FIFTH EDITION

THE ASQ CERTIFIED QUALITY ENGINEER HANDBOOK

SCOTT A. LAMAN, Editor

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Preface

The purpose of this book is to help people become better quality engineers, with American Society for Quality (ASQ) certification being a tool toward that end. For many purchasing this book, you probably have a good idea about what a quality engineer is and how you fit the bill with your strengths and experience. Congratulations and thank you for choosing this valuable vocation!

For others, let's begin with what quality engineering is. It is not just one field. Quality engineers can be found in product design, manufacturing, post-market surveillance, supplier development, and auditing, for example. Some of us work on the front end of new product development, crossing into reliability engineering and proactive design assurance. Others are continuous improvement and failure analysis experts, utilizing product and process performance information and solving problems identified during manufacturing and use. Some quality engineering disciplines are more technical, some are more interpersonal, and all have various levels of leadership and management.

Quality engineering crosses all demographics, generations, and educational backgrounds. It provides a unifying influence to an organization by its nature of using objective evidence, facts, and data. Few people come out of high school or college knowing that they want to be a Quality Engineer. However, occasionally someone does. More often, however, after several years of working and being exposed to many functions in an organization, a person will decide that quality engineering is what they want to do.

Much comes down to natural inclination and knowing yourself. Have you seen yourself migrate toward using mathematical tools and numbers? Do you consider yourself to have excellent attention to detail, the ability to think and present logically and clearly, and the capability of identifying problems and helping solve them? Can you discern when to take a strong stand on an issue for compliance or safety, and when there may be a gray area involved or give-and-take needed to optimize an outcome? Have others pointed out any of these characteristics in you?

With the foundation built on your natural abilities and interests, your education, and your experiences, ASQ certification can formally get your arms around what has proudly become your professional identity. Think of it as a present, a gift to yourself and by extension to your organization and professional network. In that way, the package is the certified quality engineer (CQE) body of knowledge (BoK), consisting of seven major areas:

- Management and leadership
- The quality system

- Product, process, and service design
- Product and process control
- Continuous improvement
- Quantitative methods and tools
- Risk management

The bow and ribbon on the package are the certification itself, prestigious peer recognition for passing a difficult exam to demonstrate that you really do understand and are ready to apply this broad and comprehensive body of knowledge.

Every five to seven years, the body of knowledge of an ASQ certification is reevaluated and updated. A comprehensive process is followed, and at the end we move right into producing the references and study guides to help people prepare for the updated exam. A group of people begin to update the exam question bank by deleting, adding, and revising questions as necessary. At the same time, a separate, independent group of people begin updating ASQ training and certification preparation materials, of which this handbook is one.

The process to update a handbook is somewhat involved and takes an army of people, who you will see listed in the Acknowledgments. Quality Press provides a gap assessment between the old and new bodies of knowledge and handles logistics such as contracts and agreements. If there is one part of the process that stands out as most important, it is the selection of authors, which for this book are a collection of renowned experts in their fields and experienced contributors to other publications. Editing then becomes a matter of taking the individual contributions of the authors, fitting their content into the handbook in the logical sequence per the body of knowledge, filling gaps with some writing yourself, and polishing it all to make it look consistent.

For this edition of *The ASQ Certified Quality Engineer Handbook*, the following is a summary of changes. These changes were made to cover the new body of knowledge comprehensively and clearly. It was also acknowledged that certain content, while still of value to quality professionals of all kinds, was no longer part of the body of knowledge for this certification. The following list is being provided to be thorough in communication and honest about what has been changed and removed.

- New content
  - Cost-benefit analysis and responsible, accountable, consulted, and informed matrix (RACI) as quality management system deployment techniques in Chapter 1
  - Assessing risks in audit planning and implementation in Chapter 2
  - Critical to quality as a design input in Chapter 3
  - Hazard analysis and use failure mode and effects analysis as reliability/safety/hazard assessment tools in Chapter 3
  - Overall equipment effectiveness (OEE) as a Lean tool in Chapter 5
  - 5 Whys as a corrective action tool in Chapter 5

    - Data automation and database integration as data collection methods in Chapter 6
    - An entirely new chapter 7 on risk management
- Restructured content
    - Risk management tools were moved from Chapter 7 to Chapter 3 as part of reliability/safety/hazard assessment tools.
    - Continuous improvement tools and methodologies were aligned with the body of knowledge in Chapter 5.
    - Quality function deployment (QFD) was moved from Chapter 1 to Chapter 3.

Regarding this book's writing style, attempts were made to simplify and reduce the number of words needed to make the point. Microsoft Word was very helpful to identify opportunities for improvement in this area. For example, using the CQE BoK philosophy of Lean, simply replacing the approximately 100 previous usages of "in order to" and "a number of" with "to" and "several" made an impact on word count and readability.

Ultimately, this book was built upon the foundation laid by an outstanding group of editors of previous editions, who are mentioned in the next section.

I hope you find this edition to be helpful in preparing for the certification exam and as a reference to help you succeed in your profession.

Acknowledgments

First, thank you to the giants in quality engineering who laid the foundation to this book by serving as editors of previous editions.

- Roger W. Berger
- Donald W. Benbow
- Ahmad K. Elshennawy
- H. Fred Walker
- Connie M. Borror
- Sarah E. Burke
- Rachel T. Silvestrini

Next, the Quality Press editorial staff was tremendously helpful in providing guidance and removing roadblocks, some of which seemed significant enough hurdles that this project could have been derailed. Simple advice ranged from determining the scope of the content (what should be in and out of the book) to reducing manuscript file size. A breakthrough at one critical point was the suggestion to use skilled people to produce the equations and mathematical symbols, which I was stuck on but apparently is simple *if* you know how to do it.

- Lillian McAnally, Managing Editor, Quality Press
- Erica Barse, Associate Editor, Quality Press

This project, and editing a book is certainly a project by any measure, could not have been completed if I were not surrounded by an incredibly knowledgeable group of authors, who each took on an area of new content in their area of expertise. They also provided guidance during the project to optimize communications and information flow. This is also a call out to a few of the ASQ Technical Communities. The certified quality engineer exam does not have a sponsoring division like some exams do. Therefore, to obtain the assistance needed to determine contributing authors, I reached out to leadership in ASQ divisions whose focus is on areas including in the CQE BoK. The Audit Division, the Quality Management Division, and the Statistics divisions all provided at least one author, who are listed below followed by the subject(s) each contributed.

- Matthew A. Barsalou, BorgWarner Systems Engineering GmbH – Critical to quality, control chart selection
- Andrew Davison, Genesys Spine – Assessing audit risks, 5 Whys, and auditing standards
- Denis Devos, Devos Associates Inc. – Cost-benefit analysis and responsible, accountable, consulted, and informed matrix
- Harish Jose, Bausch + Lomb Synergetics – Overall equipment effectiveness
- Dr. Michael Mladjenovic, The Sensei Group – Data automation and database integration
- Jayet Moon, Terumo Medical Corporation – Risk management and tools

Two graduate students from the Georgia Institute of Technology produced the mathematical content and at times went above and beyond by finding editing improvements.

- Sweta Senthil
- Manav Sheth

Others provided additional sets of eyes and risk management subject matter expertise in the form of pre-submission reviews.

- Barry Craner, CQA-Associates
- Veronica Cavendish-Stephens, Auchincloss-Stephens International

Now it gets more personal. Over the years, there have been many people who have believed in me and given me a chance to advance in quality engineering when at each step of the way, someone else told me that the next step was not possible. It has been a journey. Thank you to …

- Stephen Uliana, Mitsubishi Chemical Advanced Materials, for providing my first quality engineering opportunity at Quadrant Engineering Plastic Products and for supporting my initial, brash career venture into attaining ASQ certifications.
- Jeffrey P. Lewis, Globus Medical, for being the hiring manager to provide my first so-titled quality engineering position at Arrow International (now Teleflex).
- Scott McKently, Owens & Minor, for promoting me into my first and second quality engineering management positions at Teleflex.
- Robert Z. Phillips, Siemens Healthineers, for providing support and stretch opportunities at Teleflex to prepare me for continued growth.
- Julius Aviza for providing additional new opportunities at Teleflex that led to my job growing into the quality systems area including medical device management representative responsibilities.

- Michael Byrnes, ASQExcellence, who identified me to edit *The ASQ Certified Medical Device Auditor Handbook* a couple years ago, which led to a similar opportunity with this handbook.

The company Teleflex was mentioned several times above. I would like to acknowledge the organization as a whole for recognizing the importance of individual development plans and for fully supporting ASQ certifications and activities that lead to personal growth that can be translated to the job. It is a win for all and not taken for granted.

Finally, I would like to thank my wife, Krista, for patiently tolerating my work on this book at every opportunity for several months. That support was essential.

List of Acronyms

AHP: analytical hierarchy process
AIAG: Automotive Industry Action Group
AND: activity network diagram
ANOVA: analysis of variance
AQL: acceptable quality limit
AQP: advanced quality planning
ARL: average run length
ASN: average sample number
ASQ: American Society for Quality
ASTM: American Society for Testing and Materials
ATE: automated test equipment
ATI: average total inspection
BoK: body of knowledge
cdf: cumulative density function/cumulative distribution function
CL: center line
CLA: center line average
CM: configuration management
CMM: coordinate measuring machines
COPQ: cost of poor quality
COQ: cost of quality
CQE: certified quality engineer
CSA: Canadian Standards Association
CtQ: Critical to Quality
df: degrees of freedom
dFMEA: design failure mode and effects analysis
DMAIC: define, measure, analyze, improve, control
DMRCS: define, measure, reduce, combine, select
DoD: Department of Defense
DOE: design of experiments
DPMO: defects per million opportunities

DPU: defects per unit
DR: discrimination ratio
EC: earliest completion time
ECP: engineering change proposal
EEO: equal employment opportunity
8D: eight disciplines
ES: earliest start time
ESS: environmental stress screening
ESSEH: Environmental Stress Screening of Electronic Hardware
ELT: extract, load, transform
ETL: extract, transform, load
F: Fahrenheit
FMEA: failure modes and effects analysis
FMECA: failure modes effects and criticality analysis
FS: free slack
FT: fault tree
GD&T: geometric dimensioning and tolerancing
HACCP: hazard analysis and critical control points
IATF: International Automotive Task Force
IoT: Internet of things
IQ: installation qualification
IQR: inter-quartile range
IRR: internal rate of return
ISO: International Organization for Standardization
IT: information technology
JIT: just-in-time
K: Kelvin
LC: latest completion time
LCL: lower control limit
LRM: linear responsibility matrix
LS: latest start time
LSC: least squares circle
LSL: lower specification limit
LSS: Lean-Six Sigma
LTPD: lot tolerance percent defective
MA: moving average
MAP: measurement assurance protocol
MBNQA: Malcolm Baldrige National Quality Award
MCC: minimum circumscribed circle
MIC: maximum inscribed circle

MMC: maximum material condition
MRB: material review board
MRP: manufacturing resource planning
MRS: minimum radial separation
MS: mean square
MSA: measurement systems analysis
MTBF: mean time between failures
MTTF: mean time to failure
MTTR: mean time to repair
MZC: minimum zone circle
NAVAIR: Naval Air Systems Command
NAVMAT: naval material command
NDT: nondestructive testing
NIST: National Institute of Standards and Technology
NMCM: not-mission capable equipment due to maintenance
NPV: net present value
OC: operating characteristic
OEE: Overall Equipment Effectiveness
OEM: original equipment manufacturer
OQ: operational qualification
PC: peak count
PCB: printed circuit board
PDCA: plan–do–check–act
pdf: probability density function
PDPC: process decision program chart
PDSA: plan–do–study–act
pFMEA: process failure mode and effects analysis
PII: personally identifiable information
PLC: programmable logic controller
pmf: probability mass function
PPAP: part production approval process
ppm: parts per million
PPQ: process performance qualification
PQ: process qualification
PTR: precision-to-tolerance ratio
PVC: process value chain
QE: quality engineer
QFD: quality function deployment
QIS: quality information system
QMS: quality management system

R&D: research and development
R&R: repeatability and reproducibility
RACI: responsible, accountable, consulted, and informed
RCDQ: reactive customer-driven quality
RCI: rapid continuous improvement
RFID: radio frequency identification
RMS: root mean square
ROI: return on investment
RPN: risk priority number
RQL: rejectable quality level
RRM: resource requirements matrix
RTY: rolled throughput yield
SAE: Society of Automotive Engineers
SCADA: supervisory control and data acquisition
SDWT: self-directed work team
s.e.: standard error
SI: Systems International
SIPOC: suppliers, inputs, process, outputs, customers
SMED: single minute exchange of dies
SNR: signal-to-noise ratio
SPC: statistical process control
SQA: supplier quality assurance
SQM: supplier quality management
SQP: strategic quality planning
SS: sum of squares
SWOT: strengths, weaknesses, opportunities, threats
TPM: total productive maintenance
TQM: total quality management
TS: total slack
uFMEA: use failure mode and effects analysis
UCL: upper control limit
USL: upper specification limit
VOC: voice of the customer
VSM: value stream map
WBS: work breakdown structure
WIP: work in process

Certified Quality Engineer (CQE) Body of Knowledge

The topics in this Body of Knowledge include subtext explanations and the cognitive level at which the questions will be written. This information will provide useful guidance for both the Exam Development Committee and the candidate preparing to take the exam. The subtext is not intended to limit the subject matter or be all-inclusive of the material that will be covered in the exam. It is meant to clarify the type of content that will be included on the exam. The descriptor in parentheses at the end of each entry refers to the maximum cognitive level at which the topic will be tested. A complete description of cognitive levels is provided at the end of this document.

I. Management and Leadership (17 Questions)

A. Quality Philosophies and Foundations

Describe continuous improvement tools, including lean, six sigma, statistical process control (SPC), and total quality management. Understand how modern quality has evolved from quality control through statistical process control (SPC) to total quality management and leadership principles (including Deming's 14 points). (Understand)

B. The Quality Management System (QMS)

1. Strategic planning

Identify and define top management's responsibility for the QMS, including establishing policies and objectives, setting organization-wide goals, and supporting quality initiatives. (Apply)

2. Deployment techniques

Define, describe, and use various deployment tools in support of the QMS such as:

a. Benchmarking

Define the concept of benchmarking and why it may be used. (Remember)

b. Stakeholder

Define, describe, and use stakeholder identification and analysis. (Apply)

c. Performance

Define, describe, and use performance measurement tools such as cost-benefit analysis. (Apply)

d. Project management

Define, describe, and use project management tools, including Gantt charts and the responsible, accountable, consulted and informed matrix (RACI). (Apply)

3. Quality information system (QIS)

Identify and describe the basic elements of a QIS, including who will contribute data, the kind of data to be managed, who will have access to the data, the level of flexibility for future information needs, and data analysis. (Understand)

C. ASQ Code of Ethics for Professional Conduct

Determine appropriate behavior in situations requiring ethical decisions. (Evaluate)

D. Leadership Principles and Techniques

Analyze various principles and techniques for developing and organizing teams and leading quality initiatives. (Analyze)

E. Facilitation Principles and Techniques

1. Roles and responsibilities

Describe the facilitator's roles and responsibilities on a team. (Understand)

2. Facilitation tools

Apply various tools used with teams, including brainstorming, nominal group technique, conflict resolution, and force-field analysis. (Apply)

F. Communication Skills

Identify and distinguish between specific communication methods that are used for delivering information and messages in a variety of situations across all levels of the organization. (Analyze)

G. Customer Relations

Define, apply, and analyze the results of customer relation tools such as customer satisfaction surveys. (Analyze)

H. Supplier Management

1. Techniques

Apply various supplier management techniques, including supplier qualification, certification, and evaluation. (Apply)

2. Improvement

Analyze supplier ratings and performance improvement results. (Analyze)

3. **Risk**

   Understand business continuity, resiliency, and contingency planning. (Understand)

I. **Barriers to Quality Improvement**

   Identify barriers to quality improvement, analyze their causes and impact, and implement methods for improvement. (Analyze)

II. **The Quality System (18 Questions)**

A. **Elements of the Quality System**

1. **Basic elements**

   Interpret the basic elements of a quality system, including planning, control, and improvement, from product and process design through quality cost systems and audit programs. (Evaluate)

2. **Design**

   Analyze the design and alignment of interrelated processes to the strategic plan and core processes. (Analyze)

B. **Documentation of the Quality System**

1. **Document components**

   Identify and describe quality system documentation components, including quality policies and procedures to support the system. (Understand)

2. **Document control**

   Evaluate configuration management, maintenance, and document control to manage work instructions and quality records. (Evaluate)

C. **Quality Standards and Other Guidelines**

   Apply national and international standards and other requirements and guidelines, including the Malcolm Baldrige National Quality Award (MBNQA), and describe key points of the ISO 9000 series of standards. [Note: Industry-specific standards will not be tested.] (Apply)

D. **Quality Audits**

1. **Types of audits**

   Describe and classify the various types of quality audits such as product, process, management (system), registration (certification), compliance (regulatory), first, second, and third party. (Apply)

2. **Roles and responsibilities in audits**

   Identify and define roles and responsibilities for audit participants such as audit team (leader and members), client, and auditee. (Understand)

3. **Audit planning and implementation**

   Describe and apply the stages of a quality audit, from audit planning, including assessing risks through conducting an audit. (Apply)

4. **Audit reporting and follow-up**

   Apply the steps of audit reporting and follow up, including the need to verify corrective action. (Apply)

E. **Cost of Quality (COQ)**

   Identify and apply COQ concepts, including cost categorization, data collection, reporting, and interpreting results. (Analyze)

F. **Quality Training**

   Identify and apply key elements of a training program, including conducting a needs analysis, preparing curricula and materials, and determining the program's effectiveness. (Apply)

III. Product, Process, and Service Design (21 Questions)

A. **Classification of Quality Characteristics**

   Define, interpret, assess, and classify quality characteristics for new and existing products, processes, and services. [Note: The classification of defects is covered in IV.B.3.] (Evaluate)

B. **Design Inputs, Techniques, and Review**

1. **Inputs**

   Classify design inputs such as customer needs, regulatory requirements, critical to quality, and risk assessment into robust design using techniques such as failure mode and effects analysis (FMEA). (Analyze)

2. **Techniques**

   Apply Design for X (DFX), Design for Six Sigma (DFSS), and requirements traceability. (Apply)

3. **Review**

   Identify and apply common elements of the design review process, including roles and responsibilities of participants. (Apply)

C. **Technical Drawings and Specifications**

   Interpret specification requirements in relation to product and process characteristics and technical drawings, including characteristics such as views, title blocks, dimensioning and tolerancing, and geometric dimensioning and tolerance symbols (GD&T). (Evaluate)

D. **Verification and Validation**

   Interpret the results of evaluations and tests used to verify and validate the design of products, processes and services, such as installation qualification (IQ), operational qualification (OQ), and process qualification (PQ). (Evaluate)

E. **Reliability and Maintainability**

1. **Predictive and preventive maintenance tools**

   Describe and apply the tools and techniques used to maintain and improve process and product reliability. (Apply)

2. **Reliability and maintainability indices**

   Apply indices such as mean time to failure (MTTF), mean time between failure (MTBF), mean time to repair (MTTR), availability, and failure rate. (Apply)

3. **Reliability models**

   Identify, define, and distinguish between the basic elements of reliability models such as exponential, Weibull, and bathtub curve. (Apply)

4. **Reliability/safety/hazard assessment tools**

   Define, construct, and interpret the results of failure mode and effects analysis (FMEA), design FMEA (dFMEA), process FMEA (pFMEA), use FMEA (uFMEA), failure mode, effects, and criticality analysis (FMECA), and hazard analysis. (Analyze)

IV. Product and Process Control (23 Questions)

A. Methods

Implement product and process control methods such as control plan development, critical control point identification, and work instruction development and validation. (Analyze)

B. Material Control

1. **Material identification, status, and traceability**

   Define and distinguish between these concepts, and describe methods for applying them in various situations. (Analyze)

2. **Material segregation**

   Describe material segregation and its importance, and evaluate appropriate methods for applying it in various situations. (Evaluate)

3. **Material classification**

   Assess and classify product and process defects and non-conformities. (Evaluate)

4. **Material review board (MRB)**

   Describe the purpose and function of an MRB and evaluate nonconforming product or material to make a disposition decision in various situations. (Evaluate)

C. Acceptance Sampling

1. **Sampling concepts**

   Apply the concepts of producer and consumer risk, and related terms, including operating characteristic (OC) curves, acceptable quality limit (AQL), and lot tolerance percent defective (LTPD). (Apply)

2. **Sampling standards and plans**

   Identify, interpret, and apply ANSI/ASQ Z1.4 and Z1.9 standards for attributes and variables sampling. (Analyze)

3. Sample integrity

Identify and apply techniques for establishing and maintaining sample integrity. (Apply)

D. Measurement and Test

1. Measurement tools

Select and describe appropriate uses of inspection tools such as gage blocks, calipers, micrometers, optical comparators, and coordinate measuring machines (CMM). (Analyze)

2. Destructive and nondestructive tests

Identify when destructive and nondestructive measurement test methods should be used and apply the methods appropriately. (Apply)

E. Metrology

Apply metrology techniques such as calibration, traceability to calibration standards, measurement error and its sources, and control and maintenance of measurement standards and devices. (Apply)

F. Measurement System Analysis (MSA)

Calculate, analyze, and interpret repeatability and reproducibility (Gage R&R) studies, measurement correlation, capability, bias, linearity, precision, stability and accuracy, using MSA quantitative and graphical methods. (Evaluate)

V. Continuous Improvement (26 Questions)

A. Quality Control Tools

Select, construct, apply, and interpret the following quality control tools:

1. Flowcharts
2. Pareto charts
3. Cause and effect diagrams
4. Control charts
5. Check sheets
6. Scatter diagrams
7. Histograms (Analyze)

B. Quality Management and Planning Tools

Select, construct, apply, and interpret the following quality management and planning tools:

1. Affinity diagrams and force field analysis
2. Tree diagrams
3. Process decision program charts (PDPC)
4. Matrix diagrams

5. Interrelationship digraphs
6. Prioritization matrices
7. Activity network diagrams (Analyze)

C. Continuous Improvement Methodologies

Define, describe, and apply the following continuous improvement methodologies:

1. Total quality management (TQM)
2. Kaizen
3. Plan-do-check-act (PDCA)
4. Six sigma (Analyze)

D. Lean tools

Define, describe, and apply the following lean tools:

1. 5S
2. Value-stream mapping
3. Kanban
4. Visual control
5. 8 Wastes
6. Standardized work
7. Takt time
8. Single minute exchange of die (SMED)
9. Overall equipment effectiveness (OEE) (Evaluate)

E. Corrective Action

Identify, describe, and apply elements of the corrective action process, including problem identification, failure analysis, root cause analysis, 5 Whys, problem correction, recurrence control, and verification of effectiveness. (Evaluate)

F. Preventive Action

Identify, describe and apply various preventive action tools such as error-proofing/poka-yoke and robust design and analyze their effectiveness. (Evaluate)

VI. Quantitative Methods and Tools (34 Questions)

A. Collecting and Summarizing Data

1. Types of data

Define, classify, and compare discrete (attributes) and continuous (variables) data. (Apply)

2. Measurement scales

Define and describe nominal, ordinal, interval, and ratio scales. (Understand)

3. **Data collection methods**

   Describe various methods for collecting data, including tally or check sheets, data coding, automatic gaging, data automation, database integration, and identify the strengths and weaknesses of the methods. (Apply)

4. **Data accuracy and integrity**

   Identify factors that can influence data accuracy such as source/resource issues, flexibility, versatility, inconsistency, inappropriate interpretation of data values, and redundancy to ensure data accuracy and integrity. (Apply)

5. **Data visualization techniques**

   Apply and interpret data visualization techniques using dashboards, and select the appropriate metrics for dashboards. (Apply)

6. **Descriptive statistics**

   Describe, calculate, and interpret measures of central tendency and dispersion, apply the central limit theorem, and construct and interpret frequency distributions, including simple, categorical, grouped, ungrouped, and cumulative. (Evaluate)

7. **Graphical methods for depicting distributions**

   Apply and interpret diagrams such as probability plots for normal and other distributions. [Note: Histograms are covered in V.A.] (Analyze)

B. Quantitative Concepts

1. **Terminology**

   Define and apply quantitative terms, including population, parameter, sample, statistic, random sampling, and expected value. (Analyze)

2. **Drawing statistical conclusions**

   Distinguish between numeric and analytical studies. Assess the validity of statistical conclusions by analyzing the assumptions used and the robustness of the technique used. (Evaluate)

3. **Probability terms and concepts**

   Describe concepts such as independence, mutual exclusivity, multiplication rules, complementary probability, and joint occurrence of events. (Apply)

C. Probability Distributions

1. **Continuous distributions**

   Define and distinguish between these distributions such as normal, uniform, exponential, lognormal, Weibull, Student's *t* and *F*. (Analyze)

2. **Discrete distributions**

   Define and distinguish between these distributions such as binomial, Poisson, hypergeometric, and multinomial. (Analyze)

D. **Statistical Decision-Making**

1. **Point estimates and confidence intervals**

   Define, describe, and assess the bias of estimators. Calculate and interpret standard error, tolerance intervals, and confidence intervals. (Evaluate)

2. **Hypothesis testing**

   Define, interpret, and apply hypothesis tests for means, variances, and proportions. Apply and interpret the concepts of significance level, power, type I, and type II errors. Define and distinguish between statistical and practical significance. (Evaluate)

3. **Paired-comparison tests**

   Define and use paired-comparison (parametric) hypothesis tests, and interpret the results. (Apply)

4. **Goodness-of-fit tests**

   Define and use chi-square and other goodness-of-fit tests, and understand the results. (Apply)

5. **Analysis of variance (ANOVA)**

   Define use, and interpret ANOVA and interpret the results. (Analyze)

6. **Contingency tables**

   Define and use contingency tables to evaluate statistical significance. (Apply)

E. **Relationships Between Variables**

1. **Linear regression**

   Calculate simple linear regression models. Illustrate hypothesis tests for regression statistics. Use linear regression models for estimation and prediction. (Apply)

2. **Simple linear correlation**

   Calculate the correlation coefficient and its confidence interval, and illustrate a hypothesis test for correlation statistics. (Apply)

3. **Time-series analysis**

   Define, describe, and use time-series analysis, including moving average to identify trends and seasonal or cyclical variation. (Apply)

F. **Statistical Process Control (SPC)**

1. **Objectives and benefits**

   Identify and explain the objectives and benefits of SPC. (Understand)

2. **Common and special causes**

   Describe, identify, and distinguish between these types of causes. (Analyze)

3. **Selection of variable**

   Identify and select variable characteristics for monitoring by control chart. (Analyze)

4. **Rational subgrouping**

   Define and apply the principles of rational subgrouping. (Apply)

5. **Control charts**

   Identify, select, construct, and use various control charts, including $\bar{x}$ - R, $\bar{x}$ - s, individuals and moving range (ImR or XmR), moving average and moving range (MAMR), p, np, c, and u. (Analyze)

6. **Control chart analysis**

   Read and interpret control charts and use rules for determining statistical control. (Evaluate)

7. **Short-run SPC**

   Identify and define short-run SPC rules. (Understand)

G. **Process and Performance Capability**

1. **Process capability studies**

   Define, describe, calculate, and use process capability studies, including identifying characteristics, specifications and tolerances, developing sampling plans for such studies, and establishing statistical control. (Analyze)

2. **Process performance vs. specifications**

   Distinguish between natural process limits and specification limits, and calculate percent defective, defects per million opportunities (DPMO), and parts per million (ppm). (Analyze)

3. **Process capability indices**

   Define, select, and calculate C_p , C_{pk}, C_{pm}, and C_r, and evaluate process capability. (Evaluate)

4. **Process performance indices**

   Define, select, and calculate P_p and P_{pk}, and evaluate process performance. (Evaluate)

H. **Design and Analysis of Experiments**

1. **Terminology**

   Define terms such as dependent and independent variables, factors, levels, response, treatment, error, and replication. (Understand)

2. **Planning and organizing experiments**

   Identify the basic elements of designed experiments, including determining the experiment objective, selecting factors, responses, and measurement methods, and choosing the appropriate design. (Analyze)

3. **Design principles**

   Define and apply the principles of power and sample size, balance, replication, order, efficiency, randomization, blocking, interaction, and confounding. (Apply)

4. **Full-factorial experiments**

   Construct full-factorial designs and use computational and graphical methods to analyze the significance of results. (Analyze)

5. **Two-level fractional factorial experiments**

   Construct two-level fractional factorial designs and apply computational and graphical methods to analyze the significance of results. (Analyze)

VII. Risk Management (21 Questions)

A. Risk Fundamentals

1. **Risk terminology**

   Define, describe, and apply risk terminology such as risk, risk management, severity, occurrence, detection, and risk-based thinking. (Analyze)

2. **Types of risk management**

   Understand and apply various types of enterprise (strategic, software, business, regulatory, medical, audit), operational (supplier, supply chain, safety, project, manufacturing, operations, service, quality system), and product (design, process, use, safety) risk management. (Apply)

B. Risk Planning and Assessment

1. **Risk management plan**

   Analyze and interpret a risk management plan and its components (objectives, risk criteria, stakeholder identification, and team member roles/responsibilities) to identify and prioritize risks. (Analyze)

2. **Risk assessment**

   Apply categorization methods and evaluation tools to assess risk such as failure mode and effects analysis. Identify and apply evaluation metrics including the use of risk matrices, risk priority numbers, and acceptability criteria. (Analyze)

C. Risk Treatment, Control, and Monitoring

1. **Identification and documentation**

   Identify risks, gaps, and controls and document with tools such as a risk register. (Analyze)

2. **Risk management system evaluation**

   Apply auditing techniques and testing of controls to evaluate a risk management system. (Apply)

3. **Risk treatment strategies**

   Understand and apply risk treatment strategies, such as avoid, mitigate, transfer, and accept. (Analyze)

4. **Risk monitoring**

   Apply risk monitoring techniques such as, complaint tracking, trending, and post-market surveillance. (Analyze)

5. **Mitigation planning**

   Apply and interpret risk mitigation plan. (Analyze)

LEVELS OF COGNITION BASED ON BLOOM'S TAXONOMY—REVISED (2001)

In addition to content specifics, the subtext for each topic in this BOK also indicates the intended complexity level of the test questions for that topic. These levels are based on "Levels of Cognition" (from Bloom's Taxonomy—Revised, 2001) and are presented below in rank order, from least complex to most complex.

Remember

Recall or recognize terms, definitions, facts, ideas, materials, patterns, sequences, methods, principles.

Understand

Read and understand descriptions, communications, reports, tables, diagrams, directions, regulations.

Apply

Know when and how to use ideas, procedures, methods, formulas, principles, theories.

Analyze

Break down information into its constituent parts and recognize their relationship to one another and how they are organized; identify sublevel factors or salient data from a complex scenario.

Evaluate

Make judgments about the value of proposed ideas, solutions, by comparing the proposal to specific criteria or standards.

Create

Put parts or elements together in such a way as to reveal a pattern or structure not clearly there before; identify which data or information from a complex set is appropriate to examine further or from which supported conclusions can be drawn.

Chapter 1
Management and Leadership

The two main themes of Chapter 1 are a broad perspective on the quality profession and the human element in quality. Areas such as strategic planning and leadership may require additional training and years of experience before full competency is achieved. In the same vein, developing communication skills and removing barriers to quality improvement could take a lifetime. After a careful study of this chapter, you should have a clear idea of the elements upon which the profession of quality engineering is based.

The quality profession has both a human element and a technical element, and Chapter 1 examines the human element of quality from several different perspectives. First, definitions of quality are discussed, followed by a review of the history of quality. The contributions of the leading experts over the past 80 years are noted, starting with Walter Shewhart and highlighting his two greatest successors, W. Edwards Deming and Joseph M. Juran. Some major quality programs discussed are statistical process control, total quality management, lean philosophy, and Six Sigma. No matter whether the quality program is one that is discussed here or something else, a successful organization will have a system for managing its quality. One way to view the quality management system is to break it into three parts: strategic planning of the vision and goals, deployment techniques for converting the vision/goals into reality, and an information system to collect, analyze, and report the data. Deployment techniques used for selecting and managing projects include return on investment (ROI) and Gantt charts. Heavy emphasis is also given to performance measurement tools. Next, professional ethics is discussed, including the ASQ Code of Ethics and legal constraints on the quality engineer.

Leadership, facilitation, and communication skills are all interrelated. For the organization to achieve its goals in a positive and efficient manner, leaders must translate vision and goals into tangible activities. Executive direction and indirect or "soft" leadership known as facilitation unleash the energy and motivation of mid- and lower-level employees. Communication skills are critical to effective leadership and facilitation, as well as to individual career success.

The final three sections of Chapter 1 address the role of quality in dealing with customers, suppliers, and barriers to improvement. Two typical techniques for addressing the role of quality are supplier surveys, which tell us what one can expect from suppliers, and customer surveys, which tell us what our customers think of us. Finally, the section on barriers reinforces the idea that quality improvement is a constant struggle, and that the various ideas of this book must be applied again and again to maintain momentum toward that elusive but unobtainable goal of perfection.

QUALITY PHILOSOPHIES AND FOUNDATIONS

> Describe continuous improvement tools, including lean, six sigma, statistical process control (SPC), and total quality management. Understand how modern quality has evolved from quality control through statistical process control (SPC) to total quality management and leadership principles (including Deming's 14 points). (Understand)
>
> **Body of Knowledge I.A**

This section covers the meaning of quality and provides a brief history of quality. The pioneers of the quality engineering movement are highlighted: Walter A. Shewhart, W. Edwards Deming, and Joseph M. Juran. Also introduced are several continuous improvement methods.

What Is Quality?

Quality means different things to different people in different situations. As Henry Ford said, "Quality means doing it right when no one is looking." Some additional informal descriptions and results of quality include the following:

- Quality is inversely proportional to variability
- Quality is not a program; it is an approach to business
- Quality is a collection of powerful tools and concepts that are proven to work
- Quality is defined by customers through their satisfaction
- Quality includes continual improvement and breakthrough events
- Quality tools and techniques are applicable in every aspect of business
- Quality is aimed at perfection; anything less is an improvement opportunity
- Quality increases customer satisfaction, reduces cycle time and costs, and eliminates errors and rework

Additionally, typical elements used to assess quality include totality of features, essential characteristics, ability to satisfy needs, conformance to requirements, degree or grade of excellence, free of deficiencies, and meeting/exceeding

Table 1.1 Comparing the impact quality can have.

99.74% good = 3 sigma	99.9998% good = 6 sigma
20,000 lost articles of mail per hour	Seven lost articles of mail per hour
Unsafe drinking water for almost 15 minutes each day	One minute of unsafe drinking water every seven months
5,000 incorrect surgical operations per week	1.7 incorrect surgical operations per week
Two short or long landings at most major airports each day	One short or long landing every five years
200,000 wrong drug prescriptions each year	68 wrong drug prescriptions per year
No electricity for almost seven hours each month	One hour without electricity every 34 years

customer expectations. Garvin (1987) discusses eight dimensions of quality, and Montgomery (2013) adds three more regarding service and transactional organizations. These dimensions include performance, reliability, durability, serviceability, aesthetics, features, perceived quality, conformance to standards, responsiveness, professionalism, and attentiveness.

Quality is not just for businesses; it is also for nonprofit organizations such as schools, healthcare and social services, and government agencies. Results, performance and financial, are the natural consequence of effective quality management. Table 1.1 compares the consequences and impact of quality management at two different quality levels, three sigma (99.74% good) and six sigma (99.9998% good).

The above quality descriptors show that quality is difficult to define, and no one definition can be all-inclusive. The word *quality* is highly nuanced and allows many interpretations. For example, Merriam-Webster's definition of *quality* is "an inherent or distinguishing characteristic"[1] and is one of many distinctly different definitions from the same authority. The reader quickly comes to realize that most of the definitions are quite specialized and not pertinent to the practice of quality engineering. According to ISO 9000:2015, section 3.6.2, *quality* is defined as "the degree to which a set of inherent characteristics of an object fulfills requirements."

This definition is quite interesting, first because it is published by ISO, an international standards organization, and second because it specifically rebuts the definition that Joseph Juran used throughout his career: "quality = fitness for use." In contrast, Philip Crosby used the definition "quality = conformance to specifications." There probably never will be an ultimate definition of this all-important word, as the definition is constantly evolving.

The views of eight well-known quality experts appeared in the July 2001 issue of *Quality Progress*. Although these experts differ on details and nuances, some common themes appear in all their different quality philosophies:

1. Quality improvement is a never-ending process
2. Top management commitment, knowledge, and active participation are critical

[1]http://dictionary.reference.com/search?q=quality.

3. Management is responsible for articulating a company philosophy, goals, measurable objectives, and a change strategy
4. All employees in the organization need to be active participants
5. A common language and set of procedures are important to communicate and support the quality effort
6. A process must be established to identify the most critical problems, determine their causes, and find solutions
7. Changes in company culture, roles, and responsibilities may be required

History of Quality

The quality profession has a long history, which has greatly accelerated over the past 80 years. Joseph M. Juran (1988) traced the practice of the quality profession back to the ancient Egyptians and the building of the pyramids. For centuries, quality was intrinsically associated with craftsmanship, and each craftsman controlled all aspects of the final product of his craft. This changed dramatically with the Industrial Revolution.

Modern quality practices originated in two stages: mass inspection in the early 1900s and the control chart around 1930. Mass inspection became commonplace because of Frederick Taylor's *Scientific Management*. Workers stopped checking the quality of their work and instead passed it on to specially trained inspectors. Although inspection is a vital element of quality, Walter Shewhart's invention of the process control chart really initiated the quality profession. Awareness of worker motivation and attitudes as contributors to quality became prevalent in the early 1930s because of Elton Mayo's Hawthorne studies for Western Electric.

The next big push for quality emerged during World War II when suddenly people's lives could be destroyed by poor-quality products. At the same time, hundreds of American companies were called on to manufacture goods to the most exacting requirements. Many quality control techniques, such as acceptance sampling and process control charts, which were merely encouraged before the war, became mandatory as part of the defense effort. Two of the leading practitioners of the quality profession—W. Edwards Deming and Joseph M. Juran—established their professional credentials during this time. Both later went to Japan to teach statistical and management tools. The Japanese excelled in developing quality methods, and in the 1970s, Americans made repeated trips to Japan to explore Japanese successes and to bring home proven Japanese methods.

The American Society for Quality Control, now known as the American Society for Quality (ASQ), was established soon after World War II when Martin Brumbaugh saw that great benefits would be attained if he could unify various local quality control societies into one national organization. As he struggled with this task, he recognized the superb skills of George Edwards, who was then head of inspection engineering at Bell Telephone Laboratories. Edwards became the first president of the society and helped establish policies that guide its operation to this day.

The first three awards the society created to recognize these three pioneers of quality were the Brumbaugh Award, the Shewhart Medal, and the Edwards Medal.

Table 1.2 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, inventor of the assembly line, provides a 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.

(continued)

Table 1.2 A timeline of quality methods. (Continued)

1940	The U.S. War Department publishes a guide for using control charts to analyze process data.
1940–1943	Bell Labs develops 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. 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.
1946–1949	Deming is invited to give statistical quality control seminars to Japanese industry.
1948	Genichi 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 develop 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. Kaoru 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*. 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. 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. 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.

Table 1.2 A timeline of quality methods. (Continued)

1960	G. E. P. Box and J. S. Hunter write fundamental papers on 2^{k-p} factorial designs. The quality control circle concept is introduced in Japan by Kaoru 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. Zero defects (ZD) programs are introduced in certain U.S. industries.
1969	*Industrial Quality Control by the ASQC* 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. 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. 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. 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 standards, ISO 9001, ISO 9002 and ISO 9003. Motorola's Six Sigma initiative begins.
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 by the ASQC* appears.
1990s	ISO 9001 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.

(continued)

Table 1.2 A timeline of quality methods. (Continued)

2000s	ISO 9001:2000 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. Organizations begin to integrate lean principles into their Six Sigma initiatives, and lean Six Sigma becomes a widespread approach to business development.

Source: Reprinted from D. C. Montgomery, *Introduction to Statistical Quality Control*, 7th ed. (Hoboken, NJ: John Wiley & Sons, 2013).

In time, the society created numerous other awards, each honoring a specific hero of the profession and recognizing outstanding achievement in a particular area of the profession. These awards include the Crosby Medal, Feigenbaum Medal, Juran Medal, Deming Medal, and Ishikawa Medal, among others.

Table 1.2 provides a detailed timeline that shows the development and progression of formal methods and practice in quality engineering. Management and statistics are the most critical aspects of the quality control and engineering movement. In the remainder of this section, the influences of the three people who have arguably had the biggest impact on the quality movement are discussed: Shewhart, Deming, and Juran. Shewhart, Edwards, Juran, and Deming all worked for and learned from the Bell System in one way or another. Edwards and Shewhart retired as Bell System employees. Both Juran and Deming went on from the Bell System to become world-famous consultants and authors.

Walter A. Shewhart

The industrial age was approaching its second century when a young engineer named Walter A. Shewhart altered the course of industrial history by bringing together the disciplines of statistics, engineering, and economics. He referred to his greatest achievement, the invention of the process control chart, as "the formulation of a scientific basis for securing economic control." The Shewhart control chart is sometimes referred to as a process behavior chart.

Shewhart wanted statistical theory to serve the needs of industry. He exhibited the restlessness of one looking for a better way. A man of science who patiently developed his and others' ideas, he was an astute observer of the world of science and technology. While the literature of the day discussed the stochastic nature of both biological and technical systems, and spoke of the possibility of applying statistical methodology to these systems, Shewhart actually showed how it could be done. In that respect, the field of quality control can claim a genuine pioneer in Shewhart. His book *Economic Control of Quality of Manufactured Product*, published in 1931, is regarded as a complete and thorough exposition of the basic principles of quality control.

Called on frequently as a consultant, Shewhart served the War Department, the United Nations, the government of India, and others. He was active with the National Research Council and the International Statistical Institute. He was a fellow of numerous societies and in 1947 became the first honorary member of ASQ. Many consider the Shewhart Medal, given for outstanding technical contributions to the quality profession, to be the most prestigious award ASQ offers.

As of 2016, 67 people have been awarded the Shewhart Medal in recognition of their contributions to the quality profession.

W. Edwards Deming

Deming became the best-known quality expert in the United States. He delivered his message on quality not only throughout the United States but also around the world. In recognition of his valuable contribution to Japan's postwar recovery, the Union of Japanese Scientists and Engineers established an annual award for quality achievement called the Deming Prize.

Deming (1982) emphasized that the keys to quality are in management's hands—85% of quality problems are due to the system and only 15% are due to employees. The heart of his quality strategy is the use of statistical quality control to identify special (erratic, unpredictable) causes and common (systemic) causes of variation. Statistical tools provide a common language for employees throughout a company and permit quality control efforts to be widely diffused. Each employee assumes considerable responsibility for the quality of his or her own work. Those in traditional quality control functions are then able to take more proactive roles in the quality improvement effort.

Deming introduced statistical quality control to the Japanese in the early 1950s when Japan was recovering from World War II and trying to overcome a reputation for poor workmanship. Deming's guidance was instrumental in transforming "made in Japan" from a liability to an asset. Deming asserted that there was no point in exhorting employees to produce higher-quality work because the changes needed to improve quality were almost always outside the workers' control, such as having the right tools, training, and materials. Instead, management had to accept responsibility for quality. Based on his experience, Deming developed a 14-point set of requirements called *Deming's 14 points*, shown in Figure 1.1. He also described *seven deadly diseases* of the workplace, including emphasis on short-term profits, use of personnel performance evaluations (which he labeled "management by fear"), and mobility of management (management as a profession independent of the product/service or commitment to the organization).

Joseph M. Juran

Juran, like Deming, built his quality reputation in America and then took his expertise to Japan in the 1950s. The two complemented each other well in Japan, as Deming showed the use of statistical tools and Juran taught the techniques of managing for quality. Juran originated the concept of "the vital few" and the "useful many" (originally "trivial many"). He called this concept the Pareto principle, which is now implemented in the well-known Pareto diagram. An economist, Vilfredo Pareto, had noticed the phenomenon, but it was Juran who applied it to quality improvement.

Juran recognized that improving quality requires a completely different approach from what is needed to maintain existing quality. He demonstrated this idea in his book *Managerial Breakthrough*, first published in 1964, and later condensed his ideas into the Juran trilogy:

1. Quality control: monitoring techniques to correct sporadic problems (analogous to special causes)

1. Create consistency of purpose toward improvement of products and services, with a plan to become competitive and to stay in business. Decide to whom top management is responsible.
2. Adopt the new philosophy. We are in a new economic age. We can no longer live with commonly accepted levels of delays, mistakes, defective materials, and defective workmanship.
3. Cease dependence on mass inspection. Require instead statistical evidence that quality is built-in to eliminate need for inspection. Purchasing managers have a new job and must learn it.
4. End the practice of awarding business on the basis of price tag. Instead, depend on meaningful measures of quality, along with price. Eliminate suppliers who cannot qualify with statistical evidence of quality.
5. Find problems. It is management's job to work continually on the system (design, incoming materials, composition of material, maintenance, improvement of machines, training, supervision, retraining).
6. Institute modern methods of training on the job.
7. Institute modern methods of supervision of production workers. The responsibility of foremen must be changed from sheer numbers to quality. Improvement of quality will automatically improve productivity. Management must prepare to take immediate actions on reports from foremen concerning barriers such as inherited defects, machines not maintained, poor tools, fuzzy operation definitions.
8. Drive out fear, so that everyone may work effectively for the company.
9. Break down barriers between departments. People in research, design, sales, and production must work as a team, to foresee problems of production that may be encountered with various materials and specifications.
10. Eliminate numerical goals, posters, and slogans for the workforce, asking for new levels of productivity without providing methods.
11. Eliminate work standards that prescribe numerical quotas.
12. Remove barriers that stand between the hourly worker and his right to pride of workmanship.
13. Institute a vigorous program of education and retraining.
14. Create a structure in top management that will push every day on the above 13 points.

Figure 1.1 Deming's 14 points.

2. Quality improvement: a breakthrough sequence to solve chronic problems (analogous to common causes)
3. Quality planning: an annual quality program to institutionalize managerial control and review

Juran served the quality profession well when in 1951 he created the monumental *Juran's Quality Handbook*, now in its seventh edition (Defeo 2016). Juran's contributions are extensive and varied. He defined quality as "fitness for use by the customer." He emphasized the need for top managers to become personally involved for a quality effort to be successful and for middle and lower-level managers to learn the language and thinking of top management—money, for example—to secure their involvement. Juran's universal process for quality improvement requires studying symptoms, diagnosing causes, and applying remedies. He repeatedly emphasized that major improvement could be achieved only on a project-by-project basis. The basis for selecting projects was the Return on Investment (ROI), now a major aspect of Six Sigma.

Continuous Improvement Tools

In the seven decades since World War II ended, great quality leaders have emerged. Besides those mentioned previously, the following individuals have become famous for their contributions. Philip Crosby popularized the concept of zero defects and established the Crosby Quality College. Kaoru Ishikawa, who helped sponsor Deming's seminars in Japan, created quality circles and invented the cause-and-effect diagram, also called the Ishikawa diagram. Armand Feigenbaum coined the term "total quality control" and tirelessly preached its fundamentals around the world. Genichi Taguchi, a Japanese engineer, developed a unique system for designing industrial experiments to establish robust systems. Eliyahu Goldratt created an improvement system built around the theory of constraints. Other notable contributors to the profession include George Box, Eugene Grant, Jack Lancaster, Frank Gryna, Richard Freund, and Dorian Shainin.

The most notable continuous improvement methodologies (all of which include the use of various quality tools) in quality engineering are the following:

- Statistical process control
- Total quality management
- Lean
- Six Sigma

Statistical process control (SPC) is considered one of the major areas of statistical technology useful in quality improvement. The main tool in SPC is the control chart, which has been widely adapted and is utilized by all practitioners of quality engineering. Process control and improvement are discussed in Chapter 4, while Chapter 6 covers SPC in detail.

Total quality management (TQM) is based on the principles of Feigenbaum, Deming, and Juran. The exact origin of TQM has been debated, but TQM as a process improvement methodology received the most use and attention in the mid-1980s and early 1990s before being mostly replaced by lean and Six Sigma methods. TQM is a structured approach to managing quality improvement methods within an organization. While it is important as a continuous improvement tool, its lack of recent success is attributed to insufficient effort on the technical aspects associated with improving and maintaining quality in an organization. TQM is further discussed in Chapter 5.

Lean philosophy, discussed in detail in Chapter 5, is exemplified by its terse name: get the job done as simply as possible. It was originally called lean manufacturing but has migrated into many different service industries. A good example of lean philosophy is *just-in-time* (JIT), where a process is managed so that parts arrive just prior to their actual integration into the assembly.

Six Sigma, a widely used quality philosophy, combines and exploits the strengths of other approaches to the extent that it now dominates all others. There are journals, conferences, study groups, and consulting firms devoted solely to Six Sigma. Six Sigma combines effective communication, organization of effort, financial accountability, and strong techniques to enable organizations to make sustained improvements over a period of time. Improvements such as cost reduction, quality improvement, cycle time reduction, improved morale, greater profits, and so forth, are all attainable through Six Sigma, but these improvements require a great deal of dedicated work, dedication to the process, and continuous training and learning. See Chapter 5, for more about Six Sigma.

THE QUALITY MANAGEMENT SYSTEM (QMS)

In this section, aspects of the quality management system (QMS) are discussed, including strategic planning, deployment techniques, and the quality information system.

Strategic Planning

> Identify and define top management's responsibility for the QMS, including establishing policies and objectives, setting organization-wide goals, and supporting quality initiatives. (Apply)
>
> **Body of Knowledge I.B.1**

Strategic planning usually begins with an analysis phase. The strengths and weaknesses of the organization are assessed and forecasts are generated to predict how market opportunities and competitive threats will change during the time period covered by the study. This analysis is sometimes called a SWOT (strengths, weaknesses, opportunities, and threats) analysis. Ideally, strategic planning for quality will address each aspect of the SWOT analysis.

The strengths of the organization can be leveraged to create or sustain a competitive advantage. The weaknesses of the organization should be addressed through appropriate measures such as training initiatives to develop strategic skills or process improvement efforts. The opportunities available to the organization can be identified through various marketing research techniques. Key outputs of the marketing research may include estimates of the size and growth rate of the market and clearly articulated customer expectations, desires, and perceptions. This information should drive new product development efforts.

Finally, the business environment should be assessed, with emphasis on potential threats to the success of the organization. Threats can come from direct competitors offering similar products, indirect competitors offering substitute products or services (e.g., butter vs. margarine), suppliers of critical proprietary components, and even from distributors that can influence the purchase decisions of the final customers.

After the SWOT analysis is complete, the organization can develop strategic quality plans. As the strategy is being formulated, management should evaluate

Strategic Planning Effectiveness Tests

1. Does the plan adequately address strengths, weaknesses, opportunities, and threats (SWOT)?
2. Will the plan result in a significant competitive advantage in the marketplace?
3. Is this advantage sustainable?
4. Does the vision statement inspire a sense of mission and purpose among employees?
5. Are the goals and objectives SMART (specific, measurable, achievable, realistic, and time-based)?
6. Are the goals and objectives aligned throughout the organization?
7. Have adequate resources been allocated to achieve the plan?
8. Are organizational structures, systems, and processes appropriate to execute the plan?
9. Is a review/reporting system in place to monitor the execution of the plan?
10. Does the strategic planning team include representatives from all key stakeholders?

Figure 1.2 Ten effectiveness tests for strategic quality plans.

whether the plans will ensure the success of the organization. To discern the effectiveness of strategic quality plans, management should employ a series of sequentially ordered effectiveness tests, shown in Figure 1.2 and discussed in more detail below:

1. Does the strategy adequately address all four SWOT elements? Leverage the organization's strengths; remedy the weaknesses. Exploit the opportunities in the market; minimize the potential impact of external threats. It also may be prudent to prepare contingency plans that can be implemented quickly in response to threatening actions from competitors. It is crucial for this stage of the planning process to be data-driven. The analysis should be comprehensive, including product quality, finance, purchasing, human resources, marketing and sales, delivery, customer service, and the internal processes that drive these activities. The notion that quality improvement is limited to the factory floor is obsolete. When management begins to apply quality disciplines and statistical methods to assess advertising campaigns and HR initiatives, the transformation is under way. The organization is poised to establish strategic quality plans.
2. Will the strategic plan result in a significant competitive advantage in the marketplace? Incremental improvements in quality may not be sufficient to ensure success. Furthermore, the advantage must be recognized and valued by the customer. Engineering and manufacturing can create superior products, but that may not help the organization succeed if the customers do not know about the products. Other activities must be involved in the strategic planning process. For example, marketing is responsible for raising customer awareness of product enhancements and influencing purchase decisions through advertising or promotions. Keep in mind that the current strengths of

an organization may only generate passing interest among customers. For example, a product may have best-in-class durability, but customers may be more interested in appearance, availability, or ease of use. In such cases, consider strategic initiatives that will strengthen the organization's ability to maximize customer satisfaction throughout the purchase and ownership experience. Such market research tools as conjoint analysis and the Kano quality model can measure how product or service features influence customer purchase behavior. Companies that use market research to help select targets for creating a competitive advantage are more likely to thrive in the marketplace.

3. Is the competitive advantage sustainable? Can your competitors quickly and easily imitate your strategy? Will they respond with counteroffensives that weaken your position? Will your competitors' strategic efforts pay off a year from now and undermine your leadership in the market? Some consultants recommend avoiding cost reduction as a primary strategy because price is one of the easiest things to imitate in the market. Both you and your competitors will lose if a price war erupts. Anyone can reduce costs by using cheaper components or reducing staff in service or support activities. The risk of this approach is that customers may perceive deteriorating quality, which damages the organization's reputation and results in lost sales. Insisting on a strategy that will deliver outstanding quality through continuous improvement is much more likely to generate a sustainable competitive advantage. The popularity of the Six Sigma movement and its impressive success stories demonstrate that it is possible to embark on a major strategic quality improvement initiative and reap substantial benefits on the bottom line.

4. Does the vision inspire and motivate your employees? The vision should be customer focused and provide a clear, succinct view of the desired future state of the organization. A major strategic effort will require dedication and commitment. Resources may be stretched to achieve the vision. If the vision is too difficult to achieve, employees may become discouraged and give up. If the vision is too easy to achieve, your competitors may implement something better, and you will be playing catch-up.

5. Goals and objectives are established to direct the efforts of the organization and measure whether the vision is being achieved. Are the goals and objectives SMART?

   — **Specific.** State what is expected in precise terms.

   — **Measurable.** Demonstrate progress through quantitative rather than qualitative or subjective measures.

   — **Achievable.** The goal can be achieved with available resources if appropriate actions are taken.

   — **Realistic.** A reasonable, sensible person would accept the goal after considering the degree of difficulty and the probability of success.

— **Time-based.** Deadlines serve a useful purpose. Companies that are first to market with new innovations frequently enjoy a significant, sustainable advantage over their competitors. For more information on innovation and competitive advantage, see Porter and Stern (2001), Hockman and Jensen (2016), and Box and Woodall (2012).

6. Are the goals and objectives aligned throughout the organization? Goals and objectives must be in harmony with each other. As goals are cascaded through an organization and broken down into manageable tasks to be performed by various departments or individuals, unity of purpose and alignment of priorities must be maintained to avoid conflicts.
7. Are resources (staffing, equipment, financing, etc.) adequate to achieve the plan? Can the additional workload be absorbed? Are the skill levels of the employees sufficient? Has the timeline been reviewed by affected participants to ensure that there are no scheduling conflicts? Project management techniques may be helpful.
8. Are organizational structures, systems, and processes suitable for executing the plan? Is a departmental reorganization necessary to streamline the flow of work and facilitate concurrent activities? Is a research and development (R&D) effort necessary to upgrade designs or manufacturing equipment capability?
9. Is a review and reporting system in place to periodically assess progress? These reviews should be conducted by management at a high enough level within the organization to marshal additional resources as needed when the program is in danger of falling behind schedule. Key program milestones should have clearly defined expectations to ensure consistency and excellence in the execution of the activities. Checklists are a simple yet effective means of communicating the expectations.
10. Does the strategic planning team include the participation of experienced professionals from all affected work groups? Do the team members fully understand the strategy, and have they bought into it? The benefits of a cross-functional planning effort cannot be overemphasized. Consider an analogy to the product development process: manufacturing personnel contribute expert advice during the early stages of product design and thereby avoid costly, time-consuming delays and redesigns. Ford Motor Company's advanced quality planning process lists the use of a cross-functional team as the number one expectation for executing many of the quality disciplines within a product development effort.

The importance of establishing the right strategy is critical to the success of an organization. Countless years of sincere toil have been wasted by implementing poorly developed strategies. Excellent execution will not ensure success unless the plan is also excellent. Juran argues that a structured planning process results in products that perform better and have a shorter development cycle from concept to customer (Juran and Godfrey 1999).

Management must explore strategic quality initiatives that go beyond mere incremental improvement: Drive the philosophy of continuous improvement throughout the organization and create a culture of innovation. Look beyond the factory floor for breakthroughs in all systems, such as R&D, product development, marketing, human resources, and purchasing. Strive for quality initiatives that add value for the customer and establish a sustainable competitive advantage.

Deployment Techniques

Quality improvement does not just happen; it must be planned, supported, and monitored just like any other process. Planning requires ways to identify the specific initiatives to be undertaken, while support and monitoring require methods for tracking and communicating progress. Establishing goals is not enough. Goals must be supported by measurable objectives that are in turn supported by action plans that delineate how and when the objectives are to be achieved and by whom. There must be measurable objectives to know what the projected results should be. In addition, a means for measuring the attainment of these objectives must be established. Similarly, action plans provide more specific information about attaining objectives. An example of the hierarchical relationships between strategies, goals, objectives, and action plans is as follows:

> Organizational strategy: Continually build and retain a loyal customer base.
>
> Organizational goal: Deliver all products to all customers 100% on time.
>
> Organizational objective: Given current capacity, improve delivery dates of all future customer orders from 35% to 75% on-time delivery by February of the current year and to 100% by August of the current year.
>
> Functional objectives: The quality department will assign a quality engineer to convene a cross-functional process improvement team by November 1 of the current year. The team will utilize lean manufacturing techniques to reduce cycle time and will continue its efforts until the production process has achieved 100% on-time delivery performance.
>
> Action plans: Detailed plans state how and when the objective will be achieved and by whom. Action plans may resemble mini project plans or may be more complex project planning documents as needs dictate. In either case, action plans influence planning and scheduling.

Deployment techniques in support of the QMS include benchmarking against competitors, feedback from stakeholders, performance assessment via metrics, and project management. These are all discussed in this section as well as additional information regarding deployment such as policy considerations and useful tools.

Benchmarking

> Define the concept of benchmarking and why it may be used. (Remember)
>
> **Body of Knowledge I.B.2.a**

Benchmarking is a process in which organizations compare their performance with that of their competition or with best practices found internally or in outside organizations. It was pioneered by Xerox in the late 1970s in response to growing pressure in the photocopy industry. Benchmarking is now recognized as an important input to strategic planning. It can be applied to any business process or function, such as optimizing inventory levels or improving service delivery.

Benchmarking can help an organization identify new ideas and methods to improve operational effectiveness. It can help break through institutional barriers and resistance to change because some other organization has already demonstrated that the new methods are more effective. Once these best practices are identified, the organization can develop plans to adopt them. In this way, benchmarking can become an integral part of the continuous improvement process.

Internal benchmarking is used to compare performance between plants or divisions. Competitive benchmarking is used to assess performance relative to that of direct competitors within an industry. Internal and competitive benchmarks are useful in identifying gaps in performance. For example, automotive manufacturers use customer surveys to compare quality and customer satisfaction. Poor performance must be addressed to ensure survival in the marketplace. However, competitive benchmarking may not identify the best practices needed to close the gap in performance. Furthermore, although benchmarking internally or among competitors may identify incremental improvement opportunities, it is not likely to identify breakthroughs leading to world-class performance.

Collaborative benchmarking requires cooperation between two or more organizations. Each organization freely shares information about its best practices in exchange for information about other best practices from a partner. Suppose, for example, Wal-Mart wishes to team with Dell Corporation. Wal-Mart offers to share information on forecasting consumer demand, and Dell reciprocates by sharing insights on how it minimizes order-to-delivery times. With collaborative benchmarking, the key is to identify the very best performer. Use trade associations, publications, financial analysis, market research, or other tools to find the leader.

External benchmarking may identify the best opportunities, but it requires a significant investment of time and effort. It may be useful to employ internal benchmarking first because it will generate quicker results. Internal successes should receive recognition, which can help convince skeptics that the process works. The benchmarking team also will gain valuable experience and be better prepared for pursuing external benchmarking partners. A typical benchmarking project includes the following:

- **Planning.** Identify what is to be benchmarked. Establish the objectives for the study. If the scope is too narrow, the benefits will be limited. If the scope is too broad, the task may become unmanageable and the probability of successfully implementing the best practices will diminish. Select the team members and search for target organizations to benchmark.
- **Data collection.** Develop a mutually acceptable protocol with the partner, including a code of conduct, confidentiality agreements, and performance measures to be analyzed. Data sharing may include information about procedures, standards, software, training, and other

supporting systems. The key is to gain enough understanding and direction to replicate the best practice within your organization.

- **Analysis.** Assess the data for accuracy and credibility. Determine current performance levels and identify gaps. Explore the feasibility of implementing the best practice. Some practices are not readily transferable—is adaptation necessary? Forecast the expected improvement.
- **Implementation.** Obtain the support of key stakeholders. Use project management techniques and action plans to initiate the change. Monitor performance. Document activities and communicate progress.

Benchmarking is not a precise discipline, and common pitfalls include lack of commitment, insufficient planning, comparing processes that are not sufficiently similar to generate useful insights, and measuring processes that have little potential for significant gains. A well-executed benchmarking project will help in both deploying strategic plans and suggesting modifications to future strategic plans. But real leadership means not just catching up with other industry leaders but surpassing them. Benchmarking can never accomplish that.

Stakeholder Analysis

> Define, describe and use stakeholder identification and analysis. (Apply)
>
> **Body of Knowledge I.B.2.b**

Congruence between policy and results is evaluated through audits that periodically check for conformance. The stakeholders need to be clearly identified and their differing needs must be met. If adaptation of a policy must occur, it must remain within the original intent if the policy is to remain credible to the stakeholders. Frequent feedback from all stakeholders helps to quickly identify and correct any disparity. Performance measures, discussed below, must take into account the differing needs and perceptions of each stakeholder group. Stakeholders include the following:

- Stockholders, the owners of the company. Their role is often passive and their needs are primarily of a financial nature. They expect the company to maintain its credibility in the financial markets and hope for growth in earnings and share price.
- The executive group, including the board of directors and the top tier of managers. They must acknowledge and serve the other stakeholders. Conversely, the health of any organization is critically dependent on its decision making and deployment.
- Employees other than top management. This critical group of stakeholders has little direct impact on policy but all other groups

depend on them to carry out the policy efficiently and promptly. The quality of any organization's end product depends on how well the employees are recruited, trained, and supervised.

- Suppliers and customers. These two groups are concerned with external inputs and outputs. Suppliers must adhere to contractual requirements and therefore can insist on fair and prompt payment for their goods and services. Customers are paramount stakeholders; if customers do not want the organization's products, this organization will eventually cease to exist. The "Customer Relations" and "Supplier Management" sections later in this chapter deal with customer relations and supplier management, respectively.
- The community at large. Communities, neighbors, environmental regulators, law enforcement agencies, chambers of commerce, legislatures, and similar bodies often are indirect stakeholders. Individually their impact is relatively slight, but if a major issue arises, the concerns of a community can have an overwhelming influence. This stakeholder group is especially critical when plant openings or closings are being planned. The community often is concerned about treatment of minorities, public service (or the absence thereof), and environmental abuses.

Performance

> Define, describe and use performance measurement tools such as cost-benefit analysis. (Apply)
>
> **Body of Knowledge I.B.2.c**

The strategic plan is a vision with broad goals and objectives for the organization to achieve. Management at all levels is charged with implementing the strategic plan. Metrics must be developed to monitor activities and track progress toward achieving the goals and objectives. But before discussing numbers and types of metrics, it is important to emphasize that the metrics should reflect the strategic vision. Some authors use the word "linkage" to describe the connection between strategic goals and performance metrics. An organization is on the right path if people two or three levels down from top management in the organization can articulate how their activities support a strategic objective.

Once the strategic plan is finalized, management must cascade the goals and objectives down through the organization and identify specific tasks with timelines, methods, and responsibilities. This is not a trivial task. Considerable care should be taken to select appropriate measures. Stakeholders and subject matter experts within the organization should be involved in the selection process. Team participation is more likely to result in performance measures that are aligned with strategic objectives. Participation also fosters ownership of the metrics. Some managers go a step further and link the objectives to annual employee performance evaluation programs or to bonus programs.

For a clear example of how to cascade performance measures, look to the field of reliability engineering. When designing a system, reliability targets are established for the system as a whole. When designing the components of the system, more stringent reliability targets must be established for each component so that the system as a whole continues to meet the overall performance target. This process, called reliability allocation, is a highly technical process that should be performed by someone with expertise in reliability. Unfortunately, management science has not progressed to the same level of discipline as the reliability field. Nevertheless, the basic concepts still apply. When cascading a high-level objective down to operations, one must allocate tasks and apportion the targets to ensure that the organization as a whole will meet the objectives.

Performance measures should be:

- Linked to strategic objectives
- Rigorous, objective, quantifiable, and standardized
- Achievable, realistic, and time-based
- Assigned to appropriate personnel who are held accountable and who are empowered with some level of control to influence outcomes

In general, there should only be a "vital few" performance metrics. Use your judgment and avoid using too many metrics, which may dilute the results. Automate data collection and calculations if possible. Spend more time making decisions than generating reports. Select measures that are resistant to problematic behavior. In the following subsections, performance metrics are discussed as well as two tools for assessing performance: the balanced scorecard and the dashboard.

Performance Metrics

Most of the guidelines for performance measures are self-evident, but the recommendation to select measures that are resistant to problematic behavior warrants explanation. Suppose an organization faces stiff competition in a commodity market. Cost reduction is a key strategic initiative. When the objective is cascaded to plant operations, the maintenance department decides to support the objective by postponing costly equipment overhauls. This "problematic" behavior may help in the short run but could cause a catastrophe in the future. How can this be avoided? One solution is to use combined metrics. For example, a maintenance productivity metric could be created:

$$\text{Maintenance productivity} = \frac{\Delta^R \text{MTTF}}{(\Delta^R \text{Maintenance budget})(\Delta^R \text{MTTR})}$$

In this metric, bigger is better. The symbol Δ^R is applied to each variable and refers to the ratio of the variable in period t divided by the variable in period $t - 1$. This little math trick results in a dimensionless equation that is "normalized" to a value of 1.0 when there is no change in the variable from one period to the next. If the productivity value is greater than 1, performance is improving; if it is less than 1, performance is deteriorating. Since maintenance spending is in the denominator, less spending is encouraged because it will increase the productivity metric. But the productivity metric can also be increased by increasing the equipment mean time to failure (MTTF) or by decreasing the mean time to repair (MTTR). If the maintenance department starts scrimping on the budget, breakdowns will probably occur more frequently and repair times may increase. Declining performance will offset the benefit of reduced spending in the metric. Thus, this combined metric encourages appropriate behavior.

The point of this illustration is not to advocate specifically for a maintenance productivity metric but to suggest that a little creativity can overcome inherent weaknesses in traditional performance measures.

Balanced Scorecard

Robert Kaplan and David Norton introduced the balanced scorecard in 1992. Kaplan and Norton argued that most strategic plans were unbalanced because one stakeholder group—the stockholders—was overemphasized. They proposed a "balanced" scorecard with four perspectives:

1. Financial fundamentals
2. Business processes
3. Customer
4. Learning and growth

Financial measures include traditional indicators such as cash flow, sales, and ROI. Business processes include manufacturing measures such as yield and rework, along with support activities such as order processing. Customer measures may include trends in customer satisfaction or average customer service wait times. The learning and growth perspective recognizes the human element in an organization and looks at softer measures such as participation in employee suggestion programs and training.

The balanced scorecard provides a framework to translate the strategic plan into specific tasks that can be managed by frontline employees. In a typical scorecard, the objective is listed along with associated measures, targets for performance, and initiatives that will drive the organization to achieve the objective.

Cost-benefit Analysis

Cost-benefit analysis (CBA) estimates the strengths and weaknesses of alternative courses of action to determine the best use of investment. It is used for business and policy decisions and project investments. The analysis can determine if an investment makes sense by judging how much the benefits outweigh the costs and provide a way to compare investments by assessing the total expected costs and expected benefits of each.

Cost-benefit analysis attempts to determine all the costs and benefits of an investment and express these in present-day dollars. A means of doing this calculation is using the Net Present Value (NPV) calculation as described below. Then it is a straightforward comparison of the benefits vs costs based on some established threshold or criteria for making the decision. Because the future value of money (based on future inflation and interest rates) and the future benefits of an action are unknown, probabilistic techniques such as uniform, gamma and normal distributions, based on the user's assumptions about future uncertainty, are often used in the NPV model.

Project Management

> Define, describe and use project management tools, including Gantt charts and the responsible, accountable, consulted and informed matrix (RACI). (Apply)
>
> **Body of Knowledge I.B.2.d**

Quality engineers often become involved in project, either as a project team member or as a project leader. Several proven techniques and tools are available to assist in cost-effective project management. The first is proper project selection. The following subsections cover project tools, project planning techniques, how to monitor and measure project activities, documentation, and strategies for policy deployment.

Project Tools

Projects must be prioritized to select those having the most merit. Projects should be evaluated for their fit with overall business needs, financial payoff, and potential risks. Exceptions will be made for legal mandates, consumer safety, and customer demands. Only projects that are optional should be prioritized.

Major projects involve risk of loss. Risk assessment involves identifying potential problems that could occur, their impact, and what, if any, actions should be taken to offset them (e.g., taking countermeasures, purchasing risk insurance, or developing contingency plans). For complex projects, it may be prudent to apply a formal risk assessment tool such as a failure modes and effects analysis (FMEA) or simulation.

If the benefits of a project are uncertain and multiple outcomes are possible, then a decision tree can help estimate the expected value of gain or loss (see Example 1.1). A decision tree lists the potential outcomes and assigns a probability to each branch. The financial payout for each outcome is shown at the end of the branch. A few simple rules apply to the creation of a decision tree:

- At each branch point, the probabilities must sum to 1.0.

- The expected value for each branch is calculated by multiplying all the probabilities along the branch by the financial payout.
- Add the expected payout for all the outcomes within a decision branch.
- Choose the decision with the highest payout.

There are many other financial methods for justifying projects. Three very common methods are the following:

- Payback period. The number of years it will take to recover the investment from net cash flows.
- Net present value (NPV). NPV takes the time value of money into account. NPV involves finding the present value of each cash flow (yearly) discounted at the cost of capital percentage used by the organization, summing the discounted cash flows, and determining if the project is a candidate for approval based on positive NPV (see Example 1.2).
- Internal rate of return (IRR). A discount rate that causes the NPV to equal zero. If the IRR is greater than the minimum required by the organization for typical capital investments, the project is a candidate for acceptance.

The payback period is widely used because it is easy to calculate and simple to understand. In the decision tree example (Example 1.1), the payback period for installing a new machine is less than one year, which implies a very high ROI. But a major weakness of the payback period is that it does not give any insight into the magnitude of future savings, that is, savings after the initial investment has been recovered.

EXAMPLE 1.1

A quality engineer is considering several options to fix a problem with a production machine. The machine is starting to wear out, so it has excessive variation and approximately 1% of production must be scrapped. He can replace the machine with a prototype machine. There is an 80% chance the new machine will eliminate the variability problem and it will probably increase capacity by 2%. The second choice is to overhaul the machine, with a 60% chance of improving the yield. The third choice is to perform selected repairs. This choice has the lowest initial investment but also is least likely to solve the variability problem. This problem is summarized in the decision tree in Figure 1.3. The probabilities associated with the choices are shown in brackets.

Currently, the variation problem generates scrap worth $50,000 per year. A 2% increase in capacity would be worth an additional $100,000 profit per year. Therefore, the financial payout changes depending on whether the scrap is eliminated and the capacity is increased.

Continued

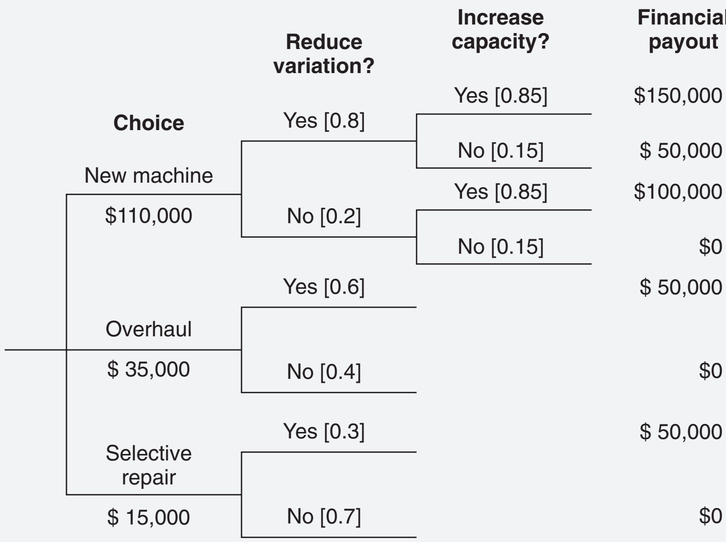

Figure 1.3 Decision tree for production machine.

The expected value (EV) for a decision is given by the equation:

$$EV = \sum x\, p(x)$$

where x is the financial payout, and $p(x)$ is the associated probability of the outcome. Expected value calculations are discussed in more detail in Chapter 6. Sum all the values within the decision branch. Therefore, the expected value of the new machine is:

$$EV = (0.8)(0.85)\$150{,}000 + (0.8)(0.15)\$50{,}000 + (0.2)(0.85)\$100{,}000 + (0.2)(0.15)\$0$$
$$EV = \$125{,}000$$

Note that the expected value of the new machine is less than the maximum payout because there is a chance the new machine will not work perfectly. One can calculate the expected value for the other options using the same approach.

$$\text{For the overhaul: } EV = (0.6)\$50{,}000 + (0.4)\$0 = \$30{,}000$$
$$\text{For the repairs: } EV = (0.3)\$50{,}000 + (0.7)\$0 = \$15{,}000$$

Finally, subtract the initial investment, shown in Figure 1.4, from the expected value to get the *net* return.

$$\text{New machine} = \$125{,}000 - \$110{,}000 = \$15{,}000$$
$$\text{Overhaul machine} = \$30{,}000 - \$35{,}000 = (\$5{,}000)$$
$$\text{Selective repairs} = \$15{,}000 - \$15{,}000 = \$0$$

In the first year, money will be made on the new machine, break even using repairs, but lose money if the overhaul is selected. (Note: when evaluating projects, always consider the savings in future years, not just the first year.) At the end of the first year, experience will be gained with the option that was implemented. The probability assumptions can be updated and the decision tree exercise repeated in subsequent years.

NPV and IRR rectify this deficiency. Both methods give more accurate information, provided that suitable estimates of future cash flows can be obtained. The major difference between the two methods is that IRR generates an interest rate that balances all future cash flows against the present outlay, while NPV generates a dollar amount of present and future cash flows. With both calculation methods, bigger is better. Many companies have an internal hurdle rate, such as an IRR greater than 10% or 20%, that projects must achieve to be considered. The company probably could not consistently earn such a high return on stocks or bonds, yet it requires projects to clear this hurdle. One reason for this conservatism is the difficulty of getting accurate estimates of future cash flows.

A final cautionary word about project estimating: sometimes things do not work out as planned. Assumptions may be misleading, probabilities may be optimistic, and factors beyond your control may come into play, such as unexpected changes in the market, new legislative policies, or changes in regulatory requirements. If you enter the calculations in a spreadsheet, it is easy to make adjustments and perform a sensitivity analysis. Sensitivity analysis allows you to evaluate how the projected results would be affected by changes in the estimated inputs (e.g., probabilities of success or potential risks). For example, how much would the NPV change if the probability of success decreased by 10%? For more details and examples see Park (2007) in References.

EXAMPLE 1.2

The NPV method converts all future cash flows to today's dollars at a specified interest rate. It is easy to calculate using a spreadsheet. From the decision tree example above, enter the initial investment and the expected values of the payouts for year 1, year 2, and so on. In year 3, the warranty expires and performing repairs begins. After year 5, the machine is starting to wear out, and by year 7, the machine is ready to be overhauled or replace d. Note: the NPV example shown here can be understood without reference to the decision tree in Example 1.1.

	A	B	C	D
1	Year	**Cash flow** New machine	**Cash flow** Overhaul	Comments
2		0.10	0.10	Interest rate
3	1	($110,000)	($35,000)	Initial investment
4	2	$125,000	$30,000	First year, expected value
5	3	$125,000	$30,000	Second year
6	4	$110,000	$15,000	Offset savings, paying for repairs
7	5	$110,000	$15,000	$15,000 in repairs
8	6	$105,000	$10,000	Machine is starting to wear out

Continued

9	7	$ 98,000	$8,500	Variability increasing, yield decreasing
10	8	$ 62,000	$2,400	Time to replace machine?

To calculate the NPV, use the formula:

$$NPV = \sum_{t=1}^{N} \frac{R_t}{(1+i)^t}$$

where R_t is the cash flow in year t, and i is the interest rate.

The interest rate should be the prevailing rate for raising cash in capital markets (that is, a bank loan). Ten percent is typical. The NPV function assumes that the initial investment is made at year 0 and the first payout is at the end of year 1. The results are surprising:

NPV, new machine = $379,136
NPV, overhaul = $ 46,200

The net return for the new machine option in the first year was $15,000. But when you consider the life of the investment, the return is enormous. The overhaul option loses money in the first year but proves to generate positive cash flows in subsequent years. The selective repair option has zero NPV—it is a basic maintenance strategy.

Project Planning and Estimation

The success of a project is significantly impacted by the effectiveness of project planning. A typical project-planning sequence for a larger project, often identified in the project charter, is as follows:

1. Statement. This first step is where the kernel of an idea or the basic concept visualized is translated into a clear statement of the problem, deficiency, or opportunity to be realized. Careful definition at this point helps later to clarify the scope of the project.
2. Project justification. Risk analyses and assessment (payback period, NPV, IRR, ROI, return on assets, and benefits/cost) are performed, and a go/no-go decision is made.
3. Drafts of mission statement, project scope, and project objectives. These documents clarify the overall direction of the project, what it is to accomplish, the breadth and depth of the project, and the measurable objectives by which progress and completion are to be measured.
4. Stakeholder requirements. Stakeholders consist of two groups: (1) those with a direct commitment to the project team, for example, a process manager who provides a skilled person to serve on a process improvement team working to reduce machine downtime, and (2) those without involvement but who can influence project results, for example, the purchasing department that selects the vendor for a new machine.

A macro-level process map may be used to identify areas from which potential team members should be selected.

5. Project team formation. Team members should be selected based on the need to represent a stakeholder group and/or specific skill sets required. Stakeholder groups not represented on the project team should have opportunities to provide input. Some members may be required on an as-needed basis only. Whenever possible, the interests, values, and personality profiles of individuals nominated should be considered. The Myers-Briggs Type Indicator (http://www.myersbriggs.org) can be a useful tool for building a team with complementary interpersonal skills and interests.
6. Finalized mission statement, project scope, project objectives, and project charter. Team members refine the original drafts. A benchmarking study may be appropriate to better define target outcomes. Items that are out of scope of the current project are also identified to prevent "scope creep."
7. Contractual requirements and deliverables. All requirements and outputs of the project are identified, defined, and documented.
8. Work breakdown structure (WBS). Project work is further defined by breaking the work down into a hierarchy of work categories (families of like work clusters) down to the task level. Boxes on a WBS may be annotated with "person/work unit responsible," "resources required," "cost estimates," various other cross-references, and so on. See Figure 1.4 and the discussion below for more on WBS.
9. Gantt chart. Major project steps or task clusters are listed vertically on a timeline chart with each item's estimated start-to-finish time depicted as a bar across the chosen time intervals (weeks, months, quarters). As the project progresses, the same chart may be used to plot the actual time expended next to the estimated time. Major milestones are shown as points along the time bar. See Figure 1.5 and the discussion below for a more detailed example.
10. Time-dependent task diagram (AND). Depending on the size, complexity, and duration of the project, it may be necessary to plot the time dependencies of each task to each other task. An activity network diagram (AND) depicts the interrelationships of each task or task cluster in the project. Typically, AND is used for shorter-term, simpler projects.
11. Resource requirements matrix (RRM). An RRM delineates the various types of resources needed (e.g., personnel, facilities, equipment, materials, consultants, etc.), quantity, when needed, and cost.
12. Linear responsibility matrix (LRM). An LRM, used for larger projects, defines the interfaces: who has what responsibility for what tasks, and to what degree (e.g., primary, secondary, resource only, need to know).
13. Responsible, accountable, consulted, and informed matrix (RACI). Responsible persons do the work to complete the task, there may be