Fundamentals of Quality Control and Improvement

FIFTH EDITION

Amitava Mitra

WILEY
FUNDAMENTALS OF QUALITY CONTROL AND IMPROVEMENT
FUNDAMENTALS
OF QUALITY CONTROL
AND IMPROVEMENT

Fifth Edition

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Auburn, USA

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

755
This book covers the foundations of modern methods of quality control and improvement that are used in the manufacturing and service industries. Quality is key to surviving tough competition in a dynamic and global environment. Consequently, organizations need 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, 10, and 12.

The book is divided into four 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 presents 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 addition 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 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 design methodology. Chapter 10 deals with reliability and explores the effects of time on the proper functioning of a product. The topic of survival analysis is included and health-care applications are provided. Chapter 11 provides the fundamentals of experimental 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 12 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. Nominal polytomous and ordinal polytomous response variables are discussed. The problem of classification of a binary response variable and associated performance measures are covered. Various sections of Part V could also be included in the core material for a quality control course.

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 IV could be covered. For a two-semester or two-quarter course, all of Parts II and III, along with portions from Part IV, could be covered as well.
Some major changes have been made keeping with the emphasis 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, 10, and 12. Case studies have been included in several chapters.

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 10. Methods are presented for comparison of survival functions of two groups in order to determine the statistical significance of a particular treatment.

The chapter on process modeling through regression analysis has been greatly expanded. 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 12 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. Coverage of nominal polytomous and ordinal polytomous response variables are included. An important problem of classification of a binary response variable and its associated performance measures are discussed.
ACKNOWLEDGMENTS

Many people have contributed to the development of 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 fifth 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 Harbert 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, Kalli Schultea, and my associate editor, Kathleen Santoloci, are to be commended for their patience and understanding.

Learning is a never-ending process. It requires dedication and perseverance. 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 continued support as well as that of Sharen, my radiant daughter-in-law, has provided the motivation to continue with this work. Adding to this enthusiasm, is the boundless source of joy from my grandson, Dev. The arrival of my second grandson, Riz, reinforces the numerous blessings, I have been fortunate to receive.
ABOUT THE COMPANION WEBSITE

This book is accompanied by a companion website:

www.wiley.com/go/mitra/QualityControl5e

The website includes:
- Instructor’s solutions manual
- Instructor’s Power Point transparencies
- Student’s data files
PART I

PHILOSOPHY AND FUNDAMENTALS
INTRODUCTION TO QUALITY CONTROL AND THE TOTAL QUALITY SYSTEM

1-1 INTRODUCTION AND CHAPTER OBJECTIVES

We were about to embark on a short trip for a few hours, when my daughter-in-law asked curiously, “Dad, have we taken the I-phone that has Dev’s favorite videos?” My grandson, Dev, gets bored if he is not actively participating in something! While snacks are obviously one of those things that will keep him happy, perhaps a diversion without food intake is better. He loves to watch short video clips of his past experiences in different situations—whether it is a birthday party, playing with his friends, or listening to storybooks being read. Hence, the enquiry about the “savior” I-phone. Isn’t it amazing of the rapid pace at which technology keeps on changing? What is more amazing is the proficiency at which children of this decade, in the twenty-first century, are comfortable with technology. It is a part-and-parcel of their life and they feel quite “at home” in maneuvering through various options available through the I-phone. Come to think of it, the design of the I-phone had to keep in minds the “needs of the
customer” as well as the “ease of use of the product.” This is precisely what quality improvement is about to create products or deliver services that meet or exceed the expectations of the customer. In that sense, as customer needs or expectations change with time, the process of quality improvement is a never-ending journey.

The objectives of this chapter are, first, to define quality as it relates to the manufacturing and service sector, to introduce the terminology related to quality, and to set up a framework for the design and implementation of quality. Of importance will be the ability to identify the unique needs of the customer, which will assist in maintaining and growing market share. A study of activity-based product costing will be introduced along with the impact of quality improvement on various quality-related costs. The reader should be able to interpret the relationships among quality, productivity, long-term growth, and customer satisfaction.

1-2 EVOLUTION OF QUALITY CONTROL

The quality of goods produced and services rendered has been monitored, either directly or indirectly, since time immemorial. However, using a quantitative base involving statistical principles to control quality is a modern concept.

The ancient Egyptians demonstrated a commitment to quality in the construction of their pyramids. The Greeks set high standards in arts and crafts. The quality of Greek architecture of the fifth century B.C. was so envied that it profoundly affected the subsequent architectural constructions of Rome. Roman-built cities, churches, bridges, and roads inspire us even today.

During the Middle Ages and up to the nineteenth century, the production of goods and services was confined predominantly to a single person or a small group. The groups were often family-owned businesses, so the responsibility for controlling the quality of a product or service lay with that person or small group—those also responsible for producing items conforming to those standards. This phase, comprising the time period up to 1900, has been labeled by Feigenbaum (1983) the operator quality control period. The entire product was manufactured by one person or by a very small group of persons. For this reason, the quality of the product could essentially be controlled by a person who was also the operator, and the volume of production was limited. The worker felt a sense of accomplishment, which lifted morale and motivated the worker to new heights of excellence. Controlling the quality of the product was thus embedded in the philosophy of the worker because pride in workmanship was widespread.

Starting in the early twentieth century and continuing to about 1920, a second phase evolved, called the foreman quality control period (Feigenbaum 1983). With the Industrial Revolution came the concept of mass production, which was based on the principle of specialization of labor. A person was responsible not for production of an entire product but rather for only a portion of it. One drawback of this approach was the decrease in the workers’ sense of accomplishment and pride in their work. However, most tasks were still not very complicated, and workers became skilled at the particular operations that they performed. People who performed similar operations were grouped together. A supervisor who directed that operation now had the task of ensuring that quality was achieved. Foremen or supervisors controlled the quality of the product, and they were also responsible for operations in their span of control.

The period from about 1920 to 1940 saw the next phase in the evolution of quality control. Feigenbaum (1983) calls this the inspection quality control period. Products and processes became more complicated, and production volume increased. As the number of workers