DOUGLAS C. MONTGOMERY

# INTRODUCTION TO STATISTICAL QUALITY CONTROL

EIGHTH EDITION

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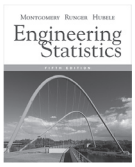


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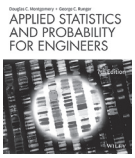


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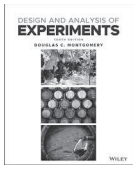


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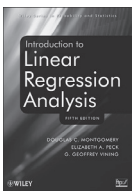


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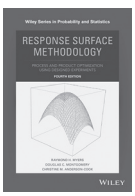


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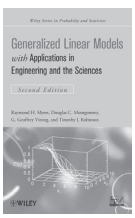


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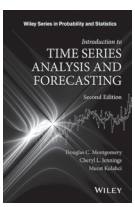


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## SPC
## Calculations for Control Limits

| | | | | | |
|---|---|---|---|---|---|
| **Notation:** | UCL | Upper Control Limit | $\bar{x}$ | Average of Measurements |
| | LCL | Lower Control Limit | $\bar{\bar{x}}$ | Average of Averages |
| | CL | Center Line | $R$ | Range |
| | $n$ | Sample Size | $\bar{R}$ | Average of Ranges |
| | PCR | Process Capability Ratio | USL | Upper Specification Limit |
| | $\hat{\sigma}$ | Process Standard Deviation | LSL | Lower Specification Limit |

### Variables Data ($\bar{x}$ and $R$ Control Charts)

$\bar{x}$ Control Chart

$\text{UCL} = \bar{\bar{x}} + A_2\bar{R}$

$\text{LCL} = \bar{\bar{x}} - A_2\bar{R}$

$\text{CL} = \bar{\bar{x}}$

R Control Chart

$\text{UCL} = \bar{R}\,D_4$

$\text{LCL} = \bar{R}\,D_3$

$\text{CL} = \bar{R}$

Capability Study

$C_p = (\text{USL} - \text{LSL})/(6\hat{\sigma});$ where $\hat{\sigma} = \bar{R}/d_2$

| $n$ | $A_2$ | $D_3$ | $D_4$ | $d_2$ |
|---|---|---|---|---|
| 2 | 1.880 | 0.000 | 3.267 | 1.128 |
| 3 | 1.023 | 0.000 | 2.574 | 1.693 |
| 4 | 0.729 | 0.000 | 2.282 | 2.059 |
| 5 | 0.577 | 0.000 | 2.114 | 2.326 |
| 6 | 0.483 | 0.000 | 2.004 | 2.534 |
| 7 | 0.419 | 0.076 | 1.924 | 2.704 |
| 8 | 0.373 | 0.136 | 1.864 | 2.847 |
| 9 | 0.337 | 0.184 | 1.816 | 2.970 |
| 10 | 0.308 | 0.223 | 1.777 | 3.078 |

### Attribute Data ($p$, $np$, $c$, and $u$ Control Charts)

| | Control Chart Formulas | | | |
|---|---|---|---|---|
| | **$p$ (fraction)** | **$np$ (number of nonconforming)** | **$c$ (count of nonconformances)** | **$u$ (count of nonconformances/unit)** |
| CL | $\bar{p}$ | $n\bar{p}$ | $\bar{c}$ | $\bar{u}$ |
| UCL | $\bar{p} + 3\sqrt{\dfrac{\bar{p}(1-\bar{p})}{n}}$ | $n\bar{p} + 3\sqrt{n\bar{p}(1-\bar{p})}$ | $\bar{c} + 3\sqrt{\bar{c}}$ | $\bar{u} + 3\sqrt{\dfrac{\bar{u}}{n}}$ |
| LCL | $\bar{p} - 3\sqrt{\dfrac{\bar{p}(1-\bar{p})}{n}}$ | $n\bar{p} - 3\sqrt{n\bar{p}(1-\bar{p})}$ | $\bar{c} - 3\sqrt{\bar{c}}$ | $\bar{u} - 3\sqrt{\dfrac{\bar{u}}{n}}$ |
| Notes | If $n$ varies, use $\bar{n}$ or individual $n_i$ | $n$ must be a constant | $n$ must be a constant | If $n$ varies, use $\bar{n}$ or individual $n_i$ |

# Introduction to Statistical Quality Control

EIGHTH EDITION

**Douglas C. Montgomery**

*Arizona State University*

WILEY

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# About the Author

**Douglas C. Montgomery** is Regents' Professor of Industrial Engineering and the Arizona State University Foundation Professor of Engineering. He received his B.S., M.S., and Ph.D. degrees from Virginia Polytechnic Institute, all in engineering. From 1969 to 1984, he was a faculty member of the School of Industrial & Systems Engineering at the Georgia Institute of Technology; from 1984 to 1988, he was at the University of Washington, where he held the John M. Fluke Distinguished Chair of Manufacturing Engineering, was Professor of Mechanical Engineering, and was Director of the Program in Industrial Engineering.

Dr. Montgomery has research and teaching interests in engineering statistics including statistical quality-control techniques, design of experiments, regression analysis and empirical model building, and the application of operations research methodology to problems in manufacturing systems. He has authored and coauthored more than 250 technical papers in these fields and is the author of twelve other books. Dr. Montgomery is an Honorary Member of the American Society for Quality (ASQ), a Fellow of the American Statistical Association, a Fellow of the Royal Statistical Society, a Fellow of the Institute of Industrial Engineers, an elected member of the International Statistical Institute, and an elected Academician of the International Academy of Quality. He is a Shewhart Medalist of the American Society for Quality, and he also has received the Distinguished Service Medal, the Brumbaugh Award, the Lloyd S. Nelson Award, the William G. Hunter Award, and two Shewell Awards from the ASQ. He has also received the Deming Lecture Award from the American Statistical Association, the George Box Medal from the European Network for Business and Industrial statistics (ENBIS), the Greenfield Medal from the Royal Statistical Society, and the Ellis R. Ott Award. He is a former editor of the *Journal of Quality Technology*, is one of the current chief editors of *Quality and Reliability Engineering International*, and serves on the editorial boards of several journals.

# Preface

## INTRODUCTION

This book is about the use of modern statistical methods for quality control and improvement. It provides comprehensive coverage of the subject from basic principles to state-of-the-art concepts and applications. The objective is to give the reader a sound understanding of the principles and the basis for applying them in a variety of situations. Although statistical techniques are emphasized throughout, the book has a strong engineering and management orientation. Extensive knowledge of statistics is not a prerequisite for using this book. Readers whose background includes a basic course in statistical methods will find much of the material in this book easily accessible.

## AUDIENCE

The book is an outgrowth of more than 40 years of teaching, research, and consulting in the application of statistical methods for industrial problems. It is designed as a textbook for students enrolled in colleges and universities who are studying engineering, statistics, management, and related fields and are taking a first course in statistical quality control. The basic quality-control course is often taught at the junior or senior level. All of the standard topics for this course are covered in detail. Some more advanced material is also available in the book, and this could be used with advanced undergraduates who have had some previous exposure to the basics or in a course aimed at graduate students. I have also used the text materials extensively in programs for professional practitioners, including quality and reliability engineers, manufacturing and development engineers, product designers, managers, procurement specialists, marketing personnel, technicians and laboratory analysts, inspectors, and operators. Many professionals have also used the material for self-study.

## CHAPTER ORGANIZATION AND TOPICAL COVERAGE

The book contains five parts. Part 1 is introductory. The first chapter is an introduction to the philosophy and basic concepts of quality improvement. It notes that quality has become a major business strategy and that organizations that successfully improve quality can increase their productivity, enhance their market penetration, and achieve greater profitability and a strong competitive advantage. Some of the managerial and implementation aspects of quality improvement are included. Chapter 2 describes DMAIC, an acronym for Define, Measure, Analyze, Improve, and Control. The DMAIC process is an excellent framework to use in conducting quality-improvement projects. DMAIC often is associated with Six Sigma, but regardless of the approach taken by an organization strategically, DMAIC is an excellent tactical tool for quality professionals to employ.

Part 2 is a description of statistical methods useful in quality improvement. Topics include sampling and descriptive statistics, the basic notions of probability and probability distributions, point and interval estimation of parameters, and statistical hypothesis testing. These topics are usually covered in a basic course in statistical methods; however, their presentation in this text is from the quality-engineering viewpoint. My experience has been that even readers with a strong statistical background will find the approach to this material useful and somewhat different from a standard statistics textbook.

Part 3 contains four chapters covering the basic methods of statistical process control (SPC) and methods for process capability analysis. Even though several SPC problem-solving tools are discussed (including Pareto charts and cause-and-effect diagrams, for example), the primary focus

in this section is on the Shewhart control chart. The Shewhart control chart certainly is not new, but its use in modern-day business and industry is of tremendous value.

There are four chapters in Part 4 that present more advanced SPC methods. Included are the cumulative sum and exponentially weighted moving average control charts (Chapter 9), several important univariate control charts such as procedures for short production runs, autocorrelated data, and multiple stream processes (Chapter 10), multivariate process monitoring and control (Chapter 11), and feedback adjustment techniques (Chapter 12). Some of this material is at a higher level than Part 3, but much of it is accessible by advanced undergraduates or first-year graduate students. This material forms the basis of a second course in statistical quality control and improvement for this audience.

Part 5 contains two chapters that show how statistically designed experiments can be used for process design, development, and improvement. Chapter 13 presents the fundamental concepts of designed experiments and introduces factorial and fractional factorial designs, with particular emphasis on the two-level system of designs. These designs are used extensively in the industry for factor screening and process characterization. Although the treatment of the subject is not extensive and is no substitute for a formal course in experimental design, it will enable the reader to appreciate more sophisticated examples of experimental design. Chapter 14 introduces response surface methods and designs, illustrates evolutionary operation (EVOP) for process monitoring, and shows how statistically designed experiments can be used for process robustness studies. Chapters 13 and 14 emphasize the important interrelationship between statistical process control and experimental design for process improvement.

Two chapters deal with acceptance sampling in Part 6. The focus is on lot-by-lot acceptance sampling, although there is some discussion of continuous sampling and MIL STD 1235C in Chapter 14. Other sampling topics presented include various aspects of the design of acceptance-sampling plans, a discussion of MIL STD 105E, and MIL STD 414 (and their civilian counterparts: ANSI/ASQC ZI.4 and ANSI/ASQC ZI.9), and other techniques such as chain sampling and skip-lot sampling.

Throughout the book, guidelines are given for selecting the proper type of statistical technique to use in a wide variety of situations. In addition, extensive references to journal articles and other technical literature should assist the reader in applying the methods described. I also have shown how the different techniques presented are used in the DMAIC process.

## NEW TO THIS EDITION

The 8th edition of the book has new material on several topics, including implementing quality improvement, applying quality tools in nonmanufacturing settings, monitoring Bernoulli processes, monitoring processes with low defect levels, and designing experiments for process and product improvement. In addition, I have rewritten and updated many sections of the book. Many new references have been added to the bibliography. I think that has led to a clearer and more current exposition of many topics. I have also added over 120 new exercises to the end-of-chapter problem sets.

The 8th edition is published for the first time as an enhanced eText (also available bundled with an abridged print companion). The new format allows integrated media, highlighting, notes, and more interactivity, such as select problems that have complete solutions that can be accessed with a click or tap. The new format also allows easy access to supplemental text material and data sets directly from the eText.

## SUPPORTING TEXT MATERIALS

**Computer Software** The computer plays an important role in a modern quality-control course. This edition of the book uses Minitab as the primary illustrative software package. I strongly recommend that the course have a meaningful computing component. To request this

book with a student version of Minitab included, contact your local Wiley representative. The student version of Minitab has limited functionality and does not include DOE capability. If your students will need DOE capability, they can download the fully functional 30-day trial at www.minitab.com or purchase a fully functional time-limited version from e-academy.com.

**Supplemental Text Material** I have written a set of supplemental materials to augment many of the chapters in the book. The supplemental material contains topics that could not easily fit into a chapter without seriously disrupting the flow. The topics are shown in the Table of Contents for the book and in the individual chapter outlines in the enhanced e-text. Some of this material consists of proofs or derivations, new topics of a (sometimes) more advanced nature, supporting details concerning remarks or concepts presented in the text, and answers to frequently asked questions. The supplemental material provides an interesting set of accompanying readings for anyone curious about the field. It is available in the Study Resources for each chapter and via the Instructor Companion Site at www.wiley.com/go/montgomery/introductiontostatisticalqualitycontrol8e.

**Instructor Materials** The instructor's section of the textbook's companion web site contains the following:

1. Solutions to the text problems
2. The supplemental text material described above
3. A set of Microsoft PowerPoint slides for the basic SPC course
4. Data sets from the book, in electronic form
5. Image Gallery illustrations from the book in electronic format
6. A set of withheld problems from each chapter available to the instructor but not in the textbook.

The instructor's section is for instructor use only and is password protected. Visit the Instructor Companion Site portion of the web site, located at www.wiley.com/go/montgomery/introductiontostatisticalqualitycontrol8e, to register for a password.

**Student Materials** The e-text contains links to the supplemental text material and the data sets. They are available in the Study Resources section for each chapter.

## ACKNOWLEDGMENTS

Many people have generously contributed their time and knowledge of statistics and quality improvement to this book. I would like to thank Dr. Bill Woodall, Dr. Doug Hawkins, Dr. Joe Sullivan, Dr. George Runger, Dr. Bert Keats, Dr. Bob Hogg, Mr. Eric Ziegel, Dr. Joe Pignatiello, Dr. John Ramberg, Dr. Ernie Saniga, Dr. Enrique Del Castillo, Dr. Sarah Streett, and Dr. Jim Alloway for their thorough and insightful comments on this and previous editions. They generously shared many of their ideas and teaching experiences with me, leading to substantial improvements in the book.

Over the years since the first edition was published, I have received assistance and ideas from a great many other people. A complete list of colleagues with whom I have interacted would be impossible to enumerate. However, some of the major contributors and their professional affiliations are as follows: Dr. George C. Runger, Dr. Connie M. Borror, Dr. Mary R. Anderson-Rowland, Dr. Dwayne A. Rollier, and Dr. Norma F. Hubele, Arizona State University; Dr. Murat Kulahci, Technical University of Denmark; Mr. Seymour M. Selig, formerly of the Office of Naval Research; Dr. Lynwood A. Johnson, Dr. Russell G. Heikes, Dr. David E. Fyffe,

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I am also indebted to the many organizations that have sponsored my research and my graduate students for a number of years, including the member companies of the National Science Foundation/Industry/University Cooperative Research Center in Quality and Reliability Engineering at Arizona State University, the Office of Naval Research, the National Science Foundation, Semiconductor Research Corporation, Aluminum Company of America, and IBM Corporation. Finally, I thank the many users of the previous editions of this book, including students, practicing professionals, and my academic colleagues. Many of the changes and improvements in this edition of the book are the direct result of your feedback.

DOUGLAS C. MONTGOMERY
*Tempe, Arizona*

# Contents

OC **Content available in eBook**
SS **Student solution available in interactive e-text**

# Introduction

PART 1

Controlling and improving quality has become an important business strategy for many organizations: manufacturers, distributors, transportation companies, financial services organizations, health care providers, and government agencies. Maintaining a high level of product or service quality provides a competitive advantage. A business that can delight customers by improving and controlling quality can dominate its competitors. This book is about the technical methods for achieving success in quality control and improvement and offers guidance on how to successfully implement these methods.

Part 1 contains two chapters. Chapter 1 contains the basic definitions of quality and quality improvement, provides a brief overview of the tools and methods discussed in greater detail in subsequent parts of the book, and discusses the management systems for quality improvement. Chapter 2 is devoted to the DMAIC (define, measure, analyze, improve, and control) problem-solving process, which is an excellent framework for implementing quality and process improvement. We also show how the methods discussed in the book are used in DMAIC.

## CHAPTER 1 DISCUSSION QUESTIONS AND EXERCISES

SS **Student solution available in interactive e-text.**

**1.1.** Why is it difficult to define quality?

**1.2.** Briefly discuss the eight dimensions of quality. Does this improve our understanding of quality?

**1.3.** Select a specific product or service, and discuss how the eight dimensions of quality impact its overall acceptance by consumers.

SS **1.4.** Can an understanding of the multidimensional nature of quality lead to improved product design or better service?

**1.5.** What are the internal customers of a business? Why are they important from a quality perspective?

SS **1.6.** What is the Juran Trilogy?

**1.7.** What are the three primary technical tools used for quality control and improvement?

**1.8.** What is the Malcolm Baldrige National Quality Award? Who is eligible for the award?

SS **1.9.** Who was Walter A. Shewhart?

**1.10.** What is meant by the cost of quality?

**1.11.** What is a Six Sigma process?

**1.12.** Compare and contrast Deming's and Juran's philosophies of quality.

SS **1.13.** What would motivate a business to compete for the Malcolm Baldrige National Quality Award?

**1.14.** Most of the quality management literature states that without top management leadership, quality improvement will not occur. Do you agree or disagree with this statement? Discuss why.

**1.15.** Explain why it is necessary to consider variability around the mean or nominal dimension as a measure of quality.

**1.16.** Hundreds of companies and organizations have won the Baldrige Award. Collect information on at least two winners. What success have they had since receiving the award?

**1.17.** Reconsider the fast-food restaurant visit discussed in the chapter. What levels of quality would you consider acceptable for the family of four on each visit and annually? What probability of good quality on each meal component would be required in order to achieve these targets?

**1.18.** How can lean and Six Sigma work together to eliminate waste? SS

**1.19.** What is the Toyota Production System?

**1.20.** What were Henry Ford's contributions to quality?

**1.21.** How could reducing the mean delivery time of a product from ten days to two days result in quality improvement?

**1.22.** What are the objectives of a supplier development program?

**1.23.** We identified reliability as a dimension of quality. Can reliability be a dimension of service quality? How?

**1.24.** How could a designed experiment be used to investigate how to improve a service process, such as a hospital emergency department?

**1.25.** Suppose that a process is currently operating at a 3.5-sigma level of quality, and it is planned to use improvement projects to move this process to a 6-sigma level? What project improvement rate would be necessary to achieve that new performance in 2 years?

**1.26.** Is Six-Sigma (or Lean Six-Sigma or Design for Six Sigma) a quality management system? Discuss.

**1.27.** We have made the point in the textbook that ISO certification is not assurance that good quality, safe, or reliable products are delivered to consumers, it remains an activity pursued by many organizations worldwide. Discuss why you think this is so.

**1.28.** Provide an example from your own experience where excessive variability can result in unacceptable performance of a product or service.

# QUALITY IMPROVEMENT IN THE MODERN BUSINESS ENVIRONMENT

CHAPTER 1

## CHAPTER OVERVIEW AND LEARNING OBJECTIVES

This book is about the use of statistical methods and other problem-solving techniques to improve the **quality** of the products used by our society. These products consist of **manufactured goods** such as automobiles, computers, and clothing, as well as **services** such as the generation and distribution of electrical energy, public transportation, banking, retailing, and health care. Quality improvement methods can be applied to any area within a company or organization, including manufacturing, process development, engineering design, finance and accounting, marketing, distribution and logistics, customer service, and field service of products. This textbook presents the technical tools that are needed to achieve quality improvement in these organizations.

In this chapter, we give the basic definitions of quality, quality improvement, and other quality engineering terminology. We also discuss the historical development of quality improvement methodology and provide an overview of the statistical tools essential for modern professional practice. A brief discussion of some management and business aspects for implementing quality improvement is also given.

After careful study of this chapter, you should be able to do the following:

1. Define and discuss quality and quality improvement
2. Discuss the different dimensions of quality
3. Discuss the evolution of modern quality improvement methods
4. Discuss the role that variability and statistical methods play in controlling and improving quality
5. Describe the quality management philosophies of W. Edwards Deming, Joseph M. Juran, and Armand V. Feigenbaum
6. Discuss total quality management, the Malcolm Baldrige National Quality Award, (lean) Six Sigma, and quality systems and standards
7. Explain the links between quality and productivity and between quality and cost
8. Discuss product liability
9. Discuss the three functions: quality planning, quality assurance, and quality control and improvement

## 1.1 THE MEANING OF QUALITY AND QUALITY IMPROVEMENT

We may define **quality** in many ways. Most people have a conceptual understanding of quality as relating to one or more desirable characteristics that a product or service should possess. Although this conceptual understanding is certainly a useful starting point, we prefer a more precise and useful definition.

Quality has become one of the most important consumer decision factors in the selection among competing products and services. The phenomenon is widespread, regardless of whether the consumer is an individual, an industrial organization, a retail store, a bank or financial institution, or a military defense program. Consequently, understanding and improving quality are key

factors leading to business success, growth, and enhanced competitiveness. There is a substantial return on investment from improved quality and from successfully employing quality as an integral part of overall business strategy. In this section, we provide operational definitions of quality and quality improvement. We begin with a brief discussion of the different dimensions of quality and some basic terminology.

### 1.1.1 DIMENSIONS OF QUALITY

The quality of a product can be described and evaluated in several ways. It is often very important to differentiate these different **dimensions of quality**. Garvin (1987) provides an excellent discussion of eight components or dimensions of quality. We summarize his key points concerning these dimensions of quality as follows:

1. **Performance** (Will the product do the intended job?) Potential customers usually evaluate a product to determine if it will perform certain specific functions and determine how well it performs them. For example, you could evaluate spreadsheet software packages for a PC to determine which data manipulation operations they perform. You may discover that one outperforms another with respect to the execution speed.

2. **Reliability** (How often does the product fail?) Complex products, such as many electronic devices, appliances, automobiles, or airplanes, will usually require some repair over their service life. For example, you should expect that an automobile will require occasional repair, but if the car requires frequent repair, we say that it is unreliable. There are many industries in which the customer's view of quality is greatly impacted by the reliability dimension of quality.

3. **Durability** (How long does the product last?) This is the effective service life of the product. Customers obviously want products that perform satisfactorily over a long period of time. The automobile and major appliance industries are examples of businesses where this dimension of quality is very important to most customers.

4. **Serviceability** (How easy is it to repair the product?) There are many industries in which the customer's view of quality is directly influenced by how quickly and economically a repair or routine maintenance activity can be accomplished. Examples include the appliance and automobile industries and many types of service industries (how long did it take a credit card company to correct an error in your bill?).

5. **Aesthetics** (What does the product look like?) This is the visual appeal of the product, often taking into account factors such as style, color, shape, packaging alternatives, tactile characteristics, and other sensory features. For example, soft-drink beverage manufacturers rely on the visual appeal of their packaging to differentiate their product from other competitors.

6. **Features** (What does the product do?) Usually, customers associate high quality with products that have added features—that is, those that have features beyond the basic performance of the competition. For example, you might consider a spreadsheet software package to be of superior quality if it had built-in statistical analysis features while its competitors did not.

7. **Perceived Quality** (What is the reputation of the company or its product?) In many cases, customers rely on the past reputation of the company concerning quality of its products. This reputation is directly influenced by failures of the product that are highly visible to the public or that require product recalls, and by how the customer is treated when a quality-related problem with the product is reported. Perceived quality, customer loyalty, and repeated business are closely interconnected. For example, if you make regular business trips using a particular airline, and the flight almost always arrives on time and the airline company does

not lose or damage your luggage, you will probably prefer to fly on that carrier instead of its competitors.

8. **Conformance to Standards** (Is the product made exactly as the designer intended?) We usually think of a high-quality product as one that exactly meets the requirements placed on it. For example, how well does the hood fit on a new car? Is it perfectly flush with the fender height, and is the gap exactly the same on all sides? Manufactured parts that do not exactly meet the designer's requirements can cause significant quality problems when they are used as the components of a more complex assembly. An automobile consists of several thousand parts. If each one is just slightly too big or too small, many of the components will not fit together properly, and the vehicle can lose visual appeal or its major subsystems may not perform as the designer intended.

These eight dimensions are usually adequate to describe quality in most industrial and many business situations. However, in service and transactional business organizations (such as banking and finance, health care, and customer service organizations), we can add the following three dimensions:

1. **Responsiveness.** How long they did it take the service provider to reply to your request for service? How willing to be helpful was the service provider? How promptly was your request handled?
2. **Professionalism.** This is the knowledge and skills of the service provider, and relates to the competency of the organization to provide the required services.
3. **Attentiveness.** Customers generally want caring and personalized attention from their service providers. Customers want to feel that their needs and concerns are important and are being carefully addressed.

We see from the foregoing discussion that quality is indeed a multifaceted entity. Consequently, a simple answer to questions such as "What is quality?" or "What is quality improvement?" is not easy. The **traditional** definition of quality is based on the viewpoint that products and services must meet the requirements of those who use them.

**DEFINITION**

**Quality** means fitness for use.

There are two general aspects of fitness for use: **quality of design** and **quality of conformance**. All goods and services are produced in various grades or levels of quality. These variations in grades or levels of quality are intentional, and, consequently, the appropriate technical term is quality of design. For example, all automobiles have as their basic objective providing safe transportation for the consumer. However, automobiles differ with respect to size, appointments, appearance, and performance. These differences are the result of intentional design differences among the types of automobiles. These design differences include the types of materials used in construction, specifications on the components, reliability obtained through engineering development of engines and drive trains, and other accessories or equipment.

The quality of conformance is how well the product conforms to the specifications required by the design. Quality of conformance is influenced by a number of factors, including the choice of manufacturing processes; the training and supervision of the workforce; the types of process

controls, tests, and inspection activities that are employed; the extent to which these procedures are followed; and the motivation of the workforce to achieve quality.

Unfortunately, this definition has become associated more with the conformance aspect of quality than with design. This is in part due to the lack of formal education most designers and engineers receive in quality engineering methodology. This also leads to much less focus on the customer and more of a "conformance-to-specifications" approach to quality, regardless of whether the product, even when produced to standards, was actually "fit-for-use" by the customer. Also, there is still a widespread belief that quality is a problem that can be dealt with solely in manufacturing, or that the only way quality can be improved is by "gold-plating" the product.

We prefer a **modern** definition of quality.

**DEFINITION**

**Quality** is inversely proportional to variability.

Note that this definition implies that if variability[1] in the important characteristics of a product decreases, the quality of the product increases.

As an example of the operational effectiveness of this definition, a few years ago, one of the automobile companies in the United States performed a comparative study of a transmission that was manufactured in a domestic plant and by a Japanese supplier. An analysis of warranty claims and repair costs indicated that there was a striking difference between the two sources of production, with the Japanese-produced transmission having much lower costs, as shown in Figure 1.1. As part of the study to discover the cause of this difference in cost and performance, the company selected random samples of transmissions from each plant, disassembled them, and measured several critical quality characteristics.

Figure 1.2 is generally representative of the results of this study. Note that both distributions of critical dimensions are centered at the desired or target value. However, the distribution of the critical characteristics for the transmissions manufactured in the United States takes up about 75% of the width of the specifications, implying that very few nonconforming units would be produced. In fact, the plant was producing at a quality level that was quite good, based on the generally accepted view of quality within the company. In contrast, the Japanese plant produced transmissions for which the same critical characteristics take up only about 25% of the specification band. As a result, there is considerably less variability in the critical quality characteristics of the Japanese-built transmissions in comparison to those built in the United States.

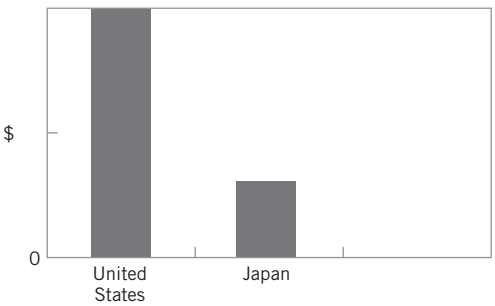



**FIGURE 1.1** Warranty costs for transmissions.

[1] We are referring to unwanted or harmful variability. There are situations in which variability is actually good. As my good friend Bob Hogg has pointed out, "I really like Chinese food, but I don't want to eat it every night."

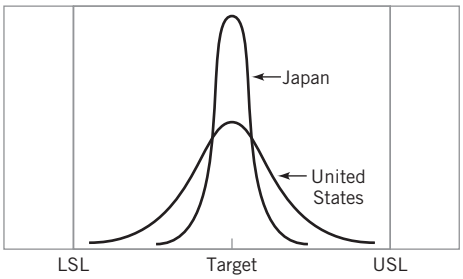



**FIGURE 1.2** Distributions of critical dimensions for transmissions.

This is a very important finding. Jack Welch, the retired chief executive officer of General Electric, has observed that your customers don't see the mean of your process (the target in Fig. 1.2), they only see the variability around that target that you have not removed. In almost all cases, this variability has significant customer impact.

There are two obvious questions here: Why did the Japanese do this? How did they do this? The answer to the "why" question is obvious from examination of Figure 1.1. Reduced variability has directly translated into lower costs (the Japanese fully understood the point made by Welch). Furthermore, the Japanese-built transmissions shifted gears more smoothly, ran more quietly, and were generally perceived by the customer as superior to those built domestically. Fewer repairs and warranty claims means less **rework** and the reduction of wasted time, effort, and money. Thus, quality truly is inversely proportional to variability. Furthermore, it can be communicated very precisely in a language that everyone (particularly managers and executives) understands—namely, money.

How did the Japanese do this? The answer lies in the systematic and effective use of the methods described in this book. It also leads to the following definition of **quality improvement.**

**DEFINITION**

**Quality improvement** is the reduction of variability in processes and products.

Excessive variability in process performance often results in **waste.** For example, consider the wasted money, time, and effort that are associated with the repairs represented in Figure 1.1. Therefore, an alternate and frequently very useful definition is that quality improvement is the **reduction of waste.** This definition is particularly effective in **service industries,** where there may not be as many things that can be directly measured (like the transmission critical dimensions in Fig. 1.2). In service industries, a quality problem may be an error or a mistake, the correction of which requires effort and expense. By improving the service process, this wasted effort and expense can be avoided.

We now present some quality engineering terminology that is used throughout the book.

### 1.1.2 QUALITY ENGINEERING TERMINOLOGY

Every product possesses a number of elements that jointly describe what the user or consumer thinks of as quality. These parameters are often called **quality characteristics**. Sometimes these are called **critical-to-quality (CTQ)** characteristics. Quality characteristics may be of several types:

1. **Physical:** length, weight, voltage, viscosity
2. **Sensory:** taste, appearance, color
3. **Time orientation:** reliability, durability, serviceability

Note that the different types of quality characteristics can relate directly or indirectly to the dimensions of quality discussed in the previous section.

**Quality engineering** is the set of operational, managerial, and engineering activities that a company uses to ensure that the quality characteristics of a product are at the nominal or required levels and that the variability around these desired levels is minimum. The techniques discussed in this book form much of the basic methodology used by engineers and other technical professionals to achieve these goals.

Most organizations find it difficult (and expensive) to provide the customer with products that have quality characteristics that are always identical from unit to unit, or are at levels that match customer expectations. A major reason for this is **variability**. There is a certain amount of variability in every product; consequently, no two products are ever identical. For example, the thickness of the blades on a jet turbine engine impeller is not identical even on the same impeller. Blade thickness will also differ between impellers. If this variation in blade thickness is small, then it may have no impact on the customer. However, if the variation is large, then the customer may perceive the unit to be undesirable and unacceptable. Sources of this variability include differences in materials, differences in the performance and operation of the manufacturing equipment, and differences in the way the operators perform their tasks. This line of thinking led to the previous definition of quality improvement.

Since variability can only be described in statistical terms, **statistical methods** play a central role in quality improvement efforts. In the application of statistical methods to quality engineering, it is fairly typical to classify data on quality characteristics as either **attributes** or **variables** data. Variables data are usually continuous measurements, such as length, voltage, or viscosity. Attributes data, on the other hand, are usually discrete data, often taking the form of counts, such as the number of loan applications that could not be properly processed because of missing required information, or the number of emergency room arrivals that have to wait more than 30 minutes to receive medical attention. We will describe statistical-based quality engineering tools for dealing with both types of data.

Quality characteristics are often evaluated relative to **specifications**. For a manufactured product, the specifications are the desired measurements for the quality characteristics of the components and subassemblies that make up the product, as well as the desired values for the quality characteristics in the final product. For example, the diameter of a shaft used in an automobile transmission cannot be too large or it will not fit into the mating bearing, nor can it be too small, resulting in a loose fit, causing vibration, wear, and early failure of the assembly. In the service industries, specifications are typically expressed in terms of the maximum amount of time to process an order or to provide a particular service.

A value of a measurement that corresponds to the desired value for that quality characteristic is called the **nominal** or **target value** for that characteristic. These target values are usually bounded by a range of values that, most typically, we believe will be sufficiently close to the target so as to not impact the function or performance of the product if the quality characteristic is in that range. The largest allowable value for a quality characteristic is called the **upper specification limit (USL),** and the smallest allowable value for a quality characteristic is called the **lower specification limit (LSL).** Some quality characteristics have specification limits on only one side of the target. For example, the compressive strength of a component used in an automobile bumper likely has a target value and a lower specification limit, but not an upper specification limit.

Specifications are usually the result of the engineering design process for the product. Traditionally, design engineers have arrived at a product design configuration through the use of engineering science principles, which often results in the designer specifying the target values for the critical design parameters. Then prototype construction and testing follow. This testing is often done in a very unstructured manner, without the use of statistically based experimental design procedures, and without much interaction with or knowledge of the manufacturing processes that must produce the component parts and final product. However, through this general

procedure, the specification limits are usually determined by the design engineer. Then the final product is released to manufacturing. We refer to this as the **over-the-wall** approach to design.

Problems in product quality usually are greater when the over-the-wall approach to design is used. In this approach, specifications are often set without regard to the inherent variability that exists in materials, processes, and other parts of the system, which results in components or products that are nonconforming; that is, **nonconforming products** are those that fail to meet one or more of their specifications. A specific type of failure is called a **nonconformity.** A nonconforming product is not necessarily unfit for use; for example, a detergent may have a concentration of active ingredients that is below the lower specification limit, but it may still perform acceptably if the customer uses a greater amount of the product. A nonconforming product is considered **defective** if it has one or more **defects,** which are nonconformities that are serious enough to significantly affect the safe or effective use of the product. Obviously, failure on the part of a company to improve its manufacturing processes can also cause nonconformities and defects.

The over-the-wall design process has been the subject of much attention in the past 30 years. CAD/CAM systems have done much to automate the design process and to more effectively translate specifications into manufacturing activities and processes. Design for manufacturability and assembly has emerged as an important part of overcoming the inherent problems with the over-the-wall approach to design, and most engineers receive some background on those areas today as part of their formal education. The recent emphasis on **concurrent engineering** has stressed a team approach to design, with specialists in manufacturing, quality engineering, and other disciplines working together with the product designer at the earliest stages of the product design process. Furthermore, the effective use of the quality improvement methodology in this book, at all levels of the process used in technology commercialization and product realization, including product design, development, manufacturing, distribution, and customer support, plays a crucial role in quality improvement.

## 1.2 A BRIEF HISTORY OF QUALITY CONTROL AND IMPROVEMENT

Quality always has been an integral part of virtually all products and services. Quality was one of the reasons that guilds of skilled craftsmen were formed in medieval Europe. However, our awareness of its importance and the introduction of formal methods for quality control and improvement have been an evolutionary development. Table 1.1 presents a timeline of some of the important milestones in this evolutionary process. We will briefly discuss some of the events on this timeline.

Frederick W. Taylor introduced some principles of scientific management as mass production industries began to develop prior to 1900. Taylor pioneered dividing work into tasks so that the product could be manufactured and assembled more easily. His work led to substantial improvements in productivity. Also, because of standardized production and assembly methods, the quality of manufactured goods was positively impacted as well. However, along with the standardization of work methods came the concept of work standards—a standard time to accomplish the work, or a specified number of units that must be produced per period. Frank Gilbreth and others extended this concept to the study of motion and work design. Much of this had a positive impact on productivity, but it often did not sufficiently emphasize the quality aspect of work. Furthermore, if carried to extremes, work standards have the risk of halting innovation and continuous improvement, which we recognize today as being a vital aspect of all work activities.

Statistical methods and their application in quality improvement have had a long history. In 1924, Walter A. Shewhart of the Bell Telephone Laboratories developed the statistical control chart concept, which is often considered the formal beginning of statistical quality control. Toward the end of the 1920s, Harold F. Dodge and Harry G. Romig, both of Bell Telephone Laboratories, developed statistically based acceptance sampling as an alternative to 100% inspection. By the middle of the 1930s, statistical quality-control methods were in wide use at Western Electric, the manufacturing arm of the Bell System. However, the value of statistical quality control was not widely recognized by industry.

**Table 1.1** A Timeline of Quality Methods

| | |
|---|---|
| 1700–1900 | Quality is largely determined by the efforts of an individual craftsman. |
| | Eli Whitney introduces standardized, interchangeable parts to simplify assembly. |
| 1875 | Frederick W. Taylor introduces "Scientific Management" principles to divide work into smaller, more easily accomplished units—the first approach to dealing with more complex products and processes. The focus was on productivity. Later contributors were Frank Gilbreth and Henry Gantt. |
| 1900–1930 | Henry Ford—the assembly line—further refinement of work methods to improve productivity and quality; Ford developed mistake-proof assembly concepts, self-checking, and in-process inspection. |
| 1901 | First standards laboratories established in Great Britain. |
| 1907–1908 | AT&T begins systematic inspection and testing of products and materials. |
| 1908 | W. S. Gosset (writing as "Student") introduces the *t*-distribution—results from his work on quality control at Guinness Brewery. |
| 1915–1919 | WWI—British government begins a supplier certification program. |
| 1919 | Technical Inspection Association is formed in England; this later becomes the Institute of Quality Assurance. |
| 1920s | AT&T Bell Laboratories forms a quality department—emphasizing quality, inspection and test, and product reliability. |
| | B. P. Dudding at General Electric in England uses statistical methods to control the quality of electric lamps. |
| 1922 | Henry Ford writes (with Samuel Crowtha) and publishes *My Life and Work*, which focused on elimination of waste and improving process efficiency. Many Ford concepts and ideas are the basis of lean principles used today. |
| 1922–1923 | R. A. Fisher publishes series of fundamental papers on designed experiments and their application to the agricultural sciences. |
| 1924 | W. A. Shewhart introduces the control chart concept in a Bell Laboratories technical memorandum. |
| 1928 | Acceptance sampling methodology is developed and refined by H. F. Dodge and H. G. Romig at Bell Labs. |
| 1931 | W. A. Shewhart publishes *Economic Control of Quality of Manufactured Product*—outlining statistical methods for use in production and control chart methods. |
| 1932 | W. A. Shewhart gives lectures on statistical methods in production and control charts at the University of London. |
| 1932–1933 | British textile and woolen industry and German chemical industry begin use of designed experiments for product/process development. |
| 1933 | The Royal Statistical Society forms the Industrial and Agricultural Research Section. |
| 1938 | W. E. Deming invites Shewhart to present seminars on control charts at the U.S. Department of Agriculture Graduate School. |
| 1940 | The U.S. War Department publishes a guide for using control charts to analyze process data. |
| 1940–1943 | Bell Labs develop the forerunners of the military standard sampling plans for the U.S. Army. |
| 1942 | In Great Britain, the Ministry of Supply Advising Service on Statistical Methods and Quality Control is formed. |
| 1942–1946 | Training courses on statistical quality control are given to industry; more than 15 quality societies are formed in North America. |
| 1944 | *Industrial Quality Control* begins publication. |
| 1946 | The American Society for Quality Control (ASQC) is formed as the merger of various quality societies.<br>The International Standards Organization (ISO) is founded. |
| | Deming is invited to Japan by the Economic and Scientific Services Section of the U.S. War Department to help occupation forces in rebuilding Japanese industry. |
| | The Japanese Union of Scientists and Engineers (JUSE) is formed. |

**Table 1.1** (*continued*)

| | |
|---|---|
| 1946–1949 | Deming is invited to give statistical quality control seminars to Japanese industry. |
| 1948 | G. Taguchi begins study and application of experimental design. |
| 1950 | Deming begins education of Japanese industrial managers; statistical quality control methods begin to be widely taught in Japan. |
| 1950–1975 | Taiichi Ohno, Shigeo Shingo, and Eiji Toyoda develops the Toyota Production System an integrated technical/social system that defined and developed many lean principles such as just-in-time production and rapid setup of tools and equipment.<br>K. Ishikawa introduces the cause-and-effect diagram. |
| 1950s | Classic texts on statistical quality control by Eugene Grant and A. J. Duncan appear. |
| 1951 | A. V. Feigenbaum publishes the first edition of his book *Total Quality Control*.<br>JUSE establishes the Deming Prize for significant achievement in quality control and quality methodology. |
| 1951+ | G. E. P. Box and K. B. Wilson publish fundamental work on using designed experiments and response surface methodology for process optimization; focus is on chemical industry. Applications of designed experiments in the chemical industry grow steadily after this. |
| 1954 | Joseph M. Juran is invited by the Japanese to lecture on quality management and improvement.<br>British statistician E. S. Page introduces the cumulative sum (CUSUM) control chart. |
| 1957 | J. M. Juran and F. M. Gryna's *Quality Control Handbook* is first published. |
| 1959 | *Technometrics* (a journal of statistics for the physical, chemical, and engineering sciences) is established; J. Stuart Hunter is the founding editor. The journal is a joint publication of the American Statistical Association and American Society for Quality Control (now the American Society for Quality).<br>S. Roberts introduces the exponentially weighted moving average (EWMA) control chart. The U.S.-manned spaceflight program makes industry aware of the need for reliable products; the field of reliability engineering grows from this starting point. |
| 1960 | G. E. P. Box and J. S. Hunter write fundamental papers on $2^{k-p}$ factorial designs.<br>The quality control circle concept is introduced in Japan by K. Ishikawa. |
| 1961 | National Council for Quality and Productivity is formed in Great Britain as part of the British Productivity Council. |
| 1960s | Courses in statistical quality control become widespread in industrial engineering academic programs.<br>Zero defects (ZD) programs are introduced in certain U.S. industries. |
| 1969 | *Industrial Quality Control* ceases publication, replaced by *Quality Progress* and the *Journal of Quality Technology* (Lloyd S. Nelson is the founding editor of *JQT*). |
| 1970s | In Great Britain, the NCQP and the Institute of Quality Assurance merge to form the British Quality Association. |
| 1975–1978 | Books on designed experiments oriented toward engineers and scientists begin to appear.<br>Interest in quality circles begins in North America—this grows into the total quality management (TQM) movement. |
| 1980s | Experimental design methods are introduced to and adopted by a wider group of organizations, including the electronics, aerospace, semiconductor, and automotive industries.<br>The works of Taguchi on designed experiments first appear in the United States. |
| 1984 | The American Statistical Association (ASA) establishes the Ad Hoc Committee on Quality and Productivity; this later becomes a full section of the ASA.<br>The journal *Quality and Reliability Engineering International* appears. |
| 1986 | Box and others visit Japan, noting the extensive use of designed experiments and other statistical methods. |
| 1987 | ISO publishes the first quality systems standard.<br>Motorola's Six Sigma initiative begins. |

*(Continued)*

**Table 1.1** (*continued*)

| | |
|---|---|
| 1988 | The Malcolm Baldrige National Quality Award is established by the U.S. Congress. |
| | The European Foundation for Quality Management is founded; this organization administers the European Quality Award. |
| 1989 | The journal *Quality Engineering* appears. |
| 1990s | ISO 9000 certification activities increase in U.S. industry; applicants for the Baldrige award grow steadily; many states sponsor quality awards based on the Baldrige criteria. |
| 1995 | Many undergraduate engineering programs require formal courses in statistical techniques, focusing on basic methods for process characterization and improvement. |
| 1997 | Motorola's Six Sigma approach spreads to other industries. |
| 1998 | The American Society for Quality Control becomes the American Society for Quality (see www.asq.org), attempting to indicate the broader aspects of the quality improvement field. |
| 2000s | ISO 9000:2000 standard is issued. Supply-chain management and supplier quality become even more critical factors in business success. Quality improvement activities expand beyond the traditional industrial setting into many other areas, including financial services, health care, insurance, and utilities. In later years the standard is updated and expanded in scope. |
| | Organizations begin to integrate lean principles into their Six Sigma initiatives, and lean Six Sigma becomes a widespread approach to business improvement. |

World War II saw a greatly expanded use and acceptance of statistical quality-control concepts in manufacturing industries. Wartime experience made it apparent that statistical techniques were necessary to control and improve product quality. The American Society for Quality Control was formed in 1946. This organization promotes the use of quality improvement techniques for all types of products and services. It offers a number of conferences, technical publications, and training programs in quality assurance. The 1950s and 1960s saw the emergence of reliability engineering, the introduction of several important textbooks on statistical quality control, and the viewpoint that quality is a way of managing the organization.

In the 1950s, designed experiments for product and process improvement were first introduced in the United States. The initial applications were in the chemical industry. These methods were widely exploited in the chemical industry, and they are often cited as one of the primary reasons that the U.S. chemical industry is one of the most competitive in the world and has lost little business to foreign companies. The spread of these methods outside the chemical industry was relatively slow until the late 1970s or early 1980s, when many Western companies discovered that their Japanese competitors had been systematically using designed experiments since the 1960s for process improvement, new process development, evaluation of new product designs, improvement of reliability and field performance of products, and many other aspects of product design, including selection of component and system tolerances. This discovery sparked further interest in statistically designed experiments and resulted in extensive efforts to introduce the methodology in engineering and development organizations in industry, as well as in academic engineering curricula.

Since 1980, there has been a profound growth in the use of statistical methods for quality and overall business improvement in the United States. This has been motivated, in part, by the widespread loss of business and markets suffered by many domestic companies that began during the 1970s. For example, the U.S. automobile industry was nearly destroyed by foreign competition during this period. One domestic automobile company estimated its operating losses at nearly $1 million *per hour* in 1980. The adoption and use of statistical methods have played a central role in the re-emergence of U.S. industry. Various management systems have also emerged as frameworks in which to implement quality improvement. In the next two sections, we briefly discuss the statistical methods that are the central focus of this book and give an overview of some key aspects of quality management.

## 1.3 STATISTICAL METHODS FOR QUALITY CONTROL AND IMPROVEMENT

This textbook concentrates on statistical and engineering technology useful in quality improvement. Specifically, we focus on three major areas: **statistical process control, design of experiments,** and (to a lesser extent) **acceptance sampling**. In addition to these techniques, a number of other statistical and analytical tools are useful in analyzing quality problems and improving the performance of processes. The role of some of these tools is illustrated in Figure 1.3, which presents a **process** as a system with a set of inputs and an output. In the case of a manufacturing process, the controllable input factors $x_1, x_2, \ldots, x_p$ are process variables such as temperatures, pressures, and feed rates. The inputs $z_1, z_2, \ldots, z_q$ are uncontrollable (or difficult to control) inputs, such as environmental factors or properties of raw materials provided by an external supplier. The production process transforms the input raw materials, component parts, and subassemblies into a finished product that has several quality characteristics. The output variable $y$ is a quality characteristic—that is, a measure of process and product quality. This model can also be used to represent **non-manufacturing** or **service processes.** For example, consider a process in a financial institution that processes automobile loan applications. The inputs are the loan applications, which contain information about the customer and his/her credit history, the type of car to be purchased, its price, and the loan amount. The controllable factors are the type of training that the loan officer receives, the specific rules and policies that the bank imposed on these loans, and the number of people working as loan officers at each time period. The uncontrollable factors include prevailing interest rates, the amount of capital available for these types of loans in each time period, and the number of loan applications that require processing each period. The output quality characteristics include whether or not the loan is funded, the number of funded loans that are actually accepted by the applicant, and the cycle time—that is, the length of time that the customer waits until a decision on his/her loan application is made. In service systems, cycle time is often a very important CTQ.

A **control chart** is one of the primary techniques of **statistical process control (SPC)**. A typical control chart is shown in Figure 1.4. This chart plots the averages of measurements of a quality characteristic in samples taken from the process versus time (or the sample number). The chart has a center line (CL) and upper and lower control limits (UCL and LCL in Fig. 1.4). The center line represents where this process characteristic should fall if there are no unusual sources of variability present. The control limits are determined from some simple statistical considerations that we will discuss in Chapters 4, 5, and 6. Classically, control charts are applied to the output variable(s) in a system such as in Figure 1.4. However, in some cases, they can be usefully applied to the inputs as well.

The control chart is a very useful **process monitoring technique**; when unusual sources of variability are present, sample averages will plot outside the control limits. This is a signal that some investigation of the process should be made and corrective action taken to remove these

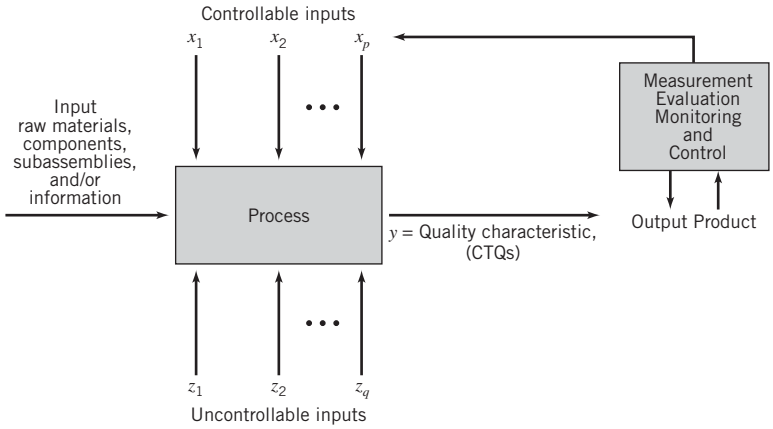



**FIGURE 1.3** Production process inputs and outputs.

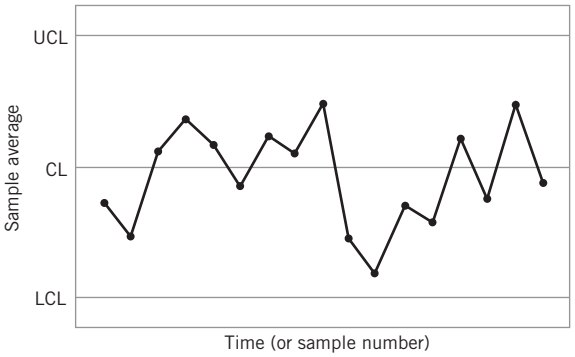



**FIGURE 1.4** A typical control chart.

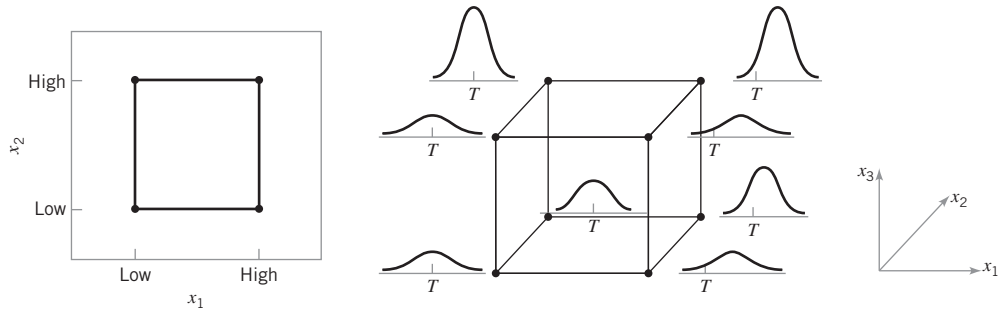
unusual sources of variability. Systematic use of a control chart is an excellent way to reduce variability.

A **designed experiment** is extremely helpful in discovering the key variables influencing the quality characteristics of interest in the process. A designed experiment is an approach to systematically varying the controllable input factors in the process and determining the effect these factors have on the output product parameters. Statistically designed experiments are invaluable in reducing the variability in the quality characteristics and in determining the levels of the controllable variables that optimize process performance. Often significant breakthroughs in process performance and product quality also result from using designed experiments.

One major type of designed experiment is the **factorial design,** in which factors are varied together in such a way that all possible combinations of factor levels are tested. Figure 1.5 shows two possible factorial designs for the process in Figure 1.3, for the cases of $p = 2$ and $p = 3$ controllable factors. In Figure 1.5*a*, the factors have two levels, low and high, and the four possible test combinations in this factorial experiment form the corners of a square. In Figure 1.5*b*, there are three factors each at two levels, giving an experiment with eight test combinations arranged at the corners of a cube. The distributions at the corners of the cube represent the process performance at each combination of the controllable factors $x_1$, $x_2$, and $x_3$. It is clear that some combinations of factor levels produce better results than others. For example, increasing $x_1$ from low to high increases the average level of the process output and could shift it off the target value ($T$). Furthermore, process variability seems to be substantially reduced when we operate the process along the back edge of the cube, where $x_2$ and $x_3$ are at their high levels.

Designed experiments are a major **off-line** quality-control tool, because they are often used during development activities and the early stages of manufacturing, rather than as a routine **on-line** or **in-process** procedure. They play a crucial role in reducing variability.

Once we have identified a list of important variables that affect the process output, it is usually necessary to model the relationship between the influential input variables and the output quality characteristics. Statistical techniques useful in constructing such models include regression




(*a*) Two factors, $x_1$ and $x_2$ (*b*) Three factors, $x_1$, $x_2$, and $x_3$

**FIGURE 1.5** Factorial designs for the process in Figure 1.3.

analysis and time series analysis. Detailed discussions of designed experiments, regression analysis, and time series modeling are in Montgomery (2018), Montgomery, Peck, and Vining (2012), and Box, Jenkins, and Reinsel (1994).

When the important variables have been identified and the nature of the relationship between the important variables and the process output has been quantified, then an on-line statistical process-control technique for monitoring and surveillance of the process can be employed with considerable effectiveness. Techniques such as control charts can be used to monitor the process output and detect when changes in the inputs are required to bring the process back to an in-control state. The models that relate the influential inputs to process outputs help determine the nature and magnitude of the adjustments required. In many processes, once the dynamic nature of the relationships between the inputs and the outputs are understood, it may be possible to routinely adjust the process so that future values of the product characteristics will be approximately on target. This routine adjustment is often called **engineering control, automatic control,** or **feedback control.** We will briefly discuss these types of process control schemes in Chapter 11 and illustrate how statistical process control (or **SPC**) methods can be successfully integrated into a manufacturing system in which engineering control is in use.

The third area of quality control and improvement that we discuss is **acceptance sampling.** This is closely connected with inspection and testing of product, which is one of the earliest aspects of quality control, dating back long before statistical methodology was developed for quality improvement. Inspection can occur at many points in a process. Acceptance sampling, defined as the inspection and classification of a sample of units selected at random from a larger batch or lot and the ultimate decision about disposition of the lot, usually occurs at two points: incoming raw materials or components, or final production.

Several different variations of acceptance sampling are shown in Figure 1.6. In Figure 1.6*a*, the inspection operation is performed immediately following production, before the product is shipped to the customer. This is usually called **outgoing inspection.** Figure 1.6*b* illustrates **incoming inspection**—that is, a situation in which lots of batches of product are sampled as they are received from the supplier. Various lot-dispositioning decisions are illustrated in Figure 1.6*c*. Sampled lots may either be accepted or rejected. Items in a rejected lot are typically either scrapped or recycled, or they may be reworked or replaced with good units. This latter case is often called **rectifying inspection.**

Modern quality assurance systems usually place less emphasis on acceptance sampling and attempt to make statistical process control and designed experiments the focus of their efforts. Acceptance sampling tends to reinforce the conformance-to-specification view of quality and does not have any feedback into either the production process or engineering design or development that would necessarily lead to quality improvement.

Figure 1.7 shows the typical evolution in the use of these techniques in most organizations. At the lowest level of maturity, management may be completely unaware of quality issues, and

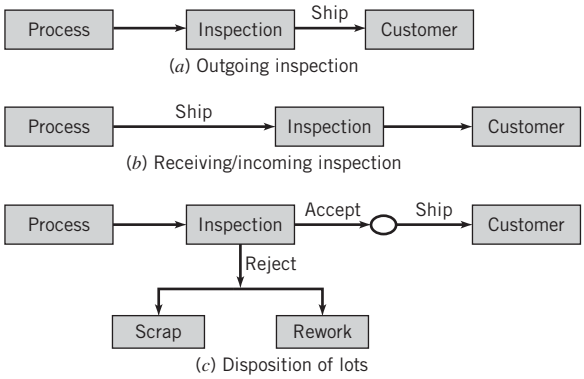



**FIGURE 1.6** Variations of acceptance sampling.

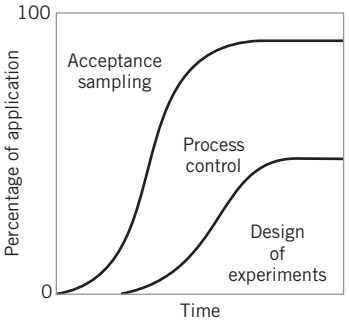



**FIGURE 1.7** Phase diagram of the use of quality-engineering methods.

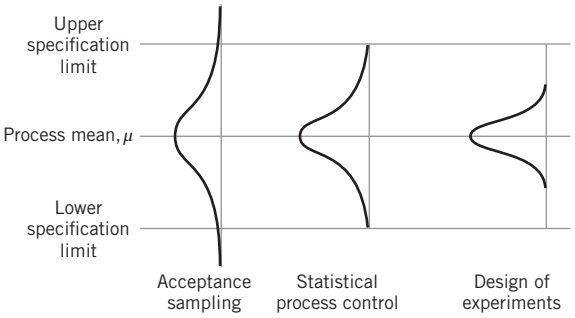



**FIGURE 1.8** Application of quality-engineering techniques and the systematic reduction of process variability.

there is likely to be no effective organized quality improvement effort. Frequently there will be some modest applications of acceptance-sampling and inspection methods, usually for incoming parts and materials. The first activity as maturity increases is to intensify the use of sampling inspection. The use of sampling will increase until it is realized that quality cannot be inspected or tested into the product.

At that point, the organization usually begins to focus on process improvement. Statistical process control and experimental design potentially have major impacts on manufacturing, product design activities, and process development. The systematic introduction of these methods usually marks the start of substantial quality, cost, and productivity improvements in the organization. At the highest levels of maturity, companies use designed experiments and statistical process control methods intensively and make relatively modest use of acceptance sampling.

The primary **objective** of quality engineering efforts is the **systematic reduction of variability** in the key quality characteristics of the product. Figure 1.8 shows how this happens over time. In the early stages, when acceptance sampling is the major technique in use, process "fallout," or units that do not conform to the specifications, constitute a high percentage of the process output. The introduction of statistical process control will stabilize the process and reduce the variability. However, it is not satisfactory just to meet requirements—further reduction of variability usually leads to better product performance and enhanced competitive position, as was vividly demonstrated in the automobile transmission example discussed earlier. Statistically designed experiments can be employed in conjunction with statistical process monitoring and control to minimize process variability in nearly all industrial settings.

## 1.4 MANAGEMENT ASPECTS OF QUALITY IMPROVEMENT

Statistical techniques, including SPC and designed experiments, along with other problem-solving tools, are the technical basis for quality control and improvement. However, to be used most effectively, these techniques must be implemented within and be part of a management system that is focused on quality improvement. The management system of an organization must be organized to properly direct the overall quality improvement philosophy and ensure its deployment in all aspects of the business. The effective management of quality involves successful execution of three activities: quality planning, quality assurance, and quality control and improvement.

**Quality planning** is a strategic activity, and it is just as vital to an organization's long-term business success as the product development plan, the financial plan, the marketing plan, and plans for the utilization of human resources. Without a strategic quality plan, an enormous amount of time, money, and effort will be wasted by the organization dealing with faulty designs, manufacturing defects, field failures, and customer complaints. Quality planning involves identifying customers, both external and those that operate internal to the business, and identifying their needs [this is sometimes called listening to the **voice of the customer (VOC)**]. Then products or services that meet or exceed customer expectations must be developed. The eight dimensions of quality discussed in Section 1.1.1 are an important part of this effort. The organization must then determine how these products and services will be realized. Planning for quality improvement on a specific, systematic basis is also a vital part of this process.

**Quality assurance** is the set of activities that ensures the quality levels of products and services are properly maintained and that supplier and customer quality issues are properly resolved. Documentation of the quality system is an important component. Quality system documentation involves four components: policy, procedures, work instructions and specifications, and records. Policy generally deals with what is to be done and why, while procedures focus on the methods and personnel that will implement policy. Work instructions and specifications are usually product-, department-, tool-, or machine-oriented. Records are a way of documenting the policies, procedures, and work instructions that have been followed. Records are also used to track specific units or batches of product, so that it can be determined exactly how they were produced. Records are often vital in providing data for dealing with customer complaints, corrective actions, and, if necessary, product recalls. Development, maintenance, and control of documentation are important quality assurance functions. One example of document control is ensuring that specifications and work instructions developed for operating personnel reflect the latest design and engineering changes.

**Quality control and improvement** involve the set of activities used to ensure that the products and services meet requirements and are improved on a continuous basis. Since variability is often a major source of poor quality, statistical techniques, including SPC and designed experiments, are the major tools of quality control and improvement. Quality improvement is often done on a project-by-project basis and involves teams led by personnel with specialized knowledge of statistical methods and experience in applying them. Projects should be selected so that they have significant business impact and are linked with the overall business goals for quality identified during the planning process. The techniques in this book are integral to successful quality control and improvement.

The next section provides a brief overview of some of the key elements of quality management. We discuss some of the important quality philosophies; quality systems and standards; the link between quality and productivity and quality and cost; economic and legal implications of quality; and some aspects of implementation. The three aspects of quality planning, quality assurance, and quality control and improvement are woven into the discussion.

### 1.4.1 QUALITY PHILOSOPHY AND MANAGEMENT STRATEGIES

Many people have contributed to the statistical methodology of quality improvement. However, in terms of implementation and management philosophy, three individuals emerge as the leaders: W. E. Deming, J. M. Juran, and A. V. Feigenbaum. We now briefly discuss the approaches and philosophy of those leaders in quality management.

#### W. Edwards Deming.

W. Edwards Deming was educated in engineering and physics at the University of Wyoming and Yale University. He worked for Western Electric and was influenced greatly by Walter A. Shewhart, the developer of the control chart. After leaving Western Electric, Deming held government jobs with the U.S. Department of Agriculture and the Bureau of the Census. During

World War II, Deming worked for the War Department and the Census Bureau. Following the war, he became a consultant to Japanese industries and convinced their top management of the power of statistical methods and the importance of quality as a competitive weapon. This commitment to and use of statistical methods has been a key element in the expansion of Japan's industry and economy. The Japanese Union of Scientists and Engineers created the Deming Prize for quality improvement in his honor. Until his death in 1993, Deming was an active consultant and speaker; he was an inspirational force for quality improvement in the United States and around the world. He firmly believed that the responsibility for quality rests with management—that is, most of the opportunities for quality improvement require management action, and very few opportunities lie at the workforce or operator level. Deming was a harsh critic of many American management practices.

The Deming philosophy is an important framework for implementing quality and productivity improvement. This philosophy is summarized in his 14 points for management. We now give a brief statement and discussion of **Deming's 14 points**:

1. **Create a constancy of purpose focused on the improvement of products and services.** Deming was very critical of the short-term thinking of American management, which tends to be driven by quarterly business results and doesn't always focus on strategies that benefit the organization in the long run. Management should constantly try to improve product design and performance. This must include investment in research, development, and innovation, which will have long-term payback to the organization.
2. **Adopt a new philosophy that recognizes we are in a different economic era.** Reject poor workmanship, defective products, or bad service. It costs as much to produce a defective unit as it does to produce a good one (and sometimes more). The cost of dealing with scrap, rework, and other losses created by defectives is an enormous drain on company resources.
3. **Do not rely on mass inspection to "control" quality.** All inspection can do is sort out defectives, and at that point it is too late—the organization already has paid to produce those defectives. Inspection typically occurs too late in the process, it is expensive, and it is often ineffective. Quality results from prevention of defectives through process improvement, not inspection.
4. **Do not award business to suppliers on the basis of price alone, but also consider quality.** Price is a meaningful measure of a supplier's product only if it is considered in relation to a measure of quality. In other words, the total cost of the item must be considered, not just the purchase price. When quality is considered, the lowest bidder frequently is not the low-cost supplier. Preference should be given to suppliers who use modern methods of quality improvement in their business and who can demonstrate process control and capability. An adversarial relationship with suppliers is harmful. It is important to build effective, long-term relationships.
5. **Focus on continuous improvement.** Constantly try to improve the production and service system. Involve the workforce in these activities and make use of statistical methods, particularly the statistically based problem-solving tools discussed in this book.
6. **Practice modern training methods and invest in on-the-job training for all employees.** Everyone should be trained in the technical aspects of their job, and in modern quality- and productivity-improvement methods as well. The training should encourage all employees to practice these methods every day. Too often, employees are not encouraged to use the results of training, and management often believes employees do not need training or already should be able to practice the methods. Many organizations devote little or no effort to training.
7. **Improve leadership, and practice modern supervision methods.** Supervision should not consist merely of passive surveillance of workers but should be focused on helping the

employees improve the system in which they work. The number-one goal of supervision should be to improve the work system and the product.

8. **Drive out fear.** Many workers are afraid to ask questions, report problems, or point out conditions that are barriers to quality and effective production. In many organizations, the economic loss associated with fear is large; only management can eliminate fear.

9. **Break down the barriers between functional areas of the business.** Teamwork among different organizational units is essential for effective quality and productivity improvement to take place.

10. **Eliminate targets, slogans, and numerical goals for the workforce.** A target such as "zero defects" is useless without a plan for the achievement of this objective. In fact, these slogans and "programs" are usually counterproductive. Work to improve the system and provide information on that.

11. **Eliminate numerical quotas and work standards.** These standards have historically been set without regard to quality. Work standards are often symptoms of management's inability to understand the work process and to provide an effective management system focused on improving this process.

12. **Remove the barriers that discourage employees from doing their jobs.** Management must listen to employee suggestions, comments, and complaints. The person who is doing the job knows the most about it and usually has valuable ideas about how to make the process work more effectively. The workforce is an important participant in the business, and not just an opponent in collective bargaining.

13. **Institute an ongoing program of education for all employees.** Education in simple, powerful statistical techniques should be mandatory for all employees. Use of the basic SPC problem-solving tools, particularly the control chart, should become widespread in the business. As these charts become widespread and as employees understand their uses, they will be more likely to look for the causes of poor quality and to identify process improvements. Education is a way of making everyone partners in the quality improvement process.

14. **Create a structure in top management that will vigorously advocate the first 13 points.** This structure must be driven from the very top of the organization. It must also include concurrent education/training activities and expedite application of the training to achieve improved business results. Everyone in the organization must know that continuous improvement is a common goal.

As we read Deming's 14 points, we notice a strong emphasis on **organizational change.** Also, the role of management in guiding this change process is of dominating importance. However, what should be changed, and how should this change process be started? For example, if we want to improve the yield of a semiconductor manufacturing process, what should we do? It is in this area that statistical methods come into play most frequently. To improve the semiconductor process, we must determine which controllable factors in the process influence the number of defective units produced. To answer this question, we must collect data on the process and see how the system reacts to change in the process variables. Then actions to improve the process can be designed and implemented. Statistical methods, such as designed experiments and control charts, can contribute to these activities.

Deming frequently wrote and spoke about the **seven deadly diseases of management,** listed in Table 1.2. He believed that each disease was a barrier to the effective implementation of his philosophy. The first, lack of constancy of purpose, relates to the first of Deming's 14 points. Continuous improvement of products, processes, and services gives assurance to all stakeholders

**Table 1.2** Deming's Seven Deadly Diseases of Management

| | |
|---|---|
| 1. | Lack of constancy of purpose |
| 2. | Emphasis on short-term profits |
| 3. | Evaluation of performance, merit rating, and annual reviews of performance |
| 4. | Mobility of top management |
| 5. | Running a company on visible figures alone |
| 6. | Excessive medical costs |
| 7. | Excessive legal damage awards |

in the enterprise (employees, executives, investors, suppliers) that dividends and increases in the value of the business will continue to grow.

The second disease, too much emphasis on short-term profits, might make the "numbers" look good, but if this is achieved by reducing research and development investment, by eliminating employees' training, and by not deploying quality and other business improvement activities, then potentially irreparable long-term damage to the business is the ultimate result. Concerning the third disease, Deming believed that performance evaluation encouraged short-term performance, rivalries and fear, and discouraged effective teamwork. Performance reviews can leave employees bitter and discouraged, and they may feel unfairly treated, especially if they are working in an organization where their performance is impacted by system forces that are flawed and out of their control.

The fourth disease, management mobility, refers to the widespread practice of job-hopping—that is, a manger spending very little time in the business function for which he or she is responsible. This often results in key decisions being made by someone who really doesn't understand the business. Managers often spend more time thinking about their next career move than about their current job and how to do it better. Frequent reorganizing and shifting management responsibilities are barriers to constancy of purpose and often a waste of resources that should be devoted to improving products and services. Bringing in a new chief executive officer to improve quarterly profits often leads to a business strategy that leaves a path of destruction throughout the business.

The fifth disease, management by visible figures alone (such as the number of defects, customer complaints, and quarterly profits), suggests that the really important factors that determine long-term organizational success are unknown and unknowable. As some evidence of this, of the 100 largest companies in 1900, only 16 still exist today, and of the 25 largest companies in 1900, only 2 are still among the top 25. Obviously, some visible figures are important; for example, suppliers and employees must be paid on time and the bank accounts must be managed. However, if visible figures alone were key determinants of success, it's likely that many more of the companies of 1900 still would be in business.

Deming's cautions about excessive medical expenses—his sixth deadly disease—are certainly prophetic: Health care costs may be the most important issue facing many sectors of business in the United States today. For example, the medical costs for current and retired employees of United States automobile manufacturers General Motors, Ford, and Chrysler currently are estimated to be between $1200 and $1600 per vehicle, contrasted with $250 to $350 per vehicle for Toyota and Honda, two Japanese automobile manufacturers with extensive North American manufacturing and assembly operations. The seventh disease, liability and excessive damage awards, is also a major issue facing many organizations. Deming was fond of observing that the United States had more lawyers per capita than any other nation. He believed that government intervention likely would be necessary to provide effective long-term solutions to the medical cost and excessive liability awards problems.

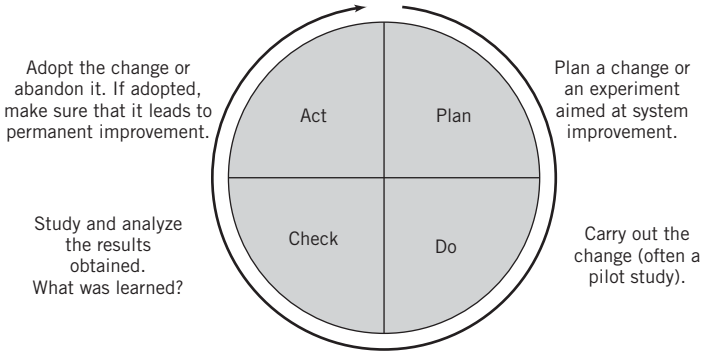



**FIGURE 1.9** The Shewhart cycle.

Deming recommended the **Shewhart cycle,** shown in Figure 1.9, as a model to guide improvement. The four steps, **Plan-Do-Check-Act,** are often called the **PDCA cycle.** Sometimes the **Check** step is called **Study,** and the cycle becomes the **PDSA cycle.** In **Plan,** we propose a change in the system that is aimed at improvement. In **Do,** we carry out the change, usually on a small or pilot scale, to ensure that the results that are desired will be obtained. **Check** consists of analyzing the results of the change to determine what has been learned about the changes that were carried out. In **Act,** we either adopt the change or, if it was unsuccessful, abandon it. The process is almost always iterative and may require several cycles for solving complex problems.

In addition to Deming's 14 points and the seven deadly diseases of management, Deming wrote and lectured about an extensive collection of **obstacles to success.** Some of these include:

1. The belief that automation, computers, and new machinery will solve problems.
2. Searching for examples—trying to copy existing solutions.
3. The "our problems are different" excuse and not realizing that the principles that will solve them are universal.
4. Obsolete schools, particularly business schools, where graduates have not been taught how to successfully run businesses.
5. Poor teaching of statistical methods in industry: Teaching tools without a framework for using them is going to be unsuccessful.
6. Reliance on inspection to produce quality.
7. Reliance on the "quality control department" to take care of all quality problems.
8. Blaming the workforce for problems.
9. False starts, such as broad teaching of statistical methods without a plan as to how to use them, quality circles, employee suggestion systems, and other forms of "instant pudding."
10. The fallacy of zero defects: Companies fail even though they produce products and services without defects. Meeting the specifications isn't the complete story in any business.
11. Inadequate testing of prototypes: A prototype may be a one-off article, with artificially good dimensions, but without knowledge of variability, testing a prototype tells very little. This is a symptom of inadequate understanding of product design, development, and the overall activity of technology commercialization.
12. "Anyone that comes to help us must understand all about our business." This is bizarre thinking: There already are competent people in the organization who know everything about the business—except how to improve it. New knowledge and ideas (often from the outside) must be fused with existing business expertise to bring about change and improvement.

### Joseph M. Juran.

Juran was born in 1904 and died in 2008. He was one of the founding fathers of the quality-control and improvement field. He worked for Walter A. Shewhart at AT&T Bell Laboratories and was at the leading edge of quality improvement throughout his career. Juran became the chief industrial engineer at Western Electric (part of the Bell System). He was an assistant administrator for the Lend-Lease Administration during World War II and played an important role in simplifying the administrative and paper work processes of that agency. After the war, he became the head of the Department of Administrative Engineering at New York University. He was invited to speak to Japanese industry leaders as they began their industrial transformation in the early 1950s. He also created an active consulting practice (the Juran Institute) and lectured widely through the American Management Association. He was the co-author (with Frank M. Gryna) of the *Quality Control Handbook*, a standard reference for quality methods and improvement since its initial publication in 1957.

The Juran quality management philosophy focuses on three components: **planning, control,** and **improvement.** These are known as the **Juran Trilogy**. As we have noted previously, planning involves identifying external customers and determining their needs. Then products or services that meet these customer needs are designed and/or developed, and the processes for producing these products or services are then developed. The planning process should also involve planning for quality improvement on a regular (typically annual) basis. Control is employed by the operating forces of the business to ensure that the product or service meets the requirements. SPC is one of the primary tools of control. Improvement aims to achieve performance and quality levels that are higher than current levels. Juran emphasizes that improvement must be on a project-by-project basis. These projects are typically identified at the planning stage of the trilogy. Improvement can either be continuous (or incremental) or by breakthrough. Typically, a breakthrough improvement is the result of studying the process and identifying a set of changes that result in a large, relatively rapid improvement in performance. Designed experiments are an important tool that can be used to achieve breakthrough.

### Armand V. Feigenbaum.

Feigenbaum was born in 1922 and died in 2014. He first introduced the concept of companywide quality control in his historic book *Total Quality Control* (first published in 1951). This book influenced much of the early philosophy of quality management in Japan in the early 1950s. In fact, many Japanese companies used the term "total quality control" to describe their efforts. He proposed a three-step approach to improving quality: quality leadership, quality technology, and organizational commitment. By **quality technology,** Feigenbaum means statistical methods and other technical and engineering methods, such as the ones discussed in this book.

Feigenbaum was concerned with organizational structure and a systems approach to improving quality. He proposed a 19-step improvement process, of which use of statistical methods was step 17. He initially suggested that much of the technical capability be concentrated in a specialized department. This is in contrast to the more modern view that knowledge and use of statistical tools need to be widespread. However, the organizational aspects of Feigenbaum's work are important, as quality improvement does not usually spring forth as a "grass roots" activity; it requires a lot of management commitment to make it work.

The brief descriptions of the philosophies of Deming, Juran, and Feigenbaum have highlighted both the common aspects and differences among their viewpoints. In this author's opinion, there are more similarities than differences among them, and the similarities are what are important. All three of these pioneers stress the importance of quality as an essential competitive weapon, the important role that management must play in implementing quality improvement, and the importance of statistical methods and techniques in the "quality transformation" of an organization.

### Total Quality Management.

**Total quality management (TQM)** is a strategy for implementing and managing quality improvement activities on an organizationwide basis. TQM began in the early 1980s, with the philosophies of Deming and Juran as the focal point. It evolved into a broader spectrum of concepts and ideas, involving participative organizations and work culture, customer focus, supplier quality improvement, integration of the quality system with business goals, and many other activities to focus all elements of the organization around the quality improvement goal. Typically, organizations that have implemented a TQM approach to quality improvement have quality councils or high-level teams that deal with strategic quality initiatives, workforce-level teams that focus on routine production or business activities, and cross-functional teams that address specific quality improvement issues.

TQM has only had moderate success for a variety of reasons, but frequently because there is insufficient effort devoted to widespread utilization of the technical tools of variability reduction. Many organizations saw the mission of TQM as one of training. Consequently, many TQM efforts engaged in widespread training of the workforce in the philosophy of quality improvement and a few basic methods. This training was usually placed in the hands of human resources departments, and much of it was ineffective. The trainers often had no real idea about *what* methods should be taught, or how the methods should be used, and success was usually measured by the percentage of the workforce that had been "trained," not by whether any measurable impact on business results had been achieved. Some general reasons for the lack of conspicuous success of TQM include (1) lack of topdown, high-level **management commitment and involvement**; (2) inadequate use of statistical methods and insufficient recognition of variability reduction as a prime objective; (3) general as opposed to specific business-results-oriented objectives; and (4) too much emphasis on widespread **training** as opposed to focused technical **education.**

Another reason for the erratic success of TQM is that many managers and executives have regarded it as just another "program" to improve quality. During the 1950s and 1960s, programs such as **Zero Defects** and **Value Engineering** abounded, but they had little real impact on quality and productivity improvement. During the heyday of TQM in the 1980s, another popular program was the **Quality is Free** initiative, in which management worked on identifying the cost of quality (or the cost of nonquality, as the Quality is Free devotees so cleverly put it). Indeed, identification of quality costs can be very useful (we discuss quality costs in Section 1.4.3), but the Quality is Free practitioners often had no idea about what to do to actually improve many types of complex industrial processes. In fact, the leaders of this initiative had no knowledge about statistical methodology and completely failed to understand its role in quality improvement. When TQM is wrapped around an ineffective program such as this, disaster is often the result.

### Quality Systems and Standards.

The International Organization for Standardization (founded in 1947 in Geneva, Switzerland), known as ISO, has developed a series of standards for quality systems. The first standards were issued in 1987. The current version of the standard is known as the ISO 9000 series. It was revised in 2008 and 2015. It is a generic standard, broadly applicable to any type of organization, and it is often used to demonstrate a supplier's ability to control its processes. The three standards of ISO 9000 are:

ISO 9000:2005 Quality Management System—Fundamentals and Vocabulary

ISO 9001:2008 Quality Management System—Requirements

ISO 9004:2009 Quality Management System—Guidelines for Performance Improvement

ISO 9000 is also an American National Standards Institute and an ASQ standard.

The ISO 9000 family contains the following standards:

ISO 9001:2015: Quality management systems—Requirements

ISO 9000:2015: Quality management systems—Fundamentals and definitions

ISO 9004:2009: Quality management systems—Managing for the sustained success of an organization (continuous improvement)

ISO 19011:2011: Guidelines for auditing management systems

IDO 9000: 2015 and ISO 9001:2015 are based on seven principles:

1.0 **Customer focus.** This involves understanding the needs of current and future customers, aligning organizational objectives with customer needs and expectations, meeting or exceeding customer requirements, measuring customer satisfaction, and managing customer relationships.

2.0 **Leadership.** Establishing a vision and direction for the organization, setting challenging goals, developing organizational values, establishing trust, equipping and empowering employees, and recognizing employee contributions.

3.0 **Engagement of people.** Ensuring that people's abilities are used and valued, making people accountable, enable participation in continuous improvement, evaluate individual performance, enable learning and knowledge sharing, and enable open discussion of problems and constraints.

4.0 **Process approach.** Manage activities as processes, measure the capability of processes and activities, identify linkages between processes and activities, identify and prioritize improvement opportunities, and deploy and utilize resources effectively.

5.0 **Improvement.** Improve organizational performance and capabilities, align improvement activities, empower people to make improvements, measure improvement consistently, and celebrate improvements.

6.0 **Employ evidence-based decision-making.** Ensure the accessibility of accurate and reliable data, use appropriate methods to analyze data, make decisions based on data and analysis, and utilize practical experience in decision-making.

7.0 **Relationship management.** Identify and select suppliers to manage costs, optimize resources, and create value, establish relationships considering both the short and long term, share expertise, resources, information, and plans with partners, collaborate on improvement and development activities, and recognize supplier successes.

ISO 9001:2015 also requires the identification of interested parties and their requirements. Typically, organizations identify or obtain specific requirements from business owners and partners, customers, and regulators, but the list of interested parties is often much larger and could include not only owners, customers, and regulators but also investors, employees, external providers, other stakeholders, competitors, other industry sectors, auditors, and society at large. For example, external providers could include things such as nondisclosure agreements, supplier quality requirements, and service-level agreements. There is also an explicit requirement for risk-based decision-making throughout the organization. While this concept was at last implicit in earlier versions of the standard, it is now a requirement and should be a part of prevention and improvement activities. Organizations are free to develop their own approaches to risk management and mitigation because there is no requirement for a documented risk management process.

To become certified under the ISO standard, a company must select a **registrar** and prepare for a **certification audit** by this registrar. There is no single independent authority that licenses, regulates, monitors, or qualifies registrars. As we will discuss later, this is a serious problem with the ISO system. Preparing for the certification audit involves many activities, including (usually) an initial or phase I audit that checks the present quality management system against the standard. This is usually followed by establishing teams to ensure that all components of the key clause are developed and implemented, training personnel, developing applicable documentation, and developing and installing all new components of the quality system that may be required. Then the certification audit takes place. If the company is certified, then periodic **surveillance audits** by the registrar continue, usually on an annual (or perhaps six-month) schedule.

Many organizations have required their suppliers to become certified under ISO 9000, or one of the standards that are more industry-specific. Examples of these industry-specific quality system standards are AS 9100 for the aerospace industry; ISO/TS 16949 and QS 9001 for the automotive industry; and TL 9000 for the telecommunications industry. Many components of these standards are very similar to those of ISO 9000.

Much of the focus of ISO 9000 (and of the industry-specific standards) is on formal documentation of the quality system—that is, on **quality assurance** activities. Organizations usually must make extensive efforts to bring their documentation into line with the requirements of the standards; this can be the Achilles' heel of ISO 9000 and other related or derivative standards. It is typical to devote far too much effort to documentation, paperwork, and bookkeeping and not nearly enough to actually reducing variability and improving processes and products. Furthermore, many of the third-party registrars, auditors, and consultants that work in this area are not sufficiently educated or experienced enough in the **technical** tools required for **quality improvement** or how these tools should be deployed. They are all too often unaware of what constitutes modern engineering and statistical practice and usually are familiar with only the most elementary techniques. Therefore, many of them concentrate largely on the documentation, recordkeeping, and paperwork aspects of certification.

There is also evidence that ISO certification or certification under one of the other industry-specific standards does little to prevent poor quality products from being designed, manufactured, and delivered to the customer. For example, in 1999–2000, there were numerous incidents of rollover accidents involving Ford Explorer vehicles equipped with Bridgestone/Firestone tires. There were nearly 300 deaths in the United States alone attributed to these accidents, which led to a recall by Bridgestone/Firestone of approximately 6.5 million tires. Apparently, many of the tires involved in these incidents were manufactured at the Bridgestone/Firestone plant in Decatur, Illinois. In an article on this story in *Time* magazine (September 18, 2000), there was a photograph (p. 38) of the sign at the entrance of the Decatur plant, which stated that the plant was "QS 9000 Certified" and "ISO 14001 Certified" (ISO 14001 is an environmental standard). Although the assignable causes underlying these incidents have not been fully discovered, there are clear indicators that despite quality systems certification, Bridgestone/Firestone experienced significant quality problems. ISO certification alone is no guarantee that good quality products are being designed, manufactured, and delivered to the customer. It is said that a company manufacturing concrete life jackets could become ISO certified if they could show the proper documentation. Relying entirely on ISO certification as the cornerstone of a quality management system is a strategic management mistake.

It has been estimated that ISO certification activities are approximately a *$40 billion annual business*, worldwide. Much of this money flows to the registrars, auditors, and consultants. This amount does not include all of the internal costs incurred by organizations to achieve registration, such as the thousands of hours of engineering and management effort, travel, internal training, and internal auditing. It is not clear whether any significant fraction of this expenditure has made its way to the bottom line of the registered organizations. Furthermore, there is no assurance that certification has any real impact on quality (as in the Bridgestone/Firestone tire incidents). Many

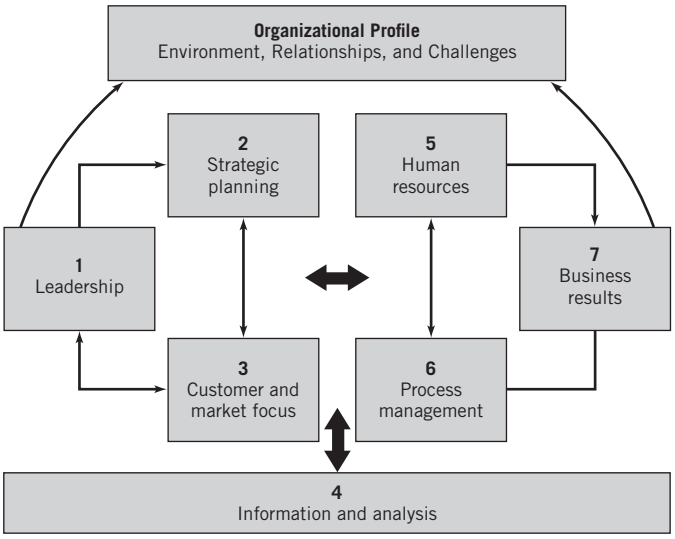



**FIGURE 1.10** The structure of the MBNQA performance excellence criteria. (Source: Foundation for the Malcolm Baldrige National Quality Award, 2002 Criteria for Performance Excellence. National Institute of Standards and Technology, U.S. Department of Commerce.)

quality engineering authorities believe that ISO certification by itself is largely a waste of effort. Often, organizations would be far better off to "just say no to ISO" and spend a small fraction of that $40 billion on their quality systems and another larger fraction on meaningful variability reduction efforts, develop their own internal (or perhaps industry-based) quality standards, rigorously enforce them, and pocket the difference.

### The Malcolm Baldrige National Quality Award.

The Malcolm Baldrige National Quality Award (MBNQA) was created by the U.S. Congress in 1987. It is given annually to recognize U.S. organizations for performance excellence. Awards are given to organizations in five categories: manufacturing, service, small business, health care, and education. Three awards may be given each year in each category. Many organizations compete for the awards, and many companies use the performance excellence criteria for self-assessment. The award is administered by NIST (the National Institute of Standards and Technology).

The performance excellence criteria and their interrelationships are shown in Figure 1.10. The point values for these criteria in the MBNQA are shown in Table 1.3. The criteria are directed toward results, where results are a composite of customer satisfaction and retention, market share and new market development, product/service quality, productivity and operational effectiveness, human resources development, supplier performance, and public/corporate citizenship. The criteria are nonprescriptive—that is, the focus is on results, not the use of specific procedures or tools.

The MBNQA process is shown in Figure 1.11. An applicant sends the completed application to NIST. This application is then subjected to a first-round review by a team of Baldrige examiners. The board of Baldrige examiners consists of highly qualified volunteers from a variety of fields. Judges evaluate the scoring on the application to determine if the applicant will continue to **consensus.** During the consensus phase, a group of examiners who scored the original application determines a consensus score for each of the items. Once consensus is reached and a consensus report written, judges then make a site-visit determination. A site visit typically is a one-week visit by a team of four to six examiners who produce a site-visit report. The site-visit reports are used by the judges as the basis of determining the final MBNQA winners.

As shown in Figure 1.10, feedback reports are provided to the applicant at up to three stages of the MBNQA process. Many organizations have found these reports very helpful and use them as the basis of planning for overall improvement of the organization and for driving improvement in business results.

**Table 1.3** Performance Excellence Categories and Point Values

| | | | |
|---|---|---|---|
| **1** | **Leadership** | | **120** |
| | 1.1 Leadership System | 80 | |
| | 1.2 Company Responsibility and Citizenship | 40 | |
| **2** | **Strategic Planning** | | **85** |
| | 2.1 Strategy Development Process | 40 | |
| | 2.2 Company Strategy | 45 | |
| **3** | **Customer and Market Focus** | | **85** |
| | 3.1 Customer and Market Knowledge | 40 | |
| | 3.2 Customer Satisfaction and Relationship Enhancement | 45 | |
| **4** | **Information and Analysis** | | **90** |
| | 4.1 Measurement and Analysis of Performance | 50 | |
| | 4.2 Information Management | 40 | |
| **5** | **Human Resource Focus** | | **85** |
| | 5.1 Work Systems | 35 | |
| | 5.2 Employee Education, Training, and Development | 25 | |
| | 5.3 Employee Well-Being and Satisfaction | 25 | |
| **6** | **Process Management** | | **85** |
| | 6.1 Management of Product and Service Processes | 45 | |
| | 6.2 Management of Business Processes | 25 | |
| | 6.3 Management of Support Processes | 15 | |
| **7** | **Business Results** | | **450** |
| | 7.1 Customer Results | 125 | |
| | 7.2 Financial and Market Results | 125 | |
| | 7.3 Human Resource Results | 80 | |
| | 7.4 Organizational Results | 120 | |
| | **Total Points** | | **1,000** |

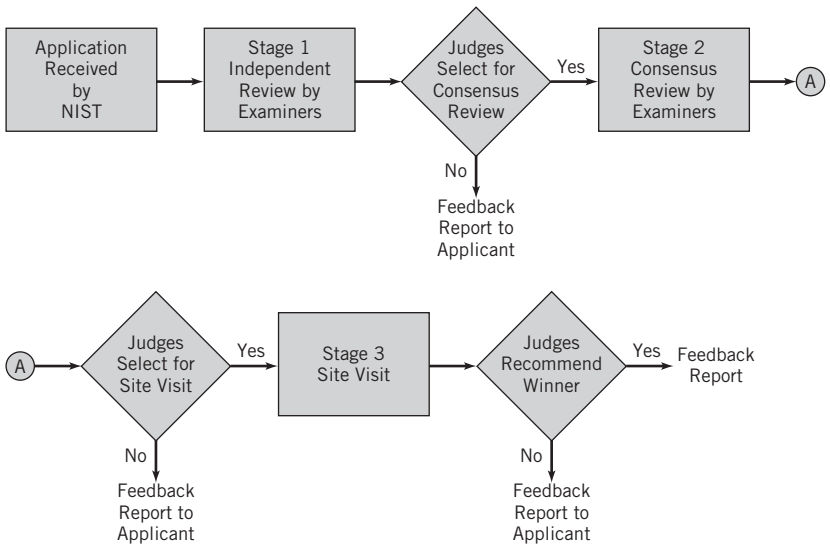



**FIGURE 1.11** MBNQA process. (Source: Foundation for the Malcolm Baldrige National Quality Award, 2002 Criteria for Performance Excellence. National Institute of Standards and Technology, U.S. Department of Commerce.)

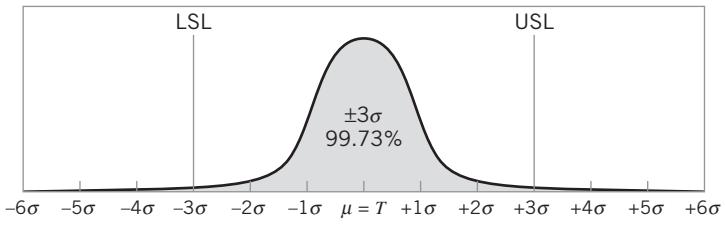
## Six Sigma.

Products with many components typically have many opportunities for failure or defects to occur. Motorola developed the **Six Sigma program** in the late 1980s as a response to the demand for its products. The focus of Six Sigma is reducing variability in key product quality characteristics to the level at which failure or defects are extremely unlikely.

Figure 1.12*a* shows a normal probability distribution as a model for a quality characteristic with the specification limits at three standard deviations on either side of the mean. Now it turns out that in this situation, the probability of producing a product within these specifications is 0.9973, which corresponds to 2,700 parts per million (ppm) defective. This is referred to as **Three Sigma quality performance,** and it actually sounds pretty good. However, suppose that we have a product that consists of an assembly of 100 independent components or parts and all 100 of these parts must be nondefective for the product to function satisfactorily. The probability that any specific unit of product is nondefective is

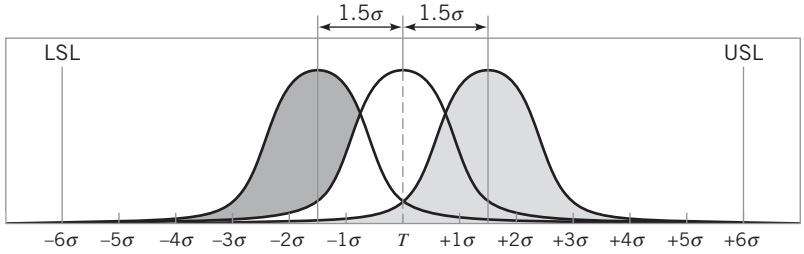
$$0.9973 \times 0.9973 \times \ldots \times 0.9973 = (0.9973)^{100} = 0.7631$$

That is, about 23.7% of the products produced under Three Sigma quality will be defective. This is not an acceptable situation, because many products used by today's society are made up of many components. Even a relatively simple service activity, such as a visit by a family of four to a fast-food restaurant, can involve the assembly of several dozen components. A typical automobile has about 100,000 components and an airplane has between one and two million!




| Spec. Limit | Percentage Inside Specs | ppm Defective |
|---|---|---|
| ±1 Sigma | 68.27 | 317300 |
| ±2 Sigma | 95.45 | 45500 |
| ±3 Sigma | 99.73 | 2700 |
| ±4 Sigma | 99.9937 | 63 |
| ±5 Sigma | 99.999943 | 0.57 |
| ±6 Sigma | 99.9999998 | 0.002 |

(*a*) Normal distribution centered at the target (*T*)




| Spec. Limit | Percentage inside specs | ppm Defective |
|---|---|---|
| ±1 Sigma | 30.23 | 697700 |
| ±2 Sigma | 69.13 | 608700 |
| ±3 Sigma | 93.32 | 66810 |
| ±4 Sigma | 99.3790 | 6210 |
| ±5 Sigma | 99.97670 | 233 |
| ±6 Sigma | 99.999660 | 3.4 |

(*b*) Normal distribution with the mean shifted by ±1.5σ from the target

**FIGURE 1.12** The Motorola Six Sigma concept.

The Motorola Six Sigma concept is to reduce the variability in the process so that the specification limits are at least six standard deviations from the mean. Then, as shown in Figure 1.12*a*, there will only be about two parts per *billion* defective. Under **Six Sigma quality,** the probability that any specific unit of the hypothetical product above is nondefective is 0.9999998, or 0.2 ppm, a much better situation.

When the Six Sigma concept was initially developed, an assumption was made that when the process reached the Six Sigma quality level, the process mean was still subject to disturbances that could cause it to shift by as much as 1.5 standard deviations off target. This situation is shown in Figure 1.12*b*. Under this scenario, a Six Sigma process would produce about 3.4 ppm defective.

There is an apparent inconsistency in this. As we will discuss in Chapter 8 on process capability, we can only make predictions about process performance when the process is **stable**—that is, when the mean (and standard deviation, too) is **constant.** If the mean is drifting around, and ends up as much as 1.5 standard deviations off target, a prediction of 3.4 ppm defective may not be very reliable, because the mean might shift by *more* than the "allowed" 1.5 standard deviations. Process **performance** isn't predictable unless the process **behavior** is stable.

However, no process or system is ever truly stable, and even in the best of situations, disturbances occur. These disturbances can result in the process mean shifting off-target, an increase in the process standard deviation, or both. The concept of a Six Sigma process is one way to **model** this behavior. Like all models, it's probably not exactly right, but it has proven to be a useful way to think about process performance and improvement.

Motorola established Six Sigma as both an objective for the corporation and as a focal point for process and product quality improvement efforts. In recent years, Six Sigma has spread beyond Motorola and has come to encompass much more. It has become a program for improving corporate **business performance** by both improving quality and paying attention to reducing costs. Companies involved in a Six Sigma effort utilize specially trained individuals, called Green Belts (GBs), Black Belts (BBs), and Master Black Belts (MBBs) to lead teams focused on projects that have both quality and business (economic) impacts for the organization. The "belts" have specialized training and education on statistical methods and the quality and process improvement tools in this textbook that equip them to function as team leaders, facilitators, and problem solvers. Typical Six Sigma projects are four to six months in duration and are selected for their potential impact on the business. The paper by Hoerl (2001) describes the components of a typical BB education program. Six Sigma uses a specific five-step problem-solving approach: Define, Measure, Analyze, Improve, and Control (DMAIC). The DMAIC framework utilizes control charts, designed experiments, process capability analysis, measurement systems capability studies, and many other basic statistical tools. The DMAIC approach is an extremely effective framework for improving processes. While it is usually associated with Six Sigma deployments, it is a very effective work to organize and manage any improvement effort. In Chapter 2, we will give a fuller presentation of DMAIC.

The goals of Six Sigma, a 3.4 ppm defect level, may seem artificially or arbitrarily high, but it is easy to demonstrate that even the delivery of relatively simple products or services at high levels of quality can lead to the need for Six Sigma thinking. For example, consider the visit to a fast-food restaurant mentioned above. The customer orders a typical meal: a hamburger (bun, meat, special sauce, cheese, pickle, onion, lettuce, and tomato), fries, and a soft drink. This product has ten components. Is 99% good quality satisfactory? If we assume that all ten components are independent, the probability of a good meal is

$$P\{\text{Single meal good}\} = (0.99)^{10} = 0.9044$$

which looks pretty good. There is better than a 90% chance that the customer experience will be satisfactory. Now suppose that the customer is a family of four. Again, assuming independence, the probability that all four meals are good is

$$P\{\text{All meals good}\} = (0.9044)^{4} = 0.6690$$

This isn't so nice. The chances are only about two out of three that all of the family meals are good. Now suppose that this hypothetical family of four visits this restaurant once a month (this is about all their cardiovascular systems can stand!). The probability that all visits result in good meals for everybody is

$$P\{\text{All visits during the year good}\} = (0.6690)^{12} = 0.0080$$

This is obviously unacceptable. So, even in a very simple service system involving a relatively simple product, very high levels of quality and service are required to produce the desired high-quality experience for the customer.

Business organizations have been very quick to understand the potential benefits of Six Sigma and to adopt the principles and methods. Between 1987 and 1993, Motorola reduced defectivity on its products by approximately, 1,300%. This success led to many organizations adopting the approach. Since its origins, there have been three generations of Six Sigma implementations. **Generation I** Six Sigma focused on defect elimination and basic variability reduction. Motorola is often held up as an exemplar of Generation I Six Sigma. In **Generation II** Six Sigma, the emphasis on variability and defect reduction remained, but now there was a strong effort to tie these efforts to projects and activities that improved business performance through cost reduction. General Electric is often cited as the leader of the Generation II phase of Six Sigma.

In **Generation III,** Six Sigma has the additional focus of creating value throughout the organization and for its stakeholders (owners, employees, customers, suppliers, and society at large). Creating value can take many forms: increasing stock prices and dividends, job retention or expansion, expanding markets for company products/services, developing new products/ services that reach new and broader markets, and increasing the levels of customer satisfaction throughout the range of products and services offered.

Many different kinds of businesses have embraced Six Sigma and made it part of the culture of doing business. Consider the following statement from Jim Owens, chairman of heavy equipment manufacturer Caterpillar, Inc., who wrote in the 2005 annual company report:

> *I believe that our people and world-class six-sigma deployment distinguish Caterpillar from the crowd. What an incredible success story six-sigma has been for Caterpillar! It is the way we do business—how we manage quality, eliminate waste, reduce costs, create new products and services, develop future leaders, and help the company grow profitably. We continue to find new ways to apply the methodology to tackle business challenges. Our leadership team is committed to encoding six-sigma into Caterpillar's "DNA" and extending its deployment to our dealers and suppliers—more than 500 of whom have already embraced the six-sigma way of doing business.*

At the annual meeting of Bank of America in 2004, then–chief executive officer Kenneth D. Lewis told the attendees that the company had record earnings in 2003, had significantly improved the customer experience, and had raised its community development funding target to $750 billion over ten years."Simply put, Bank of America has been making it happen," Lewis said."And we've been doing it by following a disciplined, customer-focused and organic growth strategy." Citing the companywide use of Six Sigma techniques for process improvement, he noted that in fewer than three years, Bank of America had "saved millions of dollars in expenses, cut cycle times in numerous areas of the company by half or more, and reduced the number of processing errors."

These are strong endorsements of Six Sigma from two highly recognized business leaders that lead two very different types of organizations: manufacturing and financial services. Caterpillar and Bank of America are good examples of Generation III Six Sigma companies, because their implementations are focused on value creation for all stakeholders in the broad sense. Note Lewis's emphasis on reducing cycle times and reducing processing errors (items that will greatly improve customer satisfaction), and Owens's remarks on extending Six Sigma to suppliers and dealers—the entire supply chain. Six Sigma has spread well beyond its manufacturing origins

into areas including health care, many types of service business, and government/public service (the U.S. Navy has a strong and very successful Six Sigma program). The reason for the success of Six Sigma in organizations outside the traditional manufacturing sphere is that variability is everywhere, and where there is variability, there is an opportunity to improve business results. Some examples of situations where a Six Sigma program can be applied to reduce variability, eliminate defects, and improve business performance include:

- Meeting delivery schedule and delivery accuracy targets
- Eliminating rework in preparing budgets and other financial documents
- Proportion of repeat visitors to an e-commerce Website, or proportion of visitors that make a purchase
- Minimizing cycle time or reducing customer waiting time in any service system
- Reducing average and variability in days outstanding of accounts receivable
- Optimizing payment of outstanding accounts
- Minimizing stock-out or lost sales in supply chain management
- Minimizing costs of public accountants, legal services, and other consultants
- Inventory management (both finished goods and work-in-process)
- Improving forecasting accuracy and timing
- Improving audit processes
- Closing financial books, improving accuracy of journal entry and posting (a 3% to 4% error rate is fairly typical)
- Reducing variability in cash flow
- Improving payroll accuracy
- Improving purchase order accuracy and reducing rework of purchase orders

The structure of a Six Sigma organization is shown in Figure 1.13. The lines in this figure identify the key links among the functional units. The **leadership team** is the executive responsible for that business unit and appropriate members of his/her staff and direct reports. This person has overall responsibility for approving the improvement projects undertaken by the Six Sigma teams. Each project has a **champion,** a business leader whose job is to facilitate project identification and selection, identify Black Belts and other team members who are necessary for successful project completion, remove barriers to project completion, make sure that the resources required for project completion are available, and conduct regular meetings with the team or the Black Belts to ensure that progress is being made and the project is on schedule. The champion role is not full time, and champions often have several projects under their supervision. Black Belts are team leaders who are involved in the actual project completion activities. Team members often spend 25% of their time on the project, and may be drawn from different areas of the business, depending on project requirements. Green Belts typically have less training and experience in Six Sigma tools and approaches than the Black Belts, and may lead projects of their own under the direction of a champion or Black Belt, or they may be part of a Black Belt–led team. A Master Black Belt is a technical leader, and may work with the champion and the leadership team in project identification and selection, project reviews, consulting with Black Belts on technical issues, and training of Green Belts and Black Belts. Typically, the Black Belt and Master Black Belt roles are full time.

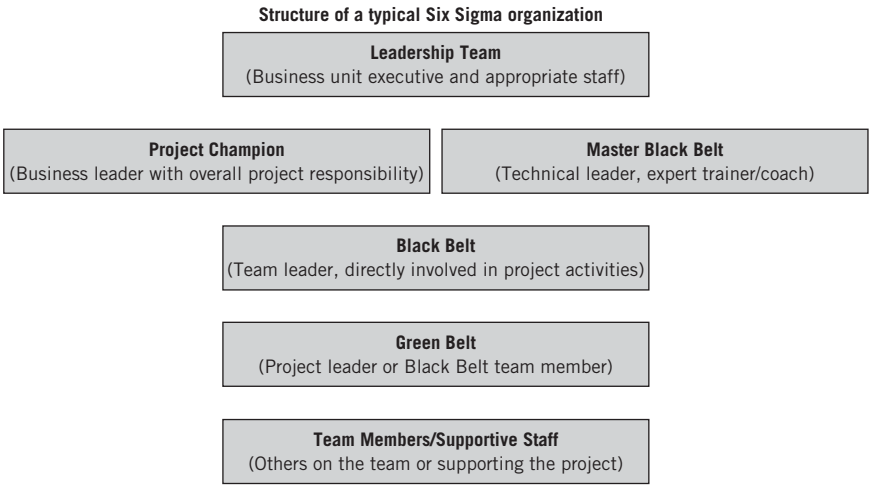



**FIGURE 1.13** The structure of a Six Sigma organization.

In recent years, two other tool sets have become identified with Six Sigma: **lean systems** and **design for Six Sigma (DFSS)**. Many organizations regularly use one or both of these approaches as an integral part of their Six Sigma implementation.

Design for Six Sigma is an approach for taking the variability reduction and process improvement philosophy of Six Sigma upstream from manufacturing or production into the design process, where new products (or services or service processes) are designed and developed. Broadly speaking, DFSS is a structured and disciplined methodology for the efficient commercialization of technology that results in new products, services, or processes. By a product, we mean anything that is sold to a consumer for use; by a service, we mean an activity that provides value or benefit to the consumer. DFSS spans the entire development process from the identification of customer needs to the final launch of the new product or service. Customer input is obtained through **voice of the customer (VOC)** activities designed to determine what the customer really wants, to set priorities based on actual customer wants, and to determine if the business can meet those needs at a competitive price that will enable it to make a profit. VOC data is usually obtained by customer interviews, by a direct interaction with and observation of the customer, through focus groups, by surveys, and by analysis of customer satisfaction data. The purpose is to develop a set of critical to quality requirements for the product or service. Traditionally, Six Sigma is used to achieve **operational** excellence, while DFSS is focused on improving business results by increasing the sales revenue generated from new products and services and finding new applications or opportunities for existing ones. In many cases, an important gain from DFSS is the reduction of development lead time—that is, the cycle time to commercialize new technology and get the resulting new products to market. DFSS is directly focused on increasing value in the organization. Many of the tools that are used in operational Six Sigma are also used in DFSS. The DMAIC process is also applicable, although some organizations and practitioners have slightly different approaches (DMADV, or Define, Measure, Analyze, Design, and Verify, is a popular variation).

DFSS makes specific the recognition that every design decision is a business decision and that the cost, manufacturability, and performance of the product are determined during design. Once a product is designed and released to manufacturing, it is almost impossible for the manufacturing organization to make it better. Furthermore, overall business improvement cannot be achieved by focusing on reducing variability in manufacturing alone (operational Six Sigma), and DFSS is required to focus on customer requirements while simultaneously keeping process capability in mind. Specifically, matching the capability of the production system and the requirements at each stage or level of the design process (refer to Fig. 1.14) is essential. When mismatches between process capabilities and design requirements are discovered, either design changes or

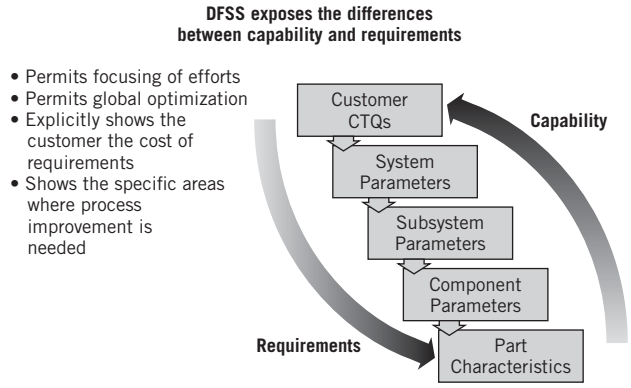



**FIGURE 1.14** Matching product requirements and production capability in DFSS.

different production alternatives are considered to resolve the conflicts. Throughout the DFSS process, it is important that the following points be kept in mind:

- Is the product concept well identified?
- Are customers real?
- Will customers buy this product?
- Can the company make this product at competitive cost?
- Are the financial returns acceptable?
- Does this product fit with the overall business strategy?
- Is the risk assessment acceptable?
- Can the company make this product better than the competition can?
- Can product reliability, maintainability goals be met?
- Has a plan for transfer to manufacturing been developed and verified?

Lean principles are designed to eliminate waste and reduce unnecessarily long cycle times. Traditionally, there are seven types of waste:

1. Unnecessary transportation
2. Inventory (work-in-process or finished goods)
3. Motion (movement of material)
4. Waiting
5. Overproduction
6. Overprocessing
7. Defects

Defects and failures leading to rework and scrap are often the result of excess variability, so there is an obvious connection between Six Sigma and lean. An important metric in lean is the process cycle efficiency (PCE) defined as

$$\text{Process cycle efficiency} = \frac{\text{Value-add time}}{\text{Process cycle time}}$$

where the value-add time is the amount of time actually spent in the process that transforms the form, fit, or function of the product or service that results in something for which the customer is willing to pay. PCE is a direct measure of how efficiently the process is converting the work that is in-process into completed products or services. In typical processed, including manufacturing and transactional businesses, PCE varies between 1% and 10%. The ideal or world-class PCE varies by the specific application, but achieving a PCE of 25% or higher is often possible.

Process cycle time is also related to the amount of work that is in-process through **Little's Law**:

$$\text{Process cycle time} = \frac{\text{Work-in-process}}{\text{Average completion rate}}$$

The average completion rate is a measure of capacity; that is, it is the output of a process over a defined time period. For example, consider a mortgage refinance operation at a bank. If the average completion rate for submitted applications is 100 completions per day, and there are 1,500 applications waiting for processing, the process cycle time is

$$\text{Process cycle time} = \frac{1500}{100} = 15 \text{ days}$$

Often the cycle time can be reduced by eliminating waste and inefficiency in the process, resulting in an increase in the completion rate.

Lean also makes use of many tools of industrial engineering and operations research. One of the most important of these is **discrete-event simulation,** in which a computer model of the system is built and used to quantify the impact of changes to the system that improve its performance. Simulation models are often very good predictors of the performance of a new or redesigned system. Both manufacturing and service organizations can greatly benefit by using simulation models to study the performance of their processes.

Ideally, Six Sigma/DMAIC, DFSS, and lean tools are used simultaneously and harmoniously in an organization to achieve high levels of process performance and significant business improvement. Figure 1.15 highlights many of the important complementary aspects of these three sets of tools.

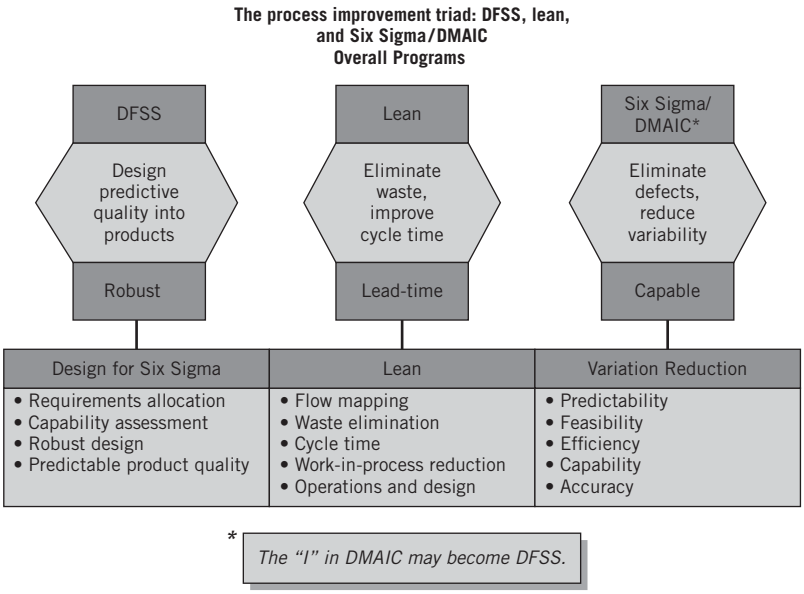



**FIGURE 1.15** Six Sigma/DMAIC, lean, and DFSS: how they fit together.

Six Sigma (often combined with DFSS and lean) has been much more successful than its predecessors, notably TQM. The project-by-project approach, the analytical focus, and the emphasis on obtaining improvement in bottom-line business results have been instrumental in obtaining management commitment to Six Sigma. Another major component in obtaining success is driving the proper deployment of statistical methods into the right places in the organization. The DMAIC problem-solving framework is an important part of this. For more information on Six Sigma, the applications of statistical methods in the solution of business and industrial problems, and related topics, see Hahn, Doganaksoy, and Hoerl (2000); Hoerl and Snee (2010); Montgomery and Woodall (2008); and Steinberg et al. (2008).

#### Just-in-Time, Poka-Yoke, and Others.

There have been many initiatives devoted to improving the production system. These are often grouped into the lean toolkit. Some of these include the Just-in-Time approach emphasizing in-process inventory reduction, rapid setup, and a pull-type production system; Poka-Yoke or mistake-proofing of processes; the Toyota production system and other Japanese manufacturing techniques (with once-popular management books by those names); reengineering; theory of constraints; agile manufacturing; and so on. Most of these programs devote far too little attention to variability reduction. It's virtually impossible to reduce the in-process inventory or operate a pull-type or agile production system when a large and unpredictable fraction of the process output is defective and where there are significant uncontrolled sources of variability. Such efforts will not achieve their full potential without a major focus on statistical methods for process improvement and variability reduction to accompany them. It is important to deploy Six Sigma jointly with the lean tools.

### 1.4.2 THE LINK BETWEEN QUALITY AND PRODUCTIVITY

Producing high-quality products in the modern industrial environment is not easy. A significant aspect of the problem is the rapid evolution of technology. The past 20 years have seen an explosion of technology in such diverse fields as electronics, metallurgy, ceramics, composite materials, biotechnology, and the chemical and pharmaceutical sciences, which has resulted in many new products and services. For example, in the electronics field, the development of the integrated circuit has revolutionized the design and manufacture of computers and many electronic office products. Basic integrated circuit technology has been supplanted by large-scale integration (LSI) and very large-scale integration (VLSI) technology, with corresponding developments in semiconductor design and manufacturing. When technological advances occur rapidly and when the new technologies are used quickly to exploit competitive advantages, the problems of designing and manufacturing products of superior quality are greatly complicated.

Often, too little attention is paid to achieving all dimensions of an optimal process: economy, efficiency, productivity, and quality. Effective quality improvement can be instrumental in increasing productivity and reducing cost. To illustrate, consider the manufacture of a mechanical component used in a copier machine. The parts are manufactured in a machining process at a rate of approximately 100 parts per day. For various reasons, the process is operating at a first-pass yield of about 75%. (That is, about 75% of the process output conforms to specifications, and about 25% of the output is nonconforming.) About 60% of the fallout (the 25% nonconforming) can be reworked into an acceptable product, and the rest must be scrapped. The direct manufacturing cost through this stage of production per part is approximately \$20. Parts that can be reworked incur an additional processing charge of \$4. Therefore, the manufacturing cost per good part produced is

$$\text{Cost/good part} = \frac{\$20(100) + \$4(15)}{90} = \$22.89$$

Note that the total yield from this process, after reworking, is 90 good parts per day.

An engineering study of this process reveals that excessive process variability is responsible for the extremely high fallout. A new statistical process-control procedure is implemented that reduces variability, and consequently, the process fallout decreases from 25% to 5%. Of the 5% fallout produced, about 60% can be reworked, and 40% are scrapped. After the process-control program is implemented, the manufacturing cost per good part produced is

$$\text{Cost/good part} = \frac{\$20(100) + \$4(3)}{98} = \$20.53$$

Note that the installation of statistical process control and the reduction of variability that follows result in a 10.3% reduction in manufacturing costs. Furthermore, productivity is up by almost 10%; 98 good parts are produced each day as opposed to 90 good parts previously. This amounts to an increase in production capacity of almost 10%, without any additional investment in equipment, workforce, or overhead. Efforts to improve this process by other methods (such as Just-in-Time, lean manufacturing) are likely to be completely ineffective until the basic problem of excessive variability is solved.

### 1.4.3 SUPPLY CHAIN QUALITY MANAGEMENT

Most companies and business organizations rely on suppliers to provide at least some of the materials and components used in their products. Almost all of these businesses rely on external organizations to distribute and deliver their products to distribution centers and ultimately to the end customers. A supply chain is the network of facilities that accomplishes these tasks. There is usually an internal component of the supply chain as well, because many design activities, development, and production operations for components and subassemblies are performed by different groups within the parent organization. **Supply chain management** (**SCM**) deals with designing, planning, executing, controlling, and monitoring all supply chain activities with the objective of optimizing system performance. Changes in the business environment over the last 25 years, including globalization, the proliferation of multinational companies, joint ventures, strategic alliances, and business partnerships, have contributed to the development and expansion of supply chain networks.

The supply chain often provides a significant component of the value or content to many products or services. Consequently, there is considerable dependence on the supply chain regarding product quality and safety. Failures in the supply chain have significant consequences for the parent company and for consumers. For example, in recent years, there have been instances of lead in paint on toys and lead in toothpaste, as well as recalls of food and pharmaceutical products because of contamination problems. Even in situations where product quality or safety is not an issue, the labor practices and lack of social responsibility of organizations in the supply chain have negatively impacted the reputation of the parent company.

Successful SCM requires integrating activities into key supply chain processes. This requires collaboration between buyers and suppliers, joint product development, common systems, and shared information. Some key supply chain processes are:

- Service management
- Demand management
- Order fulfillment
- Quality
- Manufacturing flow management
- Supplier relationship management
- Logistics and distribution
- Returns management

Sometimes the management of these processes can be simplified by single-sourcing or dual-sourcing—that is, having only one or at most two suppliers for critical components. Deming argued for this type of strategic relationship with suppliers. The danger, of course, is interruption of supply due to quality problems, labor disputes and strikes, transportation disruptions, pricing disagreements, global security problems, and natural phenomena such as earthquakes.

SCM consists of three major activities:

1. **Supplier qualification or certification.** This can involve visits to suppliers and inspection of their facilities along with evaluation of the capability of their production systems to deliver adequate quantities of product, their quality systems, and their overall business operations. The purpose of supplier qualification is to provide an analytical basis for supplier selection.
2. **Supplier development.** These are the activities that the company undertakes to improve the performance of its suppliers. Some common supplier development activities include supplier evaluation, supplier training, data and process information sharing, and consulting services. Many times these activities are performed in teams composed of representatives of both the parent company and the supplier. These teams are formed to address specific projects. Often the goals of these projects are quality improvement, capacity expansion, or cost reduction. As an example of a supplier development activity, the company may help a supplier initiate a Six Sigma deployment. Many companies provide awards to suppliers as a component of the development process. These awards may be based on criteria similar to the Baldrige criteria and may provide an awardee preferred supplier status with some advantages in obtaining future business.
3. **Supplier audits.** This activity consists of regular periodic visits to the supplier to ensure that product quality, standards, and other operational objectives are being met. Supplier audits are a way to gain insight into supplier processes and reduce supplier risk. Quality audits are frequently used to ensure that supplier have processes in place to deliver quality products. Audits are an effective way to ensure that the supplier is following the processes and procedures that were agreed to during the selection processes. The supplier audit identifies nonconformances in manufacturing processes, shipment and logistics operations, engineering and engineering change processes, and invoicing and billing. After the audit, the supplier and parent company jointly identify corrective actions that must be implemented by the supplier within an agreed-upon timeframe. A future audit ensures that these corrective actions have been successfully implemented. In addition, as regulatory and market pressures related to environmental compliance and social and ethical responsibility increase, audits often include environmental and social and ethical responsibility components. Sometimes companies engage third parties to conduct these audits.

Returns management is a critical SCM process. Many companies have found that a cost-recovery system, where suppliers are charged back for providing poor-quality materials or components, is an effective way to introduce business discipline and accountability into the supply chain. However, relatively few companies pursue full cost recovery with their suppliers. The majority of the companies that do practice cost recovery only recover material costs from their suppliers. Many of the costs attributed to poor supplier quality are non-material related. For example, some of these nonmaterial costs include:

1. Operator handling
2. Disassembly of the product
3. Administrative work to remove the part from stock
4. Quality engineering time
5. Planning/buyer activities to get new parts

6. Transportation back to receiving/shipping
7. Communications with the supplier
8. Issuing new purchase orders/instructions
9. Other engineering time
10. Packing and arranging transportation to the supplier
11. Invoicing
12. Costs associated with product recall

These costs can be substantial and are often well in excess of the material cost of the part. If a company institutes a process to aggregate these costs and use it for charge-backs, they would be able to fully recover the costs of poor quality from their suppliers, and they would institute a discipline that strongly encourages their suppliers to quickly improve their product quality.

### 1.4.4 QUALITY COSTS

Financial controls are an important part of business management. These financial controls involve a comparison of actual and budgeted costs, along with analysis and action on the differences between actual and budget. It is customary to apply these financial controls on a department or functional level. For many years, there was no direct effort to measure or account for the costs of the quality function. However, many organizations now formally evaluate the cost associated with quality. There are several reasons why the cost of quality should be explicitly considered in an organization. These include the following:

1. The increase in the cost of quality because of the increase in the complexity of manufactured products associated with advances in technology
2. Increasing awareness of life-cycle costs, including maintenance, spare parts, and the cost of field failures
3. Quality engineers and managers being able to most effectively communicate quality issues in a way that management understands

As a result, quality costs have emerged as a financial control tool for management and as an aid in identifying opportunities for reducing quality costs.

Generally speaking, quality costs are those categories of costs that are associated with producing, identifying, avoiding, or repairing products that do not meet requirements. Many manufacturing and service organizations use four categories of quality costs: prevention costs, appraisal costs, internal failure costs, and external failure costs. Some quality authorities feel that these categories define the **Cost of Poor Quality (COPQ).** These cost categories are shown in Table 1.4. We now discuss these categories in more detail.

#### Prevention Costs.

Prevention costs are those costs associated with efforts in design and manufacturing that are directed toward the prevention of nonconformance. Broadly speaking, prevention costs are all costs incurred in an effort to "make it right the first time." The important subcategories of prevention costs follow.

**Quality planning and engineering.** Costs associated with the creation of the overall quality plan, the inspection plan, the reliability plan, the data system, and all specialized plans and activities of the quality-assurance function; the preparation of manuals and procedures used to communicate the quality plan; and the costs of auditing the system.

**Table 1.4** Quality Costs

| **Prevention Costs** | **Internal Failure Costs** |
|---|---|
| Quality planning and engineering | Scrap |
| New products review | Rework |
| Product/process design | Retest |
| Process control | Failure analysis |
| Burn-in | Downtime |
| Training | Yield losses |
| Quality data acquisition and analysis | Downgrading (off-specing) |
| **Appraisal Costs** | **External Failure Costs** |
| Inspection and test of incoming material | Complaint adjustment |
| Product inspection and test | Returned product/material |
| Materials and services consumed | Warranty charges |
| Maintaining accuracy of test equipment | Liability costs |
| | Indirect costs |

**New products review.** Costs of the preparation of bid proposals, the evaluation of new designs from a quality viewpoint, the preparation of tests and experimental programs to evaluate the performance of new products, and other quality activities during the development and preproduction stages of new products or designs.

**Product/process design.** Costs incurred during the design of the product or the selection of the production processes that are intended to improve the overall quality of the product. For example, an organization may decide to make a particular circuit component redundant because this will increase the reliability of the product by increasing the mean time between failures. Alternatively, it may decide to manufacture a component using process A rather than process B, because process A is capable of producing the product at tighter tolerances, which will result in fewer assembly and manufacturing problems. This may include a vendor's process, so the cost of dealing with other than the lowest bidder may also be a prevention cost.

**Process control.** The cost of process-control techniques, such as control charts, that monitor the manufacturing process in an effort to reduce variation and build quality into the product.

**Burn-in.** The cost of preshipment operation of the product to prevent early-life failures in the field.

**Training.** The cost of developing, preparing, implementing, operating, and maintaining formal training programs for quality.

**Quality data acquisition and analysis.** The cost of running the quality data system to acquire data on product and process performance; also the cost of analyzing these data to identify problems. It includes the work of summarizing and publishing quality information for management.

### Appraisal Costs.

Appraisal costs are those costs associated with measuring, evaluating, or auditing products, components, and purchased materials to ensure conformance to the standards that have been imposed. These costs are incurred to determine the condition of the product from a quality viewpoint and ensure that it conforms to specifications. The major subcategories follow.

**Inspection and test of incoming material.** Costs associated with the inspection and testing of all material. This subcategory includes receiving inspection and test; inspection, test, and

evaluation at the vendor's facility; and a periodic audit of the quality-assurance system. This could also include intraplant vendors.

**Product inspection and test.** The cost of checking the conformance of the product throughout its various stages of manufacturing, including final acceptance testing, packing and shipping checks, and any test done at the customer's facilities prior to turning the product over to the customer. This also includes life testing, environmental testing, and reliability testing.

**Materials and services consumed.** The cost of material and products consumed in a destructive test or devalued by reliability tests.

**Maintaining accuracy of test equipment.** The cost of operating a system that keeps the measuring instruments and equipment in calibration.

### Internal Failure Costs.

Internal failure costs are incurred when products, components, materials, and services fail to meet quality requirements, and this failure is discovered prior to delivery of the product to the customer. These costs would disappear if there were no defects in the product. The major subcategories of internal failure costs follow.

**Scrap.** The net loss of labor, material, and overhead resulting from defective product that cannot economically be repaired or used.

**Rework.** The cost of correcting nonconforming units so that they meet specifications. In some manufacturing operations, rework costs include additional operations or steps in the manufacturing process that are created to solve either chronic defects or sporadic defects.

**Retest.** The cost of reinspection and retesting of products that have undergone rework or other modifications.

**Failure analysis.** The cost incurred to determine the causes of product failures.

**Downtime.** The cost of idle production facilities that results from nonconformance to requirements. The production line may be down because of nonconforming raw materials supplied by a supplier, which went undiscovered in receiving inspection.

**Yield losses.** The cost of process yields that are lower than might be attainable by improved controls (for example, soft-drink containers that are overfilled because of excessive variability in the filling equipment).

**Downgrading/off-specing.** The price differential between the normal selling price and any selling price that might be obtained for a product that does not meet the customer's requirements. Downgrading is a common practice in the textile, apparel goods, and electronics industries. The problem with downgrading is that products sold do not recover the full contribution margin to profit and overhead as do products that conform to the usual specifications.

### External Failure Costs.

External failure costs occur when the product does not perform satisfactorily after it is delivered to the customer. These costs would also disappear if every unit of product conformed to requirements. Subcategories of external failure costs follow.

**Complaint adjustment.** All costs of investigation and adjustment of justified complaints attributable to the nonconforming product.

**Returned product/material.** All costs associated with receipt, handling, and replacement of the nonconforming product or material that is returned from the field.

**Warranty charges.** All costs involved in service to customers under warranty contracts.

**Liability costs.** Costs or awards incurred from product liability litigation.

**Indirect costs.** In addition to direct operating costs of external failures, there are a significant number of indirect costs. These are incurred because of customer dissatisfaction with the level of quality of the delivered product. Indirect costs may reflect the customer's attitude toward the company. They include the costs of loss of business reputation, loss of future business, and loss of market share that inevitably results from delivering products and services that do not conform to the customer's expectations regarding fitness for use.

### The Analysis and Use of Quality Costs.

How large are quality costs? The answer, of course, depends on the type of organization and the success of their quality improvement effort. In some organizations, quality costs are 4% or 5% of sales, whereas in others, they can be as high as 35% or 40% of sales. Obviously, the cost of quality will be very different for a high-technology computer manufacturer than for a typical service industry, such as a department store or hotel chain. In most organizations, however, quality costs are higher than necessary, and management should make continuing efforts to appraise, analyze, and reduce these costs.

The usefulness of quality costs stems from the **leverage effect**; that is, dollars invested in prevention and appraisal have a payoff in reducing dollars incurred in internal and external failures that exceeds the original investment. For example, a dollar invested in prevention may return $10 or $100 (or more) in savings from reduced internal and external failures.

Quality-cost analyses have as their principal objective cost reduction through identification of improvement opportunities. This is often done with a **Pareto analysis.** The Pareto analysis consists of identifying quality costs by category, or by product, or by type of defect or nonconformity. For example, inspection of the quality-cost information in Table 1.5 concerning defects or nonconformities in the assembly of electronic components onto printed circuit boards reveals that insufficient solder is the highest quality cost incurred in this operation. Insufficient solder accounts for 42% of the total defects in this particular type of board and for almost 52% of the total scrap and rework costs. If the wave solder process can be improved, then there will be dramatic reductions in the cost of quality.

How much reduction in quality costs is possible? Although the cost of quality in many organizations can be significantly reduced, it is unrealistic to expect it can be reduced to zero. Before that level of performance is reached, the incremental costs of prevention and appraisal will rise more rapidly than the resulting cost reductions. However, paying attention to quality costs in conjunction with a focused effort on variability reduction has the capability of reducing quality costs by 50% or 60% provided that no organized effort has previously existed. This cost reduction

**Table 1.5** Monthly Quality-Costs Information for Assembly of Printed Circuit Boards

| Type of Defect | Percentage of Total Defects | Scrap and Rework Costs |
|---|---|---|
| Insufficient solder | 42% | $37,500.00 (52%) |
| Misaligned components | 21 | 12,000.00 |
| Defective components | 15 | 8,000.00 |
| Missing components | 10 | 5,100.00 |
| Cold solder joints | 7 | 5,000.00 |
| All other causes | 5 | 4,600.00 |
| Totals | 100% | $72,200.00 |

also follows the Pareto principle; that is, most of the cost reductions will come from attacking the few problems that are responsible for the majority of quality costs.

In analyzing quality costs and in formulating plans for reducing the cost of quality, it is important to note the role of prevention and appraisal. Many organizations devote far too much effort to appraisal and not enough to prevention. This is an easy mistake for an organization to make, because appraisal costs are often budget line items in manufacturing. On the other hand, prevention costs may not be routinely budgeted items. It is not unusual to find in the early stages of a quality-cost program that appraisal costs are eight or ten times the magnitude of prevention costs. This is probably an unreasonable ratio, as dollars spent in prevention have a much greater payback than do dollars spent in appraisal.

When Six Sigma and lean are deployed together, there is usually a simultaneous reduction in quality costs and an increase in process cycle efficiency. Processes with low PCE are slow processes, and slow-moving processes are expensive and wasteful. Work-in-process inventory that moves slowly often has to be handled, counted, moved, stored, retrieved, and often moved again. Handling and storage can lead to damage or other quality problems. Inventoried items may become obsolete because of design changes and improvements to the product. Quality problems in the production of a component can lead to many in-process items being in danger of having to be reworked or scrapped. Quality costs are often a direct result of the **hidden factory**—that is, the portion of the business that deals with waste, scrap, rework, work-in-process inventories, delays, and other business inefficiencies. Figure 1.16 shows a distribution of costs as a percentage of revenue for a typical manufacturing organization. Deploying quality improvement tools such as Six Sigma and lean can often reduce manufacturing overhead and quality costs by 20% within one to two years. This can lead to a 5% to 10% of revenue increase in operating profit. These numbers are business specific. But the techniques can be applied anywhere: service industries, transactional operations, creative processes such as design and development, order entry, and fulfillment.

Generating the quality-cost figures is not always easy, because most quality-cost categories are not a direct component in the accounting records of the organization. Consequently, it may be difficult to obtain extremely accurate information on the costs incurred with respect to the various categories. The organization's accounting system can provide information on those quality-cost categories that coincide with the usual business accounts, such as, for example, product testing and evaluation. In addition, many companies will have detailed information on various categories of failure cost. The information for cost categories for which exact accounting information is not available should be generated by using estimates, or, in some cases, by creating special monitoring and surveillance procedures to accumulate those costs over the study period.

The reporting of quality costs is usually done on a basis that permits straightforward evaluation by management. Managers want quality costs expressed in an index that compares quality cost with the opportunity for quality cost. Consequently, the usual method of reporting quality costs is in the form of a ratio, where the numerator is quality-cost dollars and the denominator is

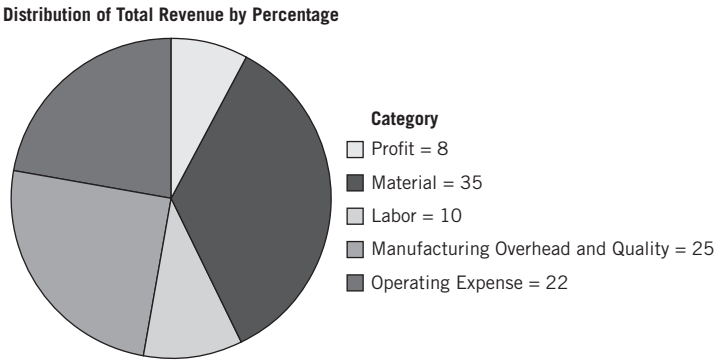



**FIGURE 1.16** The distribution of total revenue by percentage in a typical manufacturing organization.

some measure of activity, such as (1) hours of direct production labor, (2) dollars of direct production labor, (3) dollars of processing costs, (4) dollars of manufacturing cost, (5) dollars of sales, or (6) units of product.

Upper management may want a standard against which to compare the current quality-cost figures. It is difficult to obtain absolute standards and almost as difficult to obtain quality-cost levels of other companies in the same industry. Therefore, the usual approach is to compare current performance with past performance so that, in effect, quality-cost programs report variances from past performance. These trend analyses are primarily a device for detecting departures from standard and for bringing them to the attention of the appropriate managers. They are not necessarily in and of themselves a device for ensuring quality improvements.

This brings us to an interesting observation: Some quality-cost collection and analysis efforts fail; that is, a number of companies have started quality-cost analysis activities, used them for some time, and then abandoned the programs as ineffective. There are several reasons why this occurs. Chief among these is failure to use quality-cost information as a mechanism for generating improvement opportunities. If we use quality cost information as a scorekeeping tool only, and do not make conscious efforts to identify problem areas and develop improved operating procedures and processes, then the programs will not be totally successful.

Another reason why quality-cost collection and analysis don't lead to useful results is that managers become preoccupied with perfection in the cost figures. Overemphasis in treating quality costs as part of the accounting systems rather than as a management control tool is a serious mistake. This approach greatly increases the amount of time required to develop the cost data, analyze them, and identify opportunities for quality improvements. As the time required to generate and analyze the data increases, management becomes more impatient and less convinced of the effectiveness of the activity. Any program that appears to management as going nowhere is likely to be abandoned.

A final reason for the failure of a quality-cost program is that management often underestimates the depth and extent of the commitment to prevention that must be made. The author has had numerous opportunities to examine quality cost data in many companies. In companies without effective quality improvement programs, the dollars allocated to prevention rarely exceed 1% to 2% of revenue. This must be increased to a threshold of about 5% to 6% of revenue, and these additional prevention dollars must be spent largely on the technical methods of quality improvement, and not on establishing programs such as TQM, Zero Defects, or other similar activities. If management is persistent in this effort, then the cost of quality will decrease substantially. These cost savings will typically begin to occur in one to two years, although it could be longer in some companies.

### 1.4.5 LEGAL ASPECTS OF QUALITY

Consumerism and product liability are important reasons why quality assurance is an important business strategy. Consumerism is in part due to the seemingly large number of failures in the field of consumer products and the perception that service quality is declining. Highly visible field failures often prompt the questions of whether today's products are as good as their predecessors and whether manufacturers are really interested in quality. The answer to both of these questions is yes. Manufacturers are always vitally concerned about field failures because of heavy external failure costs and the related threat to their competitive position. Consequently, most producers have made product improvements directed toward reducing field failures. For example, solid-state and integrated-circuit technologies have greatly reduced the failure of electronic equipment that once depended on the electron tube. Virtually every product line of today is superior to that of yesterday.

Consumer dissatisfaction and the general feeling that today's products are inferior to their predecessors arise from other phenomena. One of these is the explosion in the number of products.

For example, a 1% field-failure rate for a consumer appliance with a production volume of 50,000 units per year means 500 field failures. However, if the production rate is 500,000 units per year and the field-failure rate remains the same, then 5,000 units will fail in the field. This is equivalent, in the total number of dissatisfied customers, to a 10% failure rate at the lower production level. Increasing production volume increases the **liability exposure** of the manufacturer. Even in situations in which the failure rate declines, if the production volume increases more rapidly than the decrease in failure rate, the total number of customers who experience failures will still increase.

A second aspect of the problem is that consumer tolerance for minor defects and aesthetic problems has decreased considerably, so that blemishes, surface-finish defects, noises, and appearance problems that were once tolerated now attract attention and result in adverse consumer reaction. Finally, the competitiveness of the marketplace forces many manufacturers to introduce new designs before they are fully evaluated and tested in order to remain competitive. These "early releases" of unproved designs are a major reason for new product quality failures. Eventually, these design problems are corrected, but the high failure rate connected with new products often supports the belief that today's quality is inferior to that of yesterday.

Product liability is a major social, market, and economic force. The legal obligation of manufacturers and sellers to compensate for injury or damage caused by defective products is not a recent phenomenon. The concept of product liability has been in existence for many years, but its emphasis has changed recently. The first major product liability case occurred in 1916 and was tried before the New York Court of Appeals. The court held that an automobile manufacturer had a product liability obligation to a car buyer, even though the sales contract was between the buyer and a third party—namely, a car dealer. The direction of the law has always been that manufacturers or sellers are likely to incur a liability when they have been unreasonably careless or negligent in what they have designed, or produced, or how they have produced it. In recent years, the courts have placed a more stringent rule in effect called **strict liability.** Two principles are characteristic of strict liability. The first is a strong responsibility for both manufacturer and merchandiser, requiring immediate responsiveness to unsatisfactory quality through product service, repair, or replacement of defective product. This extends into the period of actual use by the consumer. By producing a product, the manufacturer and seller must accept responsibility for the ultimate use of that product—not only for its performance, but also for its environmental effects, the safety aspects of its use, and so forth.

The second principle involves advertising and promotion of the product. Under strict product liability, all advertising statements must be supportable by valid company quality or certification data, comparable to that now maintained for product identification under regulations for such products as automobiles.

These two strict product liability principles result in strong pressure on manufacturers, distributors, and merchants to develop and maintain a high degree of factually based evidence concerning the performance and safety of their products. This evidence must cover not only the quality of the product as it is delivered to the consumer, but also its durability or reliability, its protection from possible side effects or environmental hazards, and its safety aspects in actual use. A strong quality-assurance program can help management in ensuring that this information will be available, if needed.

### 1.4.6 IMPLEMENTING QUALITY IMPROVEMENT

In the past few sections, we have discussed the philosophy of quality improvement, the link between quality and productivity, and both economic and legal implications of quality. These are important aspects of the management of quality within an organization. There are certain other aspects of the overall management of quality that warrant some attention.

**Table 1.6** The Eight Dimensions of Quality from Section 1.1.1

| | | | |
|---|---|---|---|
| **1.** | Performance | **5.** | Aesthetics |
| **2.** | Reliability | **6.** | Features |
| **3.** | Durability | **7.** | Perceived quality |
| **4.** | Serviceability | **8.** | Conformance to standards |

Management must recognize that quality is a multifaceted entity, incorporating the eight dimensions we discussed in Section 1.1.1. For convenient reference, Table 1.6 summarizes these quality dimensions.

A critical part of the **strategic management of quality** within any business is the recognition of these dimensions by management and the selection of dimensions along which the business will compete. It will be very difficult to compete against companies that can successfully accomplish this part of the strategy.

A good example is the Japanese dominance of the videocassette recorder (VCR) market. The Japanese did not invent the VCR; the first units for home use were designed and produced in Europe and North America. However, the early VCRs produced by these companies were very unreliable and frequently had high levels of manufacturing defects. When the Japanese entered the market, they elected to compete along the dimensions of reliability and conformance to standards (no defects). This strategy allowed them to quickly dominate the market. In subsequent years, they expanded the dimensions of quality to include added features, improved performance, easier serviceability, improved aesthetics, and so forth. They have used total quality as a competitive weapon to raise the entry barrier to this market so high that it is virtually impossible for a new competitor to enter.

Management must do this type of strategic thinking about quality. It is not necessary that the product be superior in all dimensions of quality, but management must **select and develop** the "niches" of quality along which the company can successfully compete. Typically, these dimensions will be those that the competition has forgotten or ignored. The American automobile industry has been severely impacted by foreign competitors who expertly practiced this strategy.

The critical role of **suppliers** in quality management must not be forgotten. In fact, supplier selection and **supply chain management** may be the most critical aspects of successful quality management in industries such as automotive, aerospace, and electronics, where a very high percentage of the parts in the end item are manufactured by outside suppliers. Many companies have instituted formal supplier quality-improvement programs as part of their own **internal** quality-improvement efforts. Selection of suppliers based on **quality**, **schedule**, and **cost**, rather than on cost alone, is also a vital strategic management decision that can have a long-term significant impact on overall competitiveness.

It is also critical that management recognize that quality improvement must be a total, companywide activity, and that every organizational unit *must* actively participate. Obtaining this participation is the responsibility of (and a significant challenge to) senior management. What is the role of the quality-assurance organization in this effect? The responsibility of quality assurance is to assist management in providing quality assurance for the companies' products. Specifically, the quality-assurance function is a technology warehouse that contains the skills and resources necessary to generate products of acceptable quality in the marketplace. Quality management also has the responsibility for evaluating and using quality-cost information for identifying improvement opportunities in the system, and for making these opportunities known to higher management. It is important to note, however, that the **quality function is not responsible for quality**. After all, the quality organization does not design, manufacture, distribute, or service the product. Thus, the responsibility for quality is distributed throughout the entire organization.

The philosophies of Deming, Juran, and Feigenbaum imply that responsibility for quality spans the entire organization. However, there is a danger that if we adopt the philosophy that "quality is everybody's job," then quality will become nobody's job. This is why quality planning and analysis are important. Because quality improvement activities are so broad, successful efforts require, as an initial step, top management commitment. This commitment involves emphasis on the importance of quality, identification of the respective quality responsibilities of the various organizational units, and explicit accountability for quality improvement of all managers and employees in the company.

Finally, strategic management of quality in an organization must involve all three components discussed earlier: **quality planning**, **quality assurance**, and **quality control and improvement**. Furthermore, *all* of the individuals in the organization must have an understanding of the basic tools of quality improvement. Central among these tools are the elementary statistical concepts that form the basis of process control and that are used for the analysis of process data. It is increasingly important that everyone in an organization, from top management to operating personnel, have an awareness of basic statistical methods and of how these methods are useful in manufacturing, engineering design and development, and in the general business environment. Certain individuals must have higher levels of skills; for example, those engineers and managers in the quality-assurance function would generally be experts in one or more areas of process control, reliability engineering, design of experiments, or engineering data analysis. However, the key point is the philosophy that statistical methodology is a language of communication about problems that enables management to mobilize resources rapidly and to efficiently develop solutions to such problems. Because Six Sigma or lean Six Sigma incorporates most of the elements for success that we have identified, it has proven to be a very effective framework for implementing quality improvement.