

# Unit 6 - Quality Improvement

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

1. Define and discuss quality and quality improvement
2. Discuss the different dimensions of quality
3. Discuss the evolution of modern quality improvement methods
4. Discuss the role that variability and statistical methods play in controlling and improving quality
5. Describe the quality management philosophies of W. Edwards Deming, Joseph M. Juran, and Armand V. Feigenbaum
6. Discuss total quality management, the Malcolm Baldrige National Quality Award, 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

## Definitions – Meaning of Quality and Quality Improvement

### **The Eight Dimensions of Quality**

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

2

### Definition

**Quality** means fitness for use.

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

3

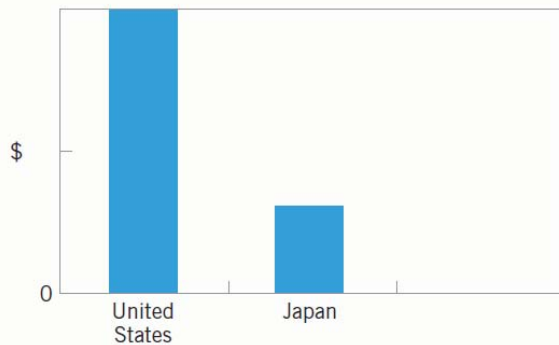
### Definition

**Quality** is inversely proportional to variability.

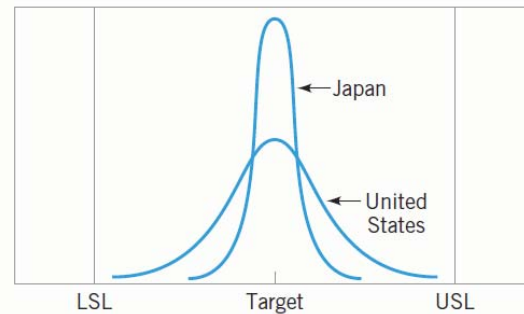
This is a modern definition of quality

4

# The Transmission Example



■ **FIGURE 1.1** Warranty costs for transmissions.



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

5

## 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.

6

# 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.

7

## 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

8

# 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 Frank Gilbreth and Henry Gantt.
1900–1930	Henry Ford—the assembly line—further refinement of work methods to improve productivity and quality; Ford developed mistake-proof assembly concepts, self-checking, and in-process inspection.
1901	First standards laboratories established in Great Britain.
1907–1908	AT&T begins systematic inspection and testing of products and materials.
1908	W. S. Gosset (writing as “Student”) introduces the <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	Henry Ford writes (with Samuel Crowtha) and publishes <i>My Life and Work</i> , 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 <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.

9

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.
1950–1975	Taiichi Ohno, Shigeo Shingo, and Eiji Toyoda develops the Toyota Production System an integrated technical/social system that defined and developed many lean principles such as just-in-time production and rapid setup of tools and equipment. K. Ishikawa introduces the cause-and-effect diagram.



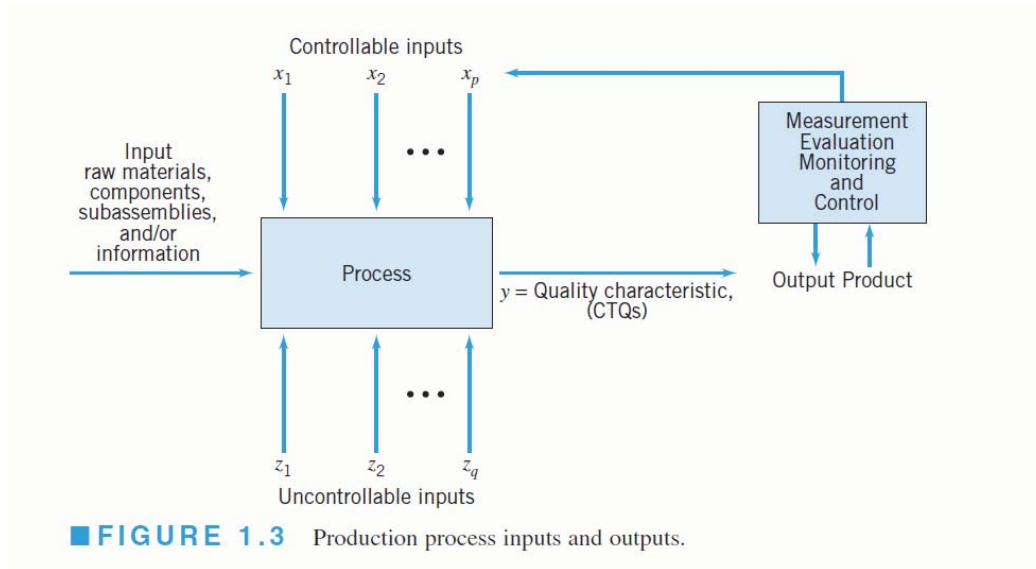
1950s	Classic texts on statistical quality control by Eugene Grant and A. J. Duncan appear.
1951	A. V. Feigenbaum publishes the first edition of his book <i>Total Quality Control</i> . JUSE establishes the Deming Prize for significant achievement in quality control and quality methodology.
1951+	G. E. 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.

11

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 <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. 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 <i>Quality Engineering</i> appears.
1990s	ISO 9000 certification activities increase in U.S. industry; applicants for the Baldrige award grow steadily; many states sponsor quality awards based on the Baldrige criteria.
1995	Many undergraduate engineering programs require formal courses in statistical techniques, focusing on basic methods for process characterization and improvement.
1997	Motorola's Six Sigma approach spreads to other industries.
1998	The American Society for Quality Control becomes the American Society for Quality (see <a href="http://www.asq.org">www.asq.org</a> ), 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. Organizations begin to integrate lean principles into their Six Sigma initiatives, and lean Six Sigma becomes a widespread approach to business improvement.

12

# Statistical Methods for Quality Control and Improvement



13

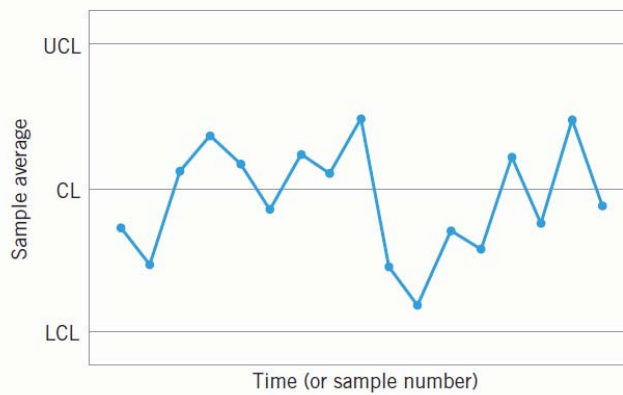
## Statistical Methods

- 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

14

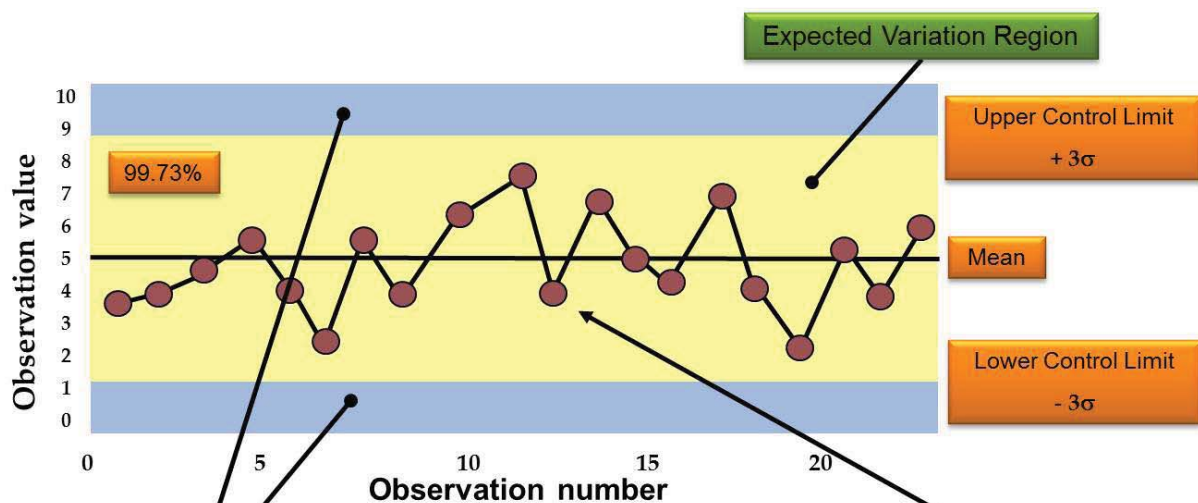
## Walter A. Shewart (1891-1967)

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



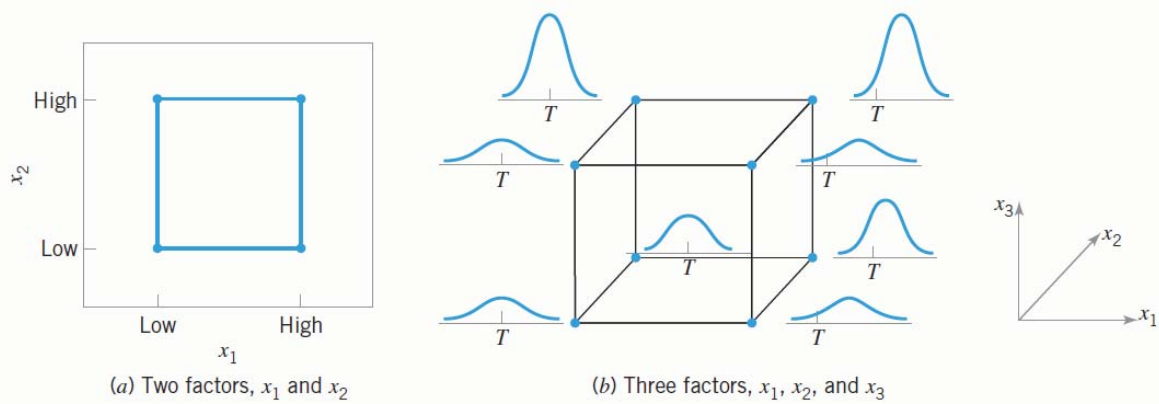
■ **FIGURE 1.4** A typical control chart.

15



Time ordered data that is evaluated for runs, trends, and patterns that are unlikely to have come from the process.



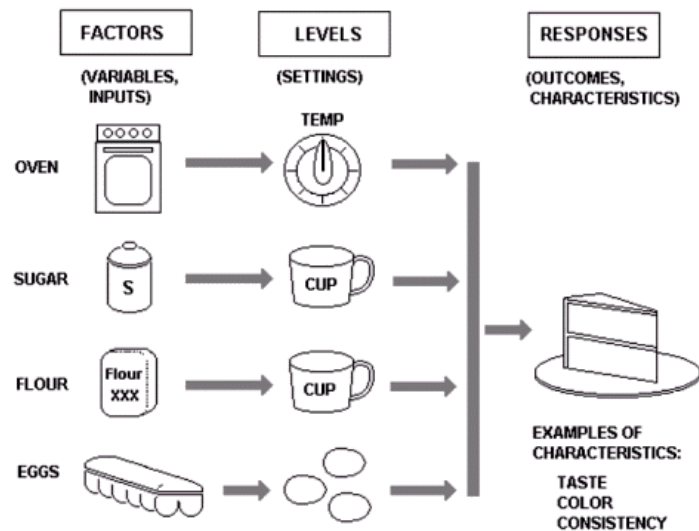
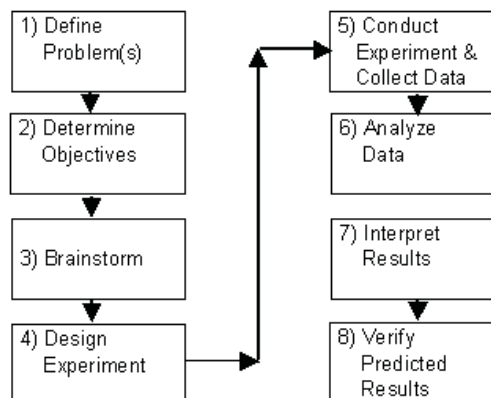


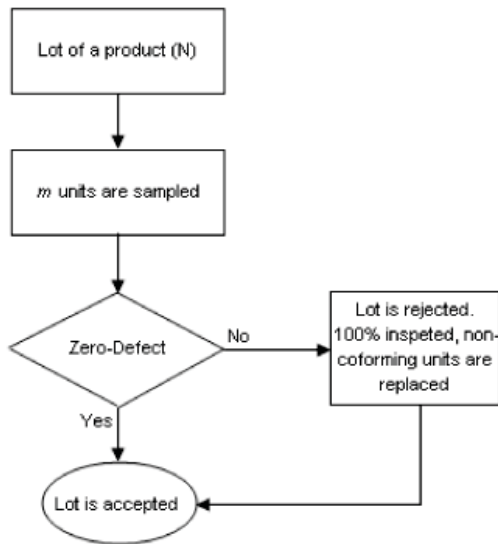
■ **FIGURE 1.5** Factorial designs for the process in Figure 1.3.

17

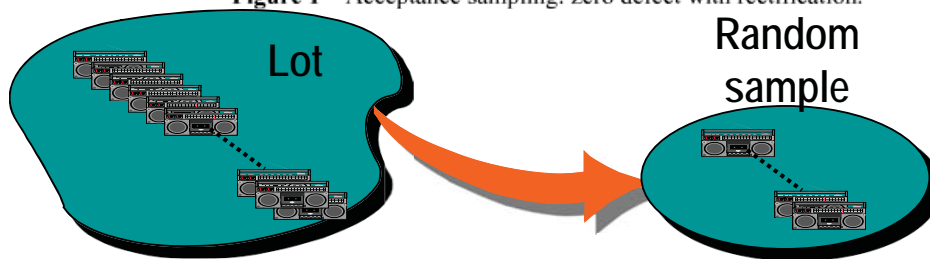
## A cake-baking process

### Experimental Design Process

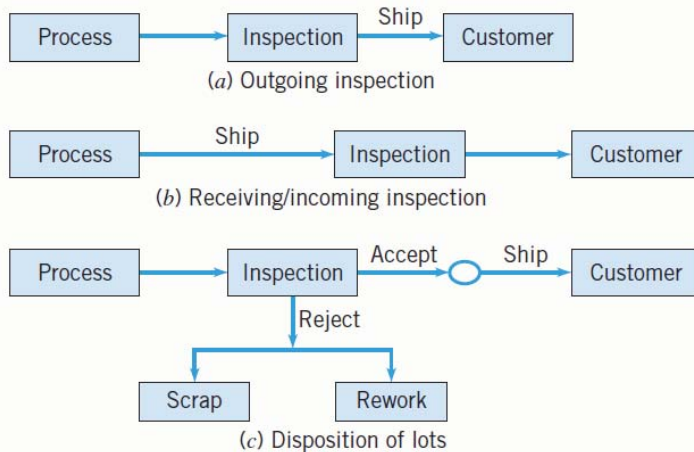




**Figure 1** – Acceptance sampling: zero defect with rectification.



19



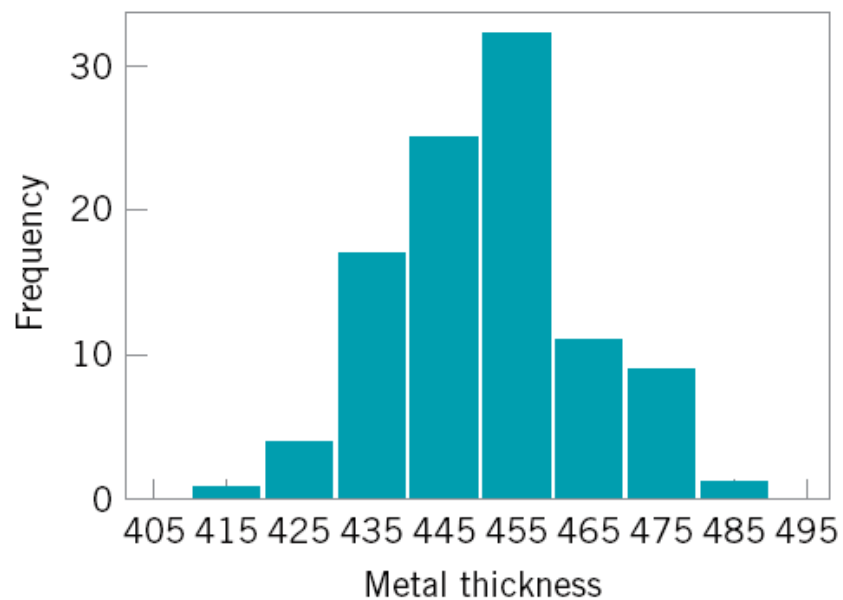
**FIGURE 1.6** Variations of acceptance sampling.

## The “Magnificent Seven” SPC Tools

1. Histogram
2. Check sheet
3. Pareto chart
4. Cause-and-effect diagram
5. Defect concentration diagram
6. Scatter diagram
7. Control chart

21

### Histogram



■ **FIGURE 3.3** Minitab histogram for the metal layer thickness data in Table 3.2.

22

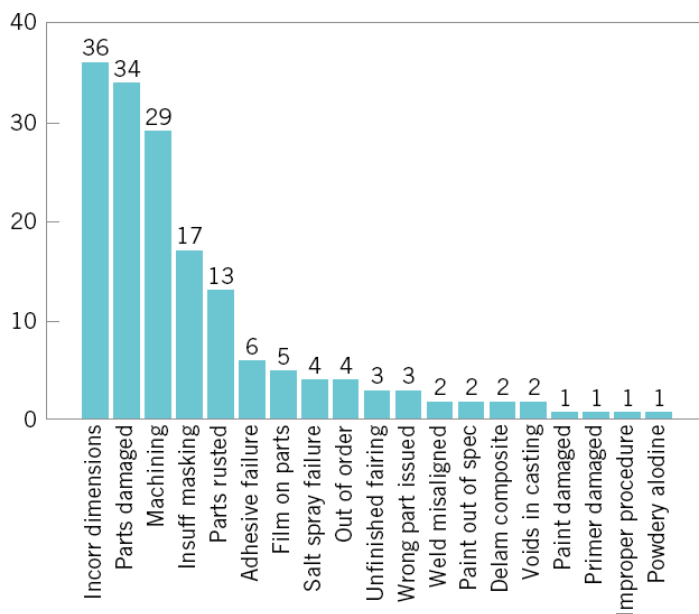
# Check Sheet

CHECK SHEET DEFECT DATA FOR 2002-2003 YTD																			
Part No.:	TAX-41																		
Location:	Bellevue																		
Study Date:	6/5/03																		
Analyst:	TCB																		
	2002												2003						
Defect	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	Total	
Parts damaged		1		3	1	2		1		10	3		2	2	7	2		34	
Machining problems			3	3				1	8		3		8	3				29	
Supplied parts rusted				1	1		2	9										13	
Masking insufficient			3	6	4	3	1											17	
Misaligned weld	2																	2	
Processing out of order	2														2			4	
Wrong part issued		1						2										3	
Unfinished fairing				3														3	
Adhesive failure					1					1			2			1	1	6	
Powdery alodine						1												1	
Paint out of limits							1							1				2	
Paint damaged by etching				1														1	
Film on parts							3		1	1								5	
Primer cans damaged								1										1	
Voids in casting										1	1							2	
Delaminated composite										2								2	
Incorrect dimensions											13	7	13	1		1	1	36	
Improper test procedure										1								1	
Salt-spray failure													4			2		4	
TOTAL	4	5	14	12	5	9	9	6	10	14	20	7	29	7	7	6	2	166	

■ FIGURE 5.16 A check sheet to record defects on a tank used in an aerospace application.

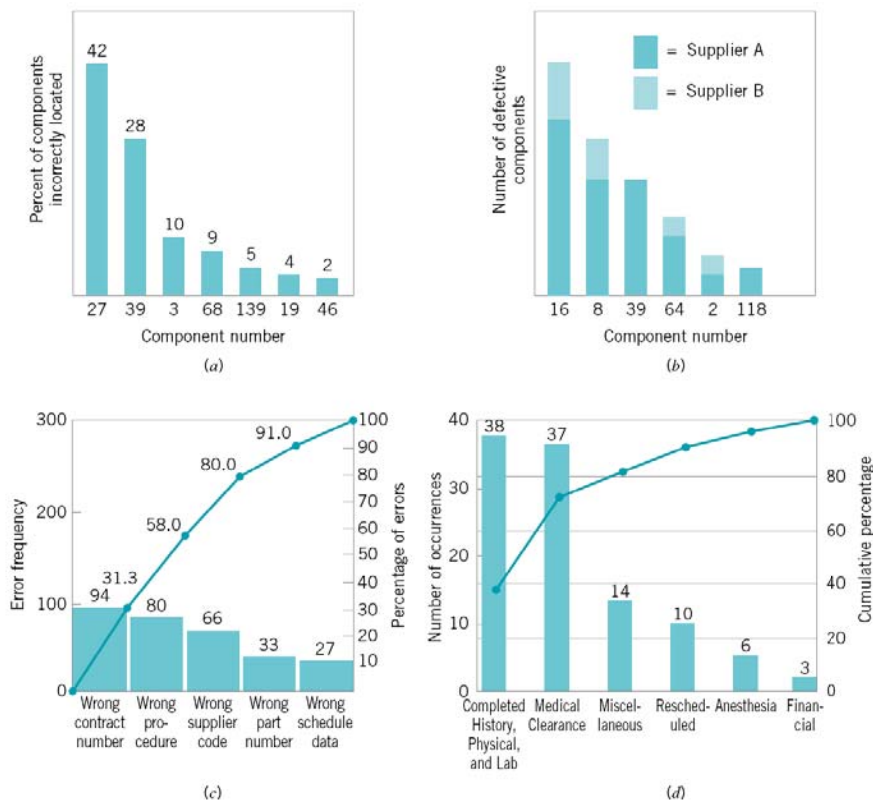
23

# Pareto Chart



■ FIGURE 5.17 Pareto chart of the tank defect data.

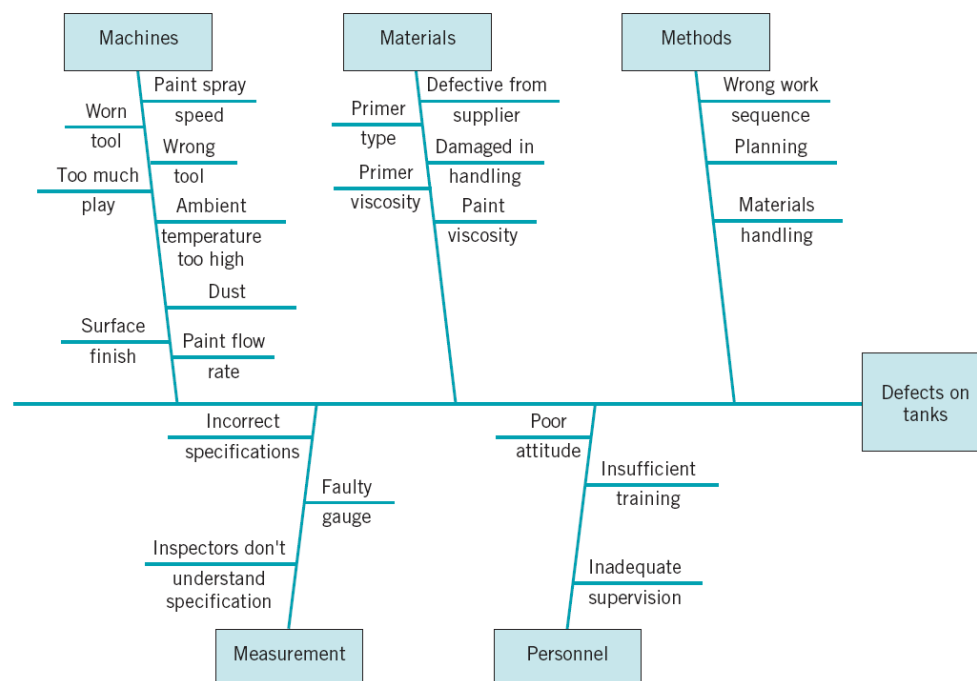
24



■ FIGURE 5.18 Examples of Pareto charts.

25

## Cause-and-Effect Diagram

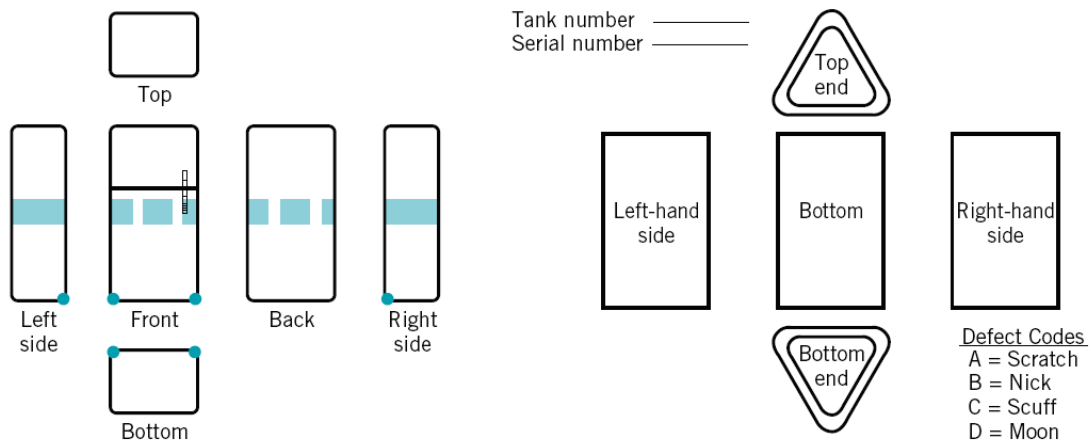


■ FIGURE 5.19 Cause-and-effect diagram for the tank defect problem.

26



## Defect Concentration Diagram

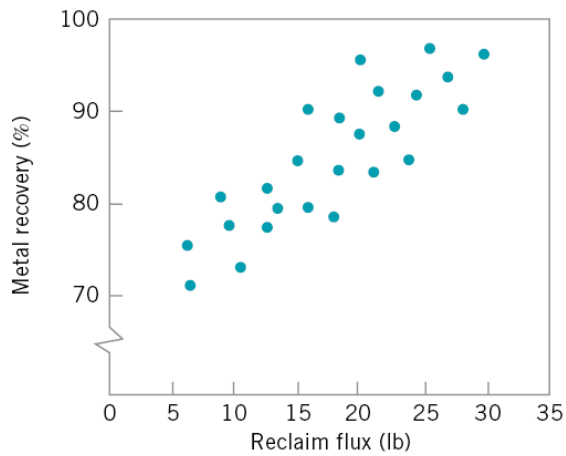


■ **FIGURE 5.20** Surface-finish defects on a refrigerator.

■ **FIGURE 5.21** Defect concentration diagram for the tank.

27

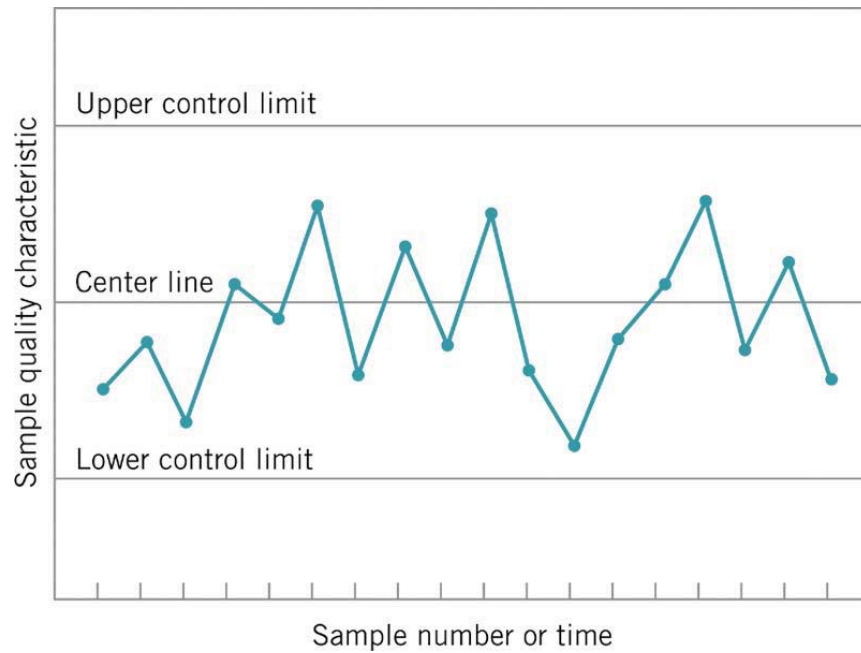
## Scatter Diagram



■ **FIGURE 5.22** A scatter diagram.

28

## Control chart



29

## Quality Costs

**■ TABLE 1.5**  
**Quality Costs**

### Prevention Costs

- Quality planning and engineering
- New products review
- Product/process design
- Process control
- Burn-in
- Training
- Quality data acquisition and analysis

### Appraisal Costs

- Inspection and test of incoming material
- Product inspection and test
- Materials and services consumed
- Maintaining accuracy of test equipment

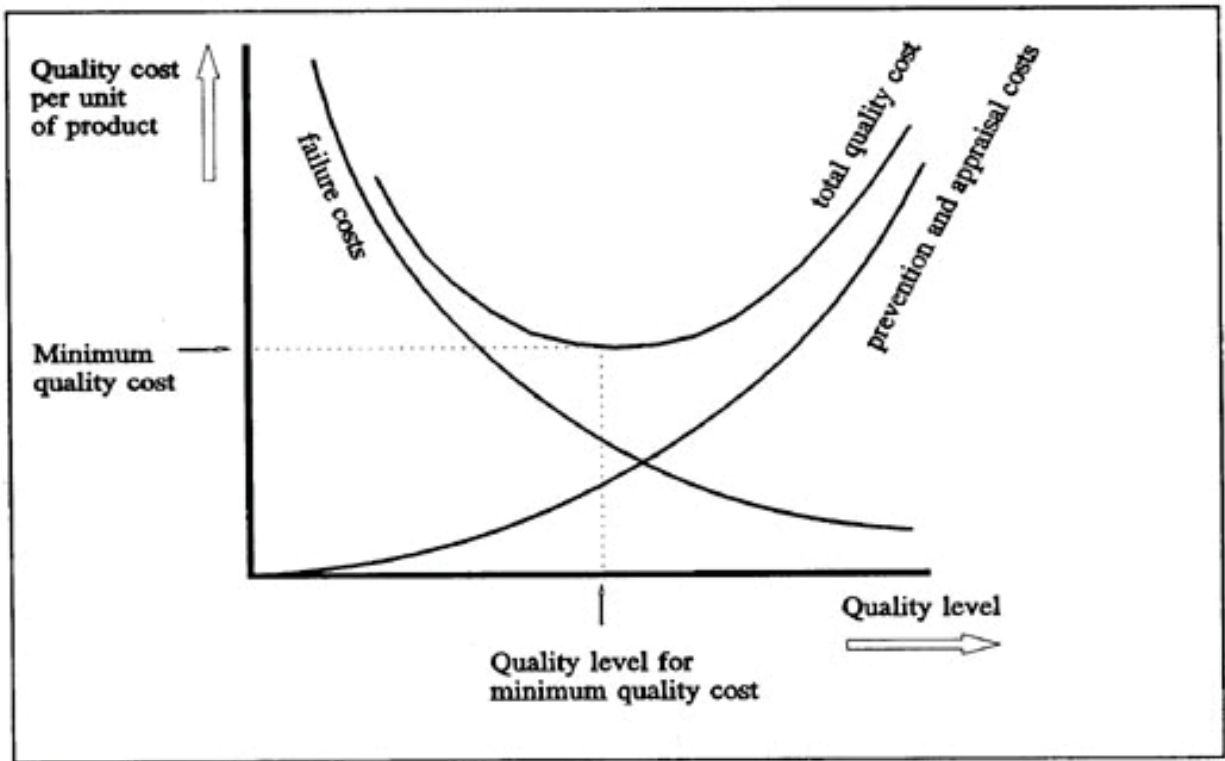
### Internal Failure Costs

- Scrap
- Rework
- Retest
- Failure analysis
- Downtime
- Yield losses
- Downgrading (off-specing)

### External Failure Costs

- Complaint adjustment
- Returned product/material
- Warranty charges
- Liability costs
- Indirect costs

30



31

## Leverage Effect on Quality Costs



32

# 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

33

**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.

34

**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.



# Implementing Quality Improvement

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

■ **TABLE 1.7**

**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

37

## 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



W. Edwards Deming  
1900 - 1993

38

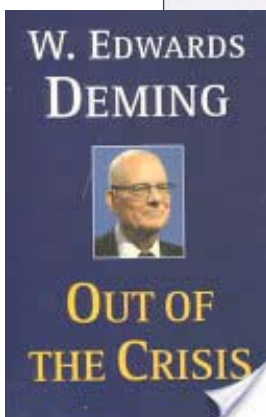
# Deming

- Deming was asked by JUSE (Japanese Union of Scientists and Engineers) 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

39

## Out of the Crisis

How Would You Rebuild a Country?

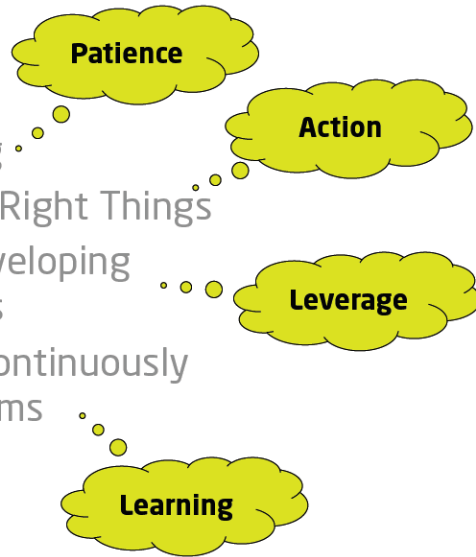


W.E. Deming

## Out of the Crisis

### Key Concepts

- Long-Term Thinking
- Focus on Doing the Right Things
- Create Value by Developing People and Partners
- Drive Learning by Continuously Solving Root Problems



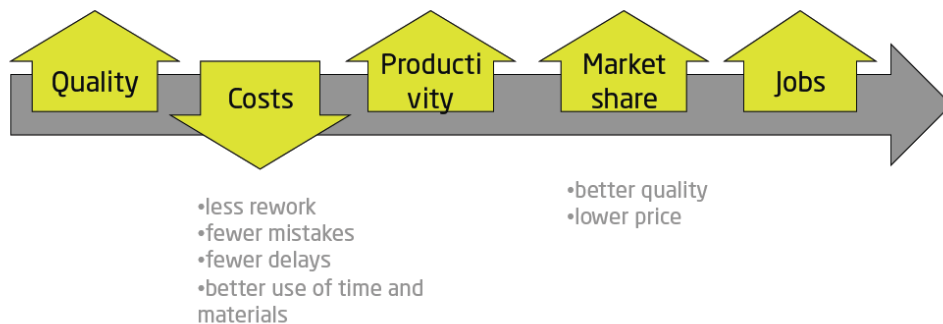
Manage.avi



41

## Out of the Crisis

### Fundamental Chain Reaction (1950)



**What will happen to our children in the United States if we don't solve the problem of quality?**



42

# 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

43

## 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

**Watch Video**

(<https://www.youtube.com/watch?v=tsF-8u-V4j4>)

44

## Out of the Crisis

### Sustainability and Long-Term Thinking

- 1. Create constancy of purpose toward improvement of product and service, with the aim to become competitive and stay in business, and to provide jobs.*



45

## Out of the Crisis

### Be the Change You Wish to See

- 2. Adopt the new philosophy. We are in a new economic age. Western management must awaken to the challenge, must learn their responsibilities, and take on leadership for change.*



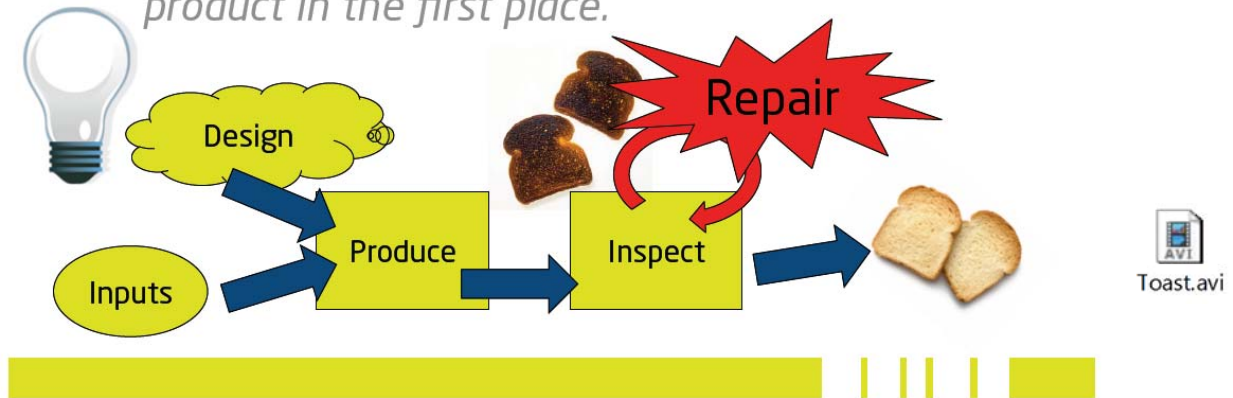
46



## Out of the Crisis

### Build Quality In

3. Cease dependence on inspection to achieve quality. Eliminate the need for inspection on a mass basis by building quality into the product in the first place.

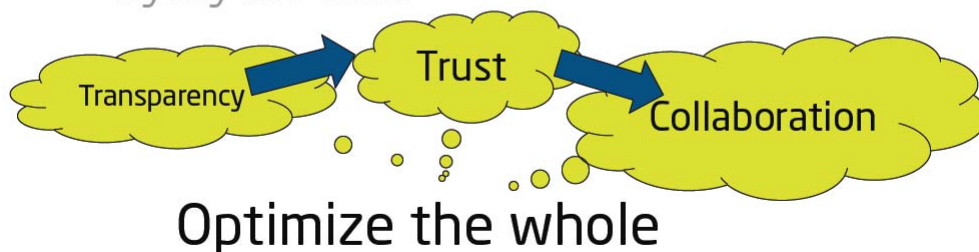


47

## Out of the Crisis

### Build on Trust and Respect for People

4. End the practice of awarding business on the basis of price tag. Instead, minimize total cost. Move towards a single supplier for any one item, on a long-term relationship of loyalty and trust.



48

# Out of the Crisis

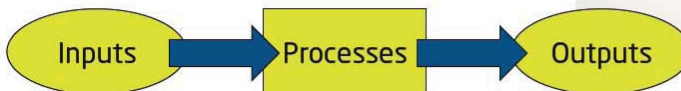
## Learn and Improve Continuously

*5. Improve constantly and forever the system of production and service, to improve quality and productivity, and thus constantly decrease cost.*

Look for the hundreds of small things you can improve. Don't try to plan a whole new department layout - or go after a big new installation of new equipment. There isn't time for these major items. Look for improvements on existing jobs, with your present equipment.

### Good Thinking, Good Products

品質と効率  
Quality and Efficiency  
品质与效率

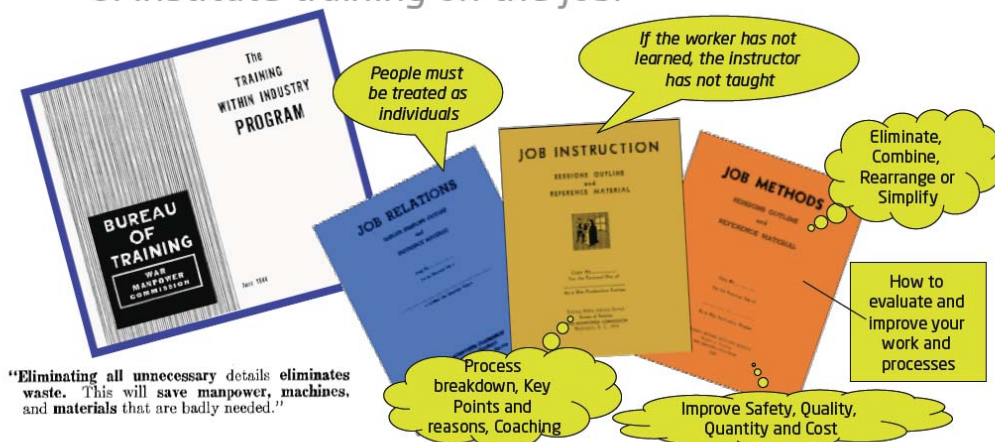


49

# Out of the Crisis

## Practise!

*6. Institute training on the job.*

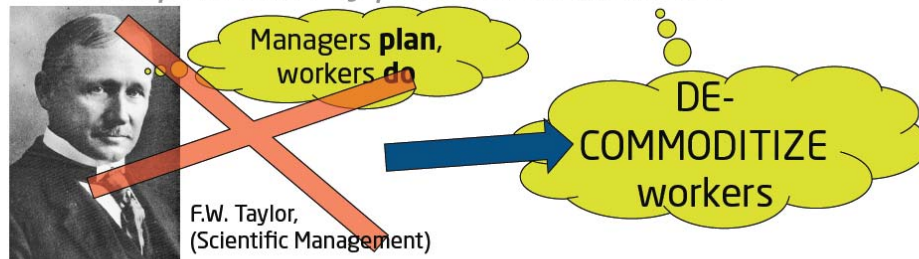


50

## Out of the Crisis

### Collaborative Leadership

*7. Institute leadership. The aim of supervision should be to help people and machines and gadgets to do a better job. Supervision of management is in need of overhaul, as well as supervision of production workers.*

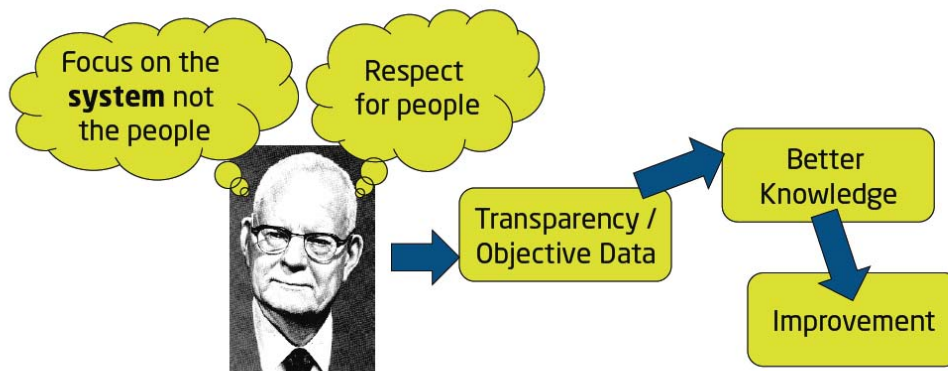


51

## Out of the Crisis

### Eliminate Fear

*8. Drive out fear, so that everyone may work effectively for the company.*



52

## Out of the Crisis

### Collaborate Across The Departments

9. Break down barriers between departments. People in research, design, sales, and production must work as a team, to foresee problems of production and in use that may be encountered with the product or service.



## Out of the Crisis

### Respect for People

10. Eliminate slogans, exhortations, and targets for the work force asking for zero defects and new levels of productivity. Such exhortations only create adversarial relationships, as the bulk of the causes of low quality and low productivity belong to the system and thus lie beyond the power of the work force.

Remove the CAUSE of the problem

The worker is not the problem. The problem is at the top! Management!



## Out of the Crisis

### Build on Intrinsic Motivation

11. a. *Eliminate work standards (quotas) on the factory floor. Substitute leadership.*  
b. *Eliminate management by objective. Eliminate management by numbers, numerical goals. Substitute workmanship.*

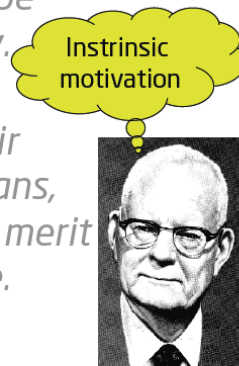


55

## Out of the Crisis

### Let Everyone Do a Good Job

12. a. *Remove barriers that rob the hourly worker of his right to pride of workmanship. The responsibility of supervisors must be changed from sheer numbers to quality.*  
b. *Remove barriers that rob people in management and in engineering of their right to pride of workmanship. This means, inter alia, abolishment of the annual or merit rating and of management by objective.*



56



## Out of the Crisis

### Keep Learning

*13. Institute a vigorous program of education and self-improvement.*



57

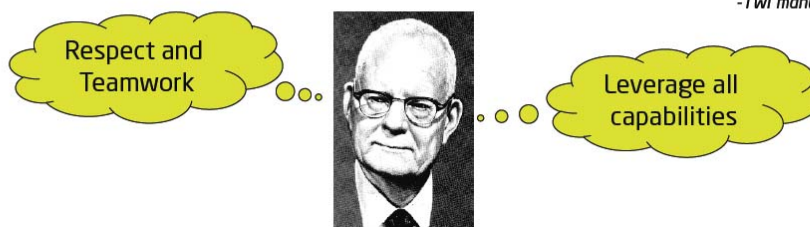
## Out of the Crisis

### Everyone's Contribution Counts

*14. Put everyone in the company to work to accomplish the transformation. The transformation is everyone's work.*

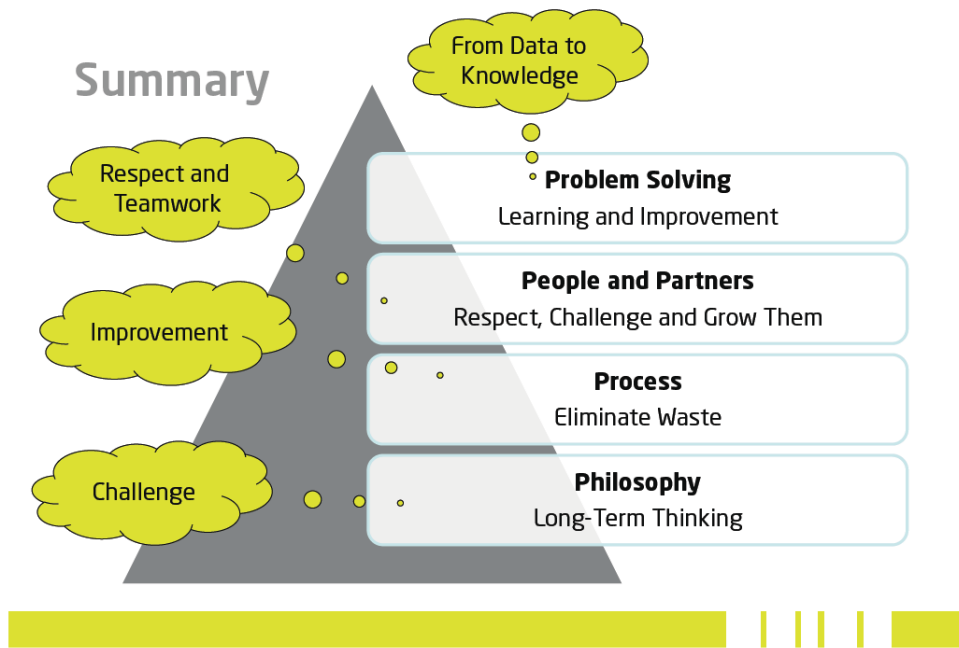
Confidence and resourcefulness in how to proceed, not standardized solutions and rules, are developed. These enable supervisors to get good teamwork, to give better service, and to get out more production.

-TWI manual, WW2

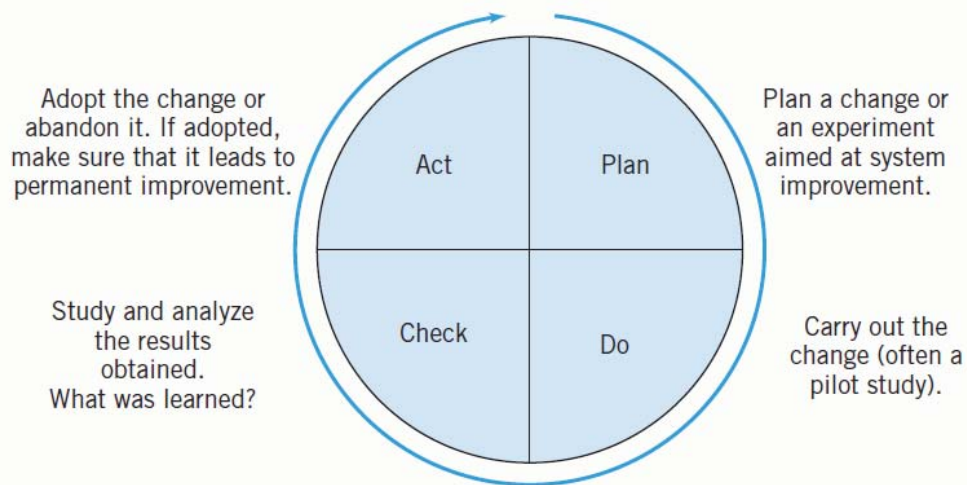


58

# Out of the Crisis



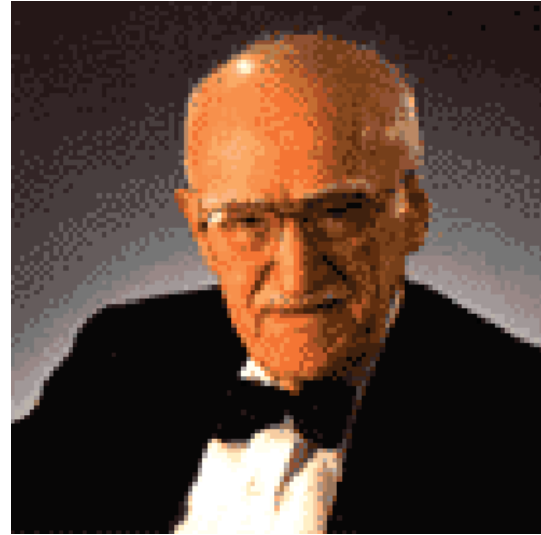
59



■ **FIGURE 1.9** The Shewhart cycle.

# 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



61

## The Juran Trilogy

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

62

## 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

63

## 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

64

# Total Quality Management (TQM)

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

## Recipes for Ineffectiveness and maybe Disaster

65

## 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

66

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

67

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.

68

# 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)

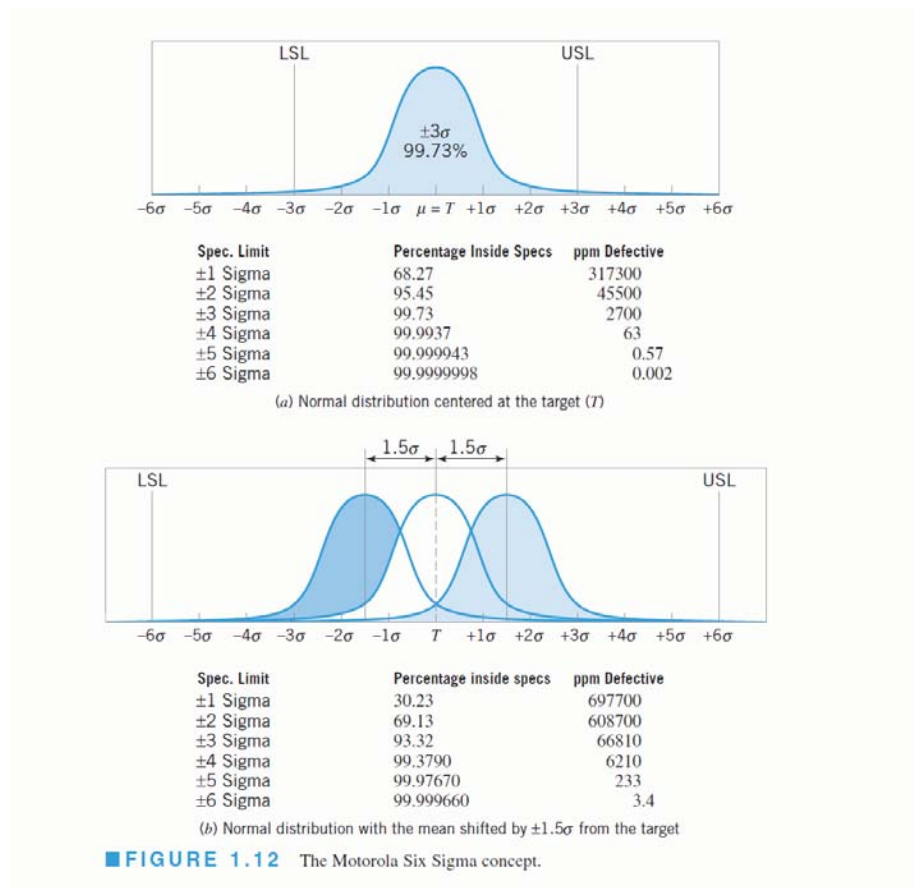
69

## 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

70





71

## 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?

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

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

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

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

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

72

# 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)

73

## 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

74

# 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

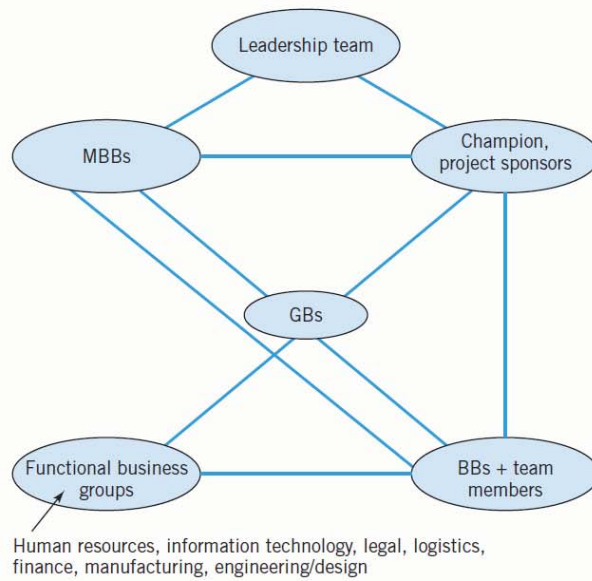
75

## 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)

76

Structure of a typical Six Sigma organization



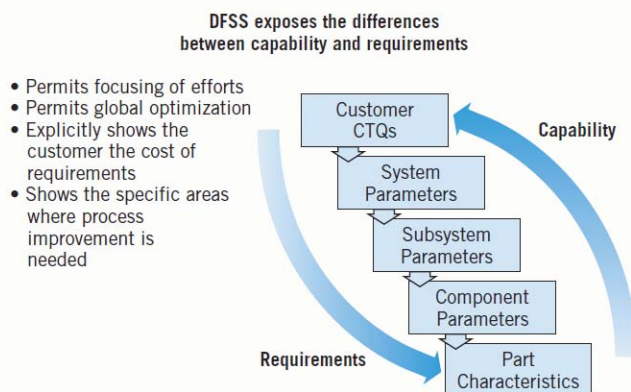
■ **FIGURE 1.13** The structure of a Six Sigma organization. (Adapted from R. D. Snee and R. W. Hoerl, *Six Sigma Beyond the Factory Floor*, Upper Saddle River, NJ: Pearson Prentice Hall, 2005.)

77

## 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



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

\* **CTQs** are the internal critical quality parameters that relate to the wants and needs of the customer.

78

# 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.***

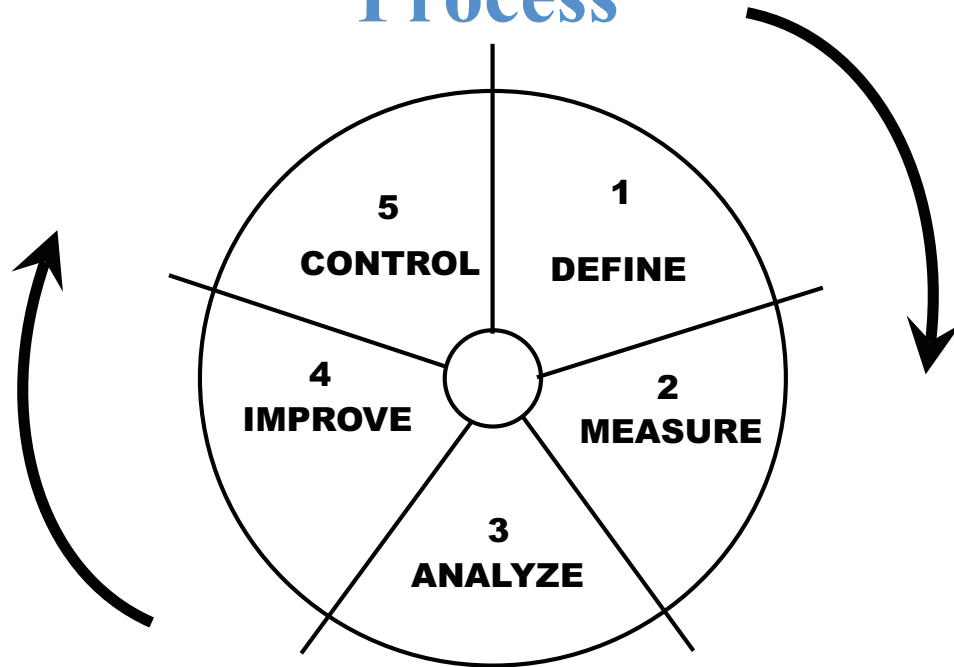
79

## Question asked in the DFSS process

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

80

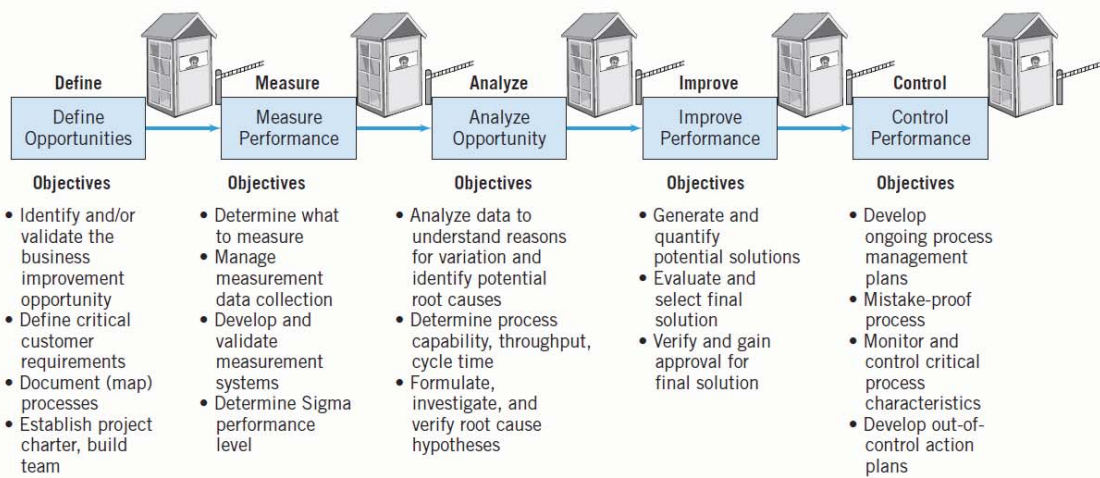
# Overview of the DMAIC Process



*Adapted from: [www.asq702.org/downloads/Intro\\_to\\_DMAIC.ppt](http://www.asq702.org/downloads/Intro_to_DMAIC.ppt)*

## DMAIC Solves Problems by Using Six Sigma Tools

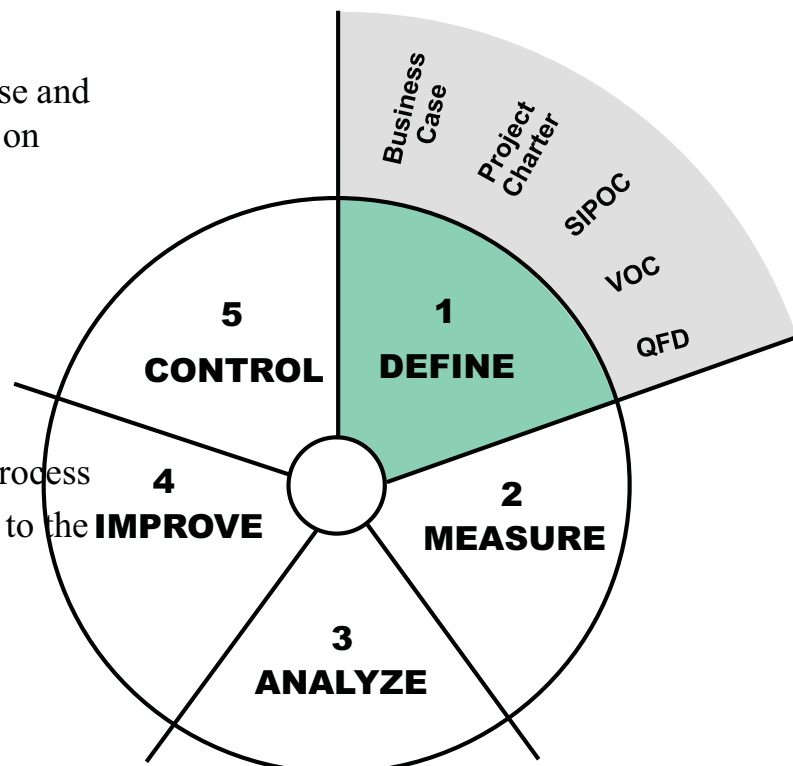
- DMAIC is a problem solving methodology
- Closely related to the Shewhart Cycle
- Use this method to solve problems:
  - Define problems in processes
  - Measure performance
  - Analyze causes of problems
  - Improve processes – remove variations and non-value-added activities
  - Control processes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



■ **FIGURE 2.1** The DMAIC process.

## Phase 1: Define

- **Goal**
  - Define the project's purpose and scope and get background on the process and customer
- **Output**
  - A clear statement of the intended improvement and how it is to be measured
  - A high-level map of the process
  - A list of what is important to the customer





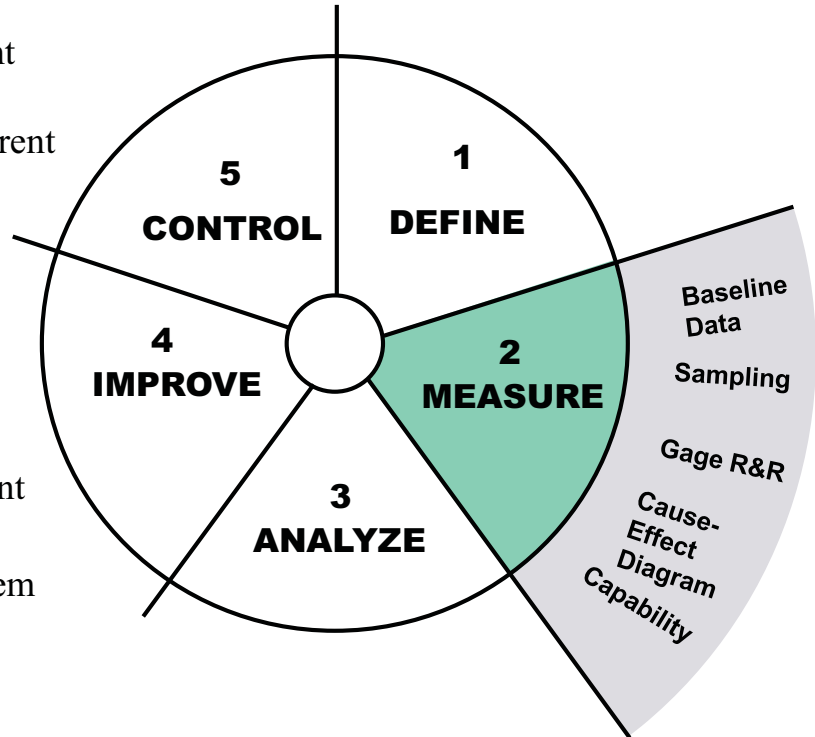
## Phase 2: Measure

- **Goal**

- Focus the improvement effort by gathering information on the current situation

- **Output**

- Data that pinpoints problem location or occurrence
- Baseline data on current process sigma
- A more focused problem statement



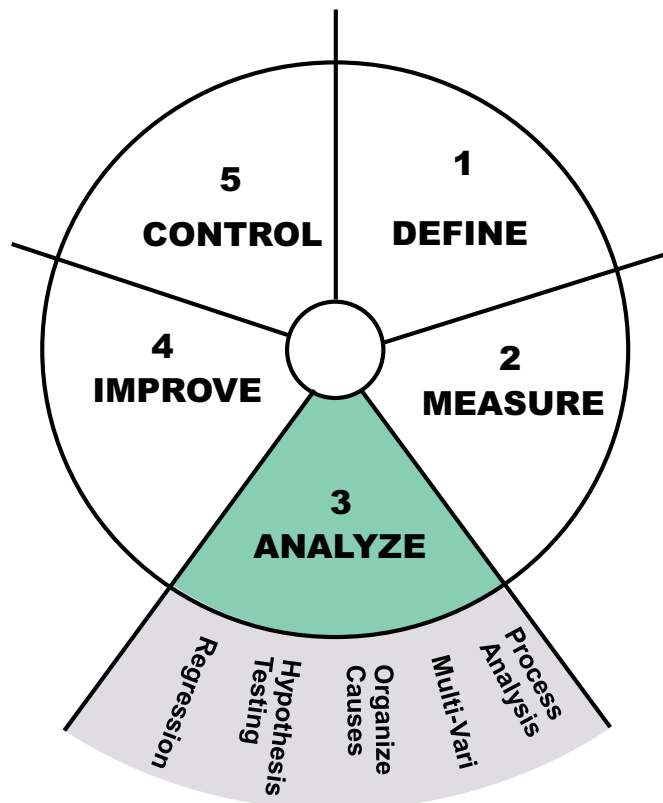
## Phase 3: Analyze

- **Goal**

- Identify deep root causes and confirm them with data

- **Output**

- A theory that has been tested and confirmed



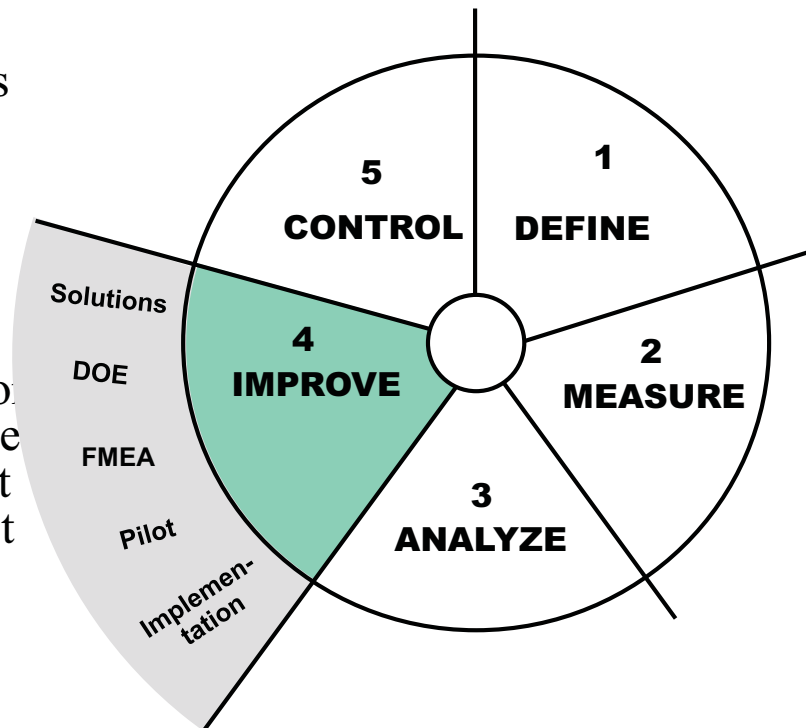
## Phase 4: Improve

- **Goal**

- Develop, pilot, and implement solutions that address root causes.

- **Output**

- Identification of planned, tested actions that should eliminate or reduce the impact of the identified root causes



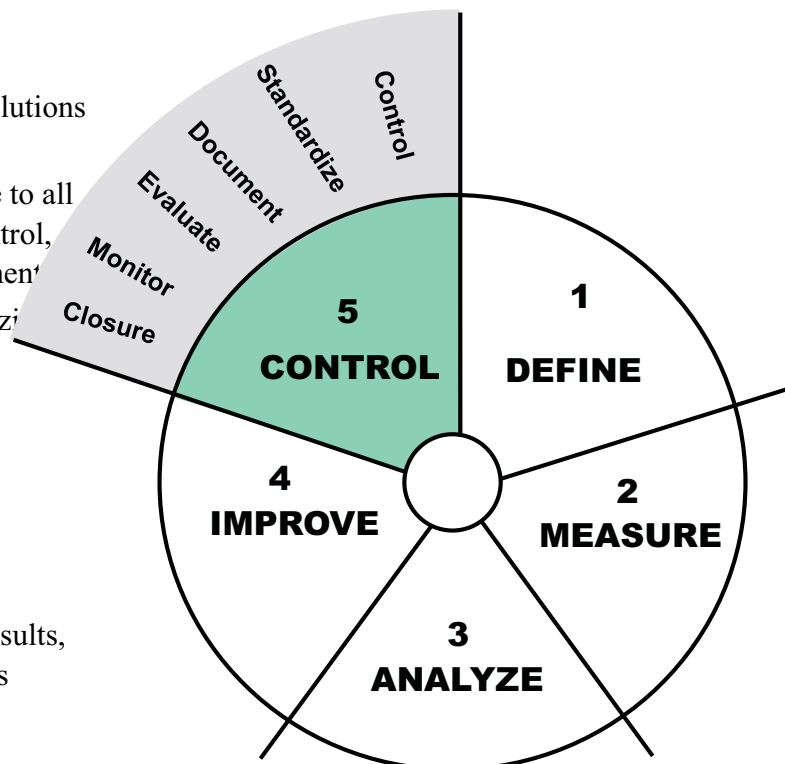
## Phase 5: Control

- **Goal**

- Use data to evaluate both the solutions and the plans
- Validate that all changes adhere to all operating company change control, GMP, and compliance requirements
- Maintain the gains by standardizing processes
- Outline next steps for on-going improvement

- **Output**

- Before-and-After analysis
- Monitoring system
- Completed documentation of results, learnings, and recommendations



# DMAIC Pathway

