mean and standard deviation, individual units, cumulative sum, moving average, and geometric moving average are presented. Several types of risk-adjusted control charts are included. Multivariate control charts are also introduced. Control charts for attributes are discussed in Chapter 8. Charts such as the p-chart, np-chart, c-chart, u-chart, g-chart, and U-chart are presented. Here also, risk-adjusted p-charts and u-charts are included. The topic of process capability analysis is discussed in Chapter 9. The ability of a process to meet customer specifications is examined in detail. Process capability analysis procedures and process capability indices are also treated in depth. The chapter covers proper approaches to setting tolerances on assemblies and components. Part III should form a core of material to be covered in most courses.

Part IV deals with acceptance sampling procedures and cosists of one chapter. Methods of acceptance of a product based on information from a sample are described. Chapter 10 presents acceptance sampling plans for attributes and variables. Lot-by-lot attribute and variable sampling plans are described. With the emphasis on process control and improvement, sampling plans do not occupy the forefront. Nevertheless, they are included to make the discussion complete.

Part V deals with product and process design and consists of three chapters. With the understanding that quality improvement efforts are generally being moved further upstream, these chapters constitute the backbone of current methodology. Chapter 11 deals with reliability and explores the effects of time on the proper functioning of a product. The topic of survival analysis is included. Chapter 12 provides the fundamentals of experimentals design and the Taguchi method. Different designs, such as the completely randomized design, randomized block design, and Latin square design are presented. Estimation of treatment effects using factorial experiments is included. This chapter also provides a treatment of the Taguchi method for design and quality improvement; the philosophy and fundamentals of this method are discussed. Chapter 13 discusses process modeling through regression analysis. Estimation of model parameters, making inferences from the model, and issues in multiple regression are covered. Logistic regression analysis is also introduced. Various sections of Part V could also be included in the core material for a quality control course.

This book may serve as a text for an undergraduate or graduate course for students in business and management. It may also serve the needs of students in engineering, technology, and related disciplines. For a one-semester or one-quarter course, Part I, selected portions of Part II, selected portions of Part III, and selected portions of Part V could be covered. For a

two-semester or two-quarter course, all of Parts II, III, and V, along with portions from Part IV, could be covered as well.

CHANGES IN THE FOURTH EDITION

Some major changes have been made in the fourth edition. With the growing importance of the field of health care, an effort has been made to incorporate concepts, tools, and techniques to address issues in the domain of health care quality. These are dealt with over a multitude of chapters, that is, Chapters 3, 5, 7, 8, 11, and 13.

Chapter 3 now includes a discussion of the uniqueness of the health care sector and the utilization of health care analytics using data, from various sources, to create a decision support system. Such a system will not only improve processes and patient outcomes as well as physician performance but also lead to an improved population health.

An important form of feedback from customers on a product or service is through surveys. In health care, patients, for example, indicate their degree of satisfaction, with the various processes/procedures encountered, through questionnaires that are usually based on a five-point ordinal Likert scale. Chapter 5 presents some methods for displaying and analyzing ordinal or count data based on questionnaires. *Strategic implications* on decisions for management are also discussed, based on the *degree of satisfaction* and the *degree of importance* of each question item included in the survey.

The concept of risk adjustment, as it applies to health care applications, has been incorporated in the material on variable control charts in Chapter 7. In this context, the risk-adjusted cumulative sum chart, risk-adjusted sequential probability ratio test, risk-adjusted exponentially weighted moving average chart, and variable life-adjusted display chart are presented in this chapter.

Under attribute control charts, risk-adjusted p-charts for the proportion of patients that survive a certain type of illness or surgical procedure and risk-adjusted u-charts for monitoring the number of nonconformities per unit, for example, the number of pressure ulcers per patient day, are presented in Chapter 8. Further, monitoring of low-occurrence nonconformities in health care, such as surgical wound infections or gastrointestinal infections, are also discussed. Such monitoring may be accomplished through tracking of the time between events, in this case, infections, through a g-chart.

Another important application in health care is that of survival analysis. Often, in observational studies dealing with patients, the exact time of death of a patient may not be known. Moreover, some patients may leave the observational study. In such instances, censored data are available. The Kaplan–Meier product limit estimator of the survival function is introduced in Chapter 11. Methods are presented for comparison of survival functions of two groups in order to determine the statistical significance of a particular treatment.

A new chapter on process modeling through regression analysis has been added in this edition. Regression modeling is a versatile tool that may be used in manufacturing and service applications. It promotes the development of a functional relationship between a selected dependent variable and one or more independent variables. Chapter 13 discusses the concepts in the formulation of such models and assists with the identification of independent variables that have a significant effect on the dependent variable. In this chapter, logistic regression models are also introduced where the dependent variable is binary in nature. Such models have useful applications in health care.

ACKNOWLEDGMENTS

Many people have contributed to the development this book, and thanks are due to them. Modern trends in product/process quality through design and improvement, as well as discussions and questions from undergraduate and graduate classes over the years, have shaped this book. Applications encountered in a consulting environment have provided a scenario for examples and exercises. Input from faculty and professional colleagues, here and abroad, has facilitated composition of the material. Constructive comments from the reviewers have been quite helpful. Many of the changes in the fourth edition are based on input from those who have used the book as well as from reviewers.

I am grateful to Margie Maddox of the College of Business at Auburn University for a remarkable job in the preparation of the manuscript. I would like to thank Minitab, Inc. (Quality Plaza, 1829 Pine Hall Road, State College, PA 16801-3008) for its assistance in providing software support. My editor, Jon Gurstelle, is to be commended for his patience and understanding.

Learning is a never-ending process. It takes time and a lot of effort. So does writing and revising a book. That has been my reasoning to my wife, Sujata, and son, Arnab. I believe they understand this—my appreciation to them. Their continual support has provided an endless source of motivation. As I complete this edition, a source of joy has been my daughter-in-law, Sharen, who brings a charisma that bonds the family.

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ABOUT THE COMPANION WEBSITE

This book is accompanied by a companion website:
www.wiley.com\go\mitra\QualityControl4e

The website includes:
- Instructor's solutions manual

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