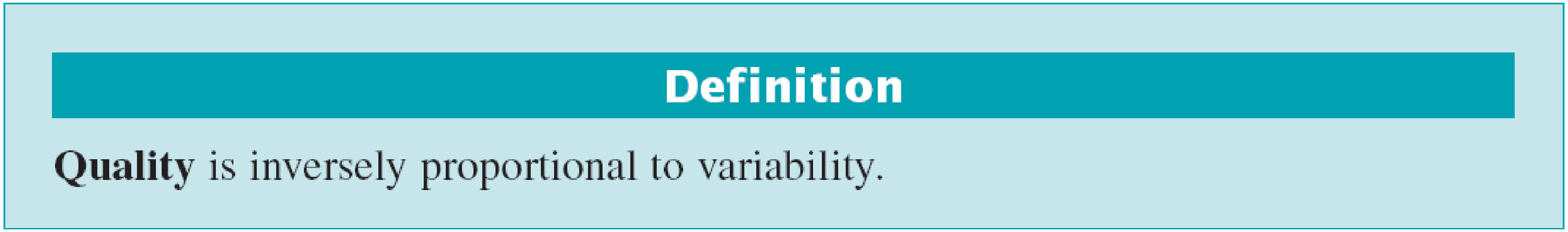
Statistical Quality Control

Definition

Quality means fitness for use.

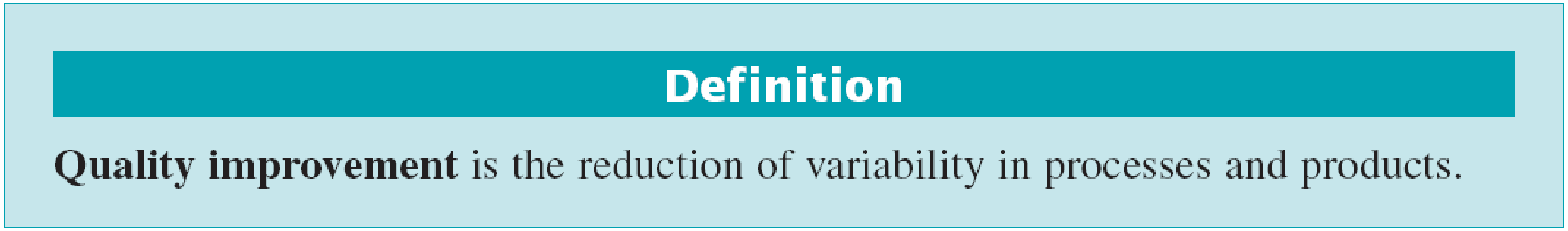
- This is a traditional definition
- Quality of design
- Quality of conformance



Definition

Quality is inversely proportional to variability.

This is a modern definition of quality



Definition

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

- The transmission example illustrates the utility of this definition

- An equivalent definition is that quality improvement is the **elimination of waste**. This is useful in service or transactional businesses.

1.2. History of Quality Improvement

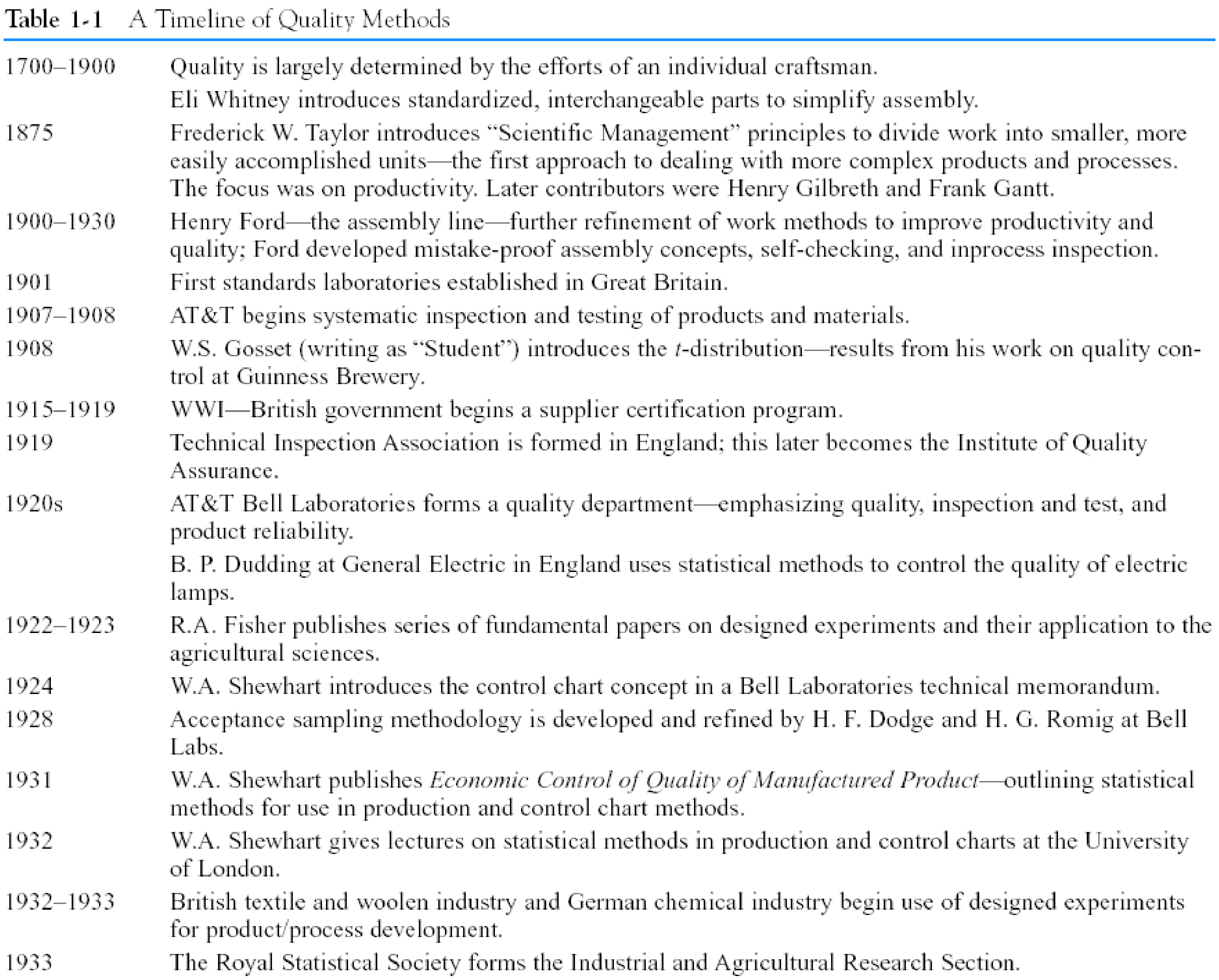
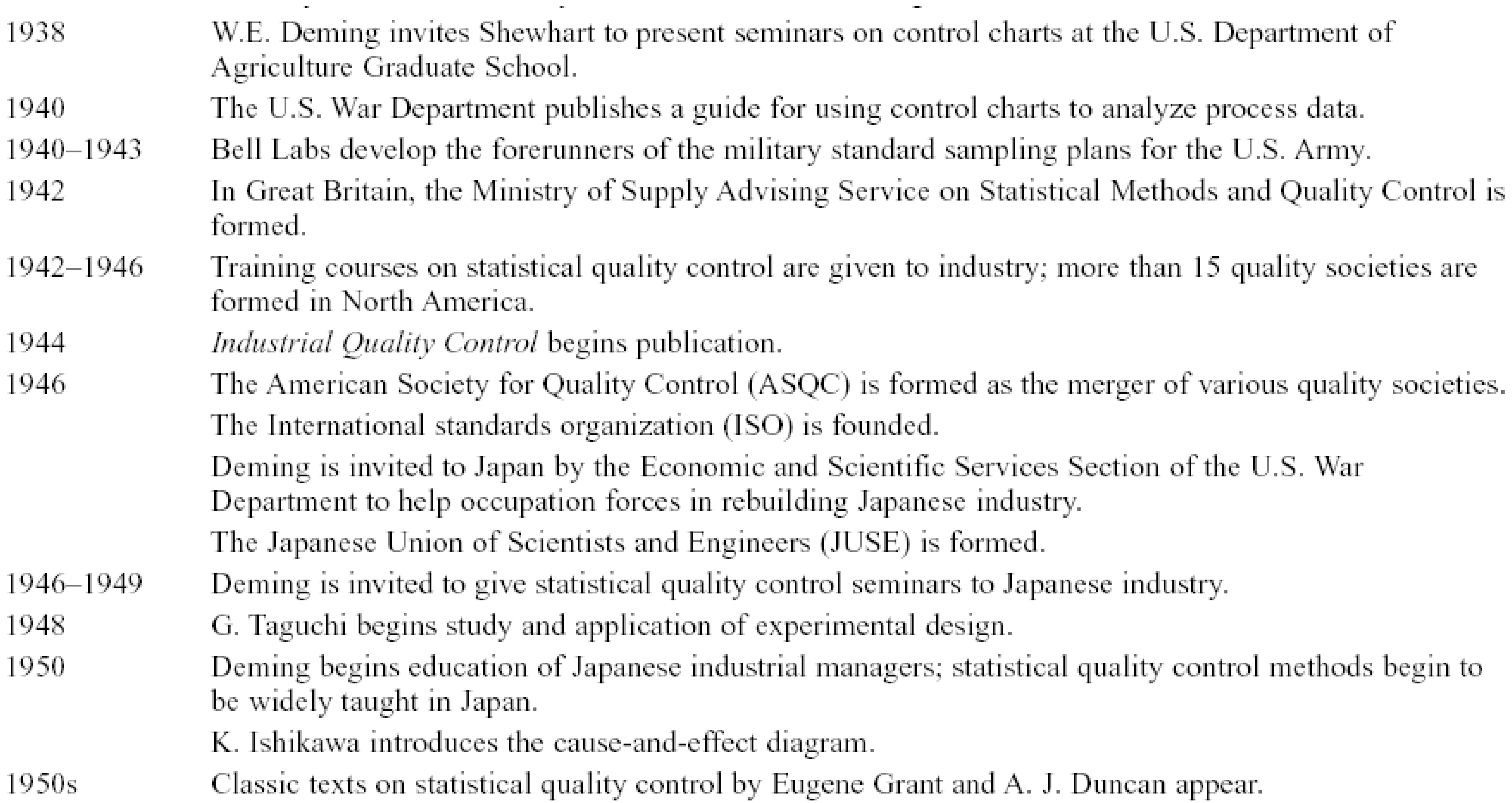


Table 1-1 A Timeline of Quality Methods

1700–1900	Quality is largely determined by the efforts of an individual craftsman.
	Eli Whitney introduces standardized, interchangeable parts to simplify assembly.
1875	Frederick W. Taylor introduces "Scientific Management" principles to divide work into smaller, more easily accomplished units—the first approach to dealing with more complex products and processes. The focus was on productivity. Later contributors were Henry Gilbreth and Frank Gantt.
1900–1930	Henry Ford—the assembly line—further refinement of work methods to improve productivity and quality; Ford developed mistake-proof assembly concepts, self-checking, and inprocess 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.
1922–1923	R.A. Fisher publishes series of fundamental papers on designed experiments and their application to the agricultural sciences.
1924	W.A. Shewhart introduces the control chart concept in a Bell Laboratories technical memorandum.
1928	Acceptance sampling methodology is developed and refined by H. F. Dodge and H. G. Romig at Bell Labs.
1931	W.A. Shewhart publishes *Economic Control of Quality of Manufactured Product*—outlining statistical methods for use in production and control chart methods.
1932	W.A. Shewhart gives lectures on statistical methods in production and control charts at the University of London.
1932–1933	British textile and woolen industry and German chemical industry begin use of designed experiments for product/process development.
1933	The Royal Statistical Society forms the Industrial and Agricultural Research Section.



1938	W.E. Deming invites Shewhart to present seminars on control charts at the U.S. Department of Agriculture Graduate School.
1940	The U.S. War Department publishes a guide for using control charts to analyze process data.
1940–1943	Bell Labs develop the forerunners of the military standard sampling plans for the U.S. Army.
1942	In Great Britain, the Ministry of Supply Advising Service on Statistical Methods and Quality Control is formed.
1942–1946	Training courses on statistical quality control are given to industry; more than 15 quality societies are formed in North America.
1944	*Industrial Quality Control* begins publication.
1946	The American Society for Quality Control (ASQC) is formed as the merger of various quality societies.
	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	G. Taguchi begins study and application of experimental design.
1950	Deming begins education of Japanese industrial managers; statistical quality control methods begin to be widely taught in Japan.
	K. Ishikawa introduces the cause-and-effect diagram.
1950s	Classic texts on statistical quality control by Eugene Grant and A. J. Duncan appear.

1951	A. V. Feigenbaum publishes the first edition of his book, *Total Quality Control.*
	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.
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 K. Ishikawa.
1961	National Council for Quality and Productivity is formed in Great Britain as part of the British Productivity Council.
1960s	Courses in statistical quality control become widespread in Industrial Engineering academic programs.
	Zero defects (ZD) programs are introduced in certain U.S. industries.
1969	*Industrial Quality Control* ceases publication, replaced by *Quality Progress* and the *Journal of Quality Technology* (Lloyd S. Nelson is the founding editor of *JQT*).
1970s	In Great Britain the NCQP and the Institute of Quality Assurance merge to form the British Quality Association.
1975–1978	Books on designed experiments oriented toward engineers and scientists begin to appear.
	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 electronics, aerospace, semiconductor, and the 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 standard.
1988	The Malcolm Baldrige National Quality Award is established by the U.S. Congress.
	The European Foundation for Quality Management is founded; this organization administers the European Quality Award.
1989	The journal *Quality Engineering* appears.
	Motorola's six-sigma initiative begins.
1990s	ISO 9000 certification activities increase in U.S. industry; applicants for the Baldrige award grow steadily; many states sponsor quality awards based on the Baldrige criteria.
1995	Many undergraduate engineering programs require formal courses in statistical techniques, focusing on basic methods for process characterization and improvement.
1997	Motorola's six-sigma approach spreads to other industries.
1998	The American Society for Quality Control becomes the American Society for Quality (see www.asq.org), attempting to indicate the broader aspects of the quality improvement field.
2000s	ISO 9000:2000 standard is issued. Supply-chain management and supplier quality become even more critical factors in business success. Quality improvement activities expand beyond the traditional industrial setting into many other areas including financial services, health care, insurance, and utilities.

Walter A. Shewart (1891-1967)

- Trained in engineering and physics
- Long career at Bell Labs
- Developed the first control chart about 1924

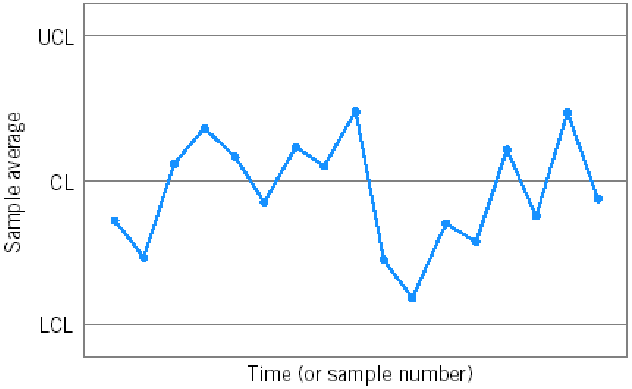


Figure 1-4 A typical control chart.

1.4.1 Quality Philosophy and Management Strategy

W. Edwards Deming

- Taught engineering, physics in the 1920s, finished PhD in 1928
- Met Walter Shewhart at Western Electric
- Long career in government statistics, USDA, Bureau of the Census
- During WWII, he worked with US defense contractors, deploying statistical methods
- Sent to Japan after WWII to work on the census

Deming

- Deming was asked by JUSE to lecture on statistical quality control to management
- Japanese adopted many aspects of Deming’s management philosophy
- Deming stressed “continual never-ending improvement”
- Deming lectured widely in North America during the 1980s; he died 24 December 1993

Deming's 14 Points

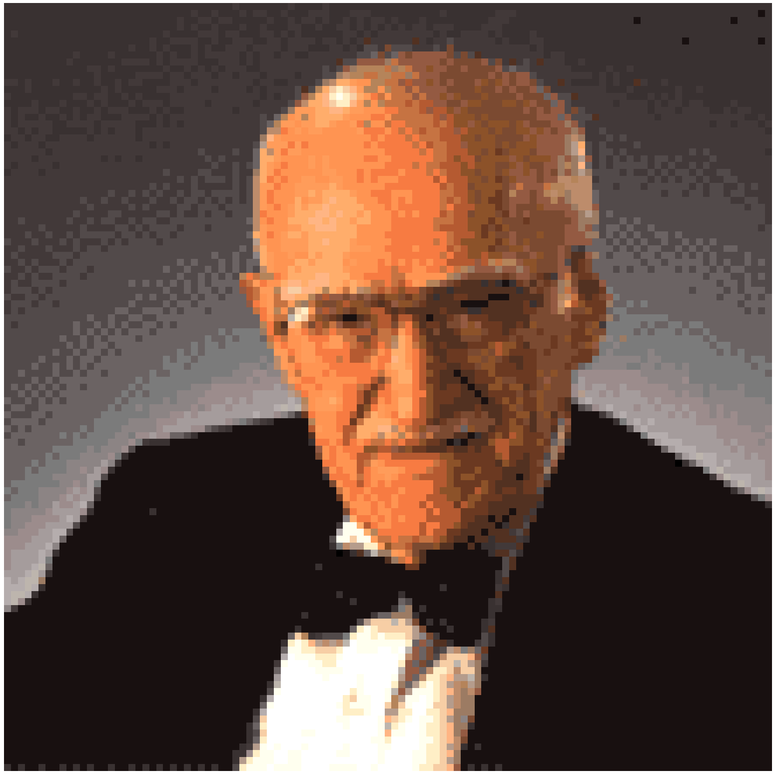
1. Create constancy of purpose toward improvement
2. Adopt a new philosophy, recognize that we are in a time of change, a new economic age
3. Cease reliance on mass inspection to improve quality
4. End the practice of awarding business on the basis of price alone
5. Improve constantly and forever the system of production and service
6. Institute training
7. Improve leadership, recognize that the aim of supervision is help people and equipment to do a better job
8. Drive out fear
9. Break down barriers between departments

14 Points cont’d

10. Eliminate slogans and targets for the workforce such as zero defects
11. Eliminate work standards
12. Remove barriers that rob workers of the right to pride in the quality of their work
13. Institute a vigorous program of education and self-improvement
14. Put everyone to work to accomplish the transformation

Joseph M. Juran

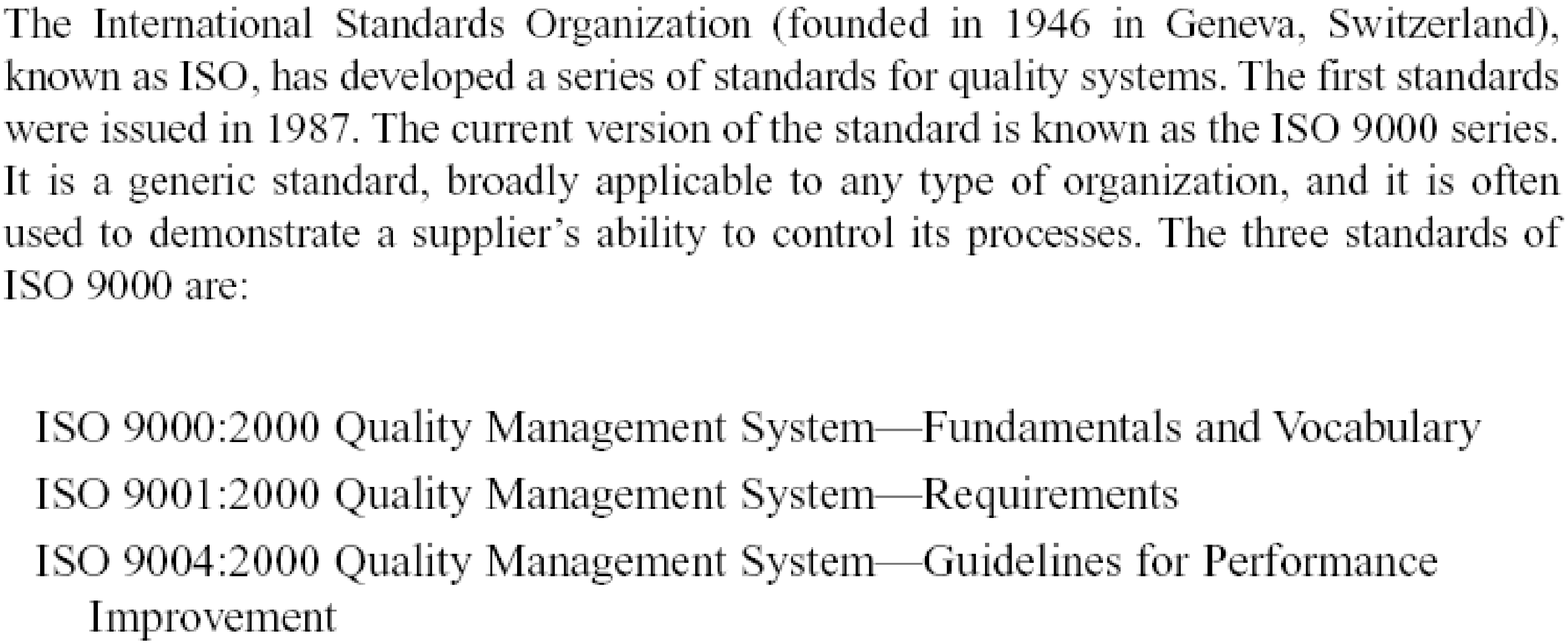
- Born in Romania (1904-2008), immigrated to the US
- Worked at Western Electric, influenced by Walter Shewhart
- Emphasizes a more strategic and planning oriented approach to quality than does Deming
- Juran Institute is still an active organization promoting the Juran philosophy and quality improvement practices



Total Quality Management (TQM)

- Started in the early 1980s, Deming/Juran philosophy as the focal point
- Emphasis on widespread training, quality awareness
- Training often turned over to HR function
- Not enough emphasis on quality control and improvement tools, poor follow-through, no project-by-project implementation strategy
- TQM was largely unsuccessful

Quality Systems and Standards



The International Standards Organization (founded in 1946 in Geneva, Switzerland), known as ISO, has developed a series of standards for quality systems. The first standards were issued in 1987. The current version of the standard is known as the ISO 9000 series. It is a generic standard, broadly applicable to any type of organization, and it is often used to demonstrate a supplier's ability to control its processes. The three standards of ISO 9000 are:

ISO 9000:2000 Quality Management System—Fundamentals and Vocabulary
ISO 9001:2000 Quality Management System—Requirements
ISO 9004:2000 Quality Management System—Guidelines for Performance Improvement

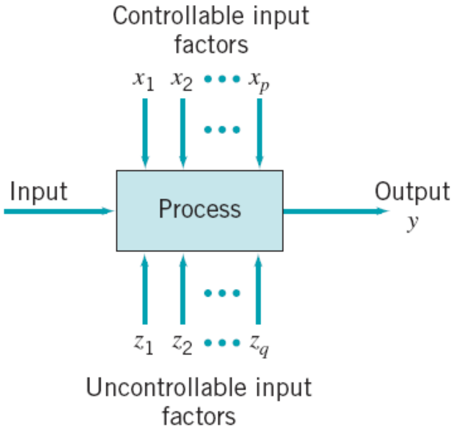
Statistical Methods

- Statistical process control (SPC)
  - Control charts, plus other problem-solving tools
  - Useful in monitoring processes, reducing variability through elimination of assignable causes
  - On-line technique
- Designed experiments (DOX)
  - Discovering the key factors that influence process performance
  - Process optimization
  - Off-line technique
- Acceptance Sampling

13.1 What Is Experimental Design?

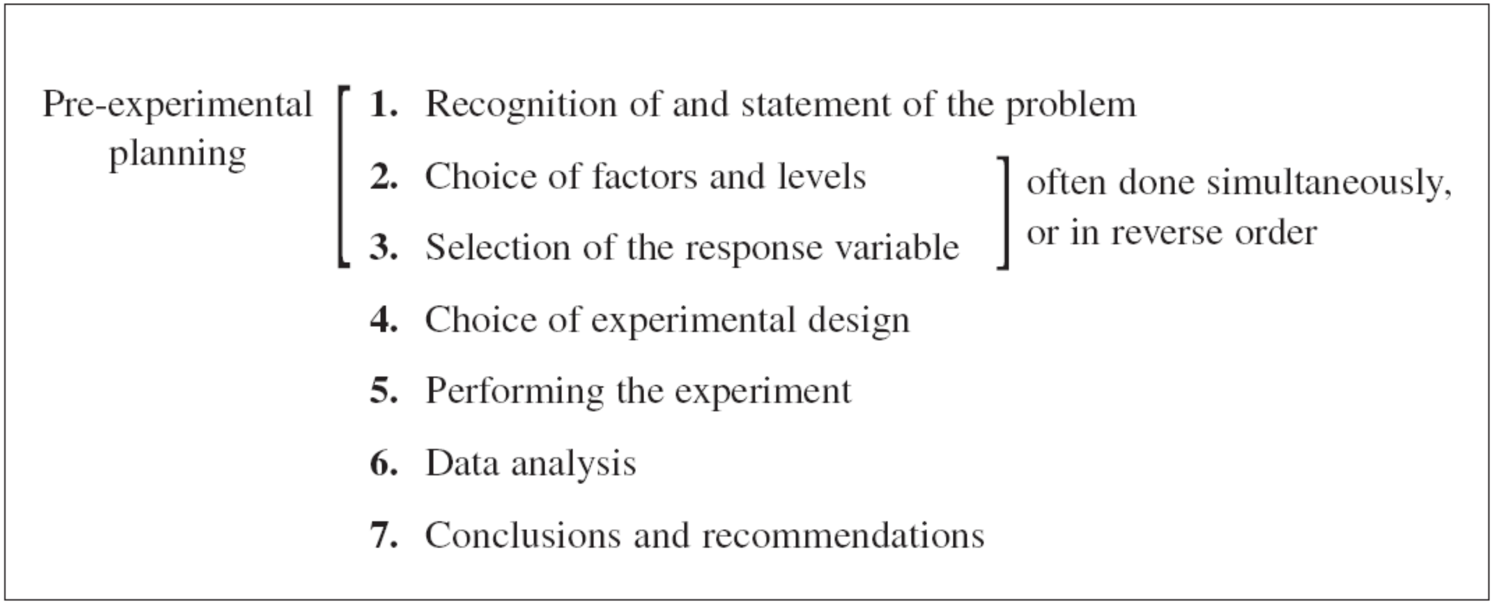
As indicated in Chapter 1, a designed experiment is a test or series of tests in which purposeful changes are made to the input variables of a process so that we may observe and identify corresponding changes in the output response. The process, as shown in Fig. 13.1, can be visualized as some combination of machines, methods, and people that transforms an input material into an output product. This output product has one or more observable quality characteristics or responses. Some of the process variables $x_1, x_2, \ldots, x_p$ are **controllable,** whereas others $z_1, z_2, \ldots, z_q$ are **uncontrollable** (although they may be controllable for purposes of the test). Sometimes these uncontrollable factors are called **noise** factors. The objectives of the experiment may include

1. Determining which variables are most influential on the response, y.
2. Determining where to set the influential x's so that y is near the nominal requirement.
3. Determining where to set the influential x's so that variability in y is small.
4. Determining where to set the influential x's so that the effects of the uncontrollable variables z are minimized.



■ FIGURE 13.1 General model of a process.

Guidelines for Designing an Experiment



Pre-experimental planning

1. Recognition of and statement of the problem
2. Choice of factors and levels
3. Selection of the response variable

often done simultaneously, or in reverse order

4. Choice of experimental design
5. Performing the experiment
6. Data analysis
7. Conclusions and recommendations

■ **FIGURE 13.4** Procedure for designing an experiment.

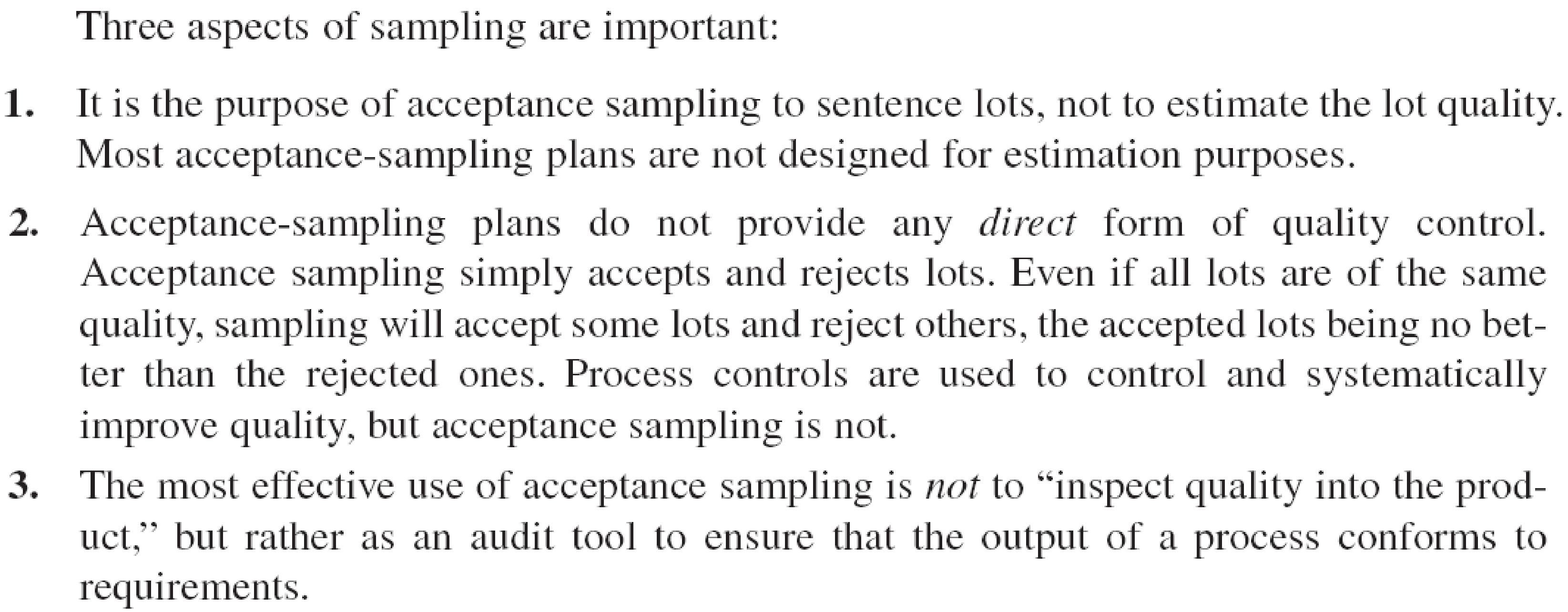
15.1 The Acceptance Sampling Problem

Typical application of acceptance sampling is for **lot disposition**, sometimes referred to as **lot sentencing**, for receiving inspection activities

Accepted lots are put into production

Rejected lots may be returned to supplier or subjected to other **lot-disposition action**

Sampling methods may also be used during various stages of production

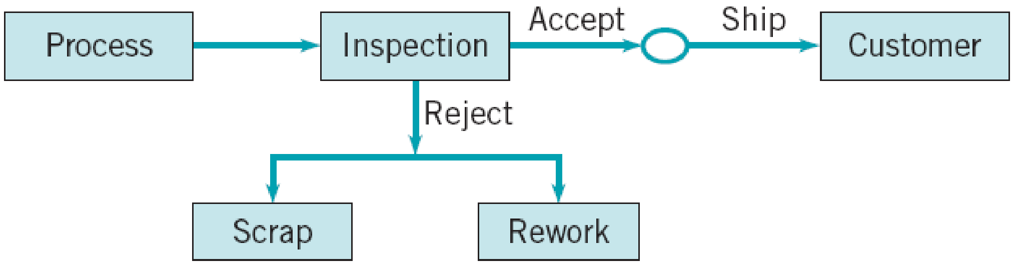


Three aspects of sampling are important:

1. It is the purpose of acceptance sampling to sentence lots, not to estimate the lot quality. Most acceptance-sampling plans are not designed for estimation purposes.
2. Acceptance-sampling plans do not provide any *direct* form of quality control. Acceptance sampling simply accepts and rejects lots. Even if all lots are of the same quality, sampling will accept some lots and reject others, the accepted lots being no better than the rejected ones. Process controls are used to control and systematically improve quality, but acceptance sampling is not.
3. The most effective use of acceptance sampling is *not* to "inspect quality into the product," but rather as an audit tool to ensure that the output of a process conforms to requirements.

(*a*) Outgoing inspection

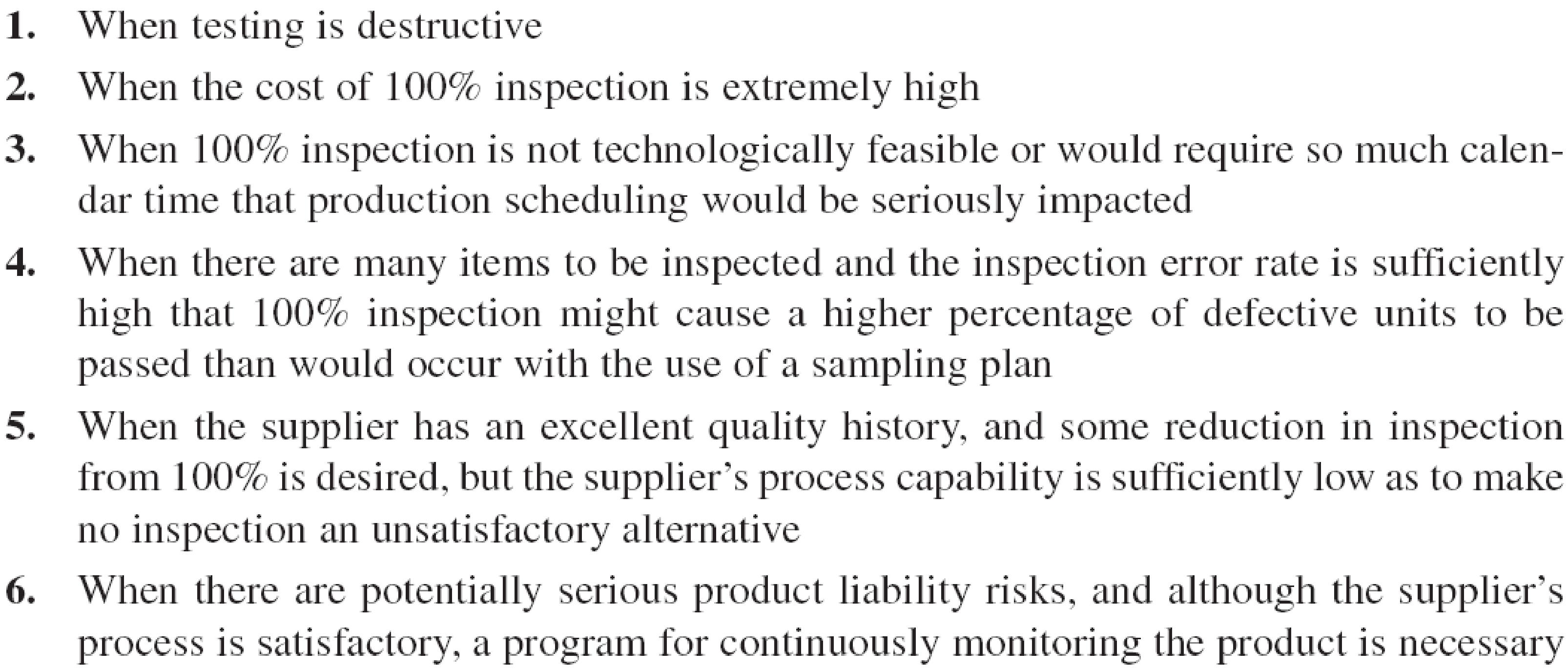
(*b*) Receiving/incoming inspection



(*c*) Disposition of lots

FIGURE 1.6 Variations of acceptance sampling.

Situations where acceptance sampling is likely to be useful:



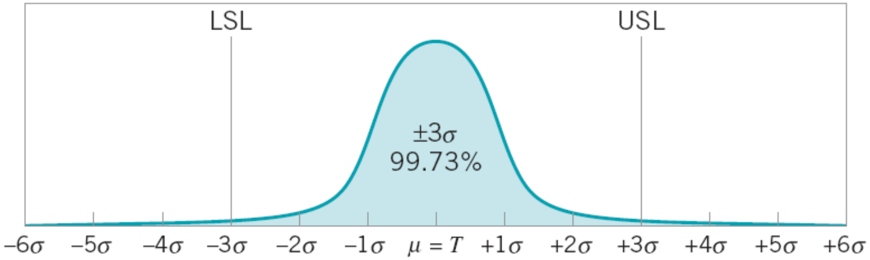
1. When testing is destructive
2. When the cost of 100% inspection is extremely high
3. When 100% inspection is not technologically feasible or would require so much calendar time that production scheduling would be seriously impacted
4. When there are many items to be inspected and the inspection error rate is sufficiently high that 100% inspection might cause a higher percentage of defective units to be passed than would occur with the use of a sampling plan
5. When the supplier has an excellent quality history, and some reduction in inspection from 100% is desired, but the supplier's process capability is sufficiently low as to make no inspection an unsatisfactory alternative
6. When there are potentially serious product liability risks, and although the supplier's process is satisfactory, a program for continuously monitoring the product is necessary

Six Sigma

- Use of statistics & other analytical tools has grown steadily for over 80 years
  - Statistical quality control (origins in 1920, explosive growth during WW II, 1950s)
  - Operations research (1940s)
  - FDA, EPA in the 1970’s
  - TQM (Total Quality Management) movement in the 1980’s
  - Reengineering of business processes (late 1980’s)
  - Six-Sigma (origins at Motorola in 1987, expanded impact during 1990s to present)

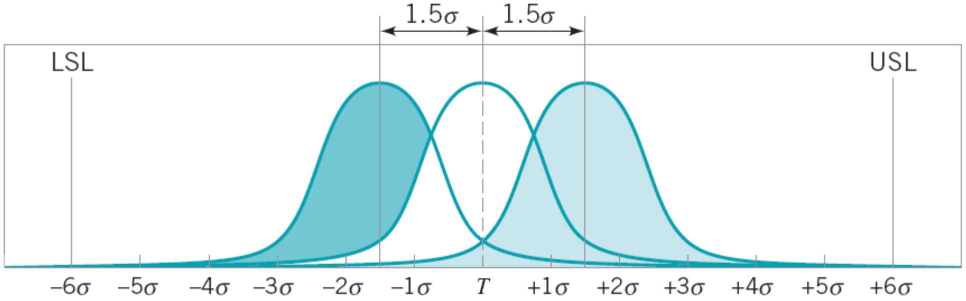
Focus of Six Sigma is on Process Improvement with an Emphasis on Achieving Significant Business Impact

- A process is an organized sequence of activities that produces an output that adds value to the organization
- All work is performed in (interconnected) processes
  - Easy to see in some situations (manufacturing)
  - Harder in others
- Any process can be improved
- An organized approach to improvement is necessary
- The process focus is essential to Six Sigma



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

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



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

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

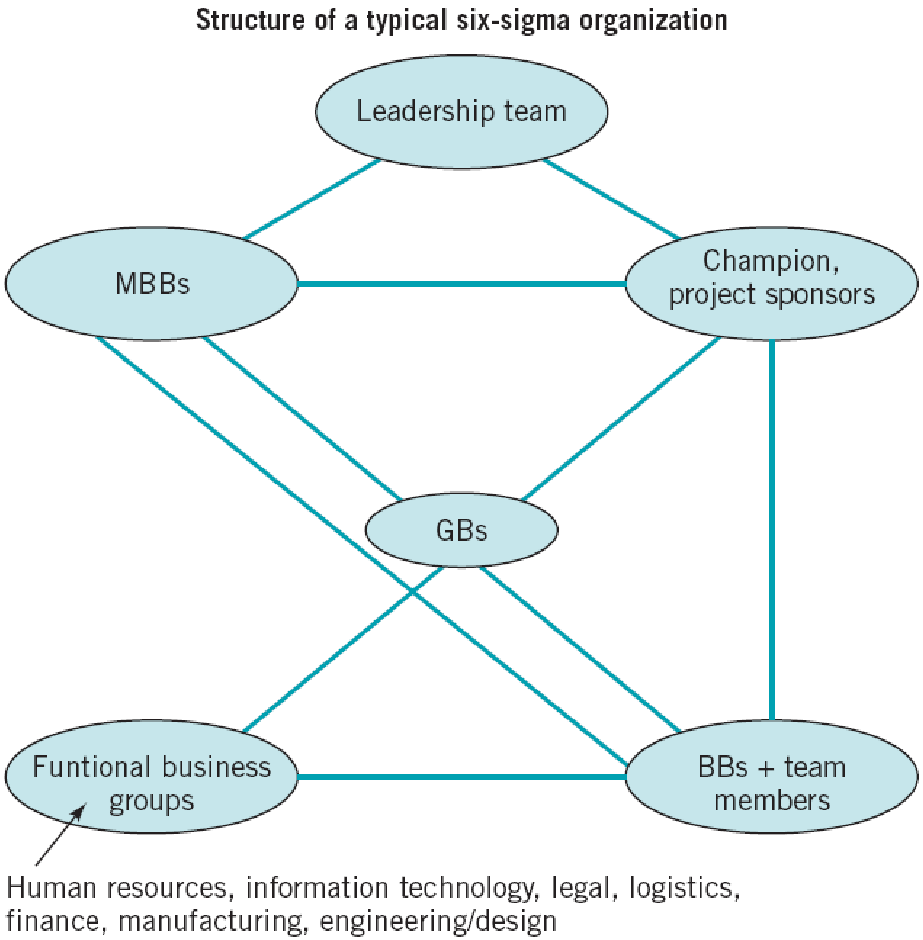
■ **FIGURE 1.12** The Motorola Six-Sigma concept.

Six Sigma Focus

- Initially in manufacturing
- Commercial applications
  - Banking
  - Finance
  - Public sector
  - Services
- DFSS – Design for Six Sigma
  - Only so much improvement can be wrung out of an existing system
  - New process design
  - New product design (engineering)

Six Sigma

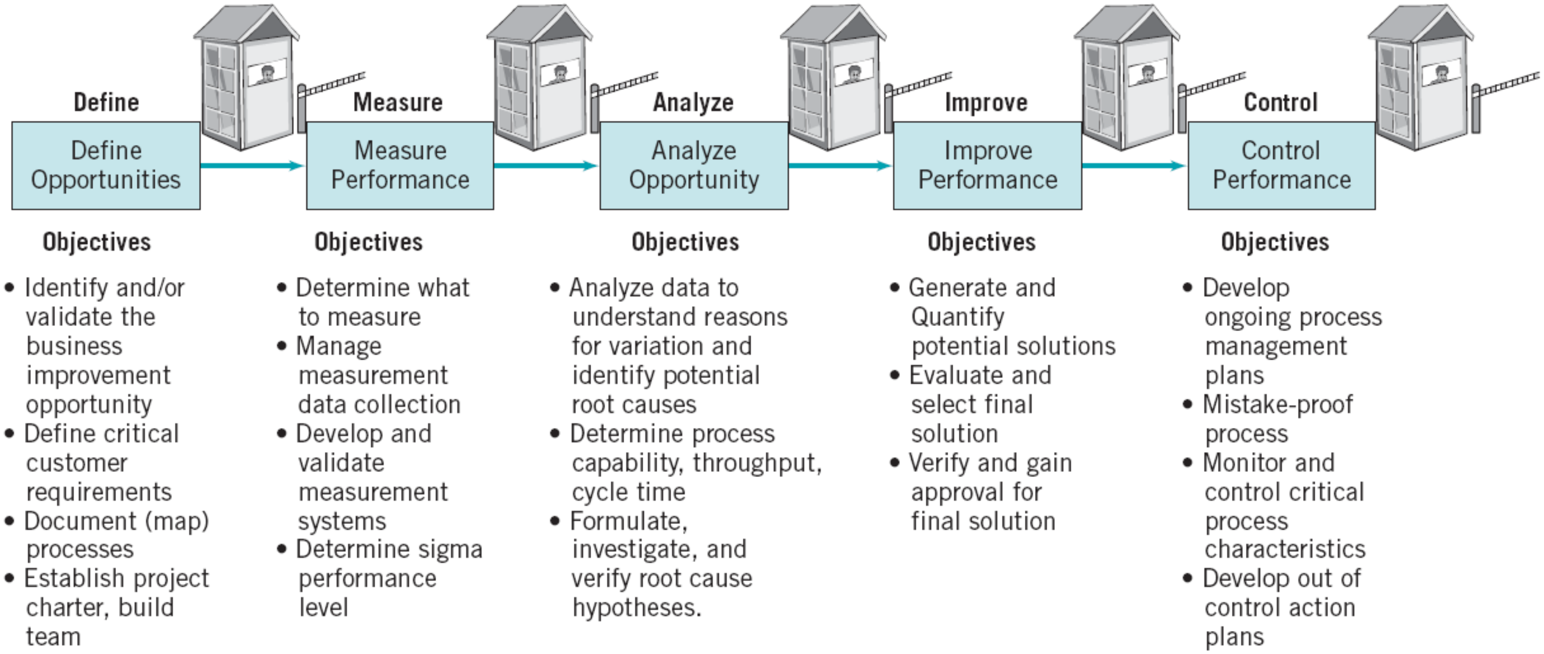
- A disciplined and analytical approach to process and product improvement
- Specialized roles for people; Champions, Master Black belts, Black Belts, Green Belts
- Top-down driven (Champions from each business)
- BBs and MBBs have responsibility (project definition, leadership, training/mentoring, team facilitation)
- Involves a five-step process (DMAIC) :
  - Define
  - Measure
  - Analyze
  - Improve
  - Control



■ **FIGURE 1.13** The structure of a six-sigma organization (Adapted from R. D. Snee and R. W. Hoerl, *Six-Sigma Beyond the Factory Floor*, Upper Saddle River, NJ: Pearson Prentice Hall, 2005).

DMAIC Solves Problems by Using Six Sigma Tools

- DMAIC is a problem solving methodology
- Closely related to the Shewhart Cycle
- Use this method to solve problems:
  - Define problems in processes
  - Measure performance
  - Analyze causes of problems
  - Improve processes – remove variations and non-value-added activities
  - Control processes so problems do not recur



Objectives

- Identify and/or validate the business improvement opportunity
- Define critical customer requirements
- Document (map) processes
- Establish project charter, build team

Objectives

- Determine what to measure
- Manage measurement data collection
- Develop and validate measurement systems
- Determine sigma performance level

Objectives

- Analyze data to understand reasons for variation and identify potential root causes
- Determine process capability, throughput, cycle time
- Formulate, investigate, and verify root cause hypotheses.

Objectives

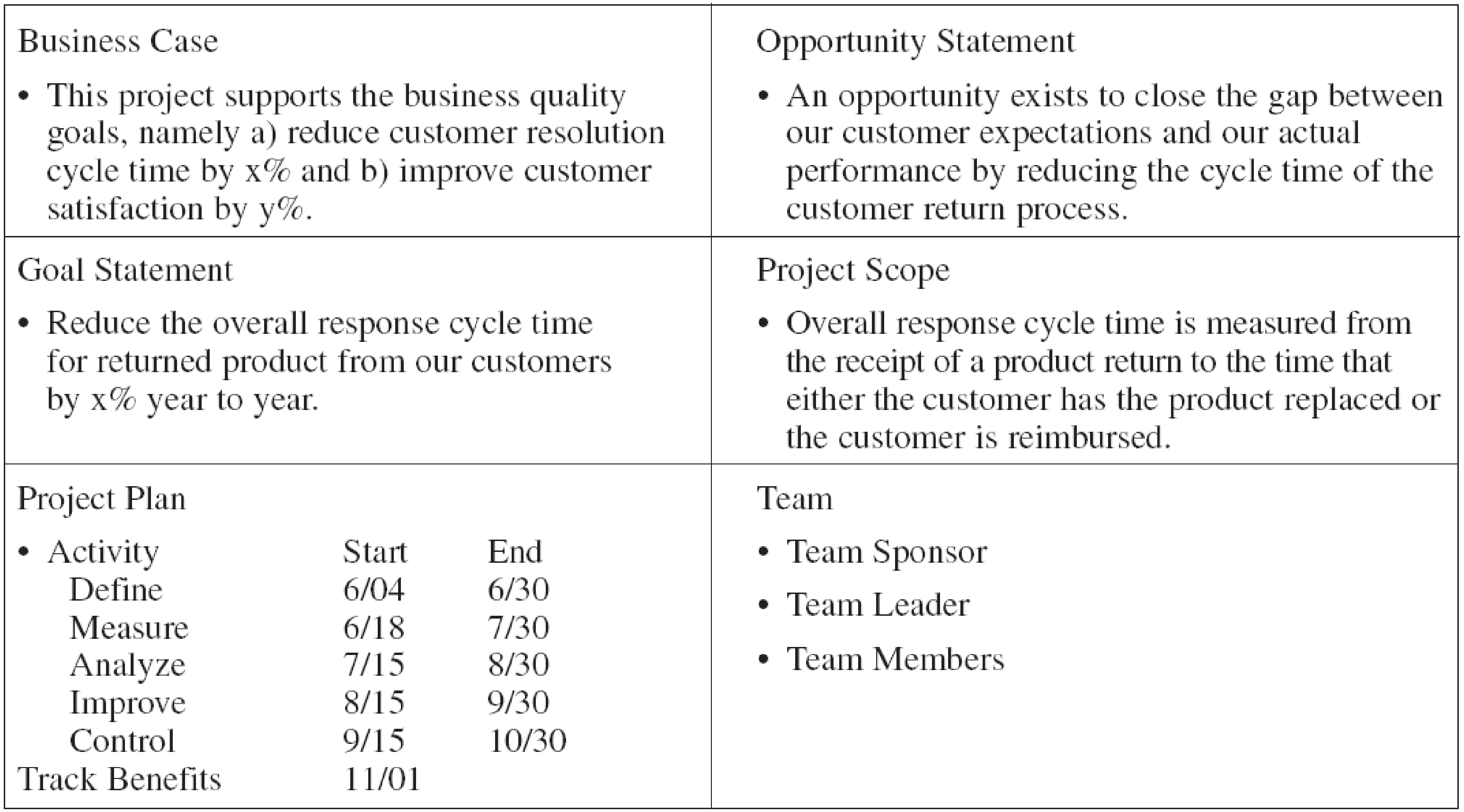
- Generate and Quantify potential solutions
- Evaluate and select final solution
- Verify and gain approval for final solution

Objectives

- Develop ongoing process management plans
- Mistake-proof process
- Monitor and control critical process characteristics
- Develop out of control action plans

■ FIGURE 2.1 The DMAIC process.

2.2 The Define Step



Business Case

- This project supports the business quality goals, namely a) reduce customer resolution cycle time by x% and b) improve customer satisfaction by y%.

Opportunity Statement

- An opportunity exists to close the gap between our customer expectations and our actual performance by reducing the cycle time of the customer return process.

Goal Statement

- Reduce the overall response cycle time for returned product from our customers by x% year to year.

Project Scope

- Overall response cycle time is measured from the receipt of a product return to the time that either the customer has the product replaced or the customer is reimbursed.

Project Plan

Activity	Start	End
Define	6/04	6/30
Measure	6/18	7/30
Analyze	7/15	8/30
Improve	8/15	9/30
Control	9/15	10/30
Track Benefits	11/01	

Team

- Team Sponsor
- Team Leader
- Team Members

FIGURE 2.2 A project charter for a customer returns process.

2.3 The Measure Step

- Purpose is to evaluate and determine the present process state
- Identify key process input variables (KPIV) and key process output variables (KPOV)
- Data – from historical records, from sampling, from observational studies
- Histograms, box plots, Pareto charts, scatter diagrams, stem-and-leaf diagrams may all be useful
- In some businesses, the measurement system must be developed
- Measurement systems capability may be important

2.4 The Analyze Step

- Determine cause-and-effect relationships
- Sources of variability – common cause versus assignable cause
- Tools – control charts, hypothesis testing, confidence intervals, regression models, failure modes and effects analysis
- Discrete event simulation

2.5 The Improve Step

- Process redesign to reduce bottlenecks
- Mistake-proofing
- Statistical tools – particularly designed experiments
- DOX can be applied to either the physical process or a computer model of the process
- Pilot test the solution to confirm that it will solve the problem

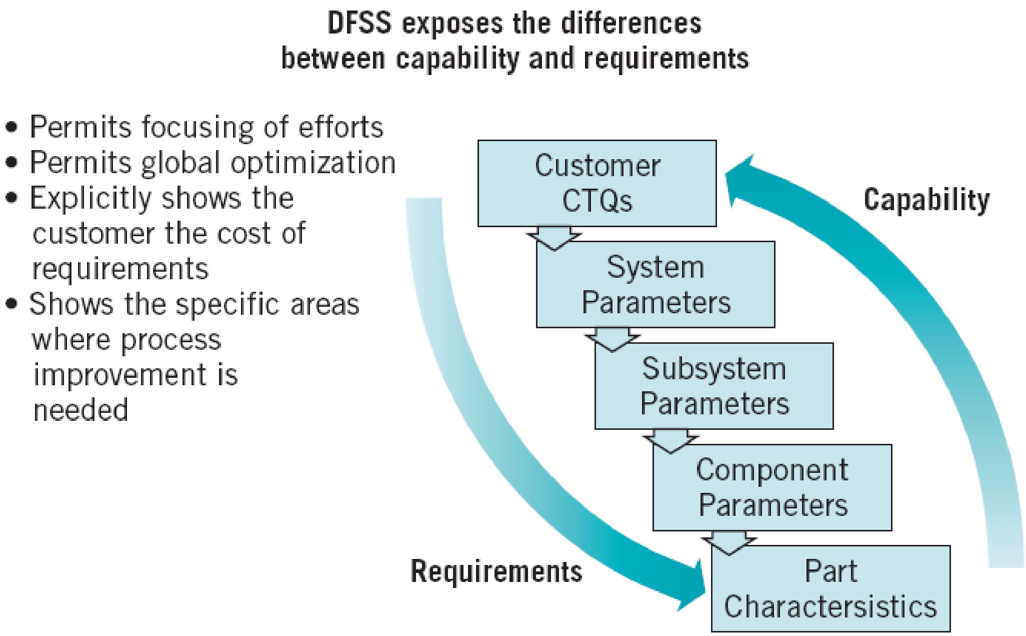
2.6 The Control Step

- Complete all remaining work on project
- Provide the process owner with a process control plan
- Training documents (if appropriate) should be provided
- Methods and metrics for future audits
- Transition plan to the new process might include a validation step

Design for Six Sigma (DFSS)

Taking variability reduction upstream from manufacturing (or **operational** six sigma) into product design and development

Every design decision is a business decision



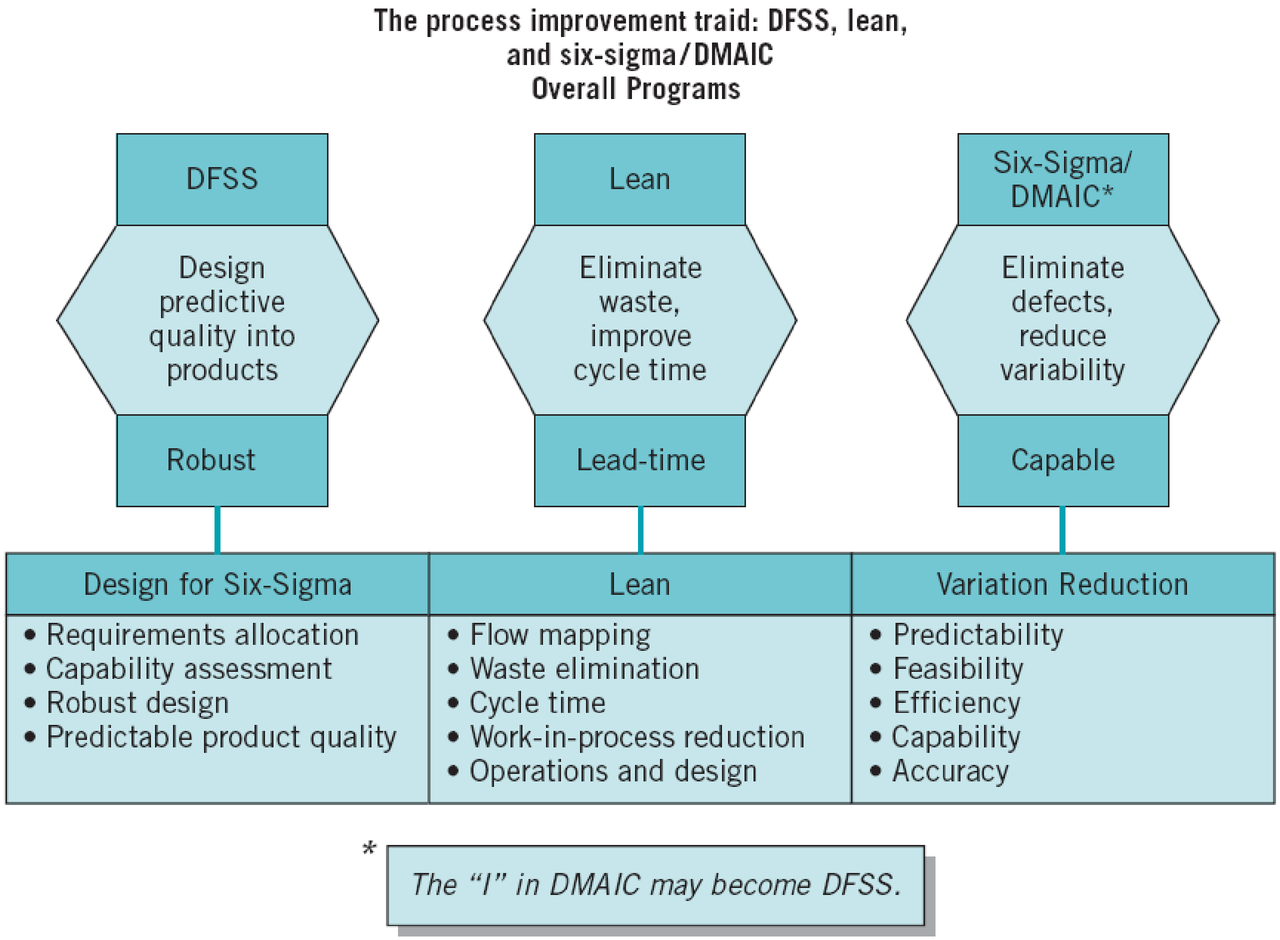
DFSS exposes the differences between capability and requirements

- Permits focusing of efforts
- Permits global optimization
- Explicitly shows the customer the cost of requirements
- Shows the specific areas where process improvement is needed

FIGURE 1.14 Matching product requirements and production capability in DFSS.

Lean Systems

- Focuses on elimination of waste
  - Long cycle times
  - Long queues – in-process inventory
  - Inadequate throughput
  - Rework
  - Non-value-added work activities
- Makes use of many of the tools of operations research and industrial engineering



The process improvement traid: DFSS, lean,
and six-sigma/DMAIC
Overall Programs

DFSS

Design predictive quality into products

Robust

Lean

Eliminate waste, improve cycle time

Lead-time

Six-Sigma/ DMAIC*

Eliminate defects, reduce variability

Capable

Design for Six-Sigma	Lean	Variation Reduction
• Requirements allocation • Capability assessment • Robust design • Predictable product quality	• Flow mapping • Waste elimination • Cycle time • Work-in-process reduction • Operations and design	• Predictability • Feasibility • Efficiency • Capability • Accuracy

* *The "I" in DMAIC may become DFSS.*

FIGURE 1.15 Six-sigma/DMAIC, lean, and DFSS: How they fit together.