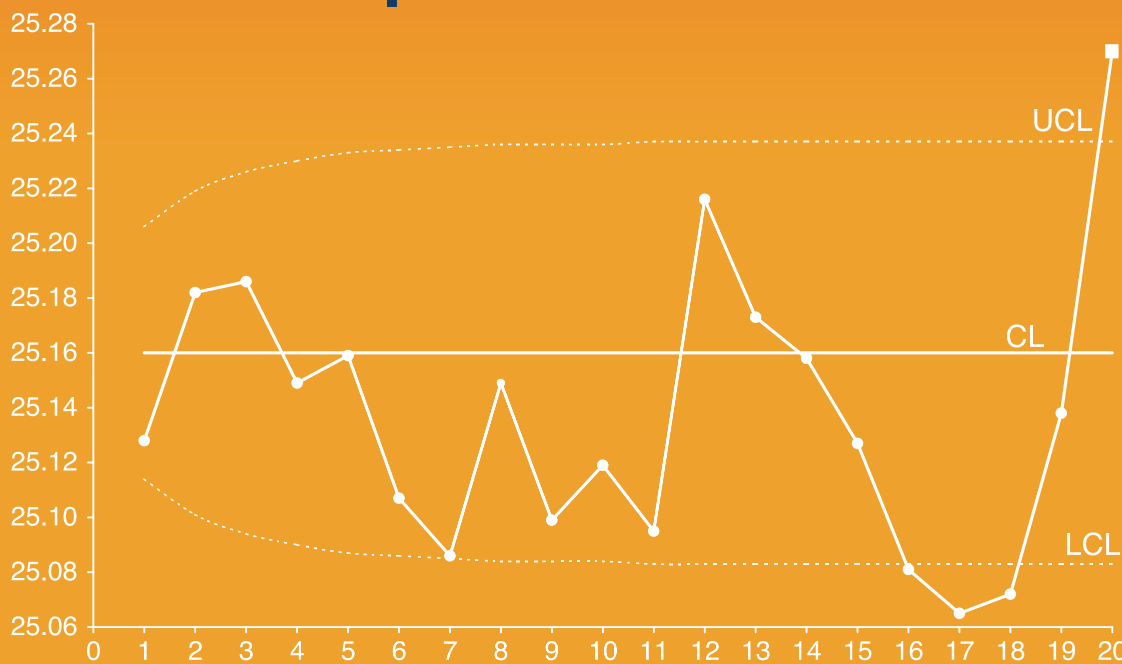
Fundamentals of Quality Control and Improvement



FOURTH EDITION

Amitava Mitra

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FUNDAMENTALS OF QUALITY CONTROL AND IMPROVEMENT

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AMITAVA MITRA
Auburn University
College of Business
Auburn, Alabama

WILEY

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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

CONTENTS

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.

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

PART I

PHILOSOPHY AND FUNDAMENTALS

1

INTRODUCTION TO QUALITY CONTROL AND THE TOTAL QUALITY SYSTEM

1-1 INTRODUCTION AND CHAPTER OBJECTIVES

"Dad, are we there yet?" "How much longer will it take?" "Mom, I am hungry!" "Is there an eating place nearby where we may stop and get something to eat?" It was a hot summer day around the middle of June as the family was headed for a summer vacation. With due thanks to advances in technology, the answers to these questions were at the couple's finger tips, reducing the uncertainty associated with traveling through a previously unknown place. Through the use of a smart phone that is able to download information via a global positioning system, directions to the nearly eating places were instantaneous. At the same time, estimates of the travel time provided a sense of relief. The developments of the twenty-first century and advances in quality make this possible. On the more philosophical question of "Are we there yet?" as far as quality is considered, the answer is clearly "No." The process of quality improvement is a never-ending journey.

Fundamentals of Quality Control and Improvement, Fourth Edition. Amitava Mitra

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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 reporting to a foreman grew in number, it became impossible for the foreman to keep close watch over individual operations. Inspectors were therefore designated to check the quality of a product after certain operations. Standards were set, and inspectors compared the quality of the item produced against those standards. In the event of discrepancies between a standard and a product, deficient items were set aside from those that met the standard. The nonconforming items were reworked, if feasible, or were discarded.

During this period, the foundations of statistical aspects of quality control were being developed, although they did not gain wide usage in U.S. industry. In 1924, Walter A. Shewhart of Bell Telephone Laboratories proposed the use of statistical charts to control the variables of a product. These came to be known as *control charts* (sometimes referred to as *Shewhart control charts*). They play a fundamental role in statistical process control. In the late 1920s, H. F. Dodge and H. G. Romig, also from Bell Telephone Laboratories, pioneered work in the areas of acceptance sampling plans. These plans were to become substitutes for 100% inspection.

The 1930s saw the application of acceptance sampling plans in industry, both domestic and abroad. Walter Shewhart continued his efforts to promote to industry the fundamentals of statistical quality control. In 1929 he obtained the sponsorship of the American Society for Testing and Materials (ASTM), the American Society of Mechanical Engineers (ASME), the American Statistical Association (ASA), and the Institute of Mathematical Statistics (IMS) in creating the Joint Committee for the Development of Statistical Applications in Engineering and Manufacturing.

Interest in the field of quality control began to gain acceptance in England at this time. The British Standards Institution Standard 600 dealt with applications of statistical methods to industrial standardization and quality control. In the United States, J. Scanlon introduced the *Scanlon plan*, which dealt with improvement of the overall quality of worklife (Feigenbaum 1983). Furthermore, the U.S. Food, Drug, and Cosmetic Act of 1938 had jurisdiction over procedures and practices in the areas of processing, manufacturing, and packing.

The next phase in the evolution process, called the *statistical quality control phase* by Feigenbaum (1983), occurred between 1940 and 1960. Production requirements escalated during World War II. Since 100% inspection was often not feasible, the principles of sampling plans gained acceptance. The American Society for Quality Control (ASQC) was formed in 1946, subsequently renamed the American Society for Quality (ASQ). A set of sampling inspection plans for attributes called MIL-STD-105A was developed by the military in 1950. These plans underwent several subsequent modifications, becoming MIL-STD-105B, MIL-STD-105C, MIL-STD-105D, and MIL-STD-105E. Furthermore, in 1957, a set of sampling plans for variables called MIL-STD-414 was also developed by the military.

Although suffering widespread damage during World War II, Japan embraced the philosophy of statistical quality control wholeheartedly. When W. Edwards Deming visited Japan and lectured on these new ideas in 1950, Japanese engineers and top management became convinced of the importance of statistical quality control as a means of gaining a competitive edge in the world market. J. M. Juran, another pioneer in quality control, visited Japan in 1954 and further impressed on them the strategic role that management plays in the achievement of a quality program. The Japanese were quick to realize the profound effects that these principles would have on the future of business, and they made a strong commitment to a massive program of training and education.

Meanwhile, in the United States, developments in the area of sampling plans were taking place. In 1958, the Department of Defense (DOD) developed the Quality Control and Reliability Handbook H-107, which dealt with single-level continuous sampling procedures and tables for inspection by attributes. Revised in 1959, this book became the Quality Control and Reliability Handbook H-108, which also covered multilevel continuous sampling procedures as well as topics in life testing and reliability.

The next phase, *total quality control*, took place during the 1960s (Feigenbaum 1983). An important feature during this phase was the gradual involvement of several departments and management personnel in the quality control process. Previously, most of these activities were dealt with by people on the shop floor, by the production foreman, or by people from the inspection and quality control department. The commonly held attitude prior to this period was that quality control was the responsibility of the inspection department. The 1960s, however, saw some changes in this attitude. People began to realize that each department had an important role to play in the production of a quality item. The concept of *zero defects*, which centered around achieving productivity through worker involvement, emerged during this time. For critical products and assemblies [e.g., missiles and rockets used in the space program by the National Aeronautics and Space Administration (NASA)] this concept proved to be very successful. Along similar lines, the use of **quality circles** was beginning to grow in Japan. This concept, which is based on the participative style of management, assumes that productivity will improve through an uplift of morale and motivation, achieved in turn, through consultation and discussion in informal subgroups.

The advent of the 1970s brought what Feigenbaum (1983) calls the *total quality control organizationwide phase*, which involved the participation of everyone in the company, from the operator to the first-line supervisor, manager, vice president, and even the chief executive officer. Quality was associated with every person. As this notion continued in the 1980s, it was termed by Feigenbaum (1983) the **total quality system**, which he defines as follows: "A quality system is the agreed on companywide and plantwide operating work structure, documented in effective, integrated technical and managerial procedures, for guiding the coordinated actions of the people, the machines, and the information of the company and plant in the best and most practical ways to assure customer quality satisfaction and economical costs of quality."

In Japan, the 1970s marked the expanded use of a graphical tool known as the **cause-and-effect diagram**. This tool was introduced in 1943 by K. Ishikawa and is sometimes called an **Ishikawa diagram**. It is also called a **fishbone diagram** because of its resemblance to a fish skeleton. This diagram helps identify possible reasons for a process to go out of control as well as possible effects on the process. It has become an important tool in the use of control charts because it aids in choosing the appropriate action to take in the event of a process being out of control. Also in this decade, G. Taguchi of Japan introduced the concept of quality improvement through statistically designed experiments. Expanded use of this technique has continued in the 1990s as companies have sought to improve the design phase.

In the 1980s, U.S. advertising campaigns placed quality control in the limelight. Consumers were bombarded with advertisements related to product quality, and frequent comparisons were made with those of competitors. These promotional efforts tried to point out certain product characteristics that were superior to those of similar products. Within the industry itself, an awareness of the importance of quality was beginning to evolve at all levels. Top management saw the critical need for the marriage of the quality philosophy to the production of goods and services in all phases, starting with the determination of customer needs and product design and continuing on to product assurance and customer service.

As computer use exploded during the 1980s, an abundance of quality control software programs came on the market. The notion of a total quality system increased the emphasis on vendor quality control, product design assurance, product and process quality audit, and related areas. Industrial giants such as the Ford Motor Company and General Motors Corporation adopted the quality philosophy and made strides in the implementation of statistical quality control methods. They, in turn, pressured other companies to use quality control techniques.

For example, Ford demanded documentation of statistical process control from its vendors. Thus, smaller companies that had not used statistical quality control methods previously were forced to adopt these methods to maintain their contracts. The strategic importance of quality control and improvement was formally recognized in the United States through the *Malcolm Baldrige National Quality Award* in 1987.

The emphasis on customer satisfaction and continuous quality improvement globally created a need for a system of standards and guidelines that support the quality philosophy. The International Organization for Standardization (ISO) developed a set of standards, *ISO 9000–9004*, in the late 1980s. The American National Standards Institute (ANSI) and ASQC brought their standards in line with the ISO standards when they developed the ANSI/ASQC Q90–Q94 in 1987, which was subsequently revised in 1994 to ANSI/ASQC Q9000–Q9004, and further in 2000, to ANSI/ISO/ASQ Q9000–2000. The ISO 9000–9004 standards were also revised in 1994, 2000, and 2008.

Beginning with the last decade of the twentieth century and continuing on to the current century, the world has seen the evolution of an era of information technology. This is the major revolution since the Industrial Revolution of the late eighteenth century. The twenty-first century is undergoing its revolution in information technology digitally, using wireless technology. Such advances promote the maintenace and protection of information quality while delivering data in an effective manner. Further, advances in computational technology have made it feasible to solve, in a timely fashion, complex and/or large-scale problems to be used for decision making. Moreover, the Internet is part and parcel of our everyday lives. Among a multitude of uses, we make travel arrangements, purchase items, look up information on a variety of topics, and correspond. All of these activities are conducted on a real-time basis, thus raising expectations regarding what constitutes timely completion. On receiving an order through the Internet, service providers will be expected to conduct an error-free transaction, for example, either assemble the product or provide the service, receive payment, and provide an online tracking system for the customer to monitor. Thus, the current century will continue to experience a thrust in growth of quality assurance and improvement methods that can, using technology, assimilate data and analyze them in real time and with no tolerance for errors.

One area that is expected to grow in the current century is that of "Big Data" and associated inferences drawn from an analysis of such data. Web-based sources of data such as the Internet and Facebook and Twitter accounts reveal the existence of databases that are dynamic and large. Data mining techniques could possibly capture trends in the variables of interest, for example, demand for certain products and services. Measures of quality could also be extracted based on customer satisfaction surveys that are ordinal scale based or qualitative data, such as textual information of product/service liking. An important factor in such analysis will be the ability to capture massive data in a "clean" format that is conducive to analysis. In addition, access to appropriate hardware and software that can store, process, and analyze such data will also be influential.

1-3 QUALITY

The notion of **quality** has been defined in different ways by various authors. Garvin (1984) divides the definition of quality into five categories: transcendent, product-based, user-based, manufacturing-based, and value-based. Furthermore, he identifies a framework of eight attributes that may be used to define quality: performance, features, reliability, conformance, durability, serviceability, aesthetics, and perceived quality. This frequently used definition is attributed to Crosby (1979): "Quality is conformance to requirements or specifications." A more general definition proposed by Juran (1974) is as follows: "Quality is fitness for use."

In this book we adopt, the latter definition and expand it to cover both the *manufacturing* and *service* sectors. The service sector accounts for a substantial segment of our present economy; it is a major constituent that is not to be neglected, an example being the health care field. Projections indicate that this service sector that includes information systems, supply chain management, health care and wellness, marketing, and the entertainment industry will expand even further in the future. Hence, quality may be defined as follows: The quality of a product or service is the fitness of that product or service for meeting or exceeding its intended use as required by the customer.

So, who is the driving force behind determining the level of quality that should be designed into a product or service? *The customer*! Therefore, as the needs of customers change, so should the level of quality. If, for example, customers prefer an automobile that gives adequate service for 15 years, then that is precisely what the notion of a quality product should be. Quality, in this sense, is not something that is held at a constant universal level. In this view, the term *quality* implies different levels of expectations for different groups of consumers. For instance, to some, a quality restaurant may be one that provides extraordinary cuisine served on the finest china with an ambience of soft music. However, to another group of consumers, the characteristics that comprise a quality restaurant may be quite different: excellent food served buffet style at moderate prices until the early morning hours.

Quality Characteristics

The preceding example demonstrates that one or more elements define the intended quality level of a product or service. These elements, known as **quality characteristics**, can be categorized in these groupings: *Structural characteristics* include such elements as the length of a part, the weight of a can, the strength of a beam, the viscosity of a fluid, and so on; *sensory characteristics* include the taste of good food, the smell of a sweet fragrance, and the beauty of a model, among others; **time-oriented characteristics** include such measures as time to process a purchase order, warranty, reliability, and maintainability associated with a product; and *ethical characteristics* include honesty, courtesy, friendliness, and so on.

Variables and Attributes

Quality characteristics fall into two broad classes: variables and attributes. *Characteristics that are measurable and are expressed on a numerical scale* are called **variables**. The waiting time in a bank before being served, expressed in minutes, is a variable, as are the density of a liquid in grams per cubic centimeter and the processing speed of a computer.

Prior to defining an attribute, we should define a nonconformity and a nonconforming unit. A **nonconformity** is a *quality characteristic that does not meet its stipulated specifications*. Let's say that the specification on the fill volume of soft drink bottles is 750 ± 3 milliliters (mL). If we have a bottle containing 745 mL, its fill volume is a nonconformity. A **nonconforming unit** has *one or more nonconformities such that the unit is unable to meet the intended standards and is unable to function as required*. An example of a nonconforming unit is a cast iron pipe whose internal diameter and weight both fail to satisfy specifications, thereby making the unit dysfunctional.

A quality characteristic is said to be an **attribute** if it is classified as *either conforming or nonconforming to a stipulated specification*. A quality characteristic that cannot be measured on a numerical scale is expressed as an attribute. For example, the smell of a cologne is characterized as either acceptable or is not; the color of a fabric is either acceptable or is not. However, there are some variables that are treated as attributes because it is simpler to measure them this way or because it is difficult to obtain data on them. Examples in this category are numerous. For instance, the diameter of a bearing is, in theory, a variable. However, if we measure the diameter using a go/no-go gage and classify it as either conforming or nonconforming (with respect to some established specifications), the characteristic is expressed as an attribute. The reasons for using a go/no-go gage, as opposed to a micrometer, could be economic; that is, the time needed to obtain a measurement using a go/no-go gage may be much shorter and consequently less expensive. Alternatively, an inspector may not have enough time to obtain measurements on a numerical scale using a micrometer, so such a classification of variables would not be feasible.

Defects

A **defect** is associated with a quality characteristic that does not meet certain standards. Furthermore, the severity of one of more defects in a product or service may cause it to be unacceptable (or defective). The modern term for *defect* is *nonconformity*, and the term for *defective* is *nonconforming item*. The American National Standards Institute, the International Organization for Standardization, and the American Society for Quality provide a definition of a defect in ANSI/ISO/ASQ Standard A8402 (ASQ 1994).

Standard or Specification

Since the definition of quality involves meeting the requirements of the customer, these requirements need to be documented. A **standard**, or a **specification**, refers to *a precise statement that formalizes the requirements of the customer; it may relate to a product, a process, or a service*. For example, the specifications for an axle might be 2 ± 0.1 centimeters (cm) for the inside diameter, 4 ± 0.2 cm for the outside diameter, and 10 ± 0.5 cm for the length. This means that for an axle to be acceptable to the customer, each of these dimensions must be within the values specified. Definitions given by the National Bureau of Standards (NBS, 2005) are as follows:

- *Specification:* a set of conditions and requirements, of specific and limited application, that provide a detailed description of the procedure, process, material, product, or service for use primarily in procurement and manufacturing. Standards may be referenced or included in a specification.
- *Standard:* a prescribed set of conditions and requirements, of general or broad application, established by authority or agreement, to be satisfied by a material, product, process, procedure, convention, test method; and/or the physical, functional, performance, or conformance characteristic thereof. A physical embodiment of a unit of measurement (for example, an object such as the standard kilogram or an apparatus such as the cesium beam clock).

Acceptable bounds on individual quality characteristics (say, 2 ± 0.1 cm for the inside diameter) are usually known as **specification limits**, whereas the document that addresses the requirements of all the quality characteristics is labeled the *standard*.