

Introduction to Statistical Quality Control, 5th edition

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品質管理課程大綱及進度表

Course Outline

- Quality Management will teach students fundamental SPC techniques and various quality improvement methods/tools through software demonstration and laboratory practices as well as application examples.
- Course Aims and Descriptions
- Introduction of various statistical quality control and experimental design methods for quality improvement in the modern business environments. This is a Quantitative Quality Management course.

I. Quality Improvement in the Modern Business Environment (Chapter 1).

II. Statistical Process Control

- 1. Methods of SPC (Chapter 2, 4).
- 2. Variable Control Charts (Chapter 5, 4).
- 3. Attribute Control Charts (Chapter 6).
- 4. Process Capability and Measurement System Analysis (Chapter 7)-----Mid Term Exam.
- 5. EWMA and Cumulative Sum Control Charts (Chapter 8).
- 6. Acceptance Sampling Plans (Chapter 14, 15).

III. Design Experiments

Factorial and Fractional Factorial Experiments for Process Design and Improvement (Chapter 12).

1

Quality Improvement in the Modern Business Environment

CHAPTER OUTLINE

- | | |
|---|--|
| 1-1 THE MEANING OF QUALITY AND QUALITY IMPROVEMENT | 1-4 MANAGEMENT ASPECTS OF QUALITY IMPROVEMENT |
| 1-1.1 Dimensions of Quality | 1-4.1 Quality Philosophy and Management Strategies |
| 1-1.2 Quality Engineering Terminology | 1-4.2 The Link Between Quality and Productivity |
| 1-2 A BRIEF HISTORY OF QUALITY CONTROL AND IMPROVEMENT | 1-4.3 Quality Costs |
| 1-3 STATISTICAL METHODS FOR QUALITY CONTROL AND IMPROVEMENT | 1-4.4 Legal Aspects of Quality |
| | 1-4.5 Implementing Quality Improvement |
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Learning Objectives

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

1-1 Definitions and Meaning of Quality

1-1.1 The Eight Dimensions of Quality

1. Performance (do the intended functions)
2. Reliability (how often does the product fail)
3. Durability (how long does the product last)
4. Serviceability (how easy is it to repair?)
5. Aesthetics (what does the product look like)
6. Features (what does the product do?)
7. Perceived Quality (reputation of the product)
8. Conformance to Standards (intended design)

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

The Transmission Example

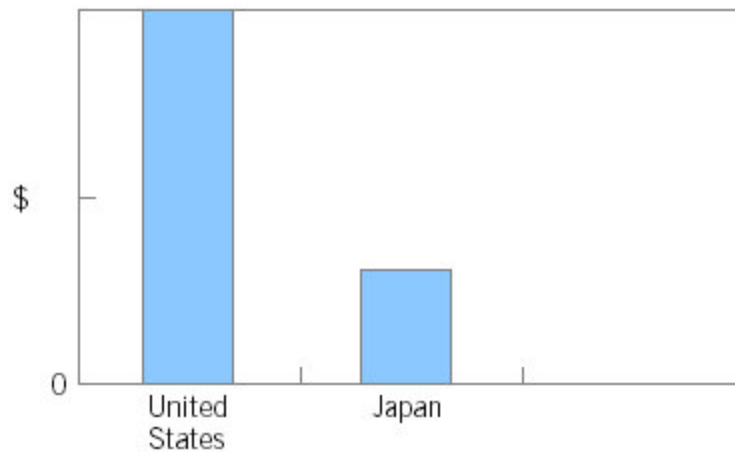


Figure 1-1 Warranty costs for transmissions.

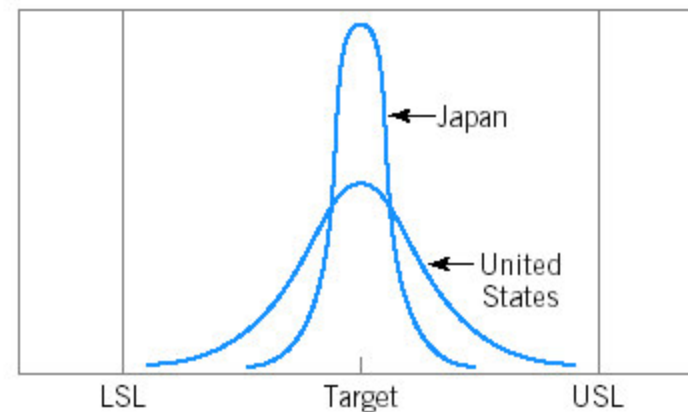


Figure 1-2 Distributions of critical dimensions for transmissions.

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.

SPC History

1. W. A. Shewhart developed SPC about 1931.
2. U. S. Army required radio headsets to fit the “average” head.
3. In World War II, American industry used SPC to get defense hardware that worked with minimal scrap and rework.

SPC History

4. Postwar, Japan learns SPC from Edward Deming and J. M. Juran.
5. Today, American industry is trying to remain competitive.
6. SPC is necessary for economic survival.

Reasons for SPC Programs

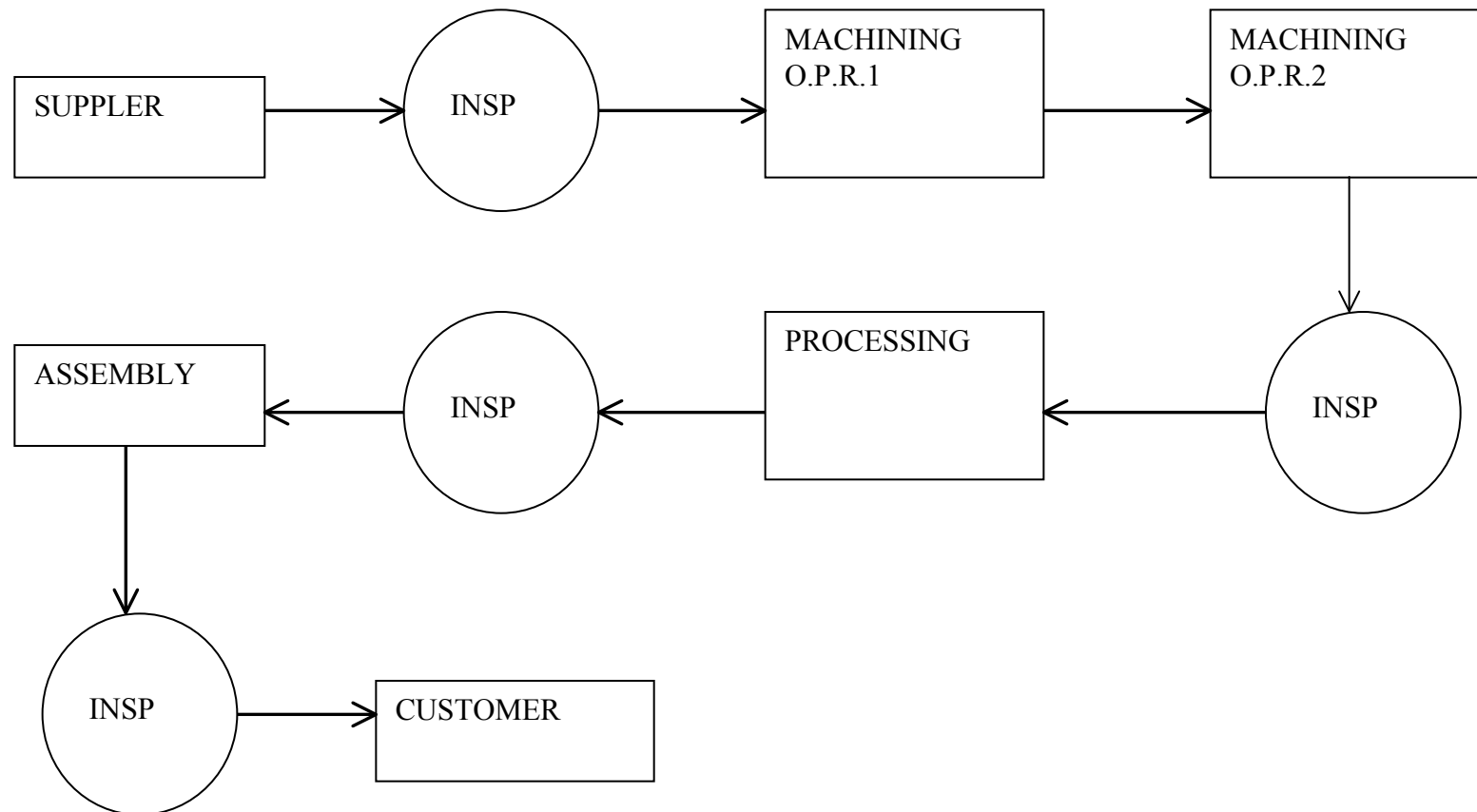
1. It's the right thing!
2. The world competition is becoming more aggressive, therefore, every company needs to improve quality and cost.
3. Every company needs continuous improvement to stay competitive.
4. Future contracts will require SPC programs.

Benefits of SPC

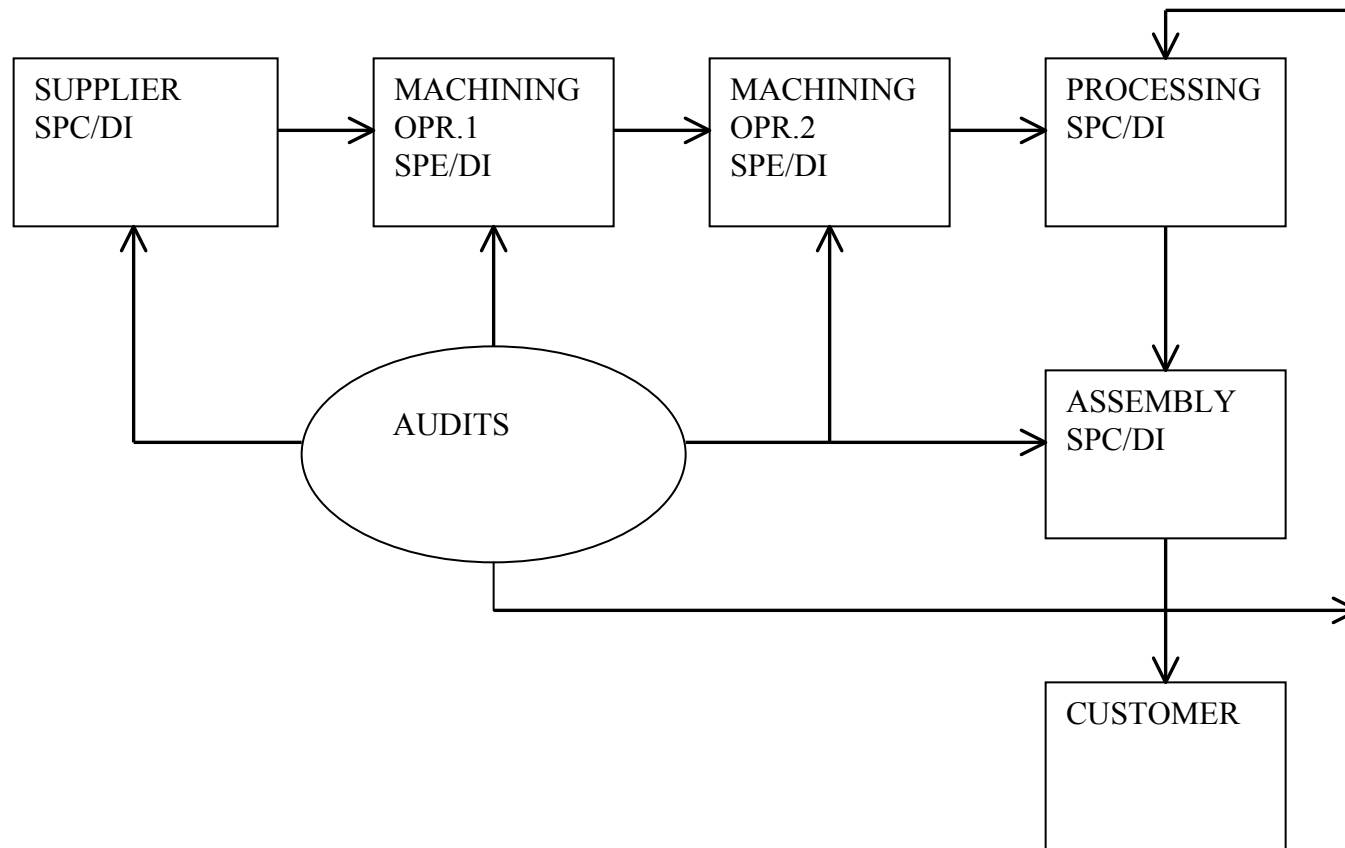
1. Increase job security
2. Increase your value to the company
3. Improve work conditions
4. Better market share
5. Greater cost savings
6. Increased profits

WHAT DOES SPC WORK?

OLD (APPRAISAL) SYSTEM



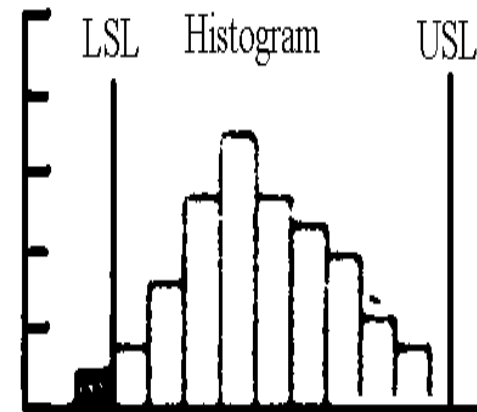
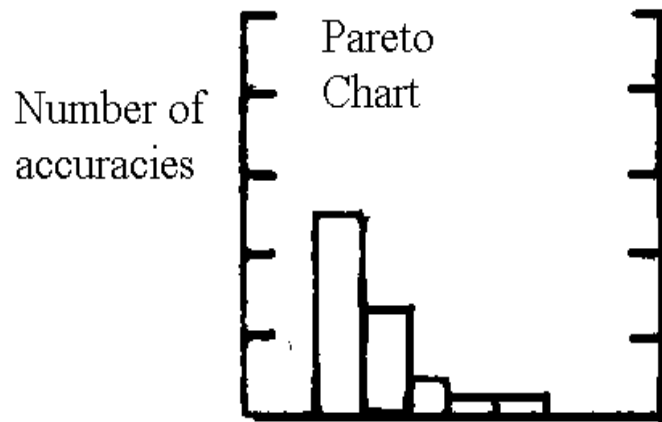
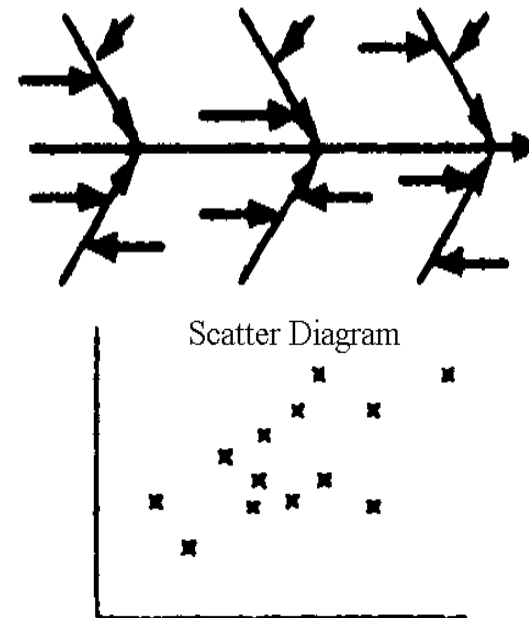
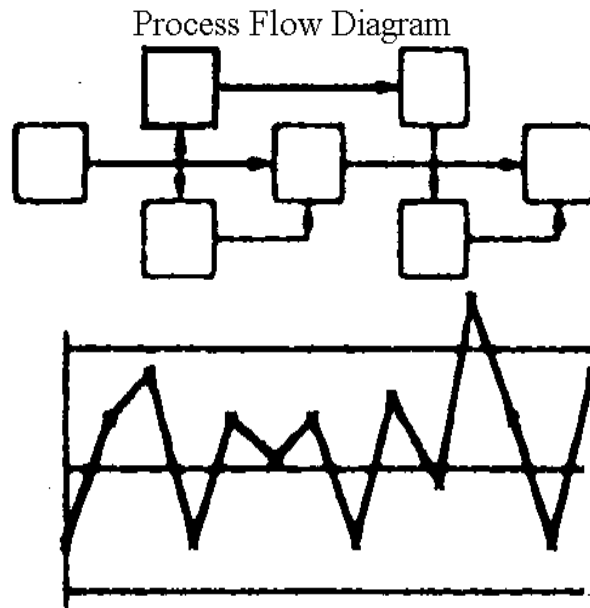
NEW (PREVENTIVE) SYSTEM



The Statistical Tool KIT

- Seven commonly used statistical quality control techniques :
 - (1)check sheets
 - (2)histograms
 - (3)pareto diagrams
 - (4)cause-and-effect diagrams
 - (5)control charts
 - (6)scatter diagrams
 - (7)stratification /flowchart

Statistical Process Control (SPC) Tools



SPC Calculations for Control Limits

- Notation

UCL-Upper Control Limit

LCL-Lower Control Limit

CL-Center Line

n-Sample Size

PCR-Process Capability Ratio

σ -Process Standard Deviation

SPC Calculations for Control Limits

- Notation

$\bar{X}$ - Average of Measurements

$\bar{\bar{X}}$ - Average of Averages

R - Range

$\bar{R}$ - Average of Ranges

USL - Upper Specification Limit

LSL - Lower Specification Limit

Variable Data($\bar{X}$ & R Control Chart)

$\bar{X}$ Control Chart

$$UCL = \bar{\bar{X}} + A_2 \bar{R}$$

$$LCL = \bar{\bar{X}} - A_2 \bar{R}$$

$$CL = \bar{\bar{X}}$$

R Control Chart

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

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

$$CL = \bar{R}$$

Capability Study

n	A2	D3	D4	d2
2	1.880	0.000	3.267	1.128
3	1.023	0.000	2.574	1.693
4	0.729	0.000	2.282	2.509
5	0.577	0.000	2.114	2.326
6	0.483	0.000	2.004	2.534
7	0.419	0.076	1.924	2.704
8	0.373	0.136	1.864	2.847
9	0.337	0.184	1.816	2.970
10	0.308	0.223	1.777	3.078

$$PCR = (USL - LSL) / 6\sigma, \quad \text{where } \sigma = \bar{R} / d_2$$

Attribute Data(P, NP, C and U control charts)

	p (percent defective)	np (number of defectives)	c (count of defects)	U (count of defects/unit)
CL	$\bar{p}$	$n\bar{p}$	$\bar{c}$	$\bar{u}$
UCL	$\bar{p} + 3\sqrt{\bar{p}(1-\bar{p})/n}$	$n\bar{p} + 3\sqrt{n\bar{p}(1-n\bar{p}/n)}$	$\bar{c} + 3\sqrt{\bar{c}}$	$\bar{u} + 3\sqrt{\bar{u}/n}$
LCL	$\bar{p} - 3\sqrt{\bar{p}(1-\bar{p})/n}$	$n\bar{p} - 3\sqrt{n\bar{p}(1-n\bar{p}/n)}$	$\bar{c} - 3\sqrt{\bar{c}}$	$\bar{u} - 3\sqrt{\bar{u}/n}$
Notes	If n varies, use $\bar{n}$ or individual n as desires	n must be a constant sample size	n must be a constant sample size	If n varies, use $\bar{n}$ or individual n as desires

AQS/SPC Tools Training Sessions

Key Contents Required For Each Module

(1) TRAIN THE TRAINERS

- Principle of Learning & Teaching Methods
- Overview of AQS/SPC tools
- Process Flow Charts
- Process Model Analysis/Key Characteristic Identification
- Variable and Attribute Control Charts
- Interpretation of Control Chart Patterns
- Process Stability and Capability Concepts
- SQC/SPC Software Demonstration

AQS/SPC Tools Training Sessions

Key Contents Required For Each Module

(2)PROCESS FLOW CHART

- Product/Process Flow Chart Construction
- Flow Chart Analysis

(3)PROCESS Analysis and Control

- Process Model and Station Control
- Process Stability and Capability Analysis
- Key Characteristics Identification and Flow down

AQS/SPC Tools Training Sessions

Key Contents Required For Each Module

(4) Variable Control Chart

- Histogram & Normal Distribution
- Measure of Center Tendency & Dispersion
- X-R Chart, Individual, Target, Pre-Control Charts

(5) Attribute Control Chart

- Defect vs. Defective
- P, NP, C and U Charts

AQS/SPC Tools Training Sessions

Key Contents Required For Each Module

(6) Interpretation of Control Chart patterns

- Pattern Evaluation
- Rule of Thumb to detect out-of-control
- Trouble Shooting with possible causes

(7) Process Capability Studies

- When and How to conduct short/long term studies
- C_p & C_{pk} calculation and evaluation

AQS/SPC Tools Training Sessions

Key Contents Required For Each Module

(8) SQC/SPC Software Demonstration

- Step by Step Instruction using SQC softwares
- Practical Examples on (4), (5) and (7)

PROPOSED BY JACK PAN, 9/20/1331

Statistical Progress Control, Training Status – Train The Trainers

TRAINING MODULES/SESSIONS	DATE COMPLETED
AQS/SPC TEACHING MTD	(OCT. 15)
CHECK SHEET/HISTOGRAM	(OCT. 17)
MEASURES,NORMAL DIST	(OCT. 22)
VARIABLE CONTRL CHAR	(OCT. 22)
PATTERN INTERPRETATION	(OCT. 29)
TAPE REVIEW,VARIABLE	(OCT. 31)
ATTRIBUTE CONTROL CH	(NOV. 5)
TAPE REVIEW,ATTRIBUTE	(NOV. 7)
PROCESS CAPABILITY	(NOV. 12)
SOFTWARE DEMONSTRATION	(NOV. 21)
PROCESS FLOW CHART	(NOV. 26)
PROCESS MODEL/ANALYSIS	(DEC. 3)
KEY CHARACTERISTICS	(DEC. 5)
SUMMARY/APPLICATION	(DEC. 10)

PREPARE TEACHING COMPLETED E

TRAINING STATUS

PREPARING/TEACHING/COMPLETED/EVALUATION

1-1.2 Terminology

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

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

Since variability can only be described in statistical terms, **statistical methods** play a central role in quality improvement efforts. In the application of statistical methods to quality engineering, it is fairly typical to classify data on quality characteristics as either **attributes** or **variables** data. Variables data are usually continuous measurements, such as length, voltage, or viscosity. Attributes data, on the other hand, are usually discrete data, often taking the form of counts. We will describe statistical-based quality engineering tools for dealing with both types of data.

Terminology cont'd

- Specifications
 - Lower specification limit
 - Upper specification limit
 - Target or nominal values
- Defective or nonconforming product
- Defect or nonconformity
- Not all products containing a defect are necessarily defective

Terminology cont'd

- Key characteristic – those having an effect on fit, performance and service life.
- Target – where we want most of the measurements to fall, approximately $\bar{X}$.
- $\bar{X}$ -Bar- The process average.

Terminology cont'd

- Control chart – a plot of key characteristics usually determined by regular sampling of product.
- Control limits – the limits within which the product of a process is expected (or required) to remain. Not the same as tolerance limits.

Terminology cont'd

- Histogram - a graphic representation of a frequency distribution.
- Sigma – the standard deviation, a measure of process dispersion.

Terminology cont'd

- Gage R & R – reproducibility and repeatability.
- Pareto – vital few, trivia many.
- Cpk – a process capability index.

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 <i>t</i> -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 <i>Economic Control of Quality of Manufactured Product</i> —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	<i>Industrial Quality Control</i> 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, <i>Total Quality Control</i> . 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 <i>Quality Control Handbook</i> is first published.
1959	<i>Technometrics</i> (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	<i>Industrial Quality Control</i> ceases publication, replaced by <i>Quality Progress</i> and the <i>Journal of Quality Technology</i> (Lloyd S. Nelson is the founding editor of <i>JQT</i>).
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 <i>Quality and Reliability Engineering International</i> 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 <i>Quality Engineering</i> 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.

1-3 STATISTICAL METHODS FOR QUALITY CONTROL AND IMPROVEMENT

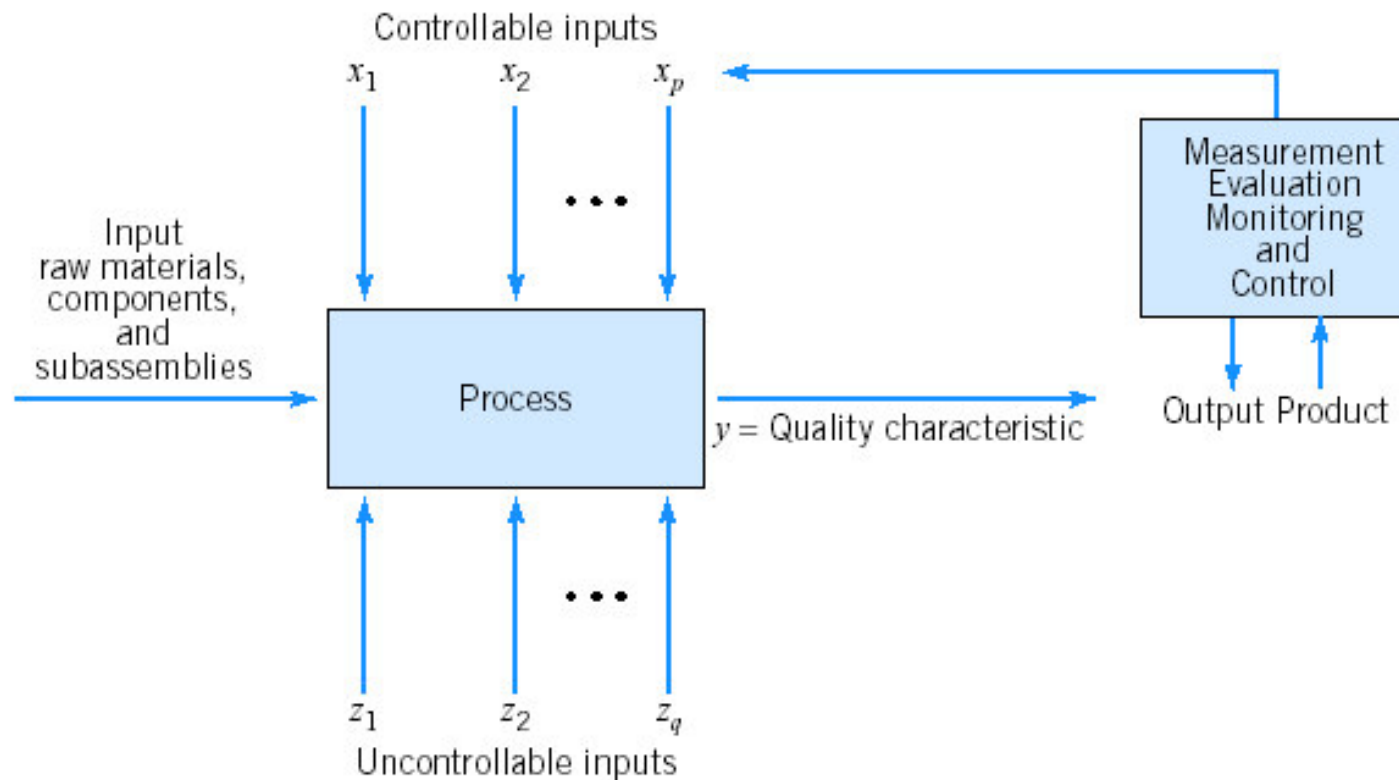


Figure 1-3 Production process inputs and outputs.

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 (DOE)
 - Discovering the key factors that influence process performance
 - Process optimization
 - Off-line technique
- Acceptance Sampling

Walter A. Shewart (1891-1967)

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

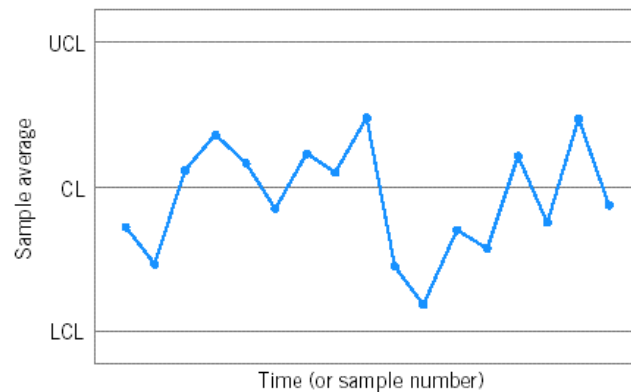
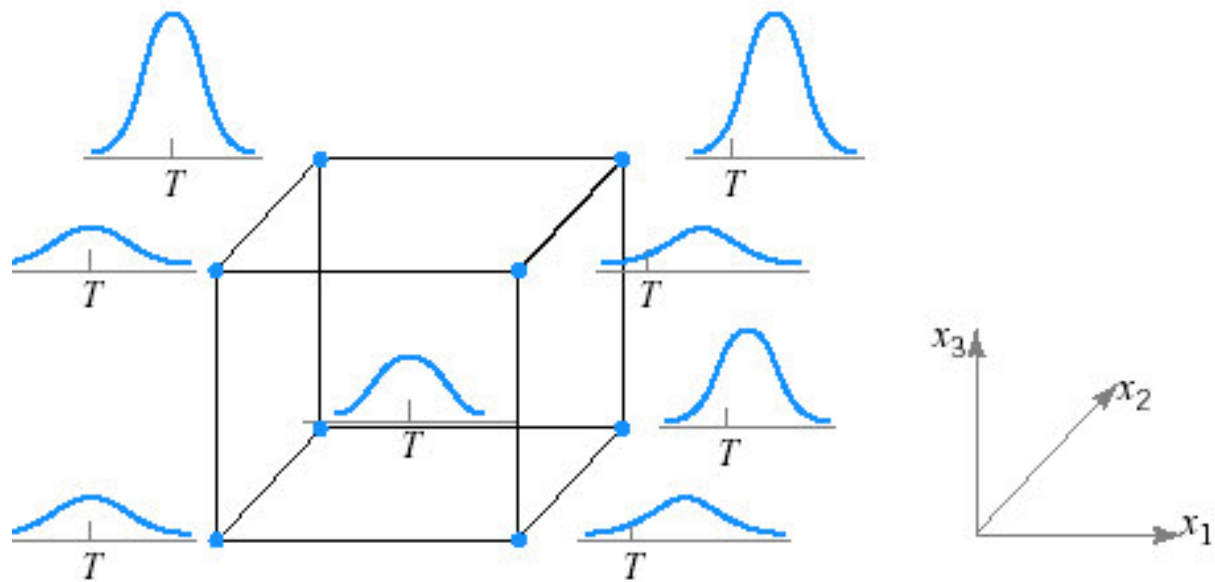


Figure 1-4 A typical control chart.





A factorial experiment with three factors

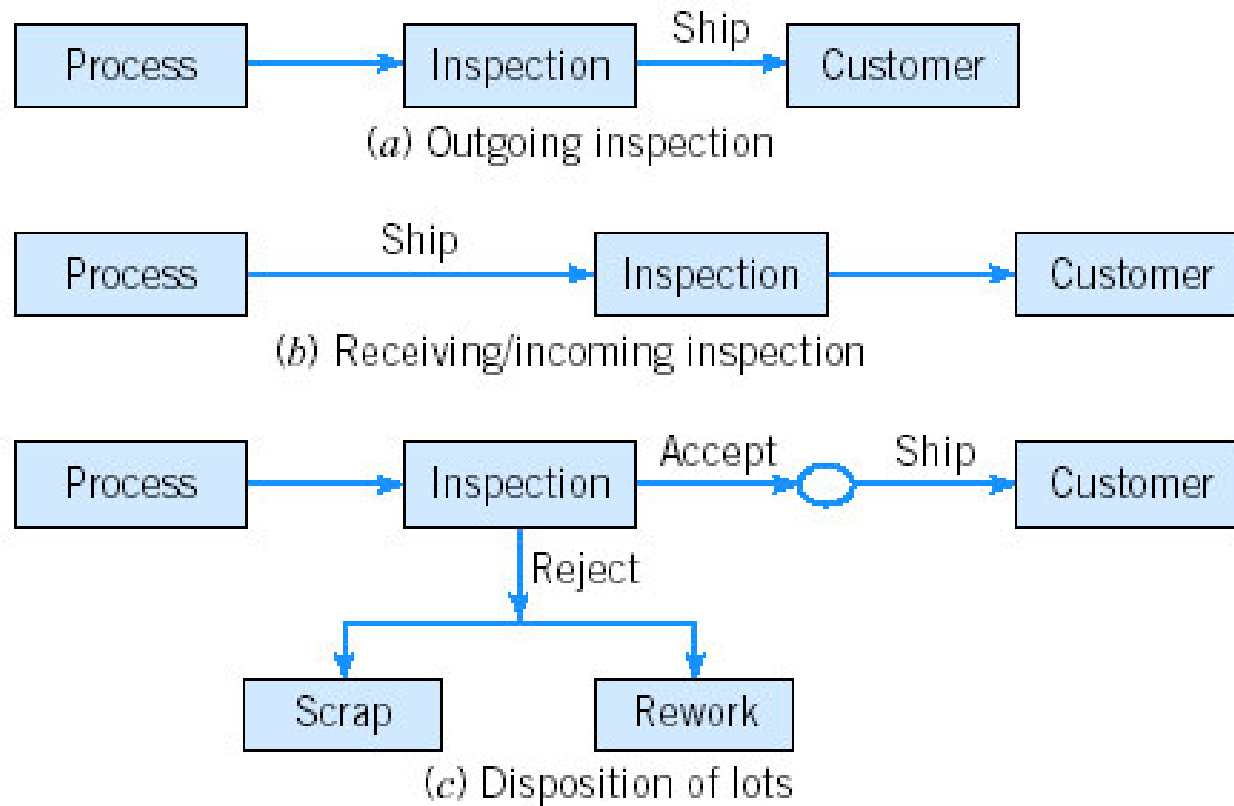


Figure 1-6 Variations of acceptance sampling.

1-4 MANAGEMENT ASPECTS OF QUALITY IMPROVEMENT

Effective management of quality requires the execution of three activities:

1. Quality Planning
2. Quality Assurance
3. Quality Control and Improvement

Quality planning is a strategic activity, and it is just as vital to an organization's long-term business success as the product development plan, the financial plan, the marketing plan, and plans for the utilization of human resources. Without a strategic quality plan, an enormous amount of time, money, and effort will be wasted by the organization dealing with faulty designs, manufacturing defects, field failures, and customer complaints. Quality planning involves identifying customers, both external and those that operate internal to the business, and identifying their needs (this is sometimes called listening to the **voice of the customer**). Then products or services that meet or exceed customer expectations must be developed. The eight dimensions of quality discussed in Section 1-1.1 are an important part of this effort. The organization must then determine how these products and services will be realized. Planning for quality improvement on a specific, systematic basis is also a vital part of this process.

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

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

1-4.1 Quality Philosophies and Management Strategies

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

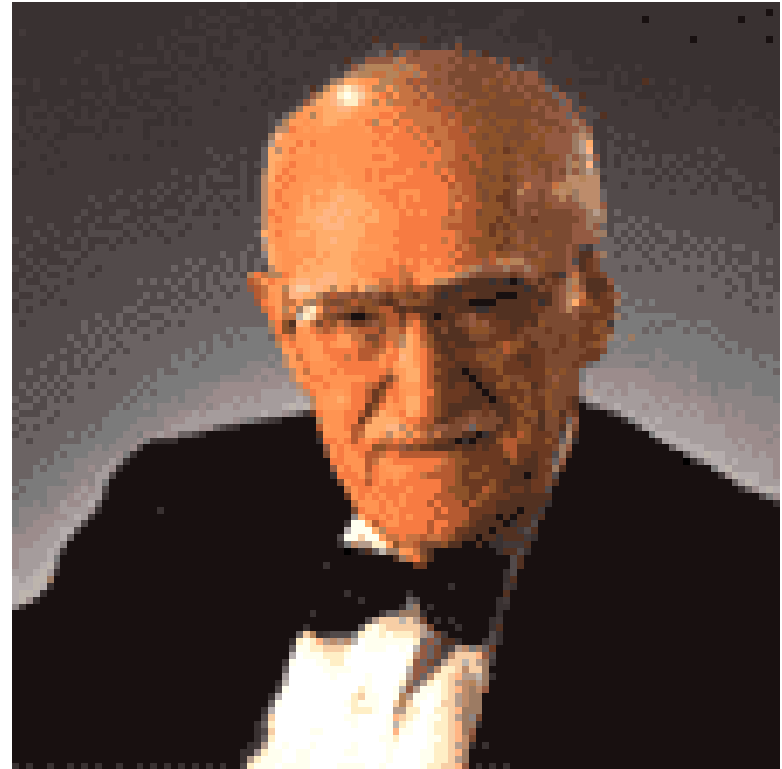
Note that the 14 points are about change

Deming's Deadly Diseases

1. Lack of constancy of purpose
2. Emphasis on short-term profits
3. Performance evaluation, merit rating, annual reviews
4. Mobility of management
5. Running a company on visible figures alone
6. Excessive medical costs for employee health care
7. Excessive costs of warranties

Joseph M. Juran

- Born in Romania (1904), 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



The Juran Trilogy

1. Planning
 2. Control
 3. Improvement
- These three processes are interrelated
 - Control versus breakthrough
 - Project-by-project improvement

Some of the Other “Gurus”

- Kaoru Ishikawa
 - Son of the founder of JUSE, promoted widespread use of basic tools
- Armand Feigenbaum
 - Author of Total Quality Control, promoted overall organizational involvement in quality,
 - Three-step approach emphasized quality leadership, quality technology, and organizational commitment
- Lesser gods, false prophets

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

Total Quality Management (TQM)

- TQM is “just another program”
- Value engineering
- Zero defects
- “Quality is free”

Recipe for Ineffectiveness and maybe Disaster

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

The ISO 9001:2000 standard has eight clauses: (1) Scope, (2) Normative References, (3) Definitions, (4) Quality Management Systems, (5) Management Responsibility, (6) Resource Management, (7) Product (or Service) Realization, and (8) Measurement, Analysis, and Improvement. Clauses 4 through 8 are the most important, and their key components and requirements are shown in Table 1-2. To become certified under the ISO standard, a company must select a **registrar** and prepare for a **certification audit** by this registrar. There is no single independent authority that licenses, regulates, monitors, or qualifies registrars. As we will discuss later, this is a serious problem with the ISO system. Preparing for the certification audit involves many activities, including (usually) an initial or phase I audit that checks the present quality management system against the standard. This is usually followed by establishing teams to ensure that all components of the key clause are developed and implemented, training of personnel, developing applicable documentation, and developing and installing all new components of the quality system that may be required. Then the certification audit takes place. If the company is certified, then periodic **surveillance audits** by the registrar continue, usually on an annual (or perhaps six-month) schedule.

- The ISO certification process focuses heavily on quality assurance, without sufficient weight given to quality planning and quality control and improvement

There is also evidence that ISO certification or certification under one of the other industry-specific standards does little to prevent poor quality products from being designed, manufactured, and delivered to the customer. For example, in 1999–2000, there were numerous incidents of rollover accidents involving Ford Explorer vehicles equipped with Bridgestone/Firestone tires and there were nearly 300 deaths in the United States alone attributed to these accidents, which led to a recall by Bridgestone/Firestone of approximately 6.5 million tires. Apparently, many of the tires involved in these incidents were manufactured at the Bridgestone/Firestone plant in Decatur, Illinois. In an article on this story in *Time* magazine (September 18, 2000), there was a photograph (p. 38) of the sign at the entrance of the Decatur plant which stated that the plant was “QS 9000 Certified” and “ISO 14001 Certified” (ISO 14001 is an environmental standard). Although the assignable causes underlying these incidents have not been fully discovered, there are clear indicators that despite quality systems certification, Bridgestone/Firestone experienced significant quality problems.

The Malcolm Baldrige National Quality Award

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

- The MBNQA process is a valuable assessment tool
- See Table 1-3 for Performance Excellence Criteria and point values

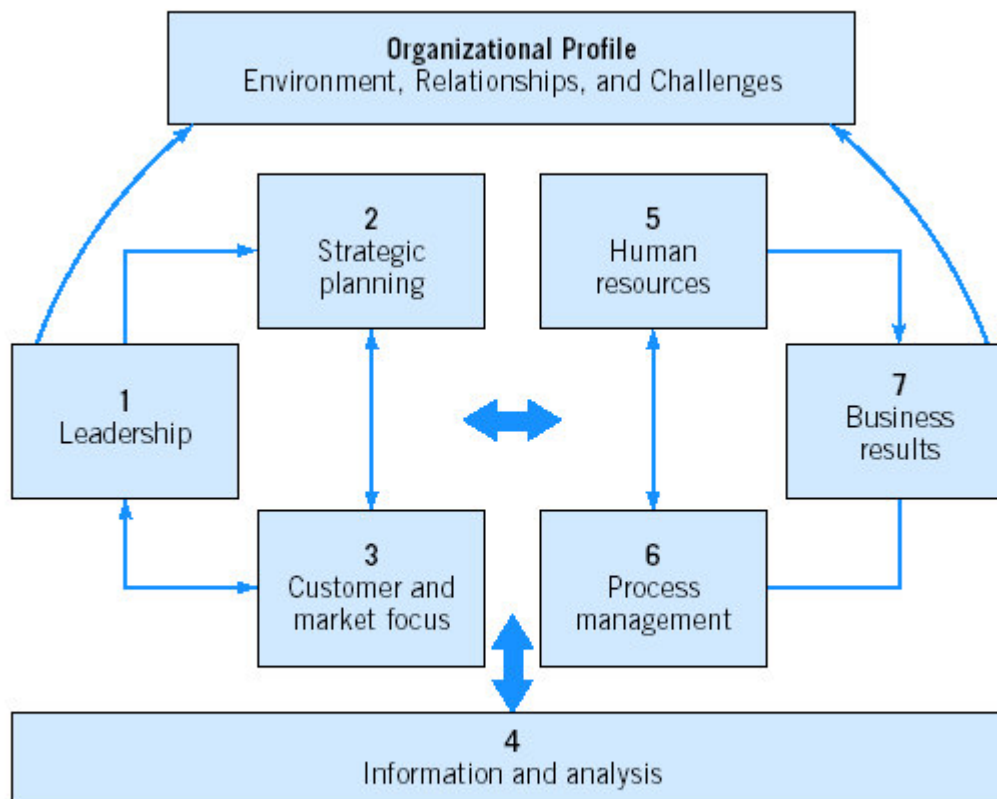


Figure 1-9 The structure of the MBNQA performance excellence criteria. (Source: Foundation for the Malcolm Baldrige National Quality Award, 2002 Criteria for Performance Excellence.)

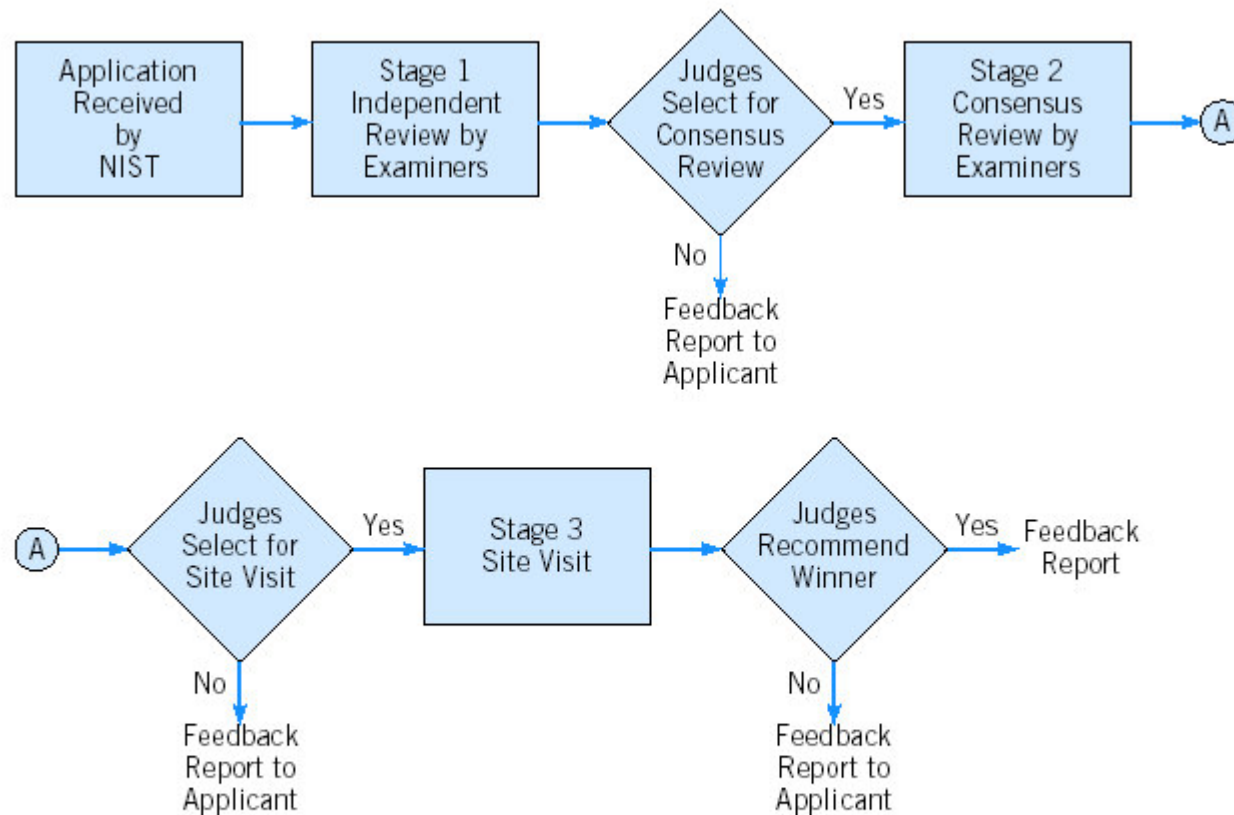


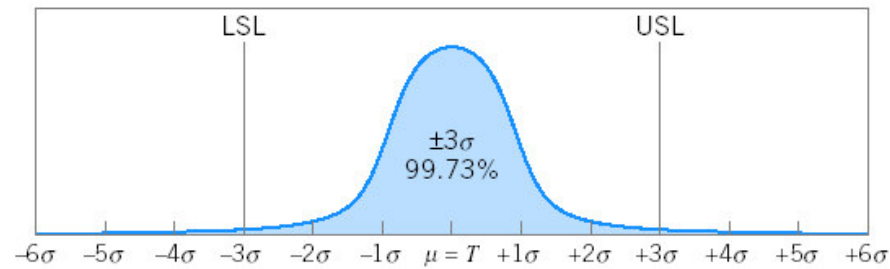
Figure 1-10 MBNQA process. (Source: Foundation for the Malcolm Baldrige National Quality Award, 2002 Criteria for Performance Excellence.)

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)

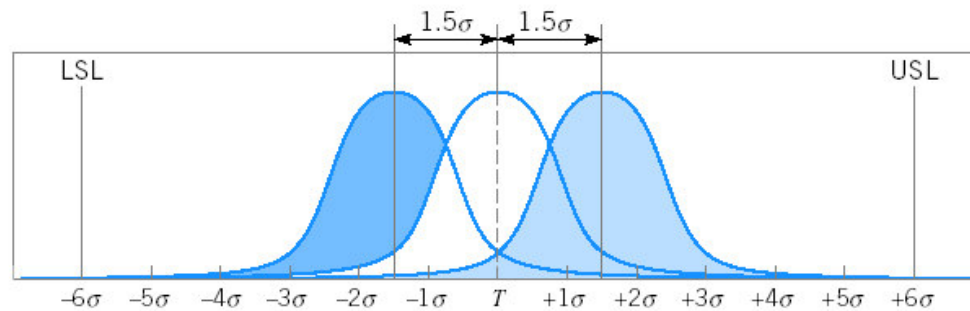
Focus of Six Sigma is on Process Improvement with an Emphasis on Achieving Significant Business Impact

- 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	99.999998	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 $\pm 1.5\sigma$ from the target

Figure 1-11 The Motorola six-sigma concept.

Why “Quality Improvement” is Important: A Simple Example

- A visit to a fast-food store: Hamburger (bun, meat, special sauce, cheese, pickle, onion, lettuce, tomato), fries, and drink.
- This product has 10 components - is 99% good okay?

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

$$\text{Family of four, once a month: } P\{\text{All meals good}\} = (0.9044)^4 = 0.6690$$

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

$$P\{\text{single meal good}\} = (0.999)^{10} = 0.9900, P\{\text{Monthly visit good}\} = (0.99)^4 = 0.9607$$

$$P\{\text{All visits in the year good}\} = (0.9607)^{12} = 0.6186$$

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)

Some Commercial Applications

- Reducing average and variation of days outstanding on accounts receivable
- Managing costs of consultants (public accountants, lawyers)
- Skip tracing
- Credit scoring
- Closing the books (faster, less variation)
- Audit accuracy, account reconciliation
- Forecasting
- Inventory management
- Tax filing
- Payroll accuracy

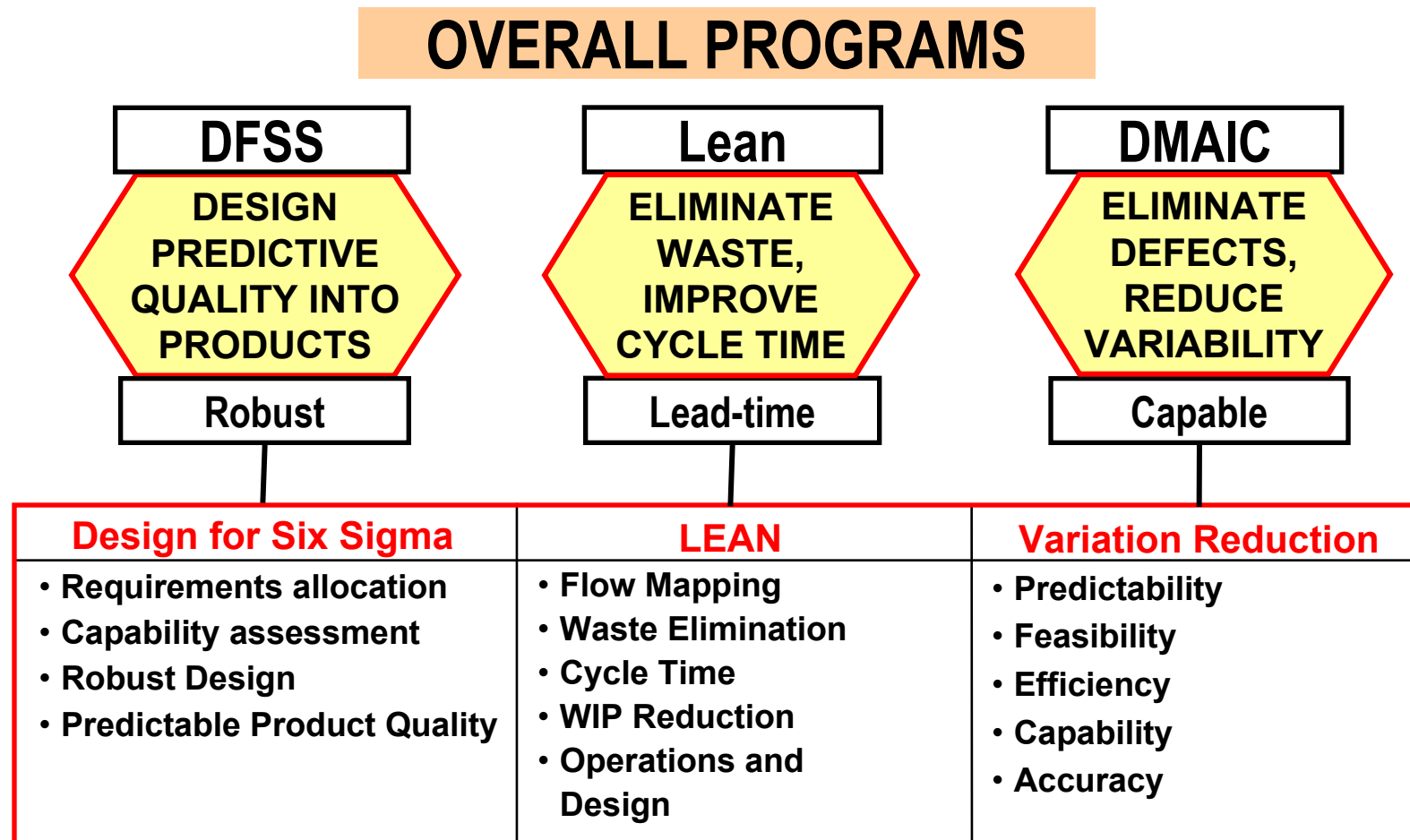
Six Sigma

- 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

What Makes it Work?

- Successful implementations characterized by:
 - Committed leadership
 - Use of top talent
 - Supporting infrastructure
 - Formal project selection process
 - Formal project review process
 - Dedicated resources
 - Financial system integration
- Project-by-project improvement strategy (borrowed from Juran)

The Process Improvement Triad: DFSS, Lean, and DMAIC



The “I” in DMAIC may become DFSS

DFSS Matches Customer Needs with Capability

- Mean and variability affects product performance and cost
 - Designers can predict costs and yields in the design phase
- Consider mean and variability in the design phase
 - Establish top level mean, variability and failure rate targets for a design
 - Rationally allocate mean, variability, and failure rate targets to subsystem and component levels
 - Match requirements against process capability and identify gaps
 - Close gaps to optimize a producible design
 - Identify variability drivers and optimize designs or make designs robust to variability
- Process capability impact design decisions

DFSS enhances product design methods.

Lean Focuses on Waste Elimination

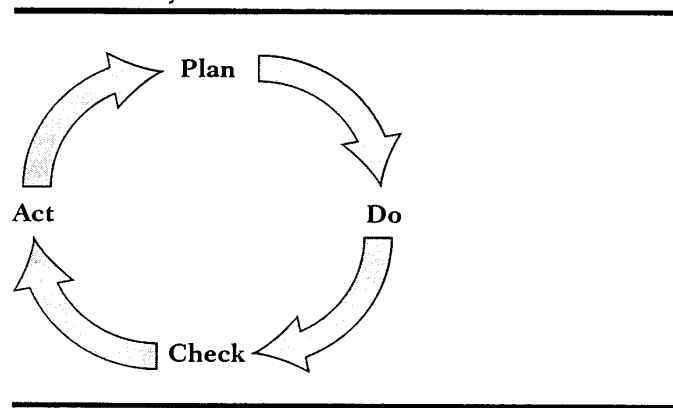
- Definition
 - A set of methods and tools used to eliminate waste in a process
 - Lean helps identify anything not absolutely required to deliver a quality product on time.
-
- Benefits of using Lean
 - Lean methods help reduce inventory, lead time, and cost
 - Lean methods increase productivity, quality, on time delivery, capacity, and sales

DMAIC Solves Problems by Using Six Sigma Tools

- DMAIC is a problem solving methodology
- Use this method to solve problems:
 - Define problems in processes
 - Measure performance
 - Analyze causes of problems
 - Improve processes—remove variations and nonvalue-added activities
 - Control processes so problems do not recur

Six Sigma

- DMAIC is closely related to the Shewhart cycle (variously called the Deming cycle, or the PDCA cycle)



Quality Costs

Table 1-4 Quality Costs

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

Legal Aspects of Quality

- Product liability exposure
- Concept of **strict liability**
 1. Responsibility of both manufacturer and seller/distributor
 2. Advertising must be supported by valid data

Implementing Quality Improvement

- A strategic management process, focused along the eight dimension of quality

Table 1-6 The Eight Dimensions of Quality from Section 1-1.1

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

- Suppliers and supply chain management must be involved
- Must focus on all three components: Quality Planning, Quality Assurance, and Quality Control and Improvement

IMPORTANT TERMS AND CONCEPTS

Acceptance sampling	Quality control and improvement
Appraisal costs	Quality engineering
Deming's 14 points	Quality of conformance
Designed experiments	Quality of design
Dimensions of quality	Quality planning
Fitness for use	Quality systems and standards
Internal and external failure costs	Six-Sigma
ISI 9000:2000	Specifications
Nonconforming product or service	Statistical process control (SPC)
Prevention costs	The Juran Trilogy
Product liability	The Malcolm Baldrige National Quality Award
Quality assurance	Total quality management (TQM)
Quality characteristics	Variability

Learning Objectives

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