

QUALITY MANAGEMENT TOOLS

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INTRODUCTION

An important characteristic of the food industry is that, in order to cope with market needs as well as legal requirements, it has to satisfy both safety and quality criteria for its products. Food quality is one of the most complex concepts because it can be assessed only in relation to food safety. A food must meet legislative, technological, and hygiene requirements, as well as transport and handling requirements, and to satisfy its intended use. The food producers must select and implement an efficient quality management and food safety system; within this or these systems they must employ quality principles and methodologies, and advanced quality improvement techniques requiring the use of statistics (e.g. control charts, process capability and performance studies). SPC and other statistical techniques for the quality improvement constantly find new applications in the food safety field, for example by their integration with HACCP for the validation and verification of Critical Control Points.

The purpose of this e-book is to assist food producers, distributors, vendors and regulators, of different backgrounds and experiences, in finding information about quality improvement techniques using statistics in order to guarantee the production and distribution of quality and safe food products.

The e-book includes three chapters: The basic concepts supporting quality and a brief enlightening history behind the idea of quality ("Basic Quality Concepts"); a description of the statistical background required to understand and employ the quality tools ("Statistical Quality Control"); and a description of the most important quality tools used in production ("The Main Quality Tools").

We hope that with this e-book we can provide information and some basic operational tools for the food industry to enhance their knowledge on statistical quality techniques and methodologies for ensuring the safe and quality food production.

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BASIC QUALITY CONCEPTS

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1.1 BASIC QUALITY DEFINITIONS

1.2 HISTORY OF QUALITY CONTROL AND IMPROVEMENT

Chapter Objectives:

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In this chapter we give the basic definitions of quality, quality improvement, and other quality terminology. We also discuss the historical development of quality improvement methodology and overview the statistical tools essential for modern professional practice.

1.1

BASIC QUALITY DEFINITIONS

What is Quality?

Quality is a very elusive attribute; it is perceived, understood and interpreted differently by different people. There have been many attempts to define it conclusively and there is a multitude of definitions and interpretations about quality that have evolved with time.

- From customer point of view: quality means fitness for use and meeting customer satisfaction.
- From process point of view: quality means conformance with the process design, standards and specifications.
- From product point of view: quality means the degree of excellence at an acceptable price.
- From the cost point of view: quality means best combination between costs and features.

The traditional however definition of quality, although not universally accepted, follows the views of quality guru Joseph Juran, which is based on the viewpoint that products and services must meet the requirements of those who use them, therefore quality means "fitness for use" or "suitability for the consumer use". This definition is comprehensive because it includes two general aspects: characteristics that lead to satisfaction with the product (quality of design) and the absence of failures (quality of conformance).

Garvin (1987) has also suggested that the quality of a product has eight (8) dimensions:

- **Performance** (Will the product do the intended job?)
- **Features** (What does the product do?)
- **Conformance** to standards (Is the product made exactly as designer intended?)
- **Reliability** (How often does the product fail?)

- **Durability** (How long does the product last?)
- **Serviceability** (How easy is it to repair the product?)
- **Aesthetics** (What does the product look like?)
- **Perceived Quality** (What is the reputation of the company or its product?)

In order to achieve these objectives, an efficient **quality management** is required, which implies continuous improvement activities at each operational level and in every functional area of the organization.

Quality management (QM) is the use of management techniques and tools to achieve consistent quality of products and services, i.e. to achieve maximum customer satisfaction at the lowest overall cost to the organization while continuing to improve the process. Specifically for the food industry, that also involves the knowledge and application of techniques and programs for product safety. Quality management is, thus, the totality of functions involved in the determination and achievement of quality, including quality assurance and quality control.

Quality assurance (QA) includes all activities designed to produce products and services of appropriate quality; i.e. all those planned or systematic actions necessary to provide adequate confidence that a product or service will satisfy given needs. QA focuses on the entire quality system including suppliers and ultimate consumers of the product or service.

Quality control (QC) has a narrower focus than quality assurance. QC focuses on the process of producing the product or service with the intent of eliminating problems that might result in defects.

Often, however, "quality assurance" and "quality control" are used interchangeably, referring to the actions performed to ensure the quality of a product, service or process.

Quality improvement includes all the actions in an organisation that are taken in order to improve products,

services or processes; it is the reduction of (unwanted or harmful) variability in processes and products.

1.2

HISTORY OF QUALITY CONTROL AND IMPROVEMENT

Quality control in production is as old as the production process itself. In the Middle Ages and up to the Industrial revolution era, quality was determined based on the abilities and the technique of the worker, whose quality of production and productivity were both determined by his talent and his experience.

Standardisation was recognized as the first step towards quality. In 1875 F.Taylor introduces Scientific Management and divides the production process in individual tasks, effectively abolishing the notion of the craftsman and introduced the skilled labor. By introducing the production line, Henry Ford starts first the mass production of small, low-cost, products for which the customer does not have great quality demands. Some of the first seeds of quality management were planted as the principles of scientific management were spreading in the U.S. industry.

The first stage of quality evolution was called "era of inspection." In this stage the quality control of products was limited to a focus on corrective inspection, i.e., was a way to check the uniformity of the final product by separating the non-conforming products. According to Garvin, only in 1922 the inspection activities were related more formally with quality management, after the publication of the book "The Control of Quality in Manufacturing" by GS Radford. For the first time, the quality was seen as a managerial responsibility having a distinct and independent function in the companies.

⁶⁴
In 1924, W.A. Shewhart, who is now considered ¹³⁵ "Father of statistical quality control", was working at Bell Telephone Laboratories; he developed a statistical ²⁴ diagram for the control of the production variables, wrote the historic memorandum of May 16, 1924, in which he ²⁴ proposed the control chart to his superiors. Shewhart then wrote "Statistical Method from the Viewpoint of Quality Control" in 1939.

¹⁰²
In the late 1920's, HF Dodge and Harry G. Romig, of the same company, developed the statistical sampling method of control of production, instead of 100% control. By the late 1930's, Bell Systems uses statistical methods of control of production quality, ⁸³ however this is not universally accepted by the industry. Manufacturing companies did not fully utilize these techniques until the late 1940s.

The 2nd World War gave a significant boost ¹⁴ and acceptance to the Statistical Quality Control (SQC). In 1946, the American Society for Quality Control is established, which promotes the necessity of quality control in the production process.

Until the 1940's, Japanese products were considered poor quality imitations. Post-war Japan then employed the assistance of quality management experts like Deming and Juran; in 1950 Deming gave a series of lectures in Japan to an audience of Business Executives and Engineers about production quality control. This can be considered the origin of TQM. With the contribution of JM Juran, the basis for quality control was set in Japan and its importance for production and product distribution was acknowledged, so that the whole world followed the Japanese example.

²⁴
In the 1950's, Armand V. Feigenbaum's book Total Quality Control, a precursor for the present understanding of TQM, was published and Philip B. Crosby's promotion of zero defects paved the way for quality improvement in many companies. The quality ²⁰s had now expanded beyond the statistics, covering the quality costs quantification, total quality control, reliability engineering and zero defect.

In 1960, the 24 quality cycles were introduced in Japan by K. Ishikawa. In 1968 the Japanese introduce their approach to total quality. It is around this time that the term quality management system arises.

In the 1960's, quality control is introduced as a university lesson.

During the first international quality management conference in 1969, Feigenbaum would first use the phrase Total Quality Management. Ishikawa however would explain the depth of the term during the conference; that TQM should apply to all employees within the organization – from the workers to the head management.

With the development of quality, there was an increasing need to become more proactive with dealing with quality problems. Emphasis was shifted from the inspection of 89 section of poor quality using Statistical Quality Control, to their use in the prevention of poor quality. Prevention of defects by applying statistical methods to control the process is known as Statistical Process Control (SPC).

83 In the 1980s to the 1990s, a new phase of quality control and management began with 123 the widespread use of Total Quality Management (TQM). The ISO 9000 series 14 quality management standards were published in 1987. Since 1980, there has been a profound growth in the use of statistical methods for quality and overall business improvement in the United States.

53 As the 21st century begins, the quality movement has matured. New quality systems have evolved beyond the foundations laid by Deming, Juran and the early Japanese practitioners of quality; some examples of this maturation include the customer centred ISO 9000 series standards, Six-sigma, Quality Function Deployment for the minimization of defects, sector-specific versions of the ISO 9000 series, integration of quality management to services, healthcare, education, and government.

Table 1 – History of quality terms

12 Terminology	Approximate year of first use	Description
Statistical quality control (SQC)	1930s	The application of statistical methods (specifically control charts and acceptance sampling) to quality control
Total quality control (TQC)	1956	Popularized by Armand V. Feigenbaum in a Harvard Business Review article and book of the same name Stresses involvement of departments in addition to production (e.g., accounting, design, finance, human resources, marketing, purchasing, sales).
Statistical process control (SPC)	1960s	The use of control charts to monitor an individual industrial process and feedback performance to the operators responsible for that process. Inspired by control systems.
Company-wide quality control (CWQC)	1968	Japanese-style total quality control
Total Quality Management (TQM)	1985	Quality movement originating in the United States Department of Defence that uses (in part) the techniques of statistical quality control to drive continuous organizational improvement
Six Sigma (6σ)	1986	Statistical quality control applied to business strategy. Originated by Motorola.

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STATISTICAL QUALITY CONTROL

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- 2.1 STATISTICS USED IN QUALITY
- 2.2 STATISTICAL PROCESS CONTROL
- 2.3 ACCEPTANCE SAMPLING

Chapter Objectives:

In this chapter we present the ideas supporting the Statistical Quality Control, i.e. the basic statistical notions and methodology used for Quality. Furthermore we present a definition and description of Statistical Process Control, as well as for Acceptance Sampling.

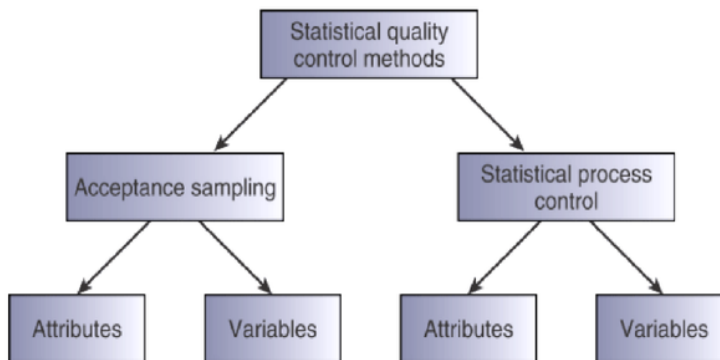
2.1

STATISTICS USED IN QUALITY

What is Statistical Quality Control?

As we have seen in previous chapters about the history and evolution of quality through the years, Statistical Quality Control is one of the pillars of what we today know as Quality Management and one of the sets of tools for Total Quality Management (TQM). So, what is Statistical Quality Control (SQC)?

In a nutshell, **Statistical Quality Control (SQC)** is the term used to describe the set of statistical tools and analysis used by quality professionals to control and improve the quality of a product or service.



- Statistical process control (SPC) involves inspecting a random sample of the output from a process; it answers the question of whether the process is functioning properly or not.
- Acceptance sampling is the process of randomly inspecting a sample of goods to determine whether the batch of goods should be accepted or rejected.

Furthermore, **descriptive statistics** are used to describe quality characteristics and relationships and to summarize the

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information in sample data. Included are statistics such as the mean, standard deviation, the range, and a measure of the distribution of data.

Types of data

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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, or characteristics that either conform to the specifications or don't.

Random variable: A variable that can take real values. These can be continuous or discrete.

Data Organising

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The frequency distribution

A frequency distribution is an arrangement of data classified according to the magnitude of the observations. When the data are grouped into classes of appropriate size indicating the number of observations in each class we get a frequency distribution. By forming frequency distribution, we can summarize the data effectively. It is a method of presenting the data in a summarized form. Frequency distribution is also known as Frequency table. For example, We have measured the volume of the liquid in a sample of 72 bottles and these were the results:

300 303 303 295 302 296 299 301
 295 298 297 297 302 296 298 299
 303 304 297 300 301 300 299 301
 301 298 299 298 296 298 299 296

305 297 302 296 297 301 297 301
 300 295 304 305 298 305 301 295
 299 300 296 304 297 298 298 301
 301 303 304 297 305 296 295 296
 299 302 295 295 299 295 297 300

A frequency distribution table for these results will look like this:

Table 2 – Frequency distribution table

Classes	Class Range	Frequency	Cumulative Frequency	Relative Cumulative Frequency
295-296	296	16	16	22,2%
297-298	298	17	33	45,8%
299-300	300	14	47	65,3%
301-302	302	13	60	83,3%

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Frequency distribution graphs

A frequency distribution graph is a diagrammatic illustration of the information in the frequency table. Common frequency distribution graphs are histograms, bar charts and frequency polygons. Some of these will be further analysed later in the chapter. An example of an histogram for our sample dataset will be:

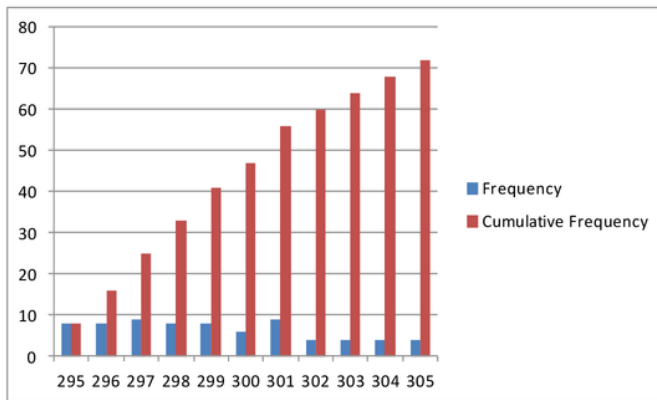


Figure 1 – Frequency & Cumulative frequency distribution graph
(Histogram)

Data Analysis

The most basic concept in statistical quality control is **variability** (or **variation**); every aspect of a manufacturing process contains **variability**.⁸ Materials vary from place to place and from time to time. Sources of this variability include differences in materials, differences in the performance and operation of the manufacturing equipment, and differences in the way the operators perform their tasks. There **are common, or random, causes of variation** that are based on random causes that we cannot identify and there are variations where the causes can be precisely identified and eliminated, which are called **assignable causes of variation**.⁴

An important task in quality control is to find out the range of natural random variation in a process.

For example, if the average bottle of a soft drink contains 300ml of liquid, we may determine that the **amount of natural variation** is between 295ml and 305ml. In this case, we would monitor the production process to make sure that the amount stays within this range. If production goes out of this range—bottles are found to contain on average 290ml— this would lead us to believe that there is a problem with the

process because the variation is greater than the natural random variation. Poor quality of raw materials, an employee who needs more training, or a machine need of repair can be the causes of variance in this case, that can all be identified and corrected.

Descriptive statistics can be helpful in describing certain characteristics of a product and a process. The most important descriptive statistics are measures of central tendency such as the mean, measures of variability and spread such as the standard deviation and range and the shape of the distribution of data.

A. Measures of Central Tendency

A measure of central tendency is a single value that attempts to describe a set of data by identifying the central position within that set of data. As such, measures of central tendency are sometimes called measures of central location. They are also classed as **summary statistics**. The mean (often called the average) is most likely the measure of central tendency that you are most familiar with, but there are others, such as the median and the mode.

Mean (Arithmetic)

The mean (or average) is the most popular and well known measure of central tendency. In the soft drink bottling example, we stated that the average bottle is filled with 300ml of liquid. The mean is the sum of all the values in the data set divided by the number of values in the data set. So, if we have n values in a data set and they have values x_1, x_2, \dots, x_n , the sample mean, usually denoted by \bar{x} (x bar), is:

$$\bar{x} = \frac{(x_1 + x_2 + \dots + x_n)}{n} \quad \text{or} \quad \bar{x} = \frac{\sum x}{n}$$

The above formula refers to the sample mean. In statistics, samples and populations have very different meanings and these differences are very important. In the case of the mean,

however, population and sample mean ¹³ are calculated in the same way. To acknowledge that we are calculating the population mean and not the sample mean, we use the letter μ instead of \bar{x} :

$$\mu = \frac{\sum x}{n}$$

However, in quality statistics it is more common to deal with samples instead of entire populations, so \bar{x} (sample mean) is more common too, as well as other sample statistics, too.

² The mean is essentially ¹³ model of your data set. It is the value that ³⁹ most common. An important property of the mean is that it includes every value in your data set as part of the calculation. In addition, the mean is the only measure of central tendency where the sum of the deviations of each value from the mean is always zero.

The mean has one main disadvantage: it is particularly susceptible to the influence of outliers. These are values that are unusual compared to the rest of the data set by being especially small or large in numerical value. If, in our example of the soft drink bottles that we have already seen, most bottles have volumes in the 295-305 range but we also have on or two large volumes (above 305ml), ¹¹³ the values are "skewing" the distribution of frequencies. Therefore, in this situation, we would like to have a better measure of central tendency, as is the median.

¹² Median

The median is the value separating the higher half of a data sample, a population, or a probability distribution, from the lower half. For a data set, it may be thought of as the "middle" value; it tells you where the middle of a data set is.

² The median is the middle value for a set of data that has been arranged in order of magnitude. The median is less affected by outliers and skewed data. In order to calculate the median,

suppose we have the data below, arranged in an order of magnitude (smallest first):

14 35 45 55 55 56 56 65 87 89 92

Our median mark is the middle mark - in this case, 56 (highlighted in bold). It is the middle mark because there are 5 values before it and 5 values after it. When you have an even number of values you simply have to take the **middle two values** and average them to get a result. So, if we look at the example below, arranged in an order of magnitude (smallest first):

14 35 45 55 55 56 56 65 87 89

Only now we have to take the 5th and 6th value in our data set and average them to get a median of 55.5.

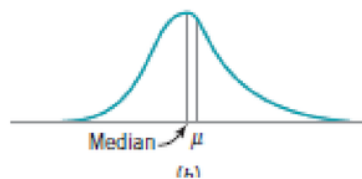


Figure 1.2 – The median and the mean in a non-normal distribution

The basic advantage of the median in describing data compared to the mean is that it is not skewed so much by extremely large or small values, and so it may give a better idea of a 'typical' value. For symmetric

distributions, the median is equal to the mean.

2

B. Measures of Spread (measures of dispersion)

A measure of spread, sometimes also called a measure of dispersion, is used to describe the variability (or variation) in a sample or population. It is usually used in conjunction with a measure of central tendency, such as the mean or median, to provide an overall description of a set of data.

4

In the bottling example we saw that the amount of natural variation in the bottling process is between 295 and 305ml. This provides us with information about the variability of the

data, it tells us how spread out the data is around the mean and gives us an idea of how well the mean, for example, represents the data. If the spread of values in the data set is large, the mean is not as representative of the data as if the spread of data is small. This is because a large spread indicates that there are probably large differences between individual observations.

The most notable measures that can be used to determine the variation in the data are the range, the variance and the standard deviation.

Range

The first measure is the **range**, which is the difference between the maximum and minimum values. In our example, the range for natural variation is 10ml. It is the simplest measure of spread. From the soft drink example, we have seen that the maximum value is 305 and the minimum value is 295. This results in a range of 20 (305 minus 295). Whilst the range as a measure of spread is of limited use, it does set the boundaries of the observations, which can be useful if you are measuring a variable that has either a critical low or high threshold (or both) that should not be crossed, for example if we don't want our soft drink volume to be below 290ml. In addition, the range can be used to easily detect any obvious errors eg from entering data or from faulty measurement.

Variance

A method for calculating the deviation of a group of values from the mean is to use the variance. The variance achieves positive values by squaring each of the deviations from the mean. Adding up these squared deviations gives us the sum of squares, which we can then divide by the total number of values in our group of data to find the variance (see below).

$$\text{variance} = \frac{\sum(X - \mu)^2}{N}$$

Where:

\sum = sum of

X = 148

μ = population mean

N = number of values in sample

2

As a measure of variability, the variance is useful. If the values in our group of data are spread out, the variance will be a large number. Conversely, if the values are spread closely around the mean, the variance will be a smaller number. However, there are two potential problems with the variance. First, it is too, very vulnerable to extreme values and outliers, because the deviations of values from the mean are squared. Secondly, the variance is not in the same units as the values in our data set: variance is measured in the units squared. Therefore, the value of our variance appears somewhat arbitrary. Calculating the standard deviation rather than the variance rectifies this problem.

Standard deviation

4

Another measure of variation is the standard deviation within a set of data. Usually, we are interested in the standard deviation of a population. However, as we are often presented with data from a sample only, we can estimate the population standard deviation from a sample standard deviation. These two standard deviations - sample and population standard deviations - are calculated differently. In quality statistics, we are usually presented with having to calculate sample standard deviations; nonetheless, we will also show the formula for a population standard deviation. The standard deviation formula is:

2

Sample standard deviation	Population standard deviation
$s = \sqrt{\frac{\sum(X - \bar{X})^2}{n - 1}}$	$\sigma = \sqrt{\frac{\sum(X - \mu)^2}{n}}$

Where:	Where:
s = sample standard deviation	σ = population standard deviation
\sum = sum of...	\sum = sum of...
\bar{X} = sample mean	μ = population mean
n = number of values in sample.	n = number of values in population.

However, we have to be careful to use the correct type of standard deviation: "Sample" standard deviation does not mean the standard deviation of the sample itself but **the estimate of the population standard deviation based on the sample.**

Small values of the range and standard deviation mean that the observations are closely clustered around the mean. Large values of the range and standard deviation mean that the observations are spread out around the mean. The standard deviation does not reflect the magnitude of the sample data, only the scatter around the mean.

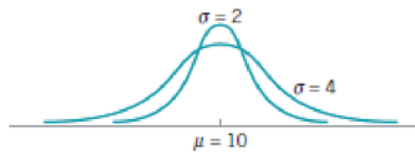


Figure 3 - Normal distributions with varying standard deviations

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2.2

STATISTICAL PROCESS CONTROL

Statistical process control (SPC) is the methodology for monitoring and optimizing the process output, mainly in terms of variability, and for judging when actions (changes) are

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required to bring the process back to a "state of control". SPC answers the question of whether the process is functioning properly or not.

3
Traditional QC programs emphasize product quality control whereas SPC is process oriented. Traditional product-oriented QC systems emphasize defect detection. By using SPC, we emphasize defect prevention through improving the production system.

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Statistical process control (SPC) involves using statistical techniques to measure and analyze the variation in processes. The intent of SPC is to monitor process quality and maintain processes to fixed targets. SPC The first objective is to ensure that the production process is stable and capable of producing product to the specifications. As these initial objectives are met, the objective of an SPC program should shift to improving the system by continuously striving to reduce variation.

3
As already pointed out, the understanding of variation is crucial to understanding SPC. Variation is unavoidable in manufactured products; every system has inherent variation due to common (also called random or chance) causes and also variation due to special (also called assignable) causes.

Common-cause variation is evidenced by a stable, repeating pattern of variation. Special-cause variation is evidenced by a break in the stable, repeating pattern of variation and is an indication that something has changed in the process. Product consistency is ensured by detecting and eliminating special-cause variation. Long-term quality improvement results from reducing common-cause variation.

3
It's difficult to give examples of common causes because what is typical for one process may not be typical for another. However, common causes might include things like normal machine wear; differences in density or moisture content; and normal, gradual changes in ambient temperature and humidity throughout the day. Just because a factor is a common cause does not mean it is an acceptable or unavoidable cause.

3

Examples of special causes might include changes in operating procedures (e.g., equipment operators on different shifts using differing procedures); damage to a cutting tool; a sudden, abrupt change in ambient temperature or humidity; and a faulty measuring device.

It is important to distinguish between these two types of variability because the remedies are completely different. Understanding the difference helps manufacturers select appropriate quality improvement efforts and thereby avoid wasted effort and expense.

3

Montgomery (2013) defines SPC as "...a powerful collection of problem-solving tools useful in achieving process stability and improving capability through the reduction of variability." Control charts and process capability analysis are the two primary tools of SPC. Other tools such as histograms, flowcharts, cause-and-effect diagrams, check sheets, and Pareto diagrams also are useful in quality and process improvement.

3

Distribution of the process output

In SPC, distribution of the process output refers to collected data that describe the process—such as data on widths of pieces coming out of a woodworking machine— and the way those data are distributed when plotted on a chart or graph.

Describing the distribution of process output is like asking, "How's your aim?" Are you accurate (on target)? Is your aim precise, or are results distributed all over the place? We can illustrate these ideas with a marksmanship example (Figure 1). In manufacturing, the questions are:

Is the process on or off target? If the latter, by how much is it off target?

Where is the process centered? How much does the process fluctuate about the center?

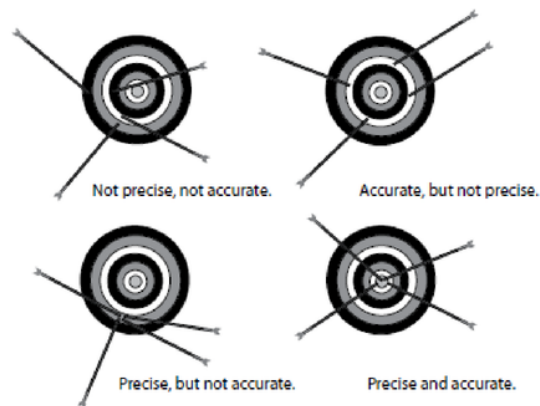


Figure 4 - Precision and accuracy

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A primary tool used for SPC is the control chart, a graphical representation of certain descriptive statistics for specific quantitative measurements of the manufacturing process. These descriptive statistics are displayed in the control chart in comparison to their "in-control" sampling distributions. The comparison detects any unusual variation in the manufacturing process, which could indicate a problem with the process. Several different descriptive statistics can be used in control charts and there are several different types of control charts that can test for different causes, such as how quickly major vs. minor shifts in process means are detected. Control charts are also used with product measurements to analyze process capability and for continuous process improvement efforts.

2.3

ACCEPTANCE SAMPLING

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Sampling inspection or acceptance sampling is a quality assurance technique where decisions to accept or reject manufactured products, raw materials, services etc are taken on the basis of sampling inspection.

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Acceptance sampling refers to the process of randomly inspecting a certain number of items from a lot or batch in order to decide whether to accept or reject the entire batch.

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This method provides only an indirect means for quality improvement.

9

Purposes of acceptance sampling:

- To determine the quality level of an incoming shipment or, at the end production
- To ensure that the quality level is within the level that has been predetermined

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Complete 100% inspection: inspecting each item produced to see if each item meets the level desired. It is used when defective items would be very detrimental in some way.

100% inspection is used for example when food products are examined for the existence of foreign parts. Because the risk of a defective item is too high, we perform 100% inspection.

9

Disadvantages of 100% inspection :

- Very expensive
- High cost when product must be destroyed to test
- Very time consuming

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Advantages of acceptance sampling:

- Less handling damages
- Fewer inspectors to put on payroll

9

Disadvantages of acceptance sampling:

- Risk included in chance of bad lot "acceptance" and good lot "rejection"
- Sample taken provides less information than 100% inspection

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Acceptance sampling is most likely to be useful in the following situations:

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

Risks of Acceptance Sampling, Sampling errors

5

Two levels of quality are considered in the design of an acceptance sampling plan. The first is the **acceptable quality level (AQL)** and the second level is the **lot tolerance proportion defective (LTPD)**.

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- **Acceptable quality level (AQL):** In a continuing series of lots, a quality level that, for the purpose of sampling inspection, is the limit of a satisfactory process average. The quality level desired by the consumer. The producer of the item strives to achieve the AQL, which typically is

- written into a contract or purchase order. For example, a contract might call for a quality level not to exceed one defective unit in 10,000, or an AQL of 0.0001.
- **Producer's risk (α):** The risk that the sampling plan will fail to verify an acceptable lot's quality and, thus, reject it (a type I error). Most often the producer's risk is set at 0.05, or 5 percent.
 - **Lot tolerance proportion defective (LTPD):** The worst level of quality that the consumer can tolerate.
 - **Consumer's risk (β):** The probability of accepting a lot with LTPD quality (a type II error). A common value for the consumer's risk is 0.10, or 10 percent.

Table 3 – Advantages of sampling at various stages

Sampling at the Input stage	Sampling at the Output stage	Sampling at the Process stage
<ul style="list-style-type: none"> • Prevents goods that don't meet standards from entering into the process • This saves rework time and money 	<ul style="list-style-type: none"> • Can reduce the risk of bad quality being passed on from the process to a consumer • Can prevent the loss of prestige, customers, and money 	<ul style="list-style-type: none"> • Can help adjust the process and reduce the amount of poor quality in production • Helps to determine the source of bad production and enables return for reprocessing before any further costs may be incurred

4 Acceptance sampling before the process involves sampling materials received from a supplier, such as randomly inspecting crates of fruit that will be used in a restaurant, boxes of glass dishes that will be sold in a department store, or metal castings that will be used in a machine shop. Sampling after the process involves sampling finished items that are to be shipped either to a customer or to a distribution center.

Lot Formation

- Lots should be homogeneous. The units in the lot should be produced by the same machines, the same operators, and from common raw materials, at approximately the same time.
- Larger lots are preferred over smaller ones.
- Lots should be conformable to the materials-handling systems used in both the supplier and consumer facilities.

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Random Sampling

The units selected for inspection from the lot should be chosen at random, and they should be representative of all the items in the lot.

Sampling plans

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An Acceptance Sampling Plan is defined by:

- N = number of items in the Lot or Lot size.
- n = number of items in the random sample of items taken from the Lot or sample size.
- D = number (unknown) of items in the Lot which are defective.
- r = number of defective items in the random sample of size n .
- c = acceptance number; if r is less than or equal to c then the Lot is deemed to be of Acceptable Quality, otherwise the Lot is rejected.

All sampling plans are devised to provide a specified producer's and consumer's risk. However, it is in the consumer's best interest to keep the average number of items inspected (ANI) to a minimum because that keeps the cost of inspection low. Sampling plans differ with respect to ANI.

- **Single-sampling plan:** A decision to accept or reject a lot based on the results of one random sample from the lot.
- **Double-sampling plan:** A plan in which management specifies two sample sizes and two acceptance numbers; if the quality of the lot is very good or very bad, the consumer

5

can make a decision to accept or reject the lot on the basis of the first sample, which is smaller than in the single-sampling plan.

- **Sequential-sampling plan:** A plan in which the consumer randomly selects items from the lot and inspects them one by one.

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The ANI is generally lower for the sequential-sampling plan than for any other form of acceptance sampling, resulting in lower inspection costs.

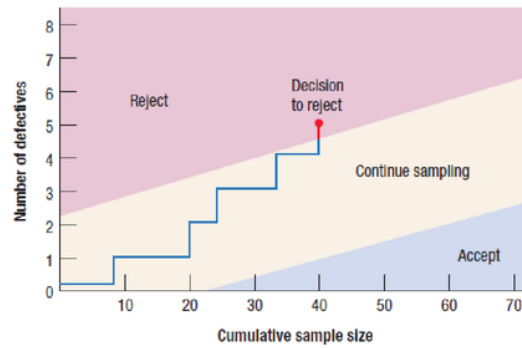


Figure 5 - Sequential Sampling Plan

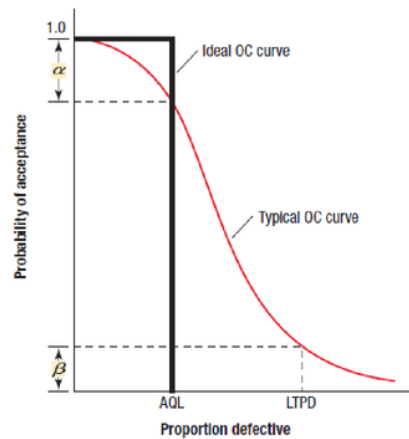


Figure 6 – An example of a typical and an ideal OC curve

5

A graphic display of the performance of a sampling plan by plotting the probability of accepting the lot for a range of proportions of defective units is the **operating characteristic (OC) curve**, describes how well a sampling plan discriminates between good and bad lots. The ideal OC curve for a single-sampling plan that accepts lots with a quality level better than the AQL 100 percent of the time and accepts lots with a quality level worse than the AQL 0 percent of the time is shown in the However, such performance can be achieved only with 100 percent inspection.

5

The probability of accepting the lot equals the probability of taking a sample of size (n) from a lot with a proportion defective of (p) and finding (c) or fewer defective items. In attribute sampling, where products are determined to be either good or bad, a binomial distribution is usually employed to build the OC curve. When the sample size (n) is large (greater than 20) and the percent defective (p) is small (less than 0.05), however, the Poisson distribution can be used as an approximation of the binomial formula to take advantage of tables prepared for the purpose of drawing OC curves.

5

To draw the OC curve, look up the probability of accepting the lot for a range of values of p . For each value of p ,

- Multiply p by the sample size n .
- Find the value of n_p in the left column of the table.
- Move to the right until you find the column for c .
- Record the value for the probability of acceptance, P_a .

When $p = \text{AQL}$, the producer's risk, α , is 1 minus the probability of acceptance. When ($p = \text{LTPD}$), the consumer's risk, β , equals the probability of acceptance.

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Effects of sample size and acceptance level to the OC-curve and the probability of acceptance

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In order to increase the probability of accepting only good lots and rejecting only bad lots, i.e. to develop a steeper, and thereby sounder, OC curve, we need to:

- Decrease the Acceptance level c
- Increase the Sample Size n

However:

- Increasing c while holding n constant decreases the producer's risk and increases the consumer's risk.
- Increasing n while holding c constant increases the producer's risk and reduces the consumer's risk.

An optimal combination of the two strategies must be employed, depending on the case characteristics.

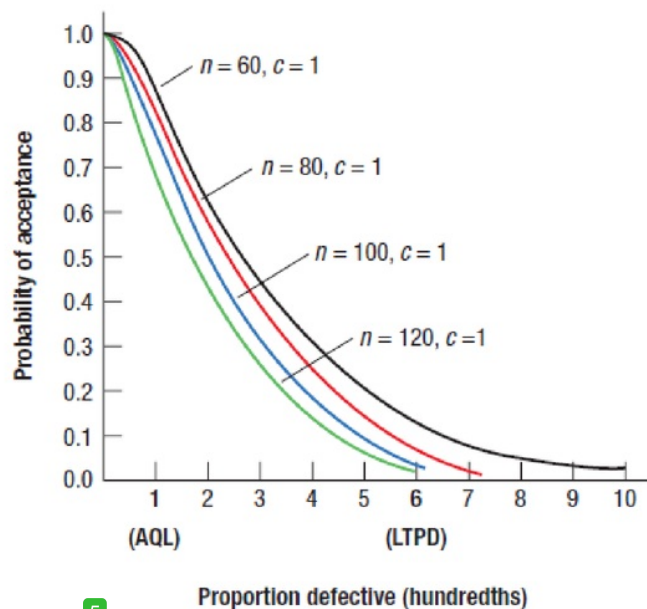


Figure 7 - Effects of Increasing Sample Size While Holding Acceptance Number Constant

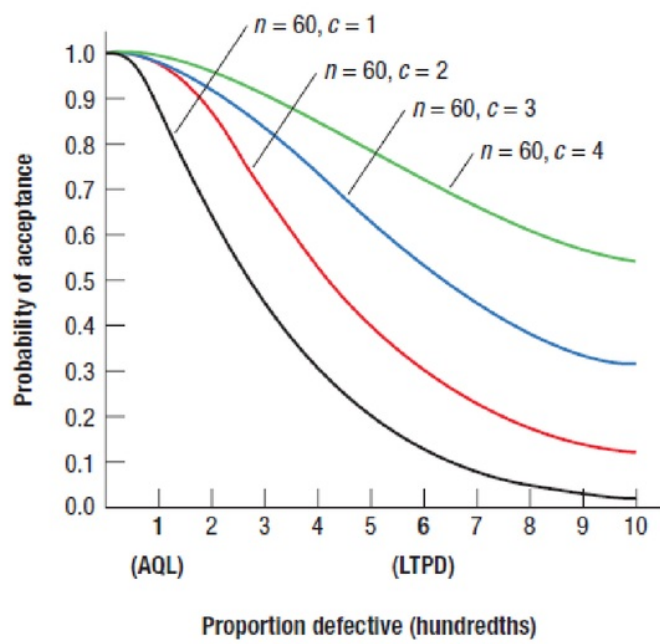


Figure 8 - Effects of Increasing Acceptance Number While Holding Sample Size Constant

3

THE MAIN QUALITY TOOLS

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3.14. QUALITY COSTS

3.14.1 TOTAL QUALITY COST

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A. PREVENTION COST

B. APPRAISAL COST

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A. INTERNAL FAILURE COST

B. EXTERNAL FAILURE COST

3.14.6 INTERNAL FAILURE COST

3.14.7 EXTERNAL FAILURE COST

Chapter objectives: In this Chapter we **118** present the Tools of Quality, starting with the 7 basic tools (Cause-and-effect diagram, Check sheet, Control charts, Histogram, Pareto chart, Scatter diagram, Flowchart), as well as some less famous but equally useful tools (Value Analysis - Value Engineering - Value Stream Mapping (VSM), Quality Costs, and Design Of Experiments (Doe)).

3.1

INTRODUCTION

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The Seven Basic Tools of Quality (also known as 7 QC Tools) originated in Japan when the country was undergoing major quality revolution and had become a mandatory topic as part of Japanese's industrial training program. These tools which comprised of simple graphical and statistical techniques were helpful in solving critical quality related issues. These tools were often referred as Seven Basics Tools of Quality because these tools could be implemented by any person with very basic training in statistics and were simple to apply to solve quality-related complex issues.

7 QC tools can be applied across any industry starting from product development phase till delivery. 7QC tools even today owns the same popularity and is extensively used in various phases of Six Sigma (DMAIC or DMADV), in continuous improvement process (PDCA cycle) and Lean management (removing wastes from process).

The seven QC tools are:

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- Cause-and-effect diagram (also called Ishikawa or fishbone chart): Identifies many possible causes for an effect or problem and sorts ideas into useful categories.
- Check sheet: A structured, prepared form for collecting and analyzing data; a generic tool that can be adapted for a wide variety of purposes.
- Control charts: Graphs used to study how a process changes over time.
- Histogram: The most commonly used graph for showing frequency distributions, or how often each different value in a set of data occurs.
- Pareto chart: Shows on a bar graph which factors are more significant.
- Scatter diagram: Graphs pairs of numerical data, one variable on each axis, to look for a relationship.

- Flowchart: a picture of the separate steps of a process in sequential order.

Also, there are other tools, such as the run chart, also known as a run-sequence plot; it is a graph that displays observed data in a time sequence. It is usually covered by the control charts and not included in the “7QC tools”.

3.2

CHECK SHEETS

A check sheet is a structured, prepared form for collecting and analyzing data. It is a generic tool that can be adapted for a wide variety of purposes. Check sheets are relatively simple forms. They include a list of nonconformities and a number of nonconformities.

Check sheets should also include the name of the project for which data is being collected, the shift when the items were produced, the names of persons collecting the data, dates of data collection and of production (if known), and the location of data collection (e.g., in house or at a customer's).

Because check sheets require you to standardize your list and definitions of nonconformities, they provide several benefits. It obliges us to agree on several important issues:

- The major categories of nonconformities. A good way to develop this list is to brainstorm with production personnel, management, QC personnel, and, most important, your customers.
- What constitutes “nonconformity”? How bad does it have to be to get thrown in the scrap or rework pile?

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When to Use a Check Sheet

- When data can be observed and collected repeatedly by the same person or at the same location.
- When collecting data on the frequency or patterns of events, problems, defects, defect location, defect causes, etc.
- When collecting data from a production process.

Check Sheet Procedure

- Decide what event or problem will be observed. Develop operational definitions.
- Decide when data will be collected and for how long.
- Design the form. Set it up so that data can be recorded simply by making check marks or Xs or similar symbols and so that data do not have to be recopied for analysis.
- Label all spaces on the form.
- Test the check sheet for a short trial period to be sure it collects the appropriate data and is easy to use.
- Each time the targeted event or problem occurs, record data on the check sheet.

Check Sheet Example

The figure below shows a check sheet used to collect data on telephone interruptions. The tick marks were added as data was collected over several weeks.

Telephone Interruptions						
Reason	Day					Total
	Mon	Tues	Wed	Thurs	Fri	
Wrong number						20
Info request						10
Boss						19
Total	12	6	10	8	13	49

Figure 9 – Example of a typical checksheet in a telephone centre

3.3

RUN CHARTS

Time is often a very important factor that contributes to variability in quality improvement problems. We could, of course, simply plot the data values versus time; such a graph is called a time series plot or a run chart.

A run chart is a particular form of a scatter plot with all the plotted points connected in some way. This chart usually shows a run of points above and below the mean or median. Run charts are mainly used as exploratory tools to understand the process variation. With run sequence plots, shifts in location and scale are typically quite evident. Also, outliers can easily be detected.

For instance, the stability of a production process can be crudely judged by plotting the quality measure or the quality characteristic against time, machine order etc. and then checking for any patterns or non-random behaviour (such as trends, clustering, oscillation, etc) in the production process.

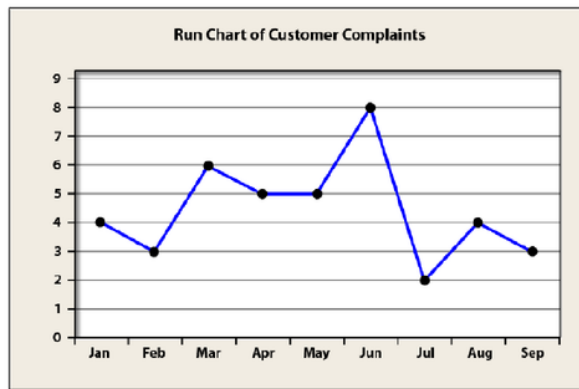


Figure 10 – Example of a run chart for customer complaints over time

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Examples could include measurements of the fill level of bottles filled at a bottling plant or the water temperature of a dish-washing machine each time it is run. Time is generally represented on the horizontal (x) axis and the property under observation on the vertical (y) axis. Often, some measure of central tendency (mean or median) of the data is indicated by a horizontal reference line.

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Run charts are similar in some regards to the control charts, but do not show the control limits of the process. They are therefore simpler to produce, but do not allow for the full range of analytic techniques supported by control charts.

3.4

HISTOGRAMS

101

Histograms (or **bar charts**) are a graphical representation in which measurements are grouped into bins; in this case each bin representing a range of values of some parameter shown in such a way that clear comparisons can be easily made.

This kind of graph uses vertical bars to display quantitative data. The heights of the bars indicate the frequencies or relative frequencies of values.

A bar chart is frequently used to emphasize the variation and unevenness in data. Using this information, further investigation could follow to determine why the Variation was occurring. The items are usually ranked from high to low, with the lengths of the bars indicating the value or frequency that a bar represents.

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When do we use it?

- A histogram is used to show clearly where the most frequently occurring values are located and the data is distributed

- **22** is a tool for determining the maximum process results
- It enables the analyst to quickly visualize the features of a complete set of data How do we construct it?

Histogram construction :

- After the data collection, count the number of data values collected (frequency)
- Compute the range of the data. Range = highest value – lowest value
- **Determine** number of intervals of the data as following:

Table 4 – Number of intervals according **76** the data values

Number of data	Number of intervals
Less than 50	5 to 7
50 to 99	6 to 10
100 to 250	7 to 12
More than 250	10 to 20

- **45** **compute** the intervals **width**, interval width = **range**/ number of intervals, when computing the interval width, you should round the data up to the next higher whole number to come up with values that are convenient to use (Ex: suppose that the range of a data is 29 and the number of intervals are **45**, then the interval width will be 5.8, you can round the interval width to 6).
- **Determine** the starting point for each interval. Use the smallest data point in your measurements as the starting point of the first interval. Suppose that the interval is starting from 3 and ending at 8, all the numbers equal to or **128** e than 3 and less than 8 will be in this interval.
- **Count** the number of points that fall within each interval- **22** which is a frequency
- **Draw** a frequency table for all values
- **Construct** a histogram based on the frequency table. For that, mark the class limits on the horizontal axis and the frequency on the vertical axis
- **Finally** write the title and number of values on the diagram

EXAMPLE:

Twenty five applicants were asked to state their years of experience the following table show the results:

Table 5 - Years of Experience of the Applicants (raw data)

Years of Experience of the Applicants				
5	10	8	10	7
9	7	8	9	9
5	5	4	11	6
13	9	12	6	13
12	10	9	14	3

- The calculated Range was $= 17-2= 15$
- The number of intervals (groups) in were **5** group
- The width of intervals was **3**

A table of five groups and their frequencies was constructed as follows:

Table 6 – Frequency distribution table for the years of experience

Interval group	Frequency
2-5	2
5-8	7
8-11	10
11-14	5
14-17	1

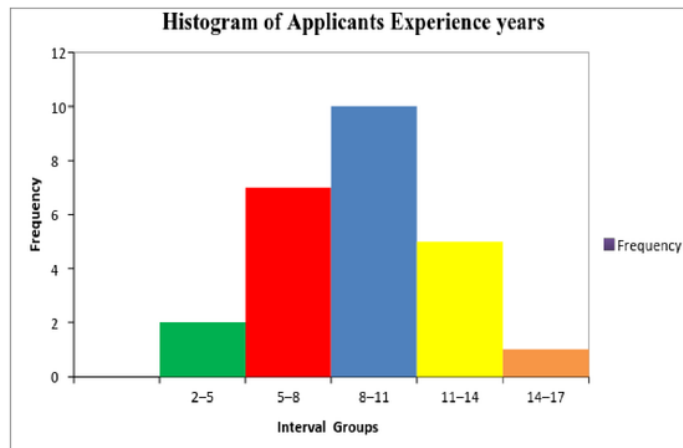


Figure 11 - Graphical histogram representation of applicant experience years

3.5

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SCATTER DIAGRAMS

Scatter diagrams are used to demonstrate correlation between two quantitative variables. Often, this correlation is linear. This means that a straight line model can be developed

Correlation classification

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- Linear : This means that a straight line model can be developed 38 is could be positive or negative correlation
- Nonlinear: Two variables may be correlated but not through a linear model. 38
- No correlation: Two quantitative variables may not be correlated at all

Important points about scatter diagrams construction

- Never draw a scatter diagram with only a few points.
- Only add a line of best fit if there is an obvious general relationship, i.e. you can see some correlation when you look at the graph.
- A line of best fit does not have to go through the origin
- When you insert a line of best fit by eye, insert it roughly half way through the points, getting an equal number on either side and as many on the line as possible
- The strength of a linear correlation between the response and the explanatory variable can be assigned based on (r), where the closer r to 1, the correlation strength is higher

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$$r = \frac{1}{n-1} \sum \left\{ \left(\frac{x-\bar{x}}{s_x} \right) \left(\frac{y-\bar{y}}{s_y} \right) \right\}$$

Classification of linear correlation

Linear correlations are classified according to the value of r as represented in the following diagrams :



Figure 12 - Linear correlations classified according to the value of r

Scatter Diagrams Construction

- **Collect** pairs of data where a relationship is suspected.
- **Draw** a graph with the independent variable on the horizontal axis and the dependent variable on the vertical axis.
- **Put** a dot or a symbol for each pair of data, where the x-axis value intersects the y-axis value.
- **Look** at the pattern of points to see if a relationship is obvious and if the variables are correlated.
- **Draw** the most fitted line
- **Calculate** r to determine the strength of correlation

Example:

JFDA made an analysis between the year of experience of employers and their financial reward to determine the correlation using scatter diagram and **r** value:

This table shows the year of experience of each employee and his financial reward:

Table 7 - Years of experience of each employee and his financial reward

Years of experience	Financial reward (JD)
2	100
3	105
4	106
5	115
6	120
7	120
8	130
9	130
10	140
11	140
12	140
13	140
14	140
15	150

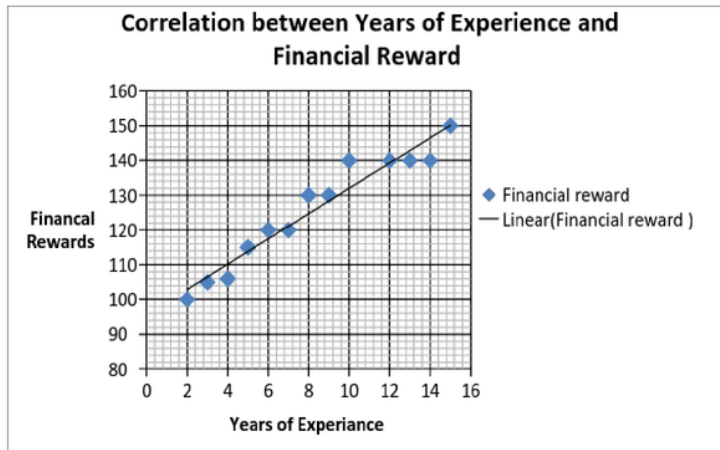


Figure 13 – Correlation between years of experience and financial reward

According to scatter diagram above the years of experience and the financial rewards are highly positive correlated ($r^2 = 0.94$, $r = 0.975$).

3.6

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PARETO CHARTS

85 Pareto chart, also called a Pareto distribution diagram, named after Vilfredo Pareto, is a type of chart that contains both bars and a line graph, where individual values are **69**resented in descending order by bars from left to right, and the cumulative total **69** represented by the line. A simple rule, pareto 80/20 rule, 20 % issues causes 80 % results. This means, 80 % if problems come from 20 of reasons. 80 % of results come from 20% of work.

42

We can apply the 80/20 rule to almost anything:

- 80% of customer complaints arise from 20% of your products and services.
- 80% of delays in the schedule result from 20% of the possible causes of the delays.
- 20% of your products and services account for 80% of your profit.
- 20% of your sales force produces 80% of your company revenues.
- 20% of a systems defects cause 80% of its problems.

55

Pareto charts are extremely useful for analyzing what problems need attention first, because the taller bars on the chart, which represent frequency, clearly illustrate which variables have the greatest cumulative effect on a given system.

A flat Pareto diagram simply means there are no significant differences among the variables

Pareto chart construction:

- Arrange the criteria in descending order based on the frequency
- Calculate the total of the frequencies
- Calculate the frequency percent for each criteria as follows:
 - $\text{Frequency percent} = (\text{frequency} / \text{total of frequencies}) \times 100$
- Calculate the accumulative frequency

Example:

In a customer satisfaction survey that was done to determine the most criteria that affect the customer satisfaction about the service provided by the JFDA, the result was as follows:

Table 8 - Criteria that affect the customer satisfaction in descending order based on the frequency

NO	Unsatisfied Criteria	Frequency
1	Quality of service	40
2	Dealing with complaint	30
3	Advice and support for the customer	60
4	Fees charged	15
5	Service time	35
6	Means of Communication	20

- The criteria are arranged in descending order based on the frequency
- The total of the frequencies was calculated which is 200
- The frequency percent for each criteria was calculated as follow
- Frequency percent = $(\text{frequency} / 200) \times 100$
- The accumulative frequency for each criteria was calculated

Table 9 – Frequency distribution table for customer satisfaction

No	Unsatisfied Criteria	Frequency	% Frequency	% Cumulative frequency
3	Advice and support for the customer	60	30.00	30.00
1	Quality of service	40	20.00	50.00
5	Service time	35	17.50	67.50
2	Dealing with complaint	30	15.00	82.50
6	Means of Communication	20	10.00	92.50
4	Fees charged	15	7.50	100.00
	Total	200		

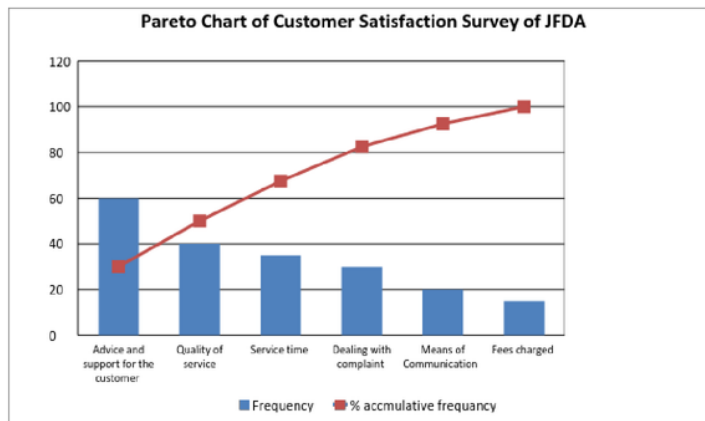


Figure 14 – Pareto chart for customer satisfaction survey

In this example the most variables that affect the customer satisfaction are advice and support, quality service, and service time. Following the Pareto Principle, at the 80% line, those are the areas where the JFDA should focus the attention to increase the customer satisfaction about the service provided.

3.7

FLOWCHARTS

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A flowchart is a visually graphic representation of a logic sequence, work or manufacturing process, organization chart, or similar formalized structure.

The main purpose of a flow chart is to provide people with a common language or reference point when dealing with a project or process.

Benefits and advantages of the flow chart

Communication: Flowcharts are better way of communicating the logic of a system to all concerned.

Effective analysis: with the help of flowchart, problem can be analyzed in more effective way.

Proper documentation: program flowcharts serve as a good program documentation, which is needed for various purposes.

Efficient Coding: the flowcharts act as a guide or blueprint during the systems analysis

Proper Debugging: the flowchart helps in debugging and fixing process.

Efficient Program Maintenance: The maintenance of operating program becomes easy with the help of flowchart.

Time estimation: the flow chart helps in estimation of the timescale of the process.

Steps to perform the Flow Chart :

First: identify the tasks and decisions that you make during a process, and write them down in order.

Second: arrange these steps in the flow chart format, using the appropriate symbols.

Finally: check the flow chart to make sure that it accurately represents the process, and that it shows the most efficient way of doing the job.

Common Flowcharting Symbols:



process step



decision tree (needs two lines leaving it)



document symbol



Flow line



connector (between two pages)



terminator



Transfer of material



Measurement or finished goods

The following flow chart describes the means of dealing with a complaint in the JFDA:

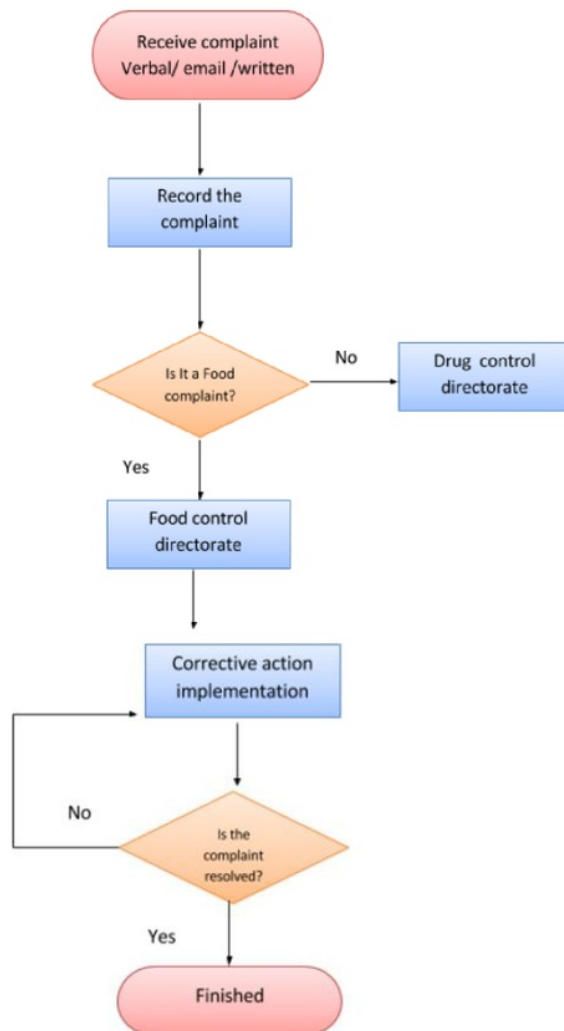


Figure 15 – Example of Flowchart

3.8

4

CAUSE AND EFFECT (FISHBONE) DIAGRAMS

The cause-and-effect diagram, often called a “fishbone” diagram or Ishikawa diagram is a tool that shows the relationship between effect and causes, so it is an important tool to assess the generation of ideas for problem causes and, in turn, serves as a basis for solution finding.

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Why use it?

- Cause-and-effect diagrams are necessary tools in allowing a brainstorming team to identify, explore, and graphically display, all of the possible causes related to a problem or condition to discover its root cause(s). A fishbone diagram is a visual way to look at cause and effect.
- It is a more structured approach than some other tools available for brainstorming causes of a problem (e.g., the Five Whys tool).

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What does it do?

- Enables teams to focus on the content of the problem, not on the history of the problem or differing personal interests of team members,
- Creates a snapshot of the collective knowledge and consensus of a team around a problem. This builds support for the resulting solutions,
- Focuses the team on causes, not symptoms.

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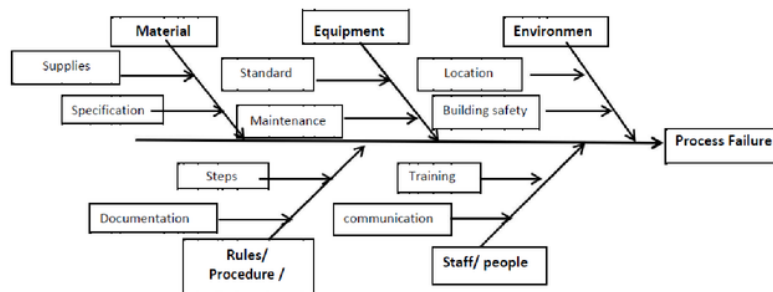
Major types of causes

- Production Process: machines (equipment), methods (how work is done), materials (components or raw materials), people (the human element),
- Service Process: policies (Higher level decision rules), procedures (steps in a task), Environment (equipment and space), people.

Construction:

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- The problem or effect is displayed at the head or mouth of the fish.
- Possible contributing causes are listed on the smaller "bones" under various cause categories.
- A fishbone diagram can be helpful in identifying possible causes for a problem that might not otherwise be considered by directing the team to look at the categories and think of alternative causes.
- Include team members who have personal knowledge of the processes and systems involved in the problem or event to be investigate



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Figure 16 – Example of a "Cause-and-effect" (fishbone) diagram

3.9

DESIGN OF EXPERIMENTS (DoE)

What is DoE?

68

DoE is the branch of applied statistics which deals with planning, conducting, analyzing and interpreting controlled tests to evaluate the factors that control the value of a parameter or group of parameters.

Why DoE?

31

In process development: to improve process yield, to reduce variability, development time or the overall costs

In Design: To Evaluate and compare material alternatives and product robustness, or to determine key design parameter.

Steps involved in DoE

Experimental Design Process

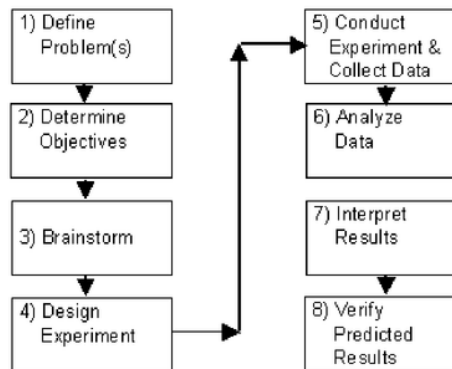


Figure 17 – Steps involved in DoE

- Clearly define the problem statement.
- Choose factors, ranges and levels.
- Choose response variable(s).
- Choose experimental design (s).
- Perform the experiment.
- Perform Statistical analysis.
- Present of the results.
- Provide conclusions.
- Provide recommendations and further work.

Nomenclature

- **Randomization**: Specifies the sequence in which the trials of an experiment are performed. Generally, a randomized sequence helps eliminating the effects of uncontrolled or unknown variables.
- **Replication**: Refers to the number of repetition of a complete experimental treatment, including the setup.
- **Blocking**: Blocking allows you to restrict randomization by carrying out all of the trials with one setting of the factor and then all the trials with the other setting. Blocking is needed when complete randomizing of a factor is either possible or costly.
- **Controlled Factors**: Set to predefined levels for DOE, e.g.
- In Manufacturing: Furnace Temp., Fill Pressure, Material Moisture, etc.
- In Service: Process Design, Follow-up, etc.
- **Uncontrollable Factors**: factors that cannot be controlled in actual operations, but may be controlled during experimentation, eg. Humidity, air pollution, arrival rate, etc.

Guidelines for a desirable DOE

- Provide sufficient distribution of information throughout region of interest.
- Provide model that predicts the response, as close as possible to true response, at all points w/in region of interest.
- Provide ability to detect model lack of fit.

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- Allow blocking.
- Allow sequential buildup of design.
- Provides internal estimate of error variance.
- Provide simple means of calculating estimates of coefficients.

How do you choose appropriate design for your experiment?

21

Types of designs can be listed according to the experimental objective they meet:

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Comparative objective: If you have one or several factors under investigation, but the primary goal of your experiment is to make a conclusion about one a-priori important factor, (in the presence of, and/or in spite of the existence of the other factors), and the question of interest is whether or not that factor is "significant"

Screening objective: The primary purpose of the experiment is to select or screen out the few important main effects from the many less important ones. These *screening designs* are also termed main effects designs.

Response Surface (method) objective: The experiment is designed to allow us to estimate interaction and even quadratic effects, and therefore give us an idea of ⁶⁷ (local) shape of the response surface we are investigating. RSM designs are used to: Find improved or optimal process settings troubleshoot process problems and weak points or make a product or process more *robust* against external and non-controllable influences. "Robust" means relatively insensitive to these influences.

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Table 10 - Design Selection Guideline *

NUMBER OF FACTORS	COMPARATIVE OBJECTIVE	SCREENING OBJECTIVE	RESPONSE SURFACE OBJECTIVE
1	1-factor completely randomized design	—	—
2 to 4	Randomized block	Full or	Central

	design	fractional factorial design	composite or Box-Behnken
More than 5	Randomized block design	Fractional factorial or Plackett-Burman	Screen first to reduce number of factors

*Ref: **Engineering statistics handbook**. Section 5.3 Choosing experimental design

Some common types of DoE:

- Completely Randomized Designs
- Randomized Complete Block Designs
- Nested Factorial Designs
- Split Plot Type Designs
- Latin Square Type Designs
- Full Factorial Designs
- Fractional Factorial Designs

Why does DOE fail?

Some important causes for not achieving the objective of the experiment are:

- Wrong choice of design for the experiment.
- Inappropriate choice of response for the experiment.
- Failure to identify the key process variables which affect the response.
- Inadequate measurement system for making measurements.
- Lack of statistical skills (analysis or interpretation).

Baking Example

Step 1: Choose relevant Factors: oven, sugar, flour and eggs

Step 2: Choose levels of each factor: oven (temperature and baking time), sugar, flour and eggs (amount used).

Step 3: Record important responses such as: taste, color, consistency, texture, etc.

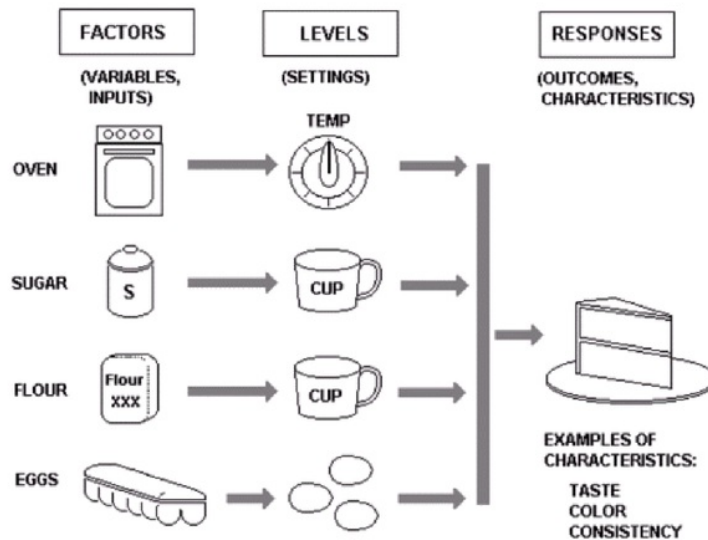


Figure 18 – Baking example for DoE

3.10

CONTROL CHARTS

A control chart is defined as a graph that establishes control limits of a certain process, where Control Limits are allowable upper and lower bands of a control chart (UCL: Upper Control Limit, LCL: Lower Control Limit).

Quality can be measured using one of two methods:

- Attributes: a characteristic that can be evaluated with a discrete response only such as: Yes - No, good - bad; acceptable - unacceptable, clean - unclean, good food quality-bad food quality

- 4 Variables: a characteristic that is continuous and can be measured: weight, length, fill volume, pH, etc.

9
When to Use Control Charts?

- When a process has the tendency to get out of control.
- When the process is particularly costly or harmful when it gets out of control

Examples:

- At the beginning of a process to avoid wasting time and money for a process with bad supplies.
- To avoid a costly or irreversible point, after which product is difficult to correct or rework.
- Before releasing the final product or service to be delivered.

Types of control charts

Attributes:

- p-chart (proportion chart: used when sample size is constant and/or known). P-chart uses portion of defectives in a sample.
- c-chart (counts chart: used when sample size is not constant and/or are unknown). C-chart uses number of defects in an item

9
Variables:

- range (R-chart) and mean (\bar{x} - chart).

9
When a process is considered in control (or under control)?

- No sample points are located outside control limits
- Most points are close or near to process average
- The number of points above and below centerline are about equal
- The point's distribution appears random.

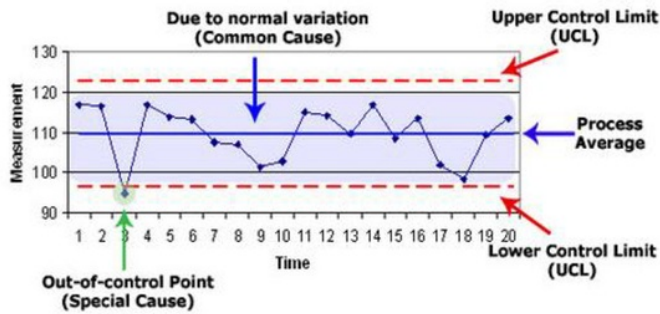


Figure 19 – Example of a control chart of an out of control process

3.10.1 CONTROL CHART FOR VARIABLES

Types of control charts for variables

- Mean (\bar{x} -bar) charts: Used to track the average value observed over time.
- Range (R) charts: Used to track the spread of the distribution over time.

Steps for constructing a control chart for variables (with example)

A quality control inspector at food canning company has taken 3 samples with 4 observations each of the volume of bottles filled. The standard deviation of the bottling operation is 5.6 g. The data given in the table will be used to construct X-bar and R control charts with limits of 3 standard deviations for the 450 g bottling operation.

Step 1: Collect data

- Run the process untouched to gather initial data for control limits.

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- Generally, collect 20-25 subgroups (100 total samples) before calculating the control limits.
- Each time a subgroup of sample size n is taken; an average is calculated for the subgroup and plotted on the control chart.

Step 2: Calculate the Mean of Each Sample

Table 11 – Volume of bottles filled for 3 samples and their means (\bar{x} -bar)

	9		
	Time 1	Time 2	Time 3
Observation 1	442.4	450.8	448
Observation 2	448	448	445.2
Observation 3	442.4	442.4	445.2
Observation 4	445.2	445.2	442.4
Mean (\bar{x} -bar)	444.5	446.6	445.2

9

Step 3: Calculate the Standard Deviation of the Sample Mean

$$\sigma_{\bar{x}} = \frac{\sigma}{\sqrt{n}} = 2.378/\sqrt{4} = 1.189$$

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Step 4: Calculate grand mean ($\bar{\bar{X}}$), central line (CL), upper and lower control limits (UCL, LCL).

$$\bar{\bar{X}} = \frac{\sum_{i=1}^m \bar{X}_i}{m} = 445.8$$

$$\begin{aligned} \text{UCL} &= \bar{\bar{X}} + 3\sigma \\ \text{LCL} &= \bar{\bar{X}} - 3\sigma \end{aligned} = (449.4, 442.23)$$

Step 5: Draw the Chart

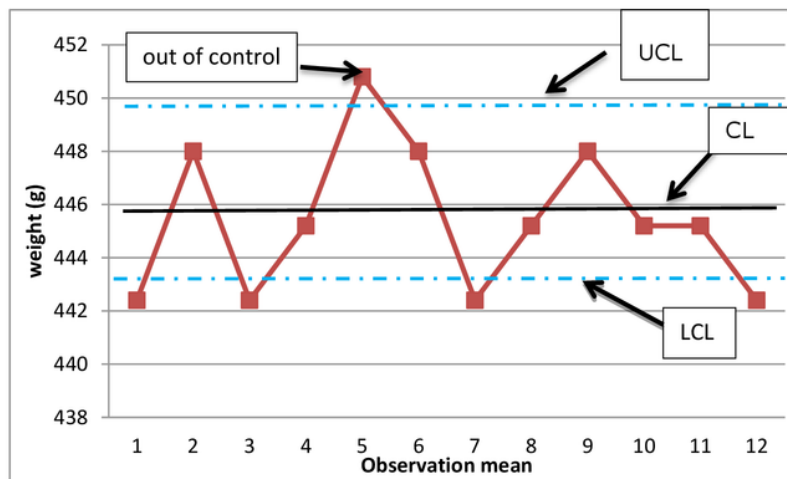


Figure 20 – Control chart based on the example calculations

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Based on our knowledge of the normal curve, a control chart exhibits a state of control when:

- Two thirds of all points are near the center value.
- The points appear to float back and forth across the centerline.
- The points are balanced on both sides of the centerline.
- No points beyond the control limits.
- No patterns or trends

Identifying patterns in control charts:

- Trends: steady, progressive changes in level
- Change, jump, or shift in level, mistakes.
- Runs - 7 points above or below; six increasing or decreasing, clusters
- Recurring cycles, Two populations

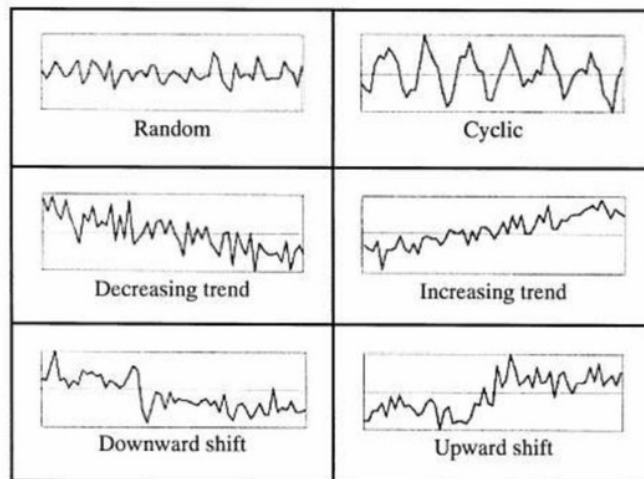


Figure 21 - Trends examples in control charts

3.10.2 CONTROL CHARTS FOR ATTRIBUTES

Definition of attribute control charts

The idea behind control charts for attribute is to be able to represent those attributes or characteristics that cannot be represented numerically or if such numerical representation isn't practical. Therefore, it is convenient to use quality parameters that can sort or classify the attributes into good or bad, acceptable or unacceptable, conforming or nonconforming, defective or non-defective, etc. Such quality characteristic is called *attribute*.

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Types of attributes control charts

Attributes control charts are classified into three categories:

- **Control charts** that deal with the number of defects or nonconformities. Those are called count charts or (c charts).
- Control charts that deal with fraction or proportion of defective product. Those are referred to as proportion charts or (p charts).
- Control charts that deal with defects per unit. Those are useful when dealing with average number of nonconformities per unit of a product. They are called unit charts or (u charts).

Count charts (c charts)

Consider a canning plant that produces canned food product. Each can is referred to as an "item of a product". There are certain specifications for the can to be conforming or of acceptable quality. When a particular can does not meet at least one of the specifications, it is classified as a nonconforming item. Therefore, a nonconforming or defective item contains at least one defect or nonconformity. However, a can can contain several defects but still be classified as conforming. This means defects may be noncritical to quality specifications. If, on the other hand, the number of the so-called "unimportant" defects becomes alarmingly large, an investigation of the production of these cans is warranted. Count charts can be either for the total number of nonconformities (defects) for the inspected units, or can be the average number of nonconformities per inspection unit.

Example:

Twenty five batches of canned food with 100 cans each were inspected for defects. Here the batch is the inspection unit. The observed number of defects for each batch is given as follows:

Table 12 - Observed number of defects for each batch

Batch Number	Number of Defects	Batch Number	Number of Defects
1	17	14	16
2	14	15	15
3	27	16	13
4	16	17	14
5	11	18	16
6	20	19	11
7	10	20	20
8	13	21	11
9	10	22	19
10	18	23	16
11	18	24	30
12	17	25	14
13	14		

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Use the table to develop a c chart for the number of defects per batch.

Step 1: calculate \bar{c} value:

$$\bar{c} = \frac{\text{total number of defects}}{\text{total number of samples}}$$

$$\bar{c} = 400/25=16$$

Step 2: calculate upper and lower control limits:

$$UCL = \bar{c} + 3\sqrt{\bar{c}} = 16 + 3\sqrt{16} = 28$$

$$LCL = \bar{c} - 3\sqrt{\bar{c}} = 16 - 3\sqrt{16} = 4$$

Step 3: develop the c-chart:

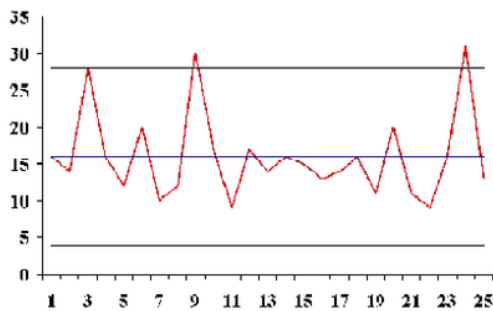


Figure 22 - c-Chart for the process

General comments about c chart⁸

- A nonconforming (defective) unit of a product does not meet one or more of the specifications for that particular product.
- Defect within a unit is defined as nonconformity of a specific point where the specification is not met.
- Not all products with nonconformities will be nonconforming. Depending on the degree of severity it may still pass operations.
- The sample size should be chosen according to statistical considerations (e.g. using a size large enough to take positive lower control limits or economic factors (the larger the sample size the more expensive the sampling process)).

Proportion chart (p-chart)⁶⁴

A p-chart is used with data collected in subgroups with varying sizes. Since the subgroup size may vary, it shows the proportion of nonconforming items rather than the actual count. P-charts show how the process changes over time. P-charts are used to determine if the process is predictable, stable and to monitor the effects of process improvement actions.

Example:

A team in a food processing plant has been working on improving the packaging of a certain product. The team is trying to reduce labelling quality problems by decreasing the fraction of packages with defective labels. The team developed the following operational definition for a defective label: a package has defective label if it has unclear nutrition label, incorrect coding, incorrect production and expiry date. The team decided to pull a random sample of 100 packages per day. If the package had one or more errors it was defective. The data from the last 15 days are given in the table.

Table 13 – Defective labels

Day Number	Packages Inspected (n)	Number Defective (np)	Fraction Defective (p)
1	100	22	0.22
2	100	33	0.33
3	100	24	0.24
4	100	20	0.2
5	100	18	0.18
6	100	24	0.24
7	100	24	0.24
8	100	29	0.29
9	100	18	0.18
10	100	27	0.27
11	100	31	0.31
12	100	26	0.26
13	100	31	0.31
14	100	24	0.24
15	100	22	0.22

Steps for building the p-chart:

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Step 1: calculate the average fraction defective. To determine the average, we add up all the np values and divide by the sum of all the n values:

$$\bar{p} = \frac{\sum np}{\sum n} = \frac{373}{1500} = 0.248$$

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Step 2: determine the average subgroup size. Since the subgroup size is constant, the average subgroup size is 100.

$$\bar{n} = \frac{\sum n}{k} = \frac{1500}{15} = 100$$

18

Step 3: calculate the control limits. The control limits calculations are shown below.

$$UCL = \bar{p} + 3\sqrt{\bar{p}(1-\bar{p})/\bar{n}} = 0.378$$

$$LCL = \bar{p} - 3\sqrt{\bar{p}(1-\bar{p})/\bar{n}} = 0.118$$

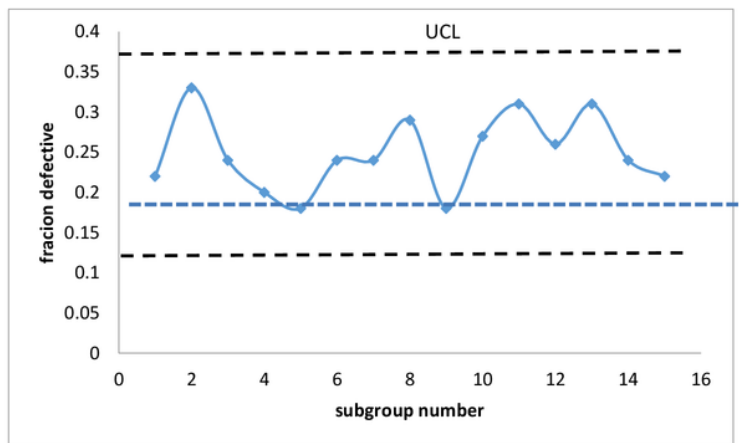


Figure 23 – p-chart for the defective items

3.11

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PROCESS CAPABILITY (CAPABILITY INDICES)

Process capability is the ability of the process to meet the design specifications for a service or product.

Nominal value is a target for design specifications.

Tolerance is an allowance above or below the nominal value.

Process capability indices: ratios that quantify the ability of a process to produce within specifications

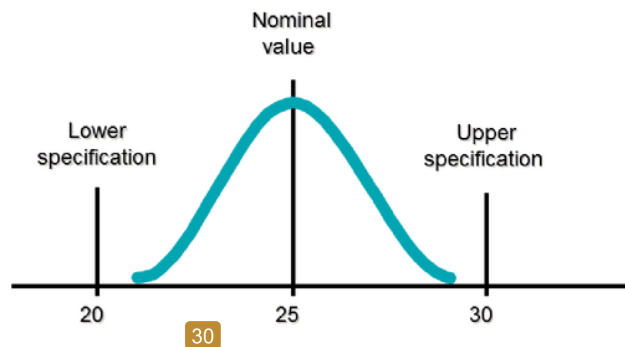


Figure 24 - The Six sigma spread versus specification limits

- Case I: $6\sigma < USL - LSL$: Most desirable; individual values fall within specification limits
- Case II: $6\sigma = USL - LSL$: Okay, as long as the process remains in control
- Case III: $6\sigma > USL - LSL$: Undesirable; process incapable of meeting specifications.

8

Process capability ratio (C_p): is the tolerance width divided by 6 standard deviations (process variability).

$$C_p = \frac{\text{Upper specification} - \text{Lower specification}}{6\sigma}$$

8

Process Capability Index (C_{pk}): Process Capability Index, C_{pk} , is an index that measures the potential for a process to generate defective outputs relative to either upper or lower specifications.

$$C_{pk} = \text{Minimum of } \left[\frac{\bar{x} - \text{Lower specification}}{3\sigma}, \frac{\text{Upper specification} - \bar{x}}{3\sigma} \right]$$

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We take the minimum of the two ratios because it gives the worst-case situation. $C_{pk} = +1$ is required and $C_{pk}=1.33$ is recommended.

Example: Quality control lab

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A certain quality control test in a food plant takes an average time of 26.2 minutes with a standard deviation of 1.35 minutes. The nominal value for this test is 25 minutes with an upper specification limit of 30 minutes and a lower specification limit of 20 minutes. The quality control technician of the lab wants to have three-sigma performance for his lab. Is the lab process capable of this level of performance?

Upper specification = 30 minutes

Lower specification = 20 minutes

Average service = 26.2 minutes

$\sigma = 1.35$ minutes

$$C_{pk} = \text{Minimum of } \left[\frac{26.2 - 20.0}{3(1.35)}, \frac{30.0 - 26.2}{3(1.35)} \right]$$

$$C_{pk} = \text{Minimum of } [1.53, 0.94] = 0.94$$

Process
Capability
Index

Conclusion: the process is incapable since C_{pk} is less than 1.0

Notes:

- C_{pk} : For process capability studies indicates whether the process will produce units within the tolerance limits.
- C_{pk} has a value equal to CP if the process is centered on the nominal; if C_{pk} is negative, the process mean is outside the specification limits; if C_{pk} is between 0 and 1, then some of the 6 sigma spread falls outside the tolerance limits. If C_{pk} is larger than 1, the 6 sigma spread is completely within tolerance limits.
- A value of $C_{pk} = 1.33$ or greater is usually desired.
- Since a C_{pk} of 1.0 indicates that 99.73% (6 sigma) of the parts produced are within specification limits, in this process it is likely that only about 3 out of 1,000 need to be scrapped or rejected.

Six Sigma: is a comprehensive and flexible system for achieving, sustaining, and maximizing business success by minimizing defects and variability in processes.

What it means to operate at 6-sigma?

Table 14 – Operation at various σ levels and 6σ

Range	Population in range	Expected frequency outside range	Approx. frequency for daily event
$\mu \pm 1\sigma$	0.682689492137	1 in 3	Twice a week
$\mu \pm 2\sigma$	0.954499736104	1 in 22	Every three weeks
$\mu \pm 3\sigma$	0.997300203937	1 in 370	Yearly
$\mu \pm 4\sigma$	0.999936657516	1 in 15,787	Every 43 years (twice in a lifetime)
$\mu \pm 5\sigma$	0.999999426697	1 in 1,744,278	Every 5,000 years (once in history)
$\mu \pm 6\sigma$	0.999999998027	1 in 506,842,372	Every 1.5 million years

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Six Sigma Improvement Model:

- Define Determine the current process characteristics critical to customer satisfaction and identify any gaps.
- Measure Quantify the work the process does that affects the gap.
- Analyze Use data on measures to perform process analysis.
- Improve Modify or redesign existing methods to meet the new performance objectives.
- Control Monitor the process to make sure high performance levels are maintained.

Six Sigma Implementation:

- Top down Commitment from corporate leaders.
- Measurement Systems to Track Progress
- Tough Goal Setting through benchmarking best-in-class companies.
- Education: Employees must be trained in the "whys" and "how-tos" of quality.
- Communication: Successes are as important to understanding as failures.
- Customer Priorities: Never lose sight of the customer's priorities.

3.12

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VALUE ANALYSIS - VALUE ENGINEERING (VA/VE)

VA/VE: Value Analysis/Value Engineering is a systematic and organized procedural decision-making process. It has been used in almost any kind of application. It helps people creatively generate alternatives to secure essential functions at the greatest worth as opposed to costs. This is referred to as

value. It is also known as Value Analysis, Value Management, Value Planning, and a host of other names.

It answers 3 big questions: What must the item do? What does the item cost? What is the item worth?

VA/VE evaluates your products and supply chain from a unique perspective allowing for cost reduction, improve²⁹ quality, and meaningful supplier relationships. VA/VE can be applied in various ways to achieve product/process cost savings.

First decide the manufacturing area that is most critical: New Product Development or Items Currently in Production.

⁷ **3.12.1 VALUE ANALYSIS**

Value Analysis (VA) is concerned with existing products. It involves a current product being analysed and evaluated by a team, to reduce costs, improve product function or both. Value Analysis exercises use a plan which step-by-step, methodically evaluates the product in a range of areas. These include costs, function, alternative components and design aspects such as ease of manufacture and assembly.

A significant part of VA is a technique called Functional Analysis, where the product is broken down and reviewed as a number of assemblies. Here, the function is identified and defined for each product assembly. Costs are also assigned to each one. This is assisted by designing and viewing products as assemblies (or modules). As with VE, VA is a group activity that involves brainstorming improvements and alternatives to improve the value of the product, particular to the customer.

7

3.12.2 VALUE ENGINEERING

Value Engineering (VE) is concerned with new products. It is applied during product development. The focus is on reducing costs, improving function or both, by way of teamwork-based product evaluation and analysis. This takes place before any capital is invested in tooling, plant or equipment.

This is very significant, because according to many reports, up to 80% of a product's costs (throughout the rest of its life-cycle), are locked in at the design development stage. This is understandable when you consider the design of any product determines many factors, such as tooling, plant and equipment, labour and skills, training costs, materials, shipping, installation, maintenance, as well as decommissioning and recycle costs.

Therefore value engineering should be considered a crucial activity late on in the product development process and is certainly a wise commercial investment, with regard to the time it takes. It is strongly recommended you build value engineering into your new product development process, to make it more robust and for sound commercial reasons.

3.13

VALUE STREAM MAPPING (VSM)

9

What is a Value Stream?

A Value Stream includes all elements (both value added and non-value added) that occur to a given product from its inception through delivery to the customer.

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Value stream mapping is a lean-management method for analyzing the current state and designing a future state for the series of events that take a product or service from its beginning through to the customer.

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Value Stream Mapping is a special type of flow chart that uses symbols known as "the language of Lean" to depict and improve the flow of inventory and information.

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A Value Stream Map depicts the flow of all of the activity, value added and otherwise, needed to fulfil a request. It is a way to visualize the steps required to transform a customer request into a good or service, or in other words, a product's production path from supplier to the customer.

A value stream map, which offers a holistic view of the process or the system, can be drawn at any scale; to map a simple administrative process as well as a complicated global-level manufacturing and sales process. It helps identify non-value adding steps that should be eliminated and areas in the process that should be improved to achieve better and faster outcomes at a lower cost in a safer work environment.

A value stream map can be divided into 3 segments:

- Production or process flow

In this section, as in a traditional process flowchart, the flow of the process is drawn from left to right. If there are subtasks or parallel tasks, they should also be drawn from left to right beneath the main flow. Drawn this way, it is easier to tell apart the major tasks that occur time and time again throughout the process, from the minor steps.

- Information or communication flow

In this section (at the top portion of the map) all the communication, both formal and informal, that occurs within the value stream is shown. There's no standardized flow of communication as communication can flow in any direction.

- Timelines and travel distances

Timelines appear at the bottom of the value stream map. This set of lines conveys the time-related data measured in the

process improvement. While the top line indicates the process lead time, the bottom line indicates the total cycle time (some maps contain labor content instead of cycle time; when that's the case, the line is called total work content). The other line, placed at the bottom of the map shows the travel distance (of the product or work or of the people moving) through the process.

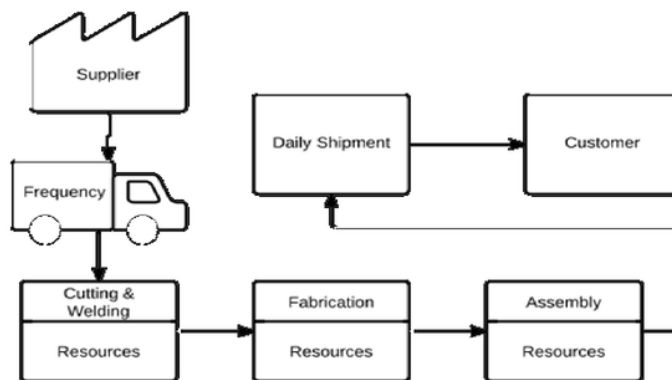


Figure 25 – Value stream map

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Value Stream Mapping Purpose: To provide optimum value to the customer through a complete value creation process with minimum waste in:

- Design (concept to customer)
- Build (order to delivery)
- Sustain (in-use through life cycle to service)

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The objective in drawing the map is to identify each significant activity required to create the desired value.

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- Many organizations pursuing "lean" conversions have realized that improvement events alone are not enough
- Improvement events create localized improvements, value stream mapping & analysis strengthens the gains by providing vision and plans that connect all improvement activities
- Value stream mapping & analysis is a tool that allows you to see waste, and plan to eliminate it

What Is Value? It is what the customer is buying. **Value** is a capability provided to a customer:

- of the highest quality,
- at the right time,
- at an appropriate price,

as defined by the customer.

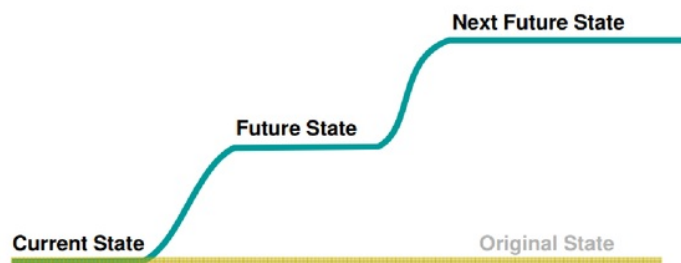


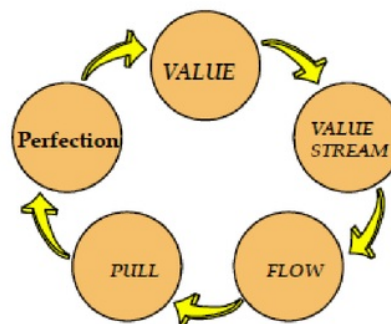
Figure 26 – Value stream current and future states

9 What Is Value Stream Analysis?

- Planning tool to optimize results of eliminating waste
- Select the product/family
- Identify the current state VSM which describes the process as it is today
- Apply lean techniques to reduce the wastes
- Create future state VSM which describes the ideal state based on lean principles

43 Apply Five Simple Principles

- Specify value from the standpoint of end customer
- Identify the value stream for each product family



- Make the product flow
- So the customer can pull
- As you manage toward perfection

What is the Value that Flows?

- Specify value from the standpoint of the end customer
- Ask how your current products and processes disappoint your customer's value expectation:
- Price?
- Quality?
- Reliable delivery?
- Rapid response to changing needs?
- Other?

	A	B	C	D	E	F
	Symbols	Description	Symbols	Description	Symbols	Description
1		Customer/Supplier		Kaizen Blitz		External Shipment
2		Process		Supermarket		FIFO
3		Machine, operation or department through which material flows		Small inventory for immediate production		First in, First out lane
4		Data Box		Buffer		In Box
5		Inventory		Pull Symbols		Internal Movement
6		Work Cell		Kanban Card		People, phones, operators, etc.
7		Push Arrow		Load Leveling		
8		NVA Delay		Go and See		Scheduling

Figure 27 – VSM symbols

3.14

QUALITY COSTS

10 Today it is universally accepted that 'Quality' is an embodiment of design and properties of a product or service or both which guarantees customer satisfaction. In the present business scenario of barrier-free global markets, elements of excellence are a necessity for any product or service those will ensure properties, services and prices. The concept of total quality management, which encompasses almost all activities of 10 organization, has become part and parcel of any business. With the advent of modern information technology customers are well aware about the design, quality and price as 10 ts of products. It is no wonder that only those organizations who can satisfy their customers with these features are surviving and flourishing.

10 In this era of competitive business, price is a major issue for a mass-manufactured product; in this issue 'Quality Cost' goes hand-in-hand with satisfactory product and service cost. One of the major obstacles to the establishment of stronger quality programme in earlier days was the wrong notion that the achievement of better quality required much higher costs.

Reasons for applying Quality Costs concept in manufacturing: Unsatisfactory quality means unsatisfactory resource utilization. This involves wastes of material, labor, equipment time and consequently higher costs. In contrast, satisfactory quality means satisfactory resource utilization and consequently lower costs. A major reason for this mistaken concept about cost was unavailability of relevant data. Today, the scenario has changed and any scientific accounting procedure recognizes that cost of quality is measurable. In fact, quality cost is the basis through which investments in quality programmes can be evaluated in terms of cost of improvement, profit enhancement and price reduction for an organization.

Costs of quality are costs that occur because poor quality may exist or actually does exist. More specifically, quality costs are the total of the costs incurred by (1) investing in the prevention of nonconformances to requirements; (2) appraising a product or service for conformance to requirements; and (3) failure to meet requirements. Quality costs are classified into three broad categories: prevention, appraisal, and failure costs.

1

3.14.1 TOTAL QUALITY COST

When it comes to Quality & Cost, there are 4 different Categories that can be utilized to capture your quality related costs, these are:

- Prevention Cost – costs associated with activities specifically designed to prevent poor quality in products.
- Appraisal Cost – costs associated with activities specifically designed to measure, inspect, evaluate or audit products to assure conformance to quality requirements.
- Internal Failure Cost – costs incurred when a product fails to conform to a quality specification before shipment to a customer.
- External Failure Cost – costs incurred when a product fails to conform to a quality specification after shipment to a customer.

The Total Quality Cost then is simply the sum of all these cost categories; Prevention, Appraisal, & Failure Costs (Internal & External).

The Total Quality Cost can be summarized as all investments in the prevention of defects, the testing of product to assure Quality, or the failure of a product to meet a customer Requirement.



As you can see, there are really two “good” quality cost categories (Prevention & Appraisal) and two “bad” categories (Internal Failures & External Failures). These are known as the Cost of Good Quality & the Cost of Poor Quality (otherwise Conformance Cost and Non-Conformance Cost, respectively).

1 This is where the Cost of Quality perspective can be very powerful in that it helps you understand where you’re investing (or wasting) your money.

Are you spending your money preventing defects and assuring quality, or are you spending your money performing rework and handling customer complaints?

This perspective can also help you understand the difference between the actual cost of the product you’re producing & what the cost could be if Quality was perfect.

These cost categories can also be re-stated from the “Right The First Time” perspective.

All you need to do is to ask yourself is “If all our processes produced the correct result the 1st time, would this cost still be here?”

For example, Prevention & Appraisal costs ensure that a task was conducted right the first time, and Failure Costs, both internal & external, occur when a task is not performed right the first time.

In 1999, Juran published the 5th addition of Juran's Quality Handbook where he included the following depiction of the Quality Cost Curve.

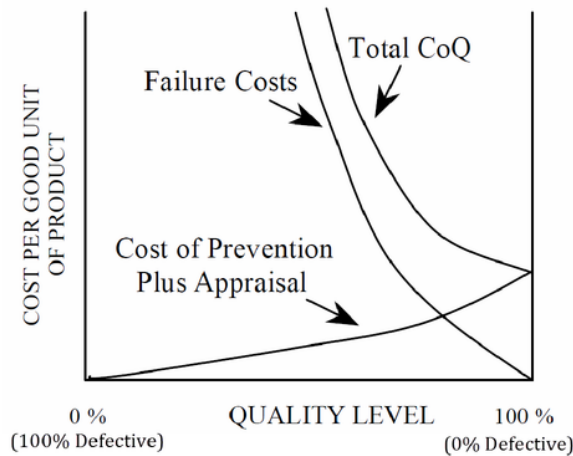


Figure 28 - The Quality Cost Curve (taken from the 5th addition of Juran's Quality Handbook, 1999)

1 This is very important – so the X-Axis is the Quality Level which moves from 0% conformance on the left to 100% conformance on the right.

As you move from 0% conformance to 100% conformance the Prevention & Appraisal Costs increase linearly. Similarly, the Failure Costs (Internal + External) begin decreasing sharply.

Then, the Total CoQ (Cost of Quality), which is a sum of these two other curves also decreases sharply.

One key conclusion that Juran is communicating with this graph is that the Total CoQ is the lowest, when conformance is 100%. At this point, the Total CoQ simply equals the Cost of Prevention & Appraisal.

3.14.2 CONFORMANCE COST

¹ A. PREVENTION COST

As we said above, Prevention Costs are those costs or activities that are specifically designed to prevent poor quality in products.

These costs ensure that product is built right the first time by preventing or reducing errors from occurring.

As we say above, investments in this category result in a lower total CoQ over time always have the best Return On Investment (ROI).

Prevention costs should be viewed as an investment in cost-avoidance.

By avoiding a non-conformance you'll eliminate all the waste associated with that non-conformance.

These include the wasted material (scrap/rework/etc), the man-power required to investigate and disposition the non-conforming material, and the lost opportunity cost/equipment capacity associated with your time & equipment and many more hidden costs.

Also if your prevention activities are powerful enough, you can also eliminate any need to appraise a product for conformance. In essence, you are ensuring that the product or service is always made right the first time; examples include:

Table 15 - Prevention Activities examples

Prevention Activities (Costs)	
Design Qualification Testing	FTA, FMEA & FMECA
Market Research	Field Evaluation or Testing for New Products
Prototype Testing & Iteration	New Product Design Review & Analysis
Design Review Meetings	Design Validation &

Prevention Activities (Costs)	
	Verification
Equipment Fixture Design	Defect Proofing (Poke-Yoke)
Supplier Evaluation	New Supplier Qualification
Supplier Capability Surveys	Supplier Reviews, Ratings & Quality Planning
Supplier Scorecard	Supplier Quality Agreements
New Employee Screening	New Employee Training & Education
Controlled Storage	Internal Process Capability Evaluations
Developing a Process Control Plan	Predictive Equipment Maintenance
Quality Planning	Quality Education & Training
Quality Improvement Projects	Process Qualification, Validation & Verification
Procedure Writing	Implementation of a Quality Data System
Quality System Audits	Development of Quality Control Plans

Edwards Deming once said "Quality comes not from inspection but from improvement of the process." What means is that we should shift our focus from failures & appraisal, to prevention through improvement.

B. APPRAISAL COST

Appraisal costs are associated with any activity specifically designed to measure, inspect, evaluate or audit products to assure conformance to quality requirements.

These are costs incurred to check & verify that product was built right the first time.

Appraisal costs are also considered an investment, not a loss, because you're assuring that quality specifications have been met, and you're preventing unnecessary failure costs, etc.

Below is a list of examples of activities that are generally classified as Appraisal activities:

Table 16 - Appraisal Activities examples

Appraisal Activities (Costs)	
Receiving Inspection	Source Inspection
Routine Supplier Audits	Routine Supplier Surveys
In-Process Testing	Finished Goods Inspection
Laboratory Testing	Equipment Setup Inspection & Testing
Measurement Equipment Costs	Destructive Testing Material Costs
Product Audits	Periodic Review of Documentation
Control Charts & SPC	Maintenance & Calibration of Test Equipment
Review of Inspection Data	Process Monitoring & Control

3.14.3 NON-CONFORMANCE COST

¹ **A. INTERNAL FAILURE COST**

Internal Failure Costs are any cost incurred due to the failure of a product to meet a customer requirement where the non-conformance was detected prior to shipment to the customer.

These costs are incurred when product is not built right the first time, prior to delivery to the customer. These costs are a financial loss.

It's important to remember that the further along in the operating process that a failure is discovered the more expensive it is to correct.

As these types of failures are identified, either internally through Appraisal or externally by the customer, corrective action should be taken to eliminate the causes of these failures, see below for a list of Failure Costs:

Table 17 - Internal Failure Costs examples

Internal Failure Costs	
Scrap or Sorting	Rebuilding or replacing Equipment tooling
Re-work or re-processing	Scrap or Rework due to Design Change
Re-inspection or re-testing	Root Cause Investigation Support Costs
Extra Material Handling	Lost Equipment capacity due to downtime
Excess Inventory Costs	Labor losses due to equipment downtime
Excess Capacity Needs	Rejected or Downgraded Raw Material
Supplier Corrective Actions	Internal Corrective Actions
Material Review Board	Employee Turnover

B. EXTERNAL FAILURE COST

External Failure Costs are any cost incurred due to the failure of a product to meet a customer requirement where the non-conformance was detected after shipment to the customer.

The graph below is an excellent representation of how Failure Costs increase dramatically as a function of time.

As you can see, Prevention Costs are low and are incurred during process development or through improvement projects and the external failure costs all the way to Litigation are off the charts expensive.

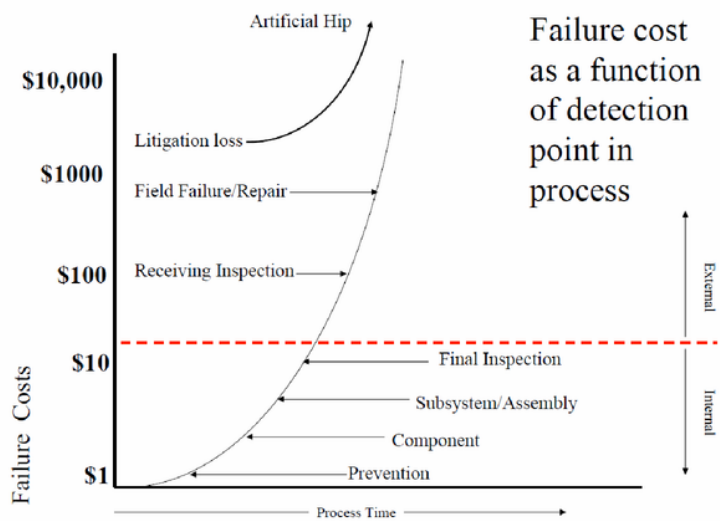


Figure 29 - Failure Costs as a function of time

1

The key takeaway here is that External Failure Costs are, by far, the most expensive category of Quality Cost.

Because the non-conformance went undetected, your company now has paid to package and ship this defect to a customer, which will only result in dissatisfaction and return.

If the non-conformance had been detected in the process, it could have been sorted, scrapped or re-worked prior to shipment.

These failures occur because the Prevention activities & Appraisal process (Inspection & Testing) did not detect the error before shipment which now has resulted in customer dissatisfaction & additional costs.

Failure Costs can also be viewed as a penalty for poor quality.

This penalty can be avoided through prevention & appraisal.

High risk or frequently occurring External Failures can also result in very costly actions like Recalls & Legal situations, see below for a list of external failure costs:

Table 18 - External Failure Costs examples

External Failure Costs	
Warranty Costs	Customer Complaints & Investigation
Repair Costs	Product Liability & Legal Fees
Customer Returns or Rejects	Overhead Cost of Field Service Team
Lost Sales & Customers	Product Recalls & Market Actions
Product Service Calls	Loss of Reputation or Goodwill

16

There are two views concerning optimal quality costs:

1. Traditional view that uses an acceptable quality level.
2. World-class view that uses total quality control.

Optimal Distribution of Quality Costs: Traditional View. The traditional approach uses an acceptable quality level (AQL) that permits a predetermined level of defective units to be produced and sold. AQL is the level where the number of defects allowed minimizes total quality costs. The reasoning of the traditional approach is that there is a tradeoff between failure costs and prevention and appraisal costs. As prevention and appraisal costs increase, internal and external failure costs are expected to decrease. As long as the decrease in failure costs is greater than the corresponding increase in prevention and failure costs, a company should continue increasing its efforts to prevent or detect defective units.

Optimal Distribution of Quality Costs: World-Class View. The world-class view uses total quality control and views the optimal level of quality costs as the level where zero defects are produced. The zero-defects approach uses a quality performance standard that requires:

1. Products to be produced according to specifications.

2. Services to be provided according to requirements. Zero defects reflect a total quality control philosophy used in JIT manufacturing.

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Keywords (Index)

-A-

Acceptance quality limit (AQL)

Acceptance sampling

Attribute

-B-

Batch

-C-

17

Cause and effect diagram

Check sheet

Control chart

Control limits

Cost of quality (CoQ)

-D-

Design of experiments (DoE)

DMAIC

-F-

Failure cost

Fishbone diagram

Flowchart

-H-

Histogram

-I-

Inspection

-L-

Lot

-M-

Mean

Median

-N-

Nonconformity/Nonconformance

Normal distribution

-O-

Operating characteristic curve (OC curve)

-P-

Pareto ²⁵ chart

Plan-do-check-act (PDCA) cycle

Prevention cost

Process capability

-Q-

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Quality assurance (QA)

Quality control (QC)

Quality management (QM)

Quality tools

-R-

Range

Run chart

-S-

Scatter diagram

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Six Sigma (6σ)

Standard deviation

Statistical process control (SPC)

Statistical quality control (SQC)

-T-

Total quality management (TQM)

-V-

Value analysis

Value engineering

Value stream mapping

Variable

Variation

Glossary

73

Acceptance quality limit (AQL): A quality level that, for the purpose of sampling inspection, is the limit of a satisfactory process average.

Acceptance sampling: Inspection of a sample from a lot to decide whether to accept that lot.

Attribute data: Characteristics that either conform to the specifications or don't.

97

Cause and effect diagram: identifies many possible causes for an effect or problem and sorts ideas into useful categories. Also known as the "Ishikawa diagram" or the "fishbone diagram" because it resembles a fish skeleton. **Check sheet:** A simple data recording device. A structured, prepared form for collecting and analyzing data.

47

Control chart: A chart with upper and lower control limits on which values of some statistical measure for a series of samples or subgroups are plotted.

Control limits: The natural boundaries of a process within specified confidence levels, expressed as the upper control limit (UCL) and the lower control limit (LCL).

17

Cost of quality (CoQ): The costs associated with providing poor quality products or services.

96

Design of experiments (DoE): Planning, conducting, analyzing and interpreting controlled tests to evaluate the factors that control the value of a parameter or group of parameters.

17

DMAIC: A data driven quality strategy for improving processes and an integral part of a Six Sigma quality initiative. DMAIC is an acronym for define, measure, analyze, improve and control.

17

Failure cost: The cost resulting from the occurrence of defects. One element of cost of quality or cost of poor quality.

82

Flowchart: A graphical representation of the steps in a process. Flowcharts are drawn to better understand processes.

24 Histogram: A graphic summary of variation in a set of data. It lets people see patterns that are difficult to detect in a simple table of numbers.

41 In-control process: A process in which the statistical measure being evaluated is in a state of statistical control; in other words, the variations among the observed sampling results can be attributed to a constant system of chance causes. Also see "out-of-control process."

Inspection: Measuring, examining, testing and gauging one or more characteristics of a product or service and comparing the results with specified requirements to determine whether conformity is achieved for each characteristic.

17 Lot, batch: A definite quantity of some product manufactured under conditions of production that are considered uniform.

75 Mean: A measure of central tendency; the arithmetic average of all measurements in a data set.

Median: The middle number or center value of a set of data in which all the data are arranged in sequence.

Nonconformity/Nonconformance: The non-fulfilment of a specified requirement.

25 Normal distribution (statistical): The charting of a data set in which most of the data points are concentrated around the average (mean), thus forming a bell shaped curve.

Operating characteristic curve (OC curve): A graph to determine the probability of accepting lots as a function of the lots' or processes' quality level when using various sampling plans.

17 Out-of-control process: A process in which the statistical measure being evaluated is not in a state of statistical control. Also see "in-control process."

Pareto chart: A graphical tool for ranking causes from most significant to least significant.

47 Plan-do-check-act (PDCA) cycle: A four-step process for quality improvement.

25

Prevention cost: The cost incurred by actions taken to prevent a nonconformance from occurring; one element of cost of quality or cost of poor quality.

Process capability: A statistical measure of the inherent process variability of a given characteristic. The most widely accepted formula for process capability is 6 sigma.

Process capability index: The value of the tolerance specified for the characteristic divided by the process capability. The several types of process capability indexes include the widely used Cpk and Cp.

72

Quality: In technical use, quality can have two meanings: 1. the characteristics of a product or service that bear on its ability to satisfy stated or implied needs; 2. a product or service free of deficiencies.

56

Quality assurance (QA): All the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfil requirements for quality.

Quality control (QC): The operational techniques and activities used to fulfill requirements for quality.

8

Quality management (QM): The application of a quality management system in managing a process to achieve maximum customer satisfaction at the lowest overall cost to the organization while continuing to improve the process.

110

Quality tool: An instrument or technique to support and improve the activities of process quality management and improvement.

117

Range (statistical): The measure of dispersion in a data set (the difference between the highest and lowest values).

25

Run chart: A chart showing a line connecting numerous data points collected from a process running over time.

Sample: In acceptance sampling, one or more units of product (or a quantity of material) drawn from a lot for purposes of inspection to reach a decision regarding acceptance of the lot.

17

Scatter diagram: A graphical technique to analyze the relationship between two variables.

24

Six Sigma (6σ): A term generally used to indicate process capability in terms of process spread measured by standard deviations in a normally distributed process.

71

Standard deviation (statistical): A computed measure of variability indicating the spread of the data set around the mean.

Statistical process control (SPC): The application of statistical techniques to control a process.

9

Statistical quality control (SQC): The application of statistical techniques to control quality.

70

Total quality management (TQM): A management approach to long-term success through customer satisfaction, based on all members of an organization participating in improving processes, products, services and the culture in which they work.

61

Value analysis: Analyzing the value stream to identify value added and non value added activities.

Value engineering: Analyzing the components and process that create a product, with an emphasis on minimizing costs while maintaining standards required by the customer.

79

Value stream mapping: Method for analyzing the current state and designing a future state for the series of events that take a product or service from its beginning to the customer.

Variable data: Measurement information.

17

Variation: A change in data, characteristic or function caused by one of four factors: special causes, common causes, tampering or structural variation.

Abbreviations

6σ: Six Sigma

AOL: Acceptable Quality Level
124

CoQ: Cost of Quality

Cp: Process capability ratio

Cpk: Process Capability Index

109

DMADV: Define, Measure, Analyze, Design, Verify

DMAIC: Define, Measure, Analyze, Improve and Control

DoE: Design of Experiments

100

LCL: Lower Control Limit

LSL: Lower Specification Limit

LTPD: Lot tolerance proportion defective

PDCA : Plan-Do-Check-Act

136

QA: Quality Assurance

QC: Quality Control

QM: Quality Management

SPC: Statistical Process Control

SOC: Statistical Quality Control

107

TQM: Total Quality Management

UCL: Upper Control Limit

USL: Upper Specification Limit

VA/VE: Value Analysis/Value Engineering

VSM: Value Stream Mapping

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