Introduction to Statistical Quality Control, 6th Edition,
Douglas C. Montgomery, 2009, Wiley
Learning Outcomes of the course:

When you complete this course, you should be able to:

- Explain the history of Quality control briefly,
- Speak about Quality Science “Gurus”,
- Discuss the characteristics and Dimensions of Quality,
- Describe the Production Process (Inputs and Outputs),
- Use different Statistical Methods for Quality Control,
- Apply Quality Control to real life tasks,
- Mention the benefits from Using the Control Charts,
- Discuss the Process Capability Index,
- Define Acceptance Sampling and Reliability,
- Use Software programs for SQC.

Learning Outcomes of the first Chapters

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
Course Content and Outline

- Introduction to Quality
- TQM
- 6 Sigma
- ISO 9001
- Fundamentals of Statistics
- Control Charts for Variables
- Additional SPC techniques for Variables

Course Content and Outline (Cont.)

- Control Charts for Attributes
- Process Capability
- Sampling
- Reliability
Definitions of Quality

What is Quality?

- Degree of excellence, or general excellence (…has quality)
- Attribute or faculty (…Has many good qualities)
- Relative nature, character, or property

Definitions of Quality-Continued

What is Quality-Continued?

- Quality is conformance to requirements or specifications (Crosby 1979)
- Fitness for use (Juran 1988)
- Degree to which a set of inherent characteristics fulfills requirements (ISO 9000-2000)
Definitions of Quality (cont.)

- Transcendent definition: excellence
- Product-based definition: quantities of product attributes
- User-based definition: fitness for intended use
- Value-based definition: quality vs. price
- Manufacturing-based definition: conformance to specifications

The Dimensions of Quality

<table>
<thead>
<tr>
<th>DIMENSION</th>
<th>MEANING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance</td>
<td>Primary product characteristics</td>
</tr>
<tr>
<td>Features</td>
<td>Secondary characteristic</td>
</tr>
<tr>
<td>Conformance</td>
<td>Meeting specifications or industry standards</td>
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<td>Reliability</td>
<td>Consistency of performance over time</td>
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<td>Durability</td>
<td>Useful life</td>
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<tr>
<td>Service</td>
<td>Resolution of problems and complaints</td>
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<td>Response</td>
<td>Human-to-human interface</td>
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<tr>
<td>Aesthetics</td>
<td>Sensory characteristics</td>
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<tr>
<td>Reputation</td>
<td>Past performance and other intangibles</td>
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</table>
The Meaning of Quality and Quality Improvement

Dimensions of Quality

Quality Engineering Technology

- Aesthetics
- Features
- Perceived Quality
- Conformance to standards
- Performance
- Reliability
- Durability
- Serviceability

- **Reliability:** How often does the product fail?
  - How often does this car require repair?
Dimensions of Quality (cont.)

- **Performance:** Will the product perform its intended job?
  - Evaluate software spreadsheet packages. One outperform another with respect to the execution speed

- **Durability:** How long does the product last?
  - The product should perform satisfactorily over a long period of life

- **Perceived quality:** What is the reputation of the company selling this product?
  - Prefer to use a particular airline in which the flight almost always arrive on time and does not lose or damage the luggage

Dimensions of Quality (cont.)

- **Serviceability:** How easy is it to repair the product?
  - If amazon.com sends the wrong book, how hard is it to get this error corrected?
  - How long did it take a credit card company to correct an error in your bill?

- **Aesthetics:** What does the product look like?
  - Do you like the box in which Shoes are packaged?

- **Features:** What will the product do beyond the basics?
  - Added features
  - Spreadsheet software package that has built in statistical analysis features
Dimensions of Quality (cont.)

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

  Alternatively, quality improvement is also seen as “waste reduction”.

Dimensions of Quality – Transmission Example

Figure 1-2  Distributions of critical dimensions for transmissions.

Your customer does not see the mean of your process, he/she only sees the variability around that target that you have not removed.
Quality Engineering Terminology

Quality Characteristics

• Physical - length, weight, voltage, viscosity
• Sensory - taste, appearance, color
• Time Orientation - reliability, durability, serviceability

*Quality engineering* is the set of operational, managerial, and engineering activities that a company uses to ensure that the quality characteristics of a product are at the nominal or required levels.
Quality Engineering Terminology

Two types of data

- Attributes Data - discrete data, often in the form of counts.
- Variables Data - continuous measurements such as length, weight.

Specifications

Quality characteristics being measured are often compared to standards or specifications.

- Nominal or target value
- Upper Specification Limit (USL)
- Lower Specification Limit (LSL)
Quality Engineering Terminology

• When a component or product does not meet specifications, they are considered to be *nonconforming.*
• A nonconforming product is considered *defective* if it has one or more *defects.*
• *Defects* are nonconformities that may seriously affect the safe or effective use of the product.

A new car is purchased
• A bubble in the paint on the door is noticed
  – Nonconformity – yes
  – Defective car - no
Quality Engineering Terminology

- Concurrent Engineering
  Team approach to design. Specialists from manufacturing, quality engineering, management, etc. work together for product or process improvement.
Inherent (natural) variability

- No two products are ever identical
  - Slight differences in materials
  - Slight differences in machine settings
  - Slight differences in operators
  - Slight differences in ambient temperature during production

Historical Review

- Skilled craftsmanship during Middle Ages
- Industrial Revolution: rise of inspection and separate quality departments
- Statistical methods at Bell System (1924)
- The American Society for Quality (1946)
- Deming (1950)
- Juran (1954)
Historical Review-Continued

- First Quality Control Circles (1960)
- 1980s
  - TQM
    - Statistical Process Control, SPC
    - Malcolm Baldrige National Quality Award
    - Taguchi
- ISO (1990)
- Via Internet (2000)

A Brief History of Quality Control and Improvement

(Refer to Table 1-1)

- Walter Shewhart (1924) introduced statistical control chart concepts.
- The American Society for Quality Control formed in 1946 (now known as the American Society for Quality (ASQ)).
- 1950s and 1960s saw an increase in reliability engineering, experimental design, and statistical quality control
A Brief History of Quality Control and Improvement

- Malcolm Baldridge National Quality Award is established in 1988.
- ISO 9000 certification activities increase in U.S. industry in the 1990s.
- EQFM (European Quality Function Model)

Walter A. Shewart (1891-1967)
- Trained in engineering and physics
- Long career at Bell Labs
- Developed the first control chart about 1924

Figure 1-1: A typical control chart.
PDCA ("Plan-Do-Check-Act") is an iterative four-step problem-solving process typically used in Quality control.

It is also known as the Deming Cycle, Shewhart cycle, Deming Wheel, or Plan-Do-Study-Act.
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Shewhart Cycle

**PLAN:**
Establish the objectives and processes necessary to deliver results in accordance with the specifications.

**DO:**
Implement the processes.

**CHECK:**
Monitor and evaluate the processes and results against objectives and specifications and report the outcome.

**ACT:** Apply actions to the outcome for necessary improvement. This means reviewing all steps (Plan, Do, Check, Act) and modifying the process to improve it before its next implementation.

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A Brief History of Quality Control and Improvement

(Refer to Table 1-1)

- Competition from foreign industries (Japan) increases during the 1970s and 1980s.
- Statistical methods for quality improvement use increases in the United States during the 1980s
- Total Quality Management (TQM) emerges during 1970s and into the 1980s as an important management tool to implement statistical methods.
Quality Philosophy and Management Strategies

Three Important Leaders:

• W. Edwards Deming  
  - Emphasis on statistical methods in quality improvement  
    (see Deming’s 14 points)

• Joseph Juran  
  - Emphasis on managerial role in quality implementation

• Armand V. Feigenbaum  
  - Emphasis on organizational structure

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
• Demanded management commitment to use statistical methods
• Deming Prize in Japan
  – For quality improvement
• Deming was a harsh critic of US management practices

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
Deming’s 14 Points (cont.)

8. Drive out fear
9. Break down barriers between departments
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

1. Create a constancy of purpose

• Focus on the improvement of products and services
• Constantly improve product design and performance
• Invest in R&D
• Innovate
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2. Adopt a new philosophy

- Eliminate defective products
  - It costs as much to produce a defective unit as a good one
- Dealing with scrap and rework is very expensive

3. Don't rely on inspection

- Inspection only sorts out defectives
  - Already have paid to produce them
- Inspection is too late in the process
- It's also ineffective
- Prevent defectives through process improvement
4. Don’t award business on price alone

- Consider supplier quality as well
  - Give preference to those suppliers that demonstrate process control and process capability

5. Focus on continuous improvement

- Involve the workforce
- Use statistical techniques
6. Invest in training

- Everyone should be trained in the technical aspects of their job, QC, and process improvement
- Workers should be encouraged to put this training to use

7. Practice modern supervision methods

- Help the employees improve the system in which they work
8. Drive out fear

- Create an environment where the workers will ask questions, report problems, or point out conditions that are barriers to quality

9. Break down the barriers

- Break down the barriers between the functional areas of the business
- Only through teamwork can quality and process improvement take place
10. Eliminate targets and slogans

- Useless without a plan for the achievement of the target or goal
- Instead, improve the system and provide information on that

11. Eliminate quotas

- Numerical quotas and work standards often conflict with quality control
12. Encourage employees to do their job

- Remove the barriers
- Listen to the workers
- The person doing the job knows more about it than anyone else

13. Have ongoing education and training

- Teach them simple yet powerful statistical techniques
- Use the basic SPC tools, particularly the control chart
14. Involve top management

- Management should be advocates for these points

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
Deming’s Obstacles to Success

1. The belief that automation, computers, and new machinery will solve problems.
2. Searching for examples—trying to copy existing solutions.
3. The “our problems are different” excuse and not realizing that the principles that will solve them are universal.
4. Obsolete schools, particularly business schools, where graduates have not been taught how to successfully run businesses.
5. Poor teaching of statistical methods in industry: Teaching tools without a framework for using them is going to be unsuccessful.
6. Reliance on inspection to produce quality.
7. Reliance on the “quality control department” to take care of all quality problems.
8. Blaming the workforce for problems.
9. False starts, such as broad teaching of statistical methods without a plan as to how to use them, quality circles, employee suggestion systems, and other forms of “instant pudding.”

Deming’s Obstacles to Success (cont.)

10. The fallacy of zero defects: Companies fail even though they produce products and services without defects. Meeting the specifications isn’t the complete story in any business.
11. Inadequate testing of prototypes: A prototype may be a one-off article, with artificially good dimensions, but without knowledge of variability, testing a prototype tells very little. This is a symptom of inadequate understanding of product design, development, and the overall activity of technology commercialization.
12. “Anyone that comes to help us must understand all about our business.” This is bizarre thinking: There already are competent people in the organization who know everything about the business—except how to improve it. New knowledge and ideas (often from the outside) must be fused with existing business expertise to bring about change and improvement.
Joseph M. Juran

- Born in Romania (1904-2008), immigrated to the US
- Worked at Western Electric, influenced by Walter Shewhart
- Juran Institute is still an active organization promoting the Juran philosophy and quality improvement practices

Dr. Joseph Juran

- A founder of SQC
- Co-author of *QC Handbook* (1957)
- His philosophy is based on management of the quality function
The Juran Trilogy

1. Planning
2. Control
3. Improvement

• These three processes are interrelated
• Control versus breakthrough
• Project-by-project improvement

Armand Feigenbaum

– Author of Total Quality Control, promoted overall organizational involvement in quality,
– Three-step approach emphasized quality leadership, quality technology, and organizational commitment
– Says that QC should be concentrated in a specialized department
  • Conflicts with Deming on this point
Three major areas:

- Statistical process control (SPC)
- Acceptance sampling
- Design of experiments (DOE)
Statistical Process Control (SPC)
- Control charts are used for process monitoring and variability reduction.
- SPC is an on-line quality control tool.

Acceptance Sampling
- Acceptance sampling is the inspection and classification of a sample of the product selected at random from a larger batch or lot and the ultimate decision about disposition of the lot.

- Two types:
  1. *Outgoing inspection* - follows production
  2. *Incoming inspection* - before use in production
Experimental design is an approach to systematically varying the controllable input factors in the process and determine the effect these factors have on the output responses.

Experimental designs are off-line quality tools.

Crucial for variability reduction.
Other Aspects of Quality Control and Improvement

Total Quality Management (TQM)

- TQM is a managerial framework to accomplish quality improvement.
- Other names and related approaches:
  - Company-Wide Quality Control (CWQC)
  - Total Quality Assurance (TQA)
  - Six-Sigma-Black Belt Program

Quality Philosophy and Management Strategies

- Total Quality Management (TQM)
- Quality Standards and Registration
  - ISO 9000
- Six Sigma
- Just-In-Time, Lean Manufacturing, Poka-Yoke, etc.
TQM

- It is a strategy for implementing and managing quality improvement activities on an organizationwide basis.
- Began in the early 80s based on the philosophies of Deming and Juran.
- Evolved into a wide spectrum of ideas:
  - Participation in quality groups
  - Work culture
  - Customer focus
  - Supplier quality improvement
  - Cross-functional teams concerned with quality

TQM

- A success?
  - Moderately

- Why not?
  - Not enough concern for reduction of variability
  - Ineffective training conducted by HR people
    - No knowledge of what is important
    - Success measured by % of workforce trained
  - Management not committed
Other Aspects of Quality Control and Improvement

- Quality Philosophy and Management Strategies
- The Link Between Quality and Productivity
- Quality Costs
- Legal Aspects of Quality
- Implementing Quality Improvement

Quality Philosophy and Management Strategies

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- Armand V. Feigenbaum
  - Emphasis on organizational structure
The Link Between Quality and Productivity

- Effective quality improvement can be instrumental in increasing productivity and reducing cost.
- The cost of achieving quality improvements and increased productivity is often negligible.

Quality Costs

*Quality Costs* are those categories of costs that are associated with producing, identifying, avoiding, or repairing products that do not meet requirements. These costs are:

- Prevention Costs
- Appraisal Costs
- Internal Failure Costs
- External Failure Costs
**Quality Costs**

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

Marketing
- Help to evaluate the level of product quality that a customer wants, needs.

Design Engineering
- Translate the customer's requirements into operating characteristics, exact specifications, and appropriate tolerances

Procurement
- Responsible for procuring quality materials and components

Process Design
- Develops processes and procedures that will produce a quality product/service

Production
- Produce quality products and services
Responsibility for Quality (cont.)

Inspection and Test
- Appraise the quality of purchased and manufactured items and to report the results

Packaging and Storage
- Preserve and protect the quality of the product

Inspection and Test
- Appraise the quality of purchased and manufactured items and to report the results

Service
- Fully realizing the intended function of the product during its expected life

Chief Executive Officer

The highest-ranking executive officer within a company or corporation, who has responsibility for overall management of its day-to-day affairs under the supervision of the board of directors

- Ultimate responsibility for quality
- 35% of the time is spent on quality
- Quality performances
Can be programmed to perform complex calculations, to control a process or test, to analyze data, to write reports, and to recall information on command

Benefits:

- Information is stored in the computer and transmitted efficiently to remote terminals
- Information is provided to employee at the same time the work assignment is given
- Ability to quickly update or change the information
- The probability of fewer errors
- Powerful tool to help in the improvement of quality
- The use of computers in quality is as effective as the people who create the total system
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Computers & Quality Control

Quality functions needs:
- Data collection
- Data analysis and reporting
- Statistical analysis
- Process control
- Test and inspection
- System design

Data collection:
- The decision as to how much data to collect and analyze is based on the reports to be issued, the processes to be controlled, the records to be retained, and the nature of the quality improvement program
- Computers are well suited for the collection of data
- Faster data transmission, fewer errors, and lower collection costs can be achieved
- Multiple sources of data can be used
- Identifiers are necessary for data analysis, report preparation, and record traceability
Computers & Quality Control

Data analysis and reporting:

- Quality info is stored in the computer for retrieval at a future time, analyzed, reduced, and disseminated in the form of a report.
- The analysis, reduction, and reporting are programmed to occur automatically in the system.
- Data can be easily summarized.
- Data can be analyzed as they are being accumulated and corrective actions are taken in real time.
- Analysis of data using tools such as: Pareto, Histogram, Software programs (Excel), Charts are made easier.

Statistical analysis

- Use of Statistical packages.
- The quality engineer can specify a particular sequence of statistical calculation to use for a given set of conditions.
- Time is saved and the calculations are error-free.

Benefits:

- No more time-consuming manual calculations.
- One-time problem.
- Process control.
Computers & Quality Control

Process control:
- Computer programs control the sequence of events performed during a process cycle
- Keep the measurement and control of critical variables on target with minimum variation and within acceptable control limits

Benefits:
- High productivity (less employees)
- Safer operation for personnel and equipment
- Computer numerically controlled (CNC) machines, robots, and automatic storage and retrieval systems (ASRS)

Benefits:
- Constant product quality
- More uniform startup and shutdown
Computers & Quality Control

Test and Inspection:
- Automated test systems can be programmed to perform a complete quality audit of a product

Disadvantage:
- High cost of the equipment

Test and Inspection:

Advantages:
- Improve test quality
- Lower operating cost
- Better report preparation
- Improve precision
- Automatic calibration
- Malfunction diagnostics
Computers & Quality Control

System Design:
- The integration of the diverse quality function with other activities requires an extremely sophisticated system design
- Expert systems are computer programs that capture the knowledge of experts as a set of rules and relationships used for such applications as problem diagnosis

Legal Aspects of Quality

The re-emergence of quality assurance as an important business strategy is in part a result of
1. Consumerism
2. Product Liability
Consumerism

- Virtually every product line of today is superior to that of yesterday
- But, many consumers see it otherwise
- Consumer tolerance for minor defects & aesthetic problems has decreased considerably
  - Blemishes, surface-finish defects, noises, appearance problems

- Many manufacturers introduce new designs before they are fully evaluated and tested
  - To remain competitive
- Unproved designs
Product liability

- Manufacturers and sellers are likely to incur a liability when they have been unreasonably careless or negligent in what they have designed, or produced, or how they have produced it.

More stringent: Strict liability

- 1. There is a strong responsibility for both manufacturer and merchandiser requiring immediate responsiveness to unsatisfactory quality through product service, repair, or replacement of defective product:
  - Extends into the period of use by the consumer
  - By producing the product, manufacturer and seller must accept responsibility for use
More stringent: Strict liability

- 2. All advertising statements must be supportable by valid company quality or certification data

Implementing Quality Improvement

- Strategic Management of Quality
- Almost all successful efforts have been management-driven.
- Too much emphasis on registration and certification programs (ISO, QS)
  - Insufficient focus on quality planning and design, quality improvement, overemphasis on quality assurance
  - Poor use of available resources
Six Sigma

- Consider an assembly of 100 parts that must all function for the assembly to function
  \[ .9973 \times .9973 \times \ldots \times .9973 = (.9973)^{100} = .7631 \]
- Thus, about 23.7% of the products under $3\sigma$ will fail
- Not usually an acceptable situation

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Pilot's Six-Sigma Performance

If pilot always lands within 1/2 the landing strip width, we say that he has Six-sigma capability.
Six Sigma

• But, $\pm 6\sigma$ results in $0.999999998$ inside specs
  – $(0.999999998)^{100} = .9999998$
  – Or, 2 parts/billion defective
    • i.e., 0.2 ppm
  – Much better than $\pm 3\sigma$

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?
  
  \[
  P\{\text{Single meal good}\} = (0.99)^{10} = 0.9044
  \]

  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
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Six sigma

• Process performance is not predictable unless the process behavior is stable

• If the mean is drifting around, and ends up as much as 1.5 standard deviations off target, a prediction of 3.4 ppm defective may not be very reliable

Six Sigma

• Has moved beyond Motorola
• Has come to encompass much more
• Has become a method for improving corporate business performance
• Companies involved in Six Sigma use teams that work on projects involving quality and costs
Islamic University, Gaza - Palestine

**What Sigma Level are you?**

- When we hire Graduates from Universities or High Schools into Industry, they are at best 4σ NOT 6σ capable.

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Islamic University, Gaza - Palestine

**All of Us Try to:**

- Hire the best people
- Invest sufficient capital
- Provide financial incentives
- Train and Educate our People

**Most Often the Result Is:** 4 Sigma Performance
Six Sigma: Ambitious Objective?

Near Perfection 99.99966% = 6.0σ, less than 3.4 defects per million opportunities, sounds excessive!!!

Why isn’t 99.9% already GOOD ENOUGH in our everyday lives (or 1000 ppm or 4.6σ)?

It would mean:

4000 wrong medical prescriptions each year,

More than 3000 newborns accidentally falling from the hands of nurses or doctors each year,

Two long or short landings at Chicago airport each day,

400 letters per hour would never arrive at their destination,

175 defects are identified while producing 5000 controllers

The manufacture of one controller allows for 1367 defect opportunities.

DPOp = 0.035 / 1367 = 0.0000256

An Example:

175 defects are identified while producing 5000 controllers

DPU = 175 / 5000 = 0.035

The manufacture of one controller allows for 1367 defect opportunities.

DPOp = 0.035 / 1367 = 0.0000256

DPMOp = 25.6

"Sigma" level : 5.55
Six Sigma

- A disciplined and analytical approach to process and product improvement
- Involves a five-step process (DMAIC):
  - Define
  - Measure
  - Analyze
  - Improve
  - Control

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
The requirements of ISO 9001: 2000

- The Quality Management System (QMS) is the collection of processes, documents, resources, and monitoring systems that direct the work of an organization regarding product and service quality. The organization needs to establish, document, carry out, and maintain this system to meet the requirements of ISO 9001:2000.

The requirements of ISO 9001: 2000

- An International Standard for Quality Management Systems
- Covers the planning, the management and operation of any Organization
- Assures Customers of your reliability and competence to deliver what you promise
- 4 Quality Management System
- 5 Management Responsibility
- 6 Resource Management
- 7 Product Realization
- 8 Measurement, analysis and improvement
The principles of ISO 9001: 2000

- Customer Focused Organization
- Leadership
- Involvement of People
- Process Approach
- System Approach to Management
- Continual Improvement
- Factual Approach to Decision Making
- Mutually Beneficial Supplier Relationships

ISO 9001: 2000 - Five chapters

- Quality Management System
- Management Responsibility
- Resource Management
- Product Realization
- Measurement, Analysis and Improvement
### ISO 9001: 2000 - The key themes

- Knowing your Customers
- Continual Improvement
- Planning
- Communications

### Steps to ISO 9000 - certification

- Initial Audit and Review
- Gain Management Commitment
- Management Steering Group
- QA Awareness for all staff
- Write Quality Manual
- Map Core Processes
- Train QMR and Auditors
- Implement and Test
- Internal Audits
- Management Review
- External Accreditation
Malcolm Baldridge National Quality Award

European Quality Function Model (EFQM)