Unit- 1

Statistical Quality Control

Learning Objectives

After completion of the unit, you should be able to:

- Explain the meaning of Statistical Quality Control
- Explain the tools of Statistical Quality Control
- Implementation process of Statistics and Quality Control
- Understand it's objectives
- Benefits of understanding Statistical Quality Control (SQC)

Structure

1.1 Introduction

1.2 Definitions

1.3 Methodology & Tools of Statistical Quality Control

1.4 Quality Tools for problem solving

1.5 Statistical Quality Control implementation

1.6 Objectives of Statistical Quality Control

1.7 Benefits of Statistical Quality Control

1.8 Let's sum-up

1.9 Key Terms

1.10 Self-assessment Questions

1.11 Further Readings

1.12 Model Questions

1.1 Introduction

Statistical Quality Control (SQC) is the term used to describe the set of statistical tools used by quality professionals. SQC is used to analyze the quality problems and solve them.

Statistical quality control refers to the use of statistical methods in the monitoring and maintaining of the quality of products and services.

All the tools of SQC are helpful in evaluating the quality of services. SQC uses different tools to analyze quality problem.

1) Descriptive Statistics

2) Statistical Process Control (SPC)

3) Acceptance Sampling

Descriptive Statistics involves describing quality characteristics and relationships. SPC involves inspect random sample of output from process for characteristic. Acceptance Sampling involves batch sampling by inspection.

1.2 Definitions

Statistics:
Statistics means the good amount of data to obtain reliable results. The Science of statistics handles this data in order to draw certain conclusions. Its techniques find extensive applications in quality control, production planning and control, business charts, linear programming etc

Quality:
Quality is a relative term and is generally explained with reference to the end use of the product. Quality is thus defined as fitness for purpose.

Control:

Control is a system for measuring and checking or inspecting a phenomenon. It suggests when to inspect, how often to inspect and how much to inspect. Control ascertains quality characteristics of an item, compares the same with prescribed quality characteristics of an item, compares the same with prescribed quality standards and separates defective item from non-defective ones. Statistical Quality Control (SQC) is the term used to describe the set of statistical tools used by quality professionals. SQC is used to analyze the quality problems and solve them.

Statistical quality control refers to the use of statistical methods in the monitoring and maintaining of the quality of products and services.

1.3 Methodology & Tools of Statistical Quality Control

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SPC involves inspect random sample of output from process for characteristic.

a) Responsibilities
b) Preliminary Engineering Activities
c) Control Chart Preparation
d) Standardized the Document
e) Engineering Notification
f) Changing Control Limits.
g) Review & Approve Process.
h) Archiving of Data and Charts.
i) Computerized Control Charts.
j) Training

3) Acceptance Sampling

Acceptance Sampling involve batch sampling by inspection

Assume that a consumer receives a shipment of parts called a lot from a producer. A sample of parts will be taken and the number of defective items counted. If the number of defective items is low, the entire lot will be accepted. If the number of defective items is high, the entire lot will be rejected. Correct decisions correspond to accepting a good-quality lot and rejecting a poor-quality lot. Because sampling is being used, the probabilities of erroneous decisions need to be considered. The error of rejecting a good-quality lot creates a problem for the producer; the probability of this error is called the producer's risk. On the other hand, the error of accepting a poor-quality lot creates a problem for the purchaser or consumer; the probability of this error is called the consumer's risk.

The design of an acceptance sampling plan consists of determining a sample size *n* and an acceptance criterion *c*, where *c* is the maximum number of defective items that can be found in the sample and the lot still be accepted. The key to understanding both the producer's risk and the consumer's risk is to assume that a lot has some known percentage of defective items and compute the probability of accepting the lot for a given sampling plan. By varying the assumed percentage of defective items in a lot, several different sampling plans can be evaluated and a sampling plan selected such that both the producer's and consumer's risks are reasonably low.

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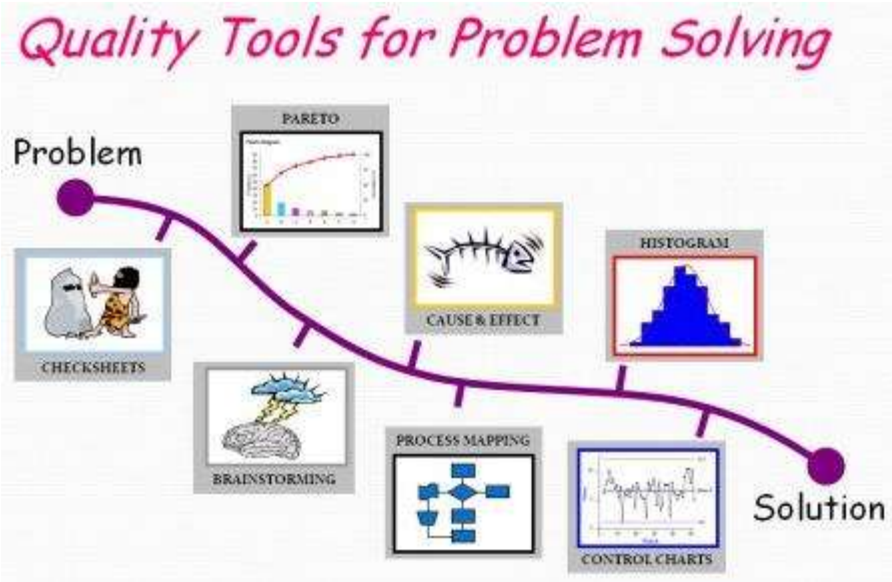
1.4 Quality Tools For Problem Solving

The seven major tools used for Statistical Process Control are,

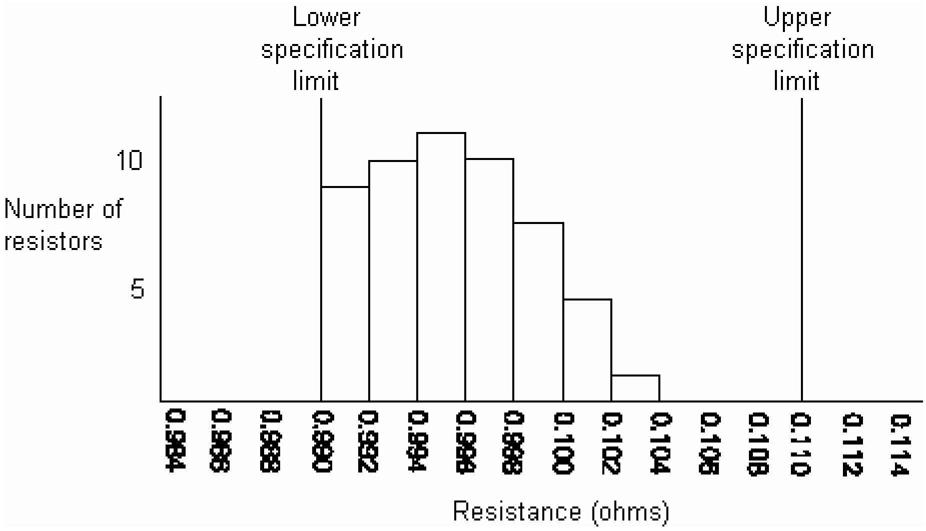


1.4.1 Histogram

A **histogram** is a graphical representation of how many times different, mutually exclusive events are observed in an experiment. To interpret a **histogram**, we find the events on the x-axis and the counts on the y-axis. Each event has a rectangle that shows what its count (or frequency) is.

Example

A power engineer required a 10 ohm, 0.1% tolerance, and high power resistor. The only resistors available were 10% tolerance. To achieve the higher tolerance, he uses a series of 100 resistors each of 0.1 ohm. The summing effect was expected to average out the low tolerance, as resistors over and under 0.1 ohm balanced each other out. When the resulting resistance started overheating, the engineer measured the value of each one and plotted a Histogram, as in Fig. 1.



The result showed that although the resistors were within specification, their distribution was not normal and not centered on 0.1 ohm (this was probably caused by selection from an off-center production system). The solution of a specially made resistor was significantly more expensive.

1.4.2 Pareto Chart

A Pareto chart is a bar graph. The lengths of the bars represent frequency or cost (time or money), and are arranged with longest bars on the left and the shortest to the right. In this way the chart visually depicts which situations are more significant.

When to Use a Pareto Chart

- When analyzing data about the frequency of problems or causes in a process.
- When there are many problems or causes and you want to focus on the most significant.
- When analyzing broad causes by looking at their specific components.
- When communicating with others about your data.

Pareto Chart Procedure

1. Decide what categories you will use to group items.
2. Decide what measurement is appropriate. Common measurements are frequency, quantity, cost and time.

3. Decide what period of time the Pareto chart will cover: One work cycle? One full day? A week?
4. Collect the data, recording the category each time. (Or assemble data that already exist.)
5. Subtotal the measurements for each category.
6. Determine the appropriate scale for the measurements you have collected. The maximum value will be the largest subtotal from step 5. (If you will do optional steps 8 and 9 below, the maximum value will be the sum of all subtotals from step 5.) Mark the scale on the left side of the chart.
7. Construct and label bars for each category. Place the tallest at the far left, then the next tallest to its right and so on. If there are many categories with small measurements, they can be grouped as "other."

   Steps 8 and 9 are optional but are useful for analysis and communication.

8. Calculate the percentage for each category: the subtotal for that category divided by the total for all categories. Draw a right vertical axis and label it with percentages. Be sure the two scales match: For example, the left measurement that corresponds to one-half should be exactly opposite 50% on the right scale.
9. Calculate and draw cumulative sums: Add the subtotals for the first and second categories, and place a dot above the second bar indicating that sum. To that sum add the subtotal for the third category, and place a dot above the third bar for that new sum. Continue the process for all the bars. Connect the dots, starting at the top of the first bar. The last dot should reach 100 percent on the right scale.

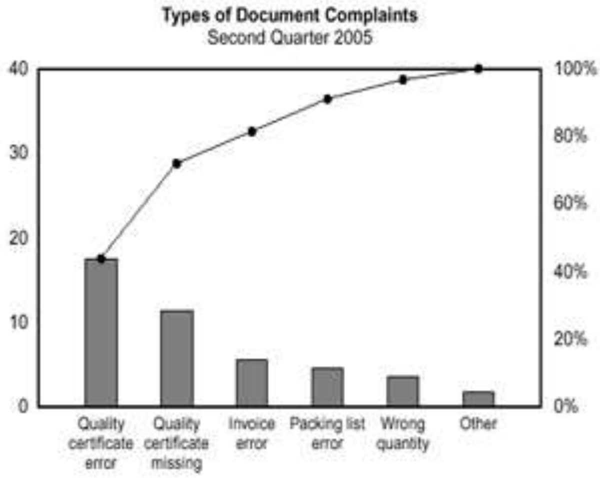
Pareto Chart Examples

Example #1 shows how many customer complaints were received in each of five categories.

Example #2 takes the largest category, "documents," from Example #1, breaks it down into six categories of document-related complaints, and shows cumulative values.

If all complaints cause equal distress to the customer, working on eliminating document-related complaints would have the most impact, and of those, working on quality certificates should be most fruitful.

Example #1



Example #2

1.4.3 Cause and Effect Diagram (also known as the "fishbone" or Ishikawa diagram)

Cause and Effect Analysis was devised by Professor Kaoru Ishikawa, a pioneer of quality management, in the 1960s. The technique was then published in his 1990 book, "Introduction to Quality Control."

The diagrams that you create with are known as Ishikawa Diagrams or Fishbone Diagrams (because a completed diagram can look like the skeleton of a fish).

Although it was originally developed as a quality control tool, you can use the technique just as well in other ways. For instance, you can use it to:

- Discover the root cause of a problem.
- Uncover bottlenecks in the process
- Identify where and why a process isn't working.

How to Use the Tool

Follow these steps to solve a problem with Cause and Effect Analysis:

Step 1: Identify the Problem

First, write down the exact problem you face. Where appropriate, identify who is involved, what the problem is, and when and where it occurs.

Then, write the problem in a box on the left-hand side of a large sheet of paper, and draw a line across the paper horizontally from the box. This arrangement, looking like the head and spine of a fish, gives you space to develop ideas.

Example:

In this simple example, a manager is having problems with an uncooperative branch office.

Figure 1 – Cause and Effect Analysis Example Step 1

Tip 1:

Some people prefer to write the problem on the right-hand side of the piece of paper, and develop ideas in the space to the left. Use whichever approach you feel most comfortable with.

Tip 2:

It's important to define your problem correctly.
By considering all of these, you can develop a comprehensive understanding of the problem.

Step 2: Work Out the Major Factors Involved

Next, identify the factors that may be part of the problem. These may be systems, equipment, materials, external forces, people involved with the problem, and so on.

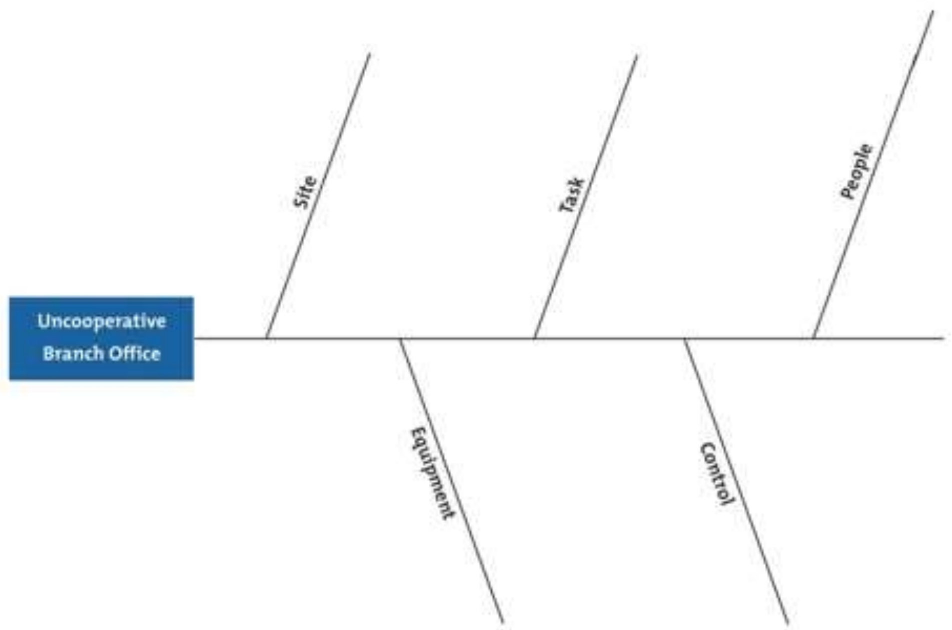
Try to draw out as many of these as possible. As a starting point, you can use models such as the **McKinsey 7S Framework** (which offers you Strategy, Structure, Systems, Shared values, Skills, Style and Staff as factors that you can consider) or the **4Ps of Marketing** (which offers Product, Place, Price, and Promotion as possible factors).
Brainstorm any other factors that may affect the situation.
Then draw a line off the "spine" of the diagram for each factor, and label each line.

Example:

The manager identifies the following factors, and adds these to his diagram:

- Site.
- Task.
- People.
- Equipment.
- Control.

Figure 2 – Cause and Effect Analysis Example Step 2



Step 3: Identify Possible Causes

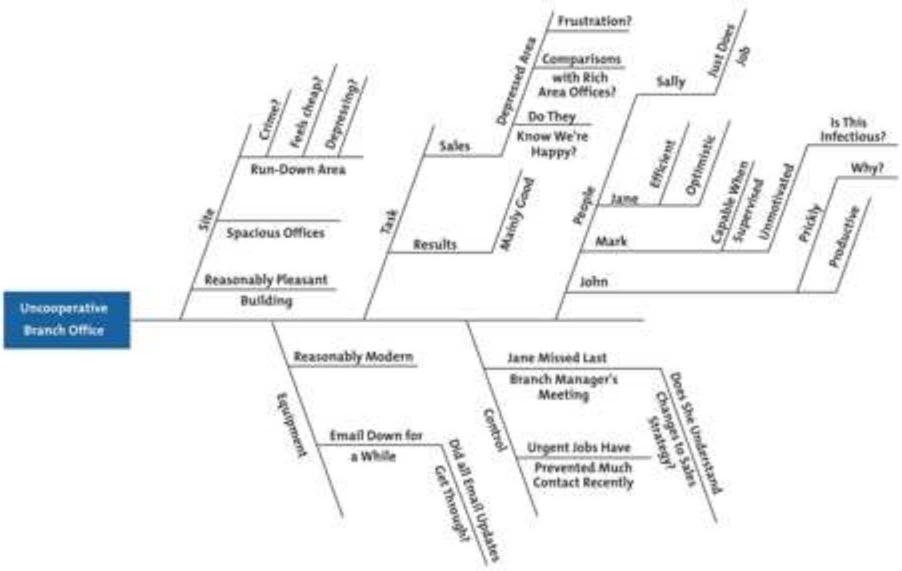
Now, for each of the factors you considered in step 2, brainstorm possible causes of the problem that may be related to the factor.

Show these possible causes as shorter lines coming off the "bones" of the diagram. Where a cause is large or complex, then it may be best to break it down into sub-causes. Show these as lines coming off each cause line.

Example:

For each of the factors he identified in step 2, the manager brainstorms possible causes of the problem, and adds these to his diagram, as shown in figure 3.

Figure 3 – Cause and Effect Analysis Example Step 3



Step 4: Analyze Your Diagram

By this stage you should have a diagram showing all of the possible causes of the problem that you can think of.

Depending on the complexity and importance of the problem, you can now investigate the most likely causes further. This may involve setting up investigations, carrying out surveys, and so on. These will be designed to test which of these possible causes is actually contributing to the problem.

Example:

The manager has now finished his analysis. If he hadn't looked at the problem this way, he might have dealt with it by assuming that people in the branch office were "being difficult."

Instead he thinks that the best approach is to arrange a meeting with the Branch Manager. This would allow him to brief the manager fully on the new strategy, and talk through any problems that she may be experiencing.

There are four steps to using the tool.

1. Identify the problem.
2. Work out the major factors involved.
3. Identify possible causes.
4. Analyze your diagram.

You'll find this method is particularly useful when you're trying to solve complicated problems.

1.4.4 Defect Concentration Diagram

A check sheet, also called: defect concentration diagram is a structured, prepared form for collecting and analyzing data. This is a generic tool that can be adapted for a wide variety of purposes.

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

1. Decide what event or problem will be observed. Develop operational definitions.
2. Decide when data will be collected and for how long.

3. 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.
4. Label all spaces on the form.
5. Test the check sheet for a short trial period to be sure it collects the appropriate data and is easy to use.
6. 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					
	Mon	Tues	Wed	Thurs	Fri	Total
Wrong number	卌	||	|	卌	卌 ||	20
Info request	||	||	||	||	||	10
Boss	卌	||	卌 ||	|	||||	19
Total	12	6	10	8	13	49

Check Sheet Example

1.4.4 Control Chart

The **control chart,** also called: statistical process control is a graph used to study how a process changes over time. Data are plotted in time order. A **control chart** always has a central line for the average, an upper line for the upper **control** limit and a lower line for the lower **control** limit. These lines are determined from historical data.

The control chart is a graph used to study how a process changes over time. Data are plotted in time order. A control chart always has a central line for the average, an upper line for the upper control limit and a lower line for the lower control limit. These lines are determined from historical data. By comparing current data to these lines, you can draw conclusions about whether the process variation is consistent (in control) or is unpredictable (out of control, affected by special causes of variation).

Control charts for variable data are used in pairs. The top chart monitors the average, or the centering of the distribution of data from the process. The bottom chart monitors the range, or the width of the distribution. If your data were shots in target practice, the average is where the shots are clustering, and the range is how tightly they are clustered. Control charts for attribute data are used singly.

When to Use a Control Chart

- When controlling ongoing processes by finding and correcting problems as they occur.
- When predicting the expected range of outcomes from a process.
- When determining whether a process is stable (in statistical control).
- When analyzing patterns of process variation from special causes (non-routine events) or common causes (built into the process).
- When determining whether your quality improvement project should aim to prevent specific problems or to make fundamental changes to the process.

Control Chart Basic Procedure

1. Choose the appropriate control chart for your data.
2. Determine the appropriate time period for collecting and plotting data.
3. Collect data, construct your chart and analyze the data.
4. Look for "out-of-control signals" on the control chart. When one is identified, mark it on the chart and investigate the cause. Document how you investigated, what you learned, the cause and how it was corrected.

Out-of-control signals

- A single point outside the control limits. In Figure 1, point sixteen is above the UCL (upper control limit).
- Two out of three successive points are on the same side of the centerline and farther than 2 σ from it. In Figure 1, point 4 sends that signal.
- Four out of five successive points are on the same side of the centerline and farther than 1 σ from it. In Figure 1, point 11 sends that signal.
- A run of eight in a row are on the same side of the centerline. Or 10 out of 11, 12 out of 14 or 16 out of 20. In Figure 1, point 21 is eighth in a row above the centerline.
- Obvious consistent or persistent patterns that suggest something unusual about your data and your process.

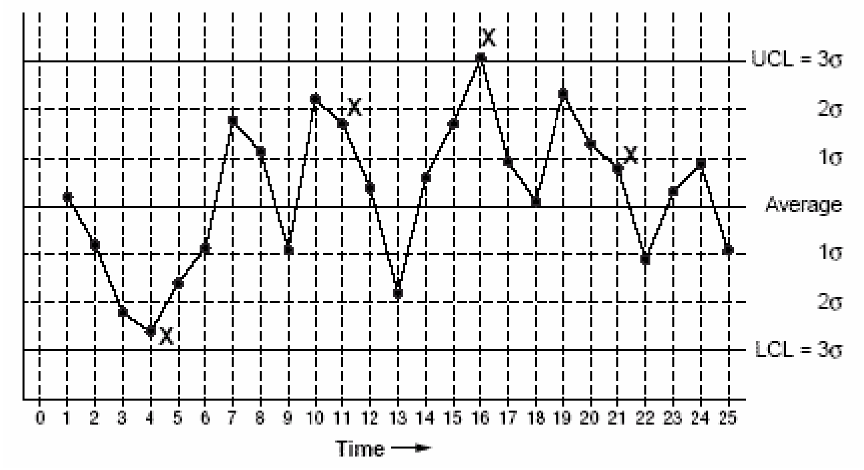


Figure 1 Control Chart: Out-of-Control Signals

1. Continue to plot data as they are generated. As each new data point is plotted, check for new out-of-control signals.
2. When you start a new control chart, the process may be out of control. If so, the control limits calculated from the first 20 points are conditional limits. When you have at least 20 sequential points from a period when the process is operating in control, recalculate control limits.

1.4.6 Scatter Diagram

The scatter diagram graphs, also called: scatter plot, X–Y graph, pairs of numerical data, with one variable on each axis, to look for a relationship between them. If the variables are correlated, the points will fall along a line or curve. The better the correlation, the tighter the points will hug the line.

When to Use a Scatter Diagram

- When you have paired numerical data.
- When your dependent variable may have multiple values for each value of your independent variable.
- When trying to determine whether the two variables are related, such as…
  - When trying to identify potential root causes of problems.
  - After brainstorming causes and effects using a fishbone diagram, to determine objectively whether a particular cause and effect are related.

- When determining whether two effects that appear to be related both occur with the same cause.
- When testing for autocorrelation before constructing a control chart.

Scatter Diagram Procedure

1. Collect pairs of data where a relationship is suspected.
2. Draw a graph with the independent variable on the horizontal axis and the dependent variable on the vertical axis. For each pair of data, put a dot or a symbol where the x-axis value intersects the y-axis value. (If two dots fall together, put them side by side, touching, so that you can see both.)
3. Look at the pattern of points to see if a relationship is obvious. If the data clearly form a line or a curve, you may stop. The variables are correlated. You may wish to use regression or correlation analysis now. Otherwise, complete steps 4 through 7.
4. Divide points on the graph into four quadrants. If there are X points on the graph,

- Count X/2 points from top to bottom and draw a horizontal line.
- Count X/2 points from left to right and draw a vertical line.
- If number of points is odd, draw the line through the middle point.

1. Count the points in each quadrant. Do not count points on a line.
2. Add the diagonally opposite quadrants. Find the smaller sum and the total of points in all quadrants.
   A = points in upper left + points in lower right
   B = points in upper right + points in lower left
   Q = the smaller of A and B
   N = A + B
3. Look up the limit for N on the trend test table.

- If Q is less than the limit, the two variables are related.
- If Q is greater than or equal to the limit, the pattern could have occurred from random chance.

Table 5.18 Trend test table.

N	Limit	N	Limit
1–8	0	51–53	18
9–11	1	54–55	19
12–14	2	56–57	20
15–16	3	58–60	21
17–19	4	61–62	22
20–22	5	63–64	23
23–24	6	65–66	24
25–27	7	67–69	25
28–29	8	70–71	26
30–32	9	72–73	27
33–34	10	74–76	28
35–36	11	77–78	29
37–39	12	79–80	30
40–41	13	81–82	31
42–43	14	83–85	32
44–46	15	86–87	33
47–48	16	88–89	34
49–50	17	90	35

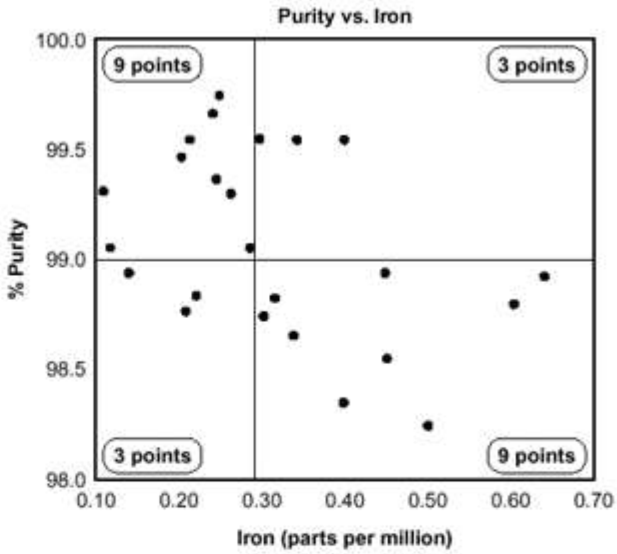
Scatter Diagram Example

The ZZ-400 manufacturing team suspects a relationship between product purity (percent purity) and the amount of iron (measured in parts per million or ppm). Purity and iron are plotted against each other as a scatter diagram, as shown in the figure below.

There are 24 data points. Median lines are drawn so that 12 points fall on each side for both percent purity and ppm iron.

To test for a relationship, they calculate:
A = points in upper left + points in lower right = 9 + 9 = 18
B = points in upper right + points in lower left = 3 + 3 = 6
Q = the smaller of A and B = the smaller of 18 and 6 = 6
N = A + B = 18 + 6 = 24

Then they look up the limit for N on the trend test table. For N = 24, the limit is 6. Q is equal to the limit. Therefore, the pattern could have occurred from random chance, and no relationship is demonstrated.



Scatter Diagram Example

Here are some examples of situations in which might you use a scatter diagram:

- Variable A is the temperature of a reaction after 15 minutes. Variable B measures the color of the product. You suspect higher temperature makes the product darker. Plot temperature and color on a scatter diagram.
- Variable A is the number of employees trained on new software, and variable B is the number of calls to the computer help line. You suspect that more training reduces the number of calls. Plot number of people trained versus number of calls.
- To test for autocorrelation of a measurement being monitored on a control chart, plot this pair of variables: Variable A is the measurement at a given time. Variable B is the same measurement, but at the previous time. If the scatter diagram shows correlation, do another diagram where variable B is the measurement two times previously. Keep increasing the separation between the two times until the scatter diagram shows no correlation.

1.4.7 Flow Chart

A flowchart, also called: process flowchart, process flow diagram.is a picture of the separate steps of a process in sequential order.

Elements that may be included are: sequence of actions, materials or services entering or leaving the process (inputs and outputs), decisions that must be made, people who become involved, time involved at each step and/or process measurements.

The process described can be anything: a manufacturing process, an administrative or service process, a project plan. This is a generic tool that can be adapted for a wide variety of purposes.

When to Use a Flowchart

- To develop understanding of how a process is done.
- To study a process for improvement.
- To communicate to others how a process is done.
- When better communication is needed between people involved with the same process.
- To document a process.
- When planning a project.

Flowchart Basic Procedure

Materials needed: sticky notes or cards, a large piece of flipchart paper or newsprint, marking pens.

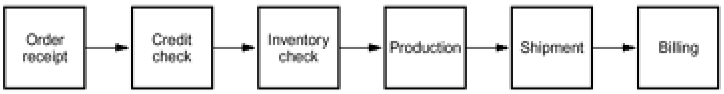
1. Define the process to be diagrammed. Write its title at the top of the work surface.
2. Discuss and decide on the boundaries of your process: Where or when does the process start? Where or when does it end? Discuss and decide on the level of detail to be included in the diagram.
3. Brainstorm the activities that take place. Write each on a card or sticky note. Sequence is not important at this point, although thinking in sequence may help people remember all the steps.
4. Arrange the activities in proper sequence.
5. When all activities are included and everyone agrees that the sequence is correct, draw arrows to show the flow of the process.
6. Review the flowchart with others involved in the process (workers, supervisors, suppliers, customers) to see if they agree that the process is drawn accurately.

Flowchart Considerations

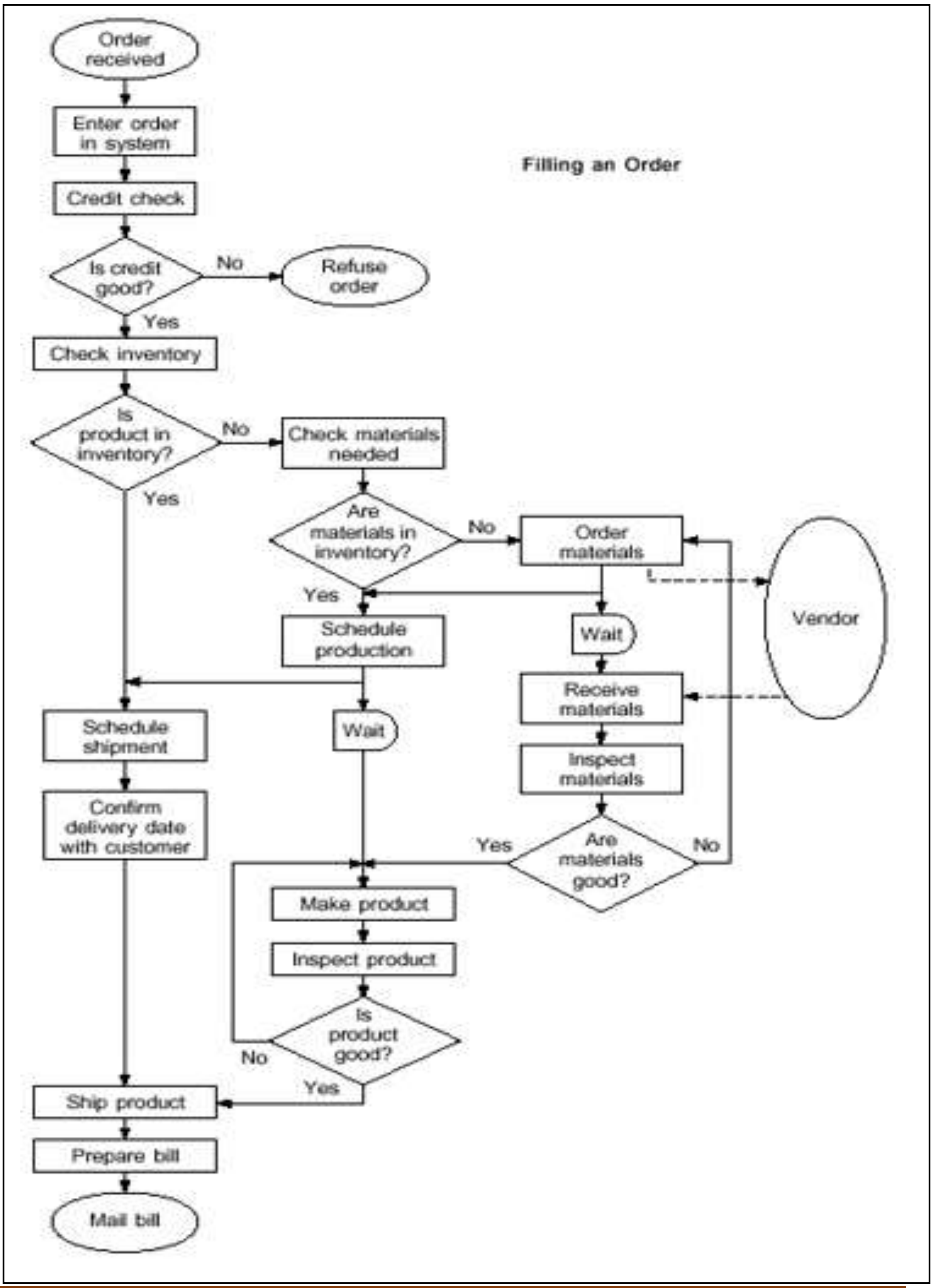
- Don’t worry too much about drawing the flowchart the “right way.” The right way is the way that helps those involved understands the process.
- Identify and involve in the flowcharting process all key people involved with the process. This includes those who do the work in the process: suppliers, customers and supervisors. Involve them in the actual flowcharting sessions by interviewing them before the sessions and/or by showing them the developing flowchart between work sessions and obtaining their feedback.
- Do not assign a “technical expert” to draw the flowchart. People who actually perform the process should do it.
- Computer software is available for drawing flowcharts. Software is useful for drawing a neat final diagram, but the method given here works better for the messy initial stages of creating the flowchart.

Flowchart Examples

High–Level Flowchart for an Order-Filling Process



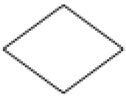
Detailed Flowchart

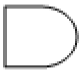


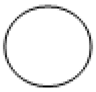
Commonly Used Symbols in Detailed Flowcharts

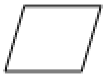

One step in the process; the step is written inside the box. Usually, only one arrow goes out of the box.


Direction of flow from one step or decision to another.

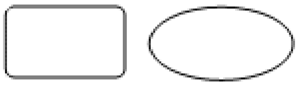

Decision based on a question. The question is written in the diamond. More than one arrow goes out of the diamond, each one showing the direction the process takes for a given answer to the question. (Often the answers are " yes" and " no.")


Delay or wait


Link to another page or another flowchart. The same symbol on the other page indicates that the flow continues there.


Input or output


Document


Alternate symbols for start and end points

1.5 Statistical Quality Control Implementation

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i) Computerized Control Charts.	j) Training

3) Acceptance Sampling

Acceptance Sampling involve batch sampling by inspection

1.6 Objectives of Statistical Quality Control

Quality Control is very important for every company. Quality control includes service quality given to customer, company management leadership, commitment of management, continuous improvement, and fast response, actions based on facts, employee participation and a quality driven culture.

The main objectives of the quality control module are to control of material reception, internal rejections, clients, claims, providers and evaluations of the same corrective actions are related to their follow-up. These systems and methods guide all quality activities. The development and use of performance indicators is linked, directly or indirectly, to customer requirements and satisfaction, and to management.

1.7 Benefits of Statistical Quality Control

1) It provides a means of detecting error at inspection.

2) It leads to more uniform quality of production.

3) It improves the relationship with the customer.

4) It reduces inspection costs.

5) It reduces the number of rejects and saves the cost of material.

6) It provides a basis for attainable specifications.

7) It points out the bottlenecks and trouble spots.

8) It provides a means of determining the capability of the manufacturing process.

9) It promotes the understanding and appreciation of quality control.

1.8 Let's sum-up

The tension between after-the-fact inspection and defect prevention has been at the heart of manufacture since the introduction of statistical methods to industry in the 1940s. Today, to clearly divide responsibilities within an organization, and tie these very different activities to existing roles, consider a division by impact to the patient. Activities which monitor a process in real-time to prevent defects while a lot is being manufactured are known as Statistical Process Controls (SPC).

In contrast, activities which occur after manufacture to keep defects from reaching a patient by additional inspection are Statistical Quality Control (SQC). The difference is one of strategy. From the patient's perspective, SPC's feedback during manufacture prevents risk while SQC's feed-forward guards against catastrophic failure. Both are necessary in an industry of low volume, high cost, and high risk goods.

Statistical quality control (SQC) is the term used to describe the set of statistical tools deployed for evaluating the organizational quality by the quality professionals. Statistical quality control can be divided into following three broad categories.

- Descriptive statistics – These are the statistics used to describe certain quality characteristics such as the central tendency and variability of the observed data. It also describes the relationship. Descriptive statistics include statistics such as the mean, standard deviation, the range, and a measure of the distribution of data.
- Statistical process control (SPC) – It consists of statistical tools that involve inspecting a random sample of the output from a process and deciding whether the process is producing products with characteristics that fall within a predetermined range. SPC answers the question whether the process is functioning properly or not. These tools are very important for a process since they help in identifying and catching a quality problem during the production process.

- Acceptance sampling – It helps in evaluating whether there is problem with quality and whether desirable quality is being achieved for a batch of product. Accepting sampling consists of the process of randomly inspecting a sample of goods and deciding whether to accept the entire lot based on the results. This sampling decides whether a batch of goods is to be accepted or rejected.

There are seven basic tools employed for SQC. The seven basic tools of quality is a designation given to a fixed set of graphical techniques identified as being most helpful in trouble shooting issues related to quality. They are called basic because they are suitable for people with little formal training in statistics and because they can be used to solve the vast majority of quality related issues. These seven basic tools are described below.

1.9 Key Terms

- **Mean** – It is an important statistic tool that measures the central tendency of a set of data. The mean is computed by simply summing up of all the observations and dividing by the total number of observations.
- **Range and standard deviation** – This information providers with the variability of the data. It tells how the data is spread out around the mean. Range is the difference between the largest and the smallest observations in a set of data while standard deviation is a statistics that measures the amount of data dispersion around the mean. Small values of the range and standard deviation mean that the observations are closely clustered around the mean while large values of the range and standard deviation mean that the observations are spread around the mean.
- **Distribution of data** – It is a measure to determine the quality characteristics. When the distribution of data is symmetric then there are same numbers of observations below and above the mean. This is what is commonly found when only normal variation is present in the data. When a disproportionate number of observations are either above or below the mean, then the data has a skewed distribution.
- **SQC**- Activities which occur after manufacture to keep defects from reaching a patient by additional inspection are Statistical Quality Control (SQC).
- **SPC**- Activities which monitor a process in real-time to prevent defects while a lot is being manufactured are known as Statistical Process Controls (SPC).
- **Flowchart,** also called: process flowchart, process flow diagram. is a picture of the separate steps of a process in sequential order.

  Elements that may be included are: sequence of actions, materials or services entering or leaving the process (inputs and outputs), decisions that must be made, people who become involved, time involved at each step and/or process measurements.

The process described can be anything: a manufacturing process, an administrative or service process, a project plan. This is a generic tool that can be adapted for a wide variety of purposes.

- **Cause and effect analysis diagram**- When one is able to relate different causes to the effect, namely the quality characteristics, then he can use this logical thinking of cause and effect for further investigations to improve and control quality. This type of linking is done through cause and effect diagrams.

1.10 Self-assessment Questions

Identify the correct answer.

Q.1 Statistical quality control is also called

A. statistical process control
B. statistical failure control
C. statistical control of prevention cost
D. statistical control of sunk cost

Ans: A

Q.2 Fishbone diagram is an example of

A. Relevant costing diagram
B. Cause and effect diagram
C. Control chart
D. Pareto diagram

Ans: B

Q.3 Factors are identified by cause and effect diagrams include

A. component and material factors
B. machine-related factors
C. human factors
D. all of above

Ans: D

Q.4 Formal way of differentiate between non-random and random variations in manufacturing process is classified as

A. statistical process control
B. statistical failure control
C. statistical control of prevention cost
D. statistical control of sunk cost

Ans: A

Q.5 The assignable cause, if the size of a product is beyond the upper or lower control limit, is

A. Machine
B. Process
C. Measurement
D. All of the above

Ans: D

Q.6 The task of exercising control over the incoming raw materials and the outgoing finished products is usually known as

A. Acceptance sampling
B. Process control
C. Quality control
D. All of the above

Ans: A

Q.7 Process control is carried out

A. Before production
B. During production
C. After production control
D. All of the above

Ans: B

Q.8 High cost, low volume items requires

A, No inspection
B. Little inspection
C. Intensive inspection
D. 100% inspection

Ans: C

1.11 Further Readings

1.11.1 Introduction to Statistical Quality Control by Douglas c Montgomery

1.11.2 Integrating SPC and SQC by Mark Schaeffers

1.11.3 Process Capability and Statistical Quality Control- Technical note

1.12 Model Questions

1.12.1 Explain the differences between SQC and SPC.

Ans: 1. "SPC" stands for "Statistical Process Control" while "SQC" stands for "Statistical Quality Control."
2. SQC refers to the use of statistical tools to analyze variations in the manufacturing process in order to make it better while SPC is a category of SQC that also uses statistical tools to oversee and control the production process to ensure the production of uniform products with less waste.
3. SPC checks the production process for flaws that may lead to low-quality products while SQC uses a specific number of samples to determine the acceptability of a product.

1.12.2 Define Fish bone diagram with an example from your working experience.

Ans: The fishbone diagram identifies many possible causes for an effect or problem. It can be used to structure a brainstorming session. It immediately sorts ideas into useful categories.

Materials needed: flipchart or whiteboard, marking pens.

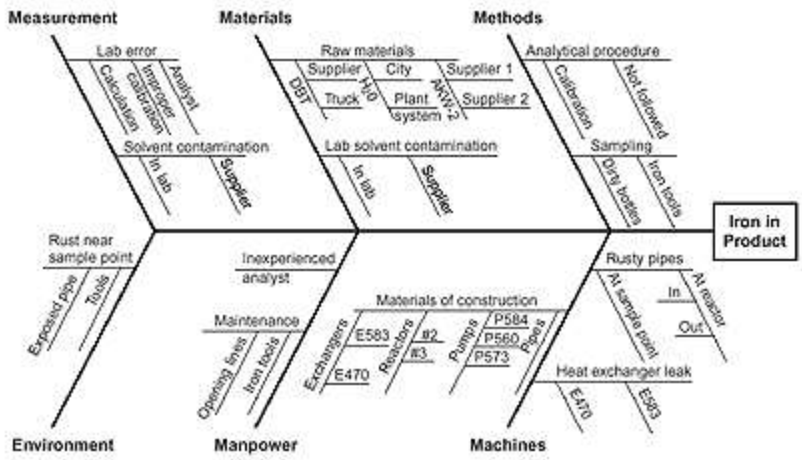
1. Agree on a problem statement (effect). Write it at the center right of the flipchart or whiteboard. Draw a box around it and draw a horizontal arrow running to it.
2. Brainstorm the major categories of causes of the problem. If this is difficult use generic headings:

- Methods
- Machines (equipment)
- People (manpower)
- Materials
- Measurement
- Environment

3. Write the categories of causes as branches from the main arrow.
4. Brainstorm all the possible causes of the problem. Ask: "Why does this happen?" As each idea is given, the facilitator writes it as a branch from the appropriate category. Causes can be written in several places if they relate to several categories.

5. Again ask "why does this happen?" about each cause. Write sub–causes branching off the causes. Continue to ask "Why?" and generate deeper levels of causes. Layers of branches indicate causal relationships.
6. When the group runs out of ideas, focus attention to places on the chart where ideas are few.

Example: This fishbone diagram was drawn by a manufacturing team to try to understand the source of periodic iron contamination. The team used the six generic headings to prompt ideas. Layers of branches show thorough thinking about the causes of the problem.



1.12.3 Enumerate benefits of Statistical Quality Control.

1) It provides a means of detecting error at inspection.

2) It leads to more uniform quality of production.

3) It improves the relationship with the customer.

4) It reduces inspection costs.

5) It reduces the number of rejects and saves the cost of material.

6) It provides a basis for attainable specifications.

7) It points out the bottlenecks and trouble spots.

8) It provides a means of determining the capability of the manufacturing process.

9) It promotes the understanding and appreciation of quality control.

Unit- 2

Quality Management System

Learning Objectives

After completion of the unit, you should be able to:

- Understand Quality Management
- Understand Management System
- Find the need of Quality Management System (QMS) in Management function
- Establish QMS
- Benefits of QMS

Structure

2.1 Introduction

2.2 Definitions

2.3 What is Business Process ?

2.4 What is Quality Management?

2.5 Evolution of Quality Management?

2.6 ISO 9000 series Quality Management Principles

2.7 Contents of ISO 9001:2015

2.8 Deming Cycle, PDCA

2.9 Why should we apply for ISO 9001 certification?

2.10 Continual improvement process

2.11 Kaizen

2.12 Let's Sum-Up

2.13 Key Terms

2.14 Self-Assessment Questions

2.15 Further Readings

2.16 Model Questions

2.1 Introduction

Quality Management System (QMS) is a system by which an organization aims to reduce and eventually eliminate nonconformance to specifications, standards and customer expectations in the most cost effective and efficient manner.

A quality management system (**QMS**) is a set of policies, processes and procedures required for planning and execution (production/development/service) in the core business area of an organisation. (i.e. areas that can impact the organisation's ability to meet customer requirements.)

A **Quality Management System** (**QMS**) is a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is aligned with an organisation's purpose and strategic direction (ISO9001:2015). It is expressed as the organisational goals and aspirations, policies, processes, documented information and resources needed to implement and maintain it. Early quality management systems emphasized predictable outcomes of an industrial product production line, using simple statistics and random sampling. By the 20th century, labour inputs were typically the most costly inputs in most industrialized societies, so focus shifted to team cooperation and dynamics, especially the early signaling of problems via a continuous improvement cycle. In the 21st century, QMS has tended to converge with sustainability and transparency initiatives, as both investor and customer satisfaction and perceived quality is increasingly tied to these factors. Of QMS regimes, the ISO 9000 family of standards is probably the most widely implemented worldwide – the ISO 19011 audit regime applies to both, and deals with quality and sustainability and their integration.

Other QMS, e.g. Natural Step, focus on sustainability issues and assume that other quality problems will be reduced as result of the systematic thinking, transparency, documentation and diagnostic discipline.

2.2 Definitions

QMS is defined as an integrated organisational approach in delighting the customers (both external and internal) by meeting their expectations on a continuous basis through everyone involved with the organisation working on continuous improvement in all products, services and processes along with proper problem solving methodology.

2.3 What is Business Process?

A **business process** or **business method** is a collection of related, structured activities or tasks that produce a specific service or product (serve a particular goal) for a particular customer or customers. It may often be visualized as a flowchart of a sequence of activities with interleaving decision points or as a process matrix of a sequence of activities with relevance rules based on data in the process.

There are three types of business processes.

1. Management processes, the processes that govern the operation of a system. Typical management processes include "corporate governance" and "strategic management".
2. Operational processes, processes that constitute the core business and create the primary value stream. For example, taking orders from customers, and opening an account in a bank branch.
3. Supporting processes, which support the core processes. Examples include Health & Safety, accounting, recruitment, call center, technical support.

A business process begins with a mission objective and ends with achievement of the business objective. Process-oriented organisations break down the barriers of structural departments and try to avoid functional silos.

A complex business process may be decomposed into several sub-processes, which have their own attributes, but also contribute to achieving the goal of the super-process. The analysis of business processes typically includes the mapping of processes and sub-processes down to activity/task level.

Business processes are designed to add value for the customer and should not include unnecessary activities. The outcome of a well-designed business process is increased effectiveness (value for the customer) and increased efficiency (less use of resources).

This definition also emphasizes the constitution of links between activities and the transformation that takes place within the process. Johansson et al. also include the upstream part of the value chain as a possible recipient of the process output. Summarizing the four definitions above, we can compile the following list of characteristics for a business process:

1. *Definability*: It must have clearly defined boundaries, input and output.
2. *Order*: It must consist of activities that are ordered according to their position in time and space (a sequence).
3. *Customer*: There must be a recipient of the process' outcome, a customer.
4. *Value-adding*: The transformation taking place within the process must add value to the recipient, either upstream or downstream.
5. *Embeddedness*: A process cannot exist in itself, it must be embedded in an organizational structure.
6. *Cross-functionality*: A process regularly can, but not necessarily must, span several functions.

2.4 What is Quality Management?

Quality Management ensures that an organisation, product or service is consistent. It has **four** main components:

1. Quality planning,
2. Quality assurance,
3. Quality control and
4. Quality improvement.

Quality management is focused not only on product and service quality, but also on the means to achieve it. Quality management, therefore, uses quality assurance and control of processes as well as products to achieve more consistent quality.

2.5 Evolution of Quality Management

Quality Management is a recent phenomenon but very important for an organisation. Advanced civilizations that supported the arts and crafts allowed clients to choose goods meeting higher quality standards rather than normal goods. In societies where arts and crafts are the responsibility of master craftsmen or artists, these masters would lead their studios and train and supervise others. The importance of craftsmen diminished as mass production and repetitive work practices were instituted. The aim was to produce large numbers of the same goods. The first proponent in the US for this approach was Eli Whitney who proposed (interchangeable) parts manufacture for muskets, hence producing the identical components and creating a musket assembly line. The next step forward was promoted by several people including Frederick Winslow Taylor, a mechanical engineer who sought to improve industrial efficiency. He is sometimes called "the father of scientific management." He was one of the intellectual leaders of the Efficiency Movement and part of his approach laid a further foundation for quality management, including aspects like standardization and adopting improved practices. Henry Ford was also important in bringing process and quality management practices into operation in his assembly lines. In Germany, Karl Friedrich Benz, often called the inventor of the motor car, was pursuing similar assembly and production practices, although real mass production was properly initiated in Volkswagen after World War II. From this period onwards, North American companies focused predominantly upon production against lower cost with increased efficiency.

Walter A. Shewhart made a major step in the evolution towards quality management by creating a method for quality control for production, using statistical methods, first proposed in 1924. This became the foundation for his ongoing work on statistical quality control. W. Edwards Deming later applied statistical process control methods in the United States during World War II, thereby successfully improving quality in the manufacture of munitions and other strategically important products.

Quality leadership from a national perspective has changed over the past five to six decades. After the Second World War, Japan decided to make quality improvement a national imperative as part of rebuilding their economy, and sought the help of Shewhart, Deming and Juran, amongst others. W. Edwards Deming championed Shewhart's ideas in Japan from 1950 onwards. He is probably best known for his management philosophy establishing quality, productivity, and competitive position. He has formulated 14 points of attention for managers, which are a high level abstraction of many of his deep insights. They should be interpreted by learning and understanding the deeper insights. These 14 points include key concepts such as:

- Break down barriers between departments
- Management should learn their responsibilities, and take on leadership
- Supervision should be to help people and machines and gadgets to do a better job
- Improve constantly and forever the system of production and service
- Institute a vigorous program of education and self-improvement

In the 1950s and 1960s, Japanese goods were synonymous with cheapness and low quality, but over time their quality initiatives began to be successful, with Japan achieving very high levels of quality in products from the 1970s onward. For example, Japanese cars regularly top the J.D. Power customer satisfaction ratings. In the 1980s Deming was asked by Ford Motor Company to start a quality initiative after they realized that they were falling behind Japanese manufacturers. A number of highly successful quality initiatives have been invented by the Japanese (see for example on this page: Genichi Taguchi, QFD, and Toyota Production System). Many of the methods not only provide techniques but also have associated quality culture (i.e. people factors). These methods are now adopted by the same western countries that decades earlier derided Japanese methods.

Customers recognize that quality is an important attribute in products and services. Suppliers recognize that quality can be an important differentiator between their own offerings and those of competitors (quality differentiation is also called the quality gap). In the past two decades this quality gap has been greatly reduced between competitive products and services. This is partly due to the contracting (also called outsourcing) of manufacture to countries like India and China, as well internationalization of trade and competition. These countries amongst many others have raised their own standards of quality in order to meet International standards and customer demands. The ISO 9000 series of standards are probably the best known International standards for quality management.

There are a huge number of books available on quality management. In recent times some themes have become more significant including quality culture, the importance of knowledge management, and the role of leadership in promoting and achieving high quality. Disciplines like systems thinking are bringing more holistic approaches to quality so that people, process and products are considered together rather than independent factors in quality management.

The influence of quality thinking has spread to non-traditional applications outside of walls of manufacturing, extending into service sectors and into areas such as sales, marketing and customer service.

2.6 ISO 9000 series Quality Management Principles

The International Standard for Quality management (ISO 9001:2015) adopts a number of management principles that can be used by top management to guide their organisations towards improved performance.

The ISO 9000 series are based on seven quality management principles (QMP)

The seven quality management principles are:

- QMP 1 – Customer focus
- QMP 2 – Leadership
- QMP 3 – Engagement of people
- QMP 4 – Process approach
- QMP 5 – Improvement
- QMP 6 – Evidence-based decision making
- QMP 7 – Relationship management

Principle 1- Customer focus

The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations. Organisations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

Rationale

Sustained success is achieved when an organisation attracts and retains the confidence of customers and other interested parties on whom it depends. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to sustained success of an organisation.

Principle 2- Leadership

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organisation's quality objectives. Leaders establish unity of purpose and direction of the organisation. They should create and maintain the internal environment in which people can become fully involved in achieving the organisation's objectives.

Rationale

Creation of unity of purpose and direction and engagement of people enable an organisation to align its strategies, policies, processes and resources to achieve its objectives.

Principle 3- Engagement of people

Competent, empowered and engaged people at all levels throughout the organisation are essential to enhance its capability to create and deliver value. People at all levels are the essence of an organisation and their full involvement enables their abilities to be used for the organisation's benefit.

Rationale

To manage an organisation effectively and efficiently, it is important to involve all people at all levels and to respect them as individuals. Recognition, empowerment and enhancement of competence facilitate the engagement of people in achieving the organisation's quality objectives.

Principle 4- Process approach

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system. A desired result is achieved more efficiently when activities and related resources are managed as a process.

Rationale

The quality management system consists of interrelated processes. Understanding how results are produced by this system enables an organization to optimise the system and its performance.

Principle 5- Improvement

Successful organisations have an ongoing focus on improvement. Improvement of the organisation's overall performance should be a permanent objective of the organisation.

Rationale

Improvement is essential for an organisation to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities.

Principle 6- Evidence based decision making

Decisions based on the analysis and evaluation of data and information are more likely to produce desired results. Effective decisions are based on the analysis of data and information.

Rationale

Decision making can be a complex process, and it always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause-and-effect relationships and potential unintended consequences. Facts, evidence and data analysis lead to greater objectivity and confidence in decision making.

Principle 7- Relationship Management

For sustained success, an organisation manages its relationships with interested parties, such as suppliers. An organisation and its external providers (suppliers, contractors, and service providers) are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

Rationale

Interested parties influence the performance of an organisation. Sustained success is more likely to be achieved when the organisation manages relationships with all of its interested parties to optimise their impact on its performance. Relationship management with its supplier and partner networks is of particular importance.

2.7 Contents of ISO 9001:2015

ISO 9001:2015 Quality management systems — Requirements is a document of approximately 30 pages which is available from the national standards organisation in each country. Only ISO 9001 is directly audited against for third party assessment purposes. Outline requirements for ISO 9001:2015 are as follows:

Requirements

- Section 4: Context of the Organization
- Section 5: Leadership
- Section 6: Planning
- Section 7: Support
- Section 8: Operation
- Section 9: Performance evaluation
- Section 10: Improvement

Essentially the layout of the standard is similar to the previous ISO 9001:2008 standard in that it follows the Plan, Do, Check, Act cycle in a process based approach, but is now further encouraging this to have risk based thinking. (Section 0.3.3 of the introduction)

Before the certification body can issue or renew a certificate, the auditor must be satisfied that the company being assessed has implemented the requirements of sections 4 to 10. Sections 1 to 3 are not directly audited against, but because they provide context and definitions for the rest of the standard, not that of the organisation, their contents must be taken into account.

The standard no longer specifies that the organisation shall issue and maintain documented procedures, however ISO 9001:2015 requires the organisation to document any other procedures required for its effective operation. The standard also requires the organisation to issue and communicate a documented quality policy, a Quality Manual (which may or may not include documented procedures) and numerous records, as specified throughout the standard. New for the 2015 release is a requirement for an organisation to assess risks and opportunities (section 6.1) and to determine internal and external issues relevant to its purpose and strategic direction (section 4.1) Interpretations of how the standards requirements are a matter for the organisation to demonstrate, and an external auditor to determine, the effectiveness of a quality management system. Further detail, interpretation and examples of implementation are often sought by organizations seeking more information in what can be seen as a very technical area.

2.8 Deming Cycle, PDCA

The Deming Cycle, or PDCA Cycle (also known as PDSA Cycle), is a continuous quality improvement model consisting out of a logical sequence of four repetitive steps for continuous improvement and learning: Plan, Do, Study (Check) and Act. The PDSA cycle (or PDCA) is also known as the Deming Cycle, the Deming wheel of continuous improvement spiral. Its origin can be traced back to the eminent statistics expert Mr. Walter A. Shewart, in the 1920's. He introduced the concept of PLAN, DO and SEE. The late Total Quality Management (TQM) guru and renowned statistician Edward W. Deming modified the SHEWART cycle as: PLAN, DO, STUDY, and ACT.

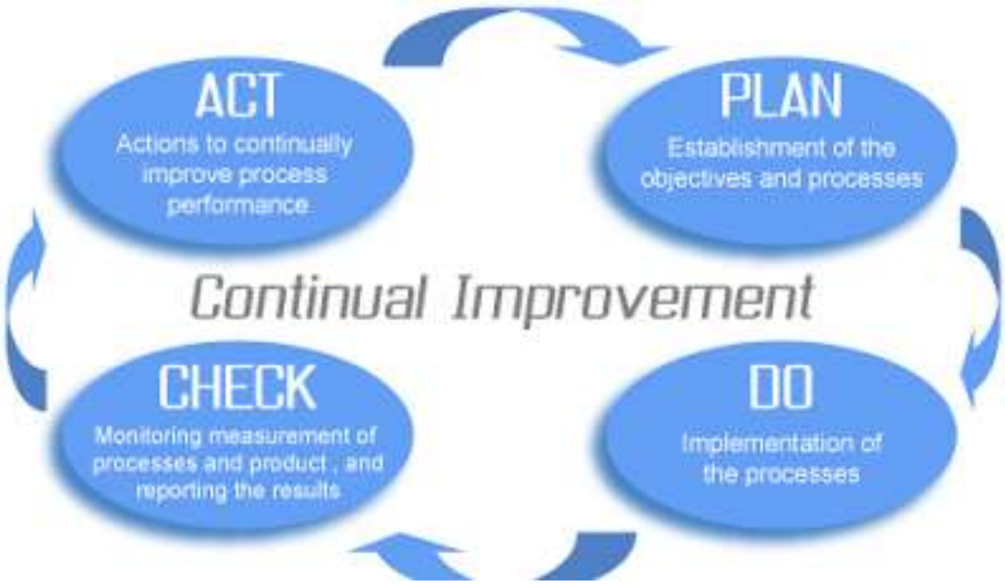
Along with the other well-known American quality guru-J.M. Juran, Deming went to Japan as part of the occupation forces of the allies after World War II. Deming taught a lot of Quality Improvement methods to the Japanese, including the usage of statistics and the PLAN, DO, STUDY, ACT cycle.

The Deming cycle, or PDSA cycle:

PLAN: plan ahead for change. Analyze and predict the results.
DO: execute the plan, taking small steps in controlled circumstances.
STUDY: check, study the results.
ACT: take action to standardize or improve the process.

Benefits of the PDSA cycle:

– Daily routine management-for the individual and/or the team
– Problem-solving process
– Project management
– Continuous development
– Vendor development
– Human resources development
– New product development
– Process trials



PDCA Cycle

2.9 Why should we apply for ISO 9001 certification?

Effectiveness

Effectiveness of the ISO system being implemented depends on a number of factors, the most significant of which are:

1. Commitments of senior management to monitor, control, and improve quality. Organizations that implement an ISO system without this desire and commitment often take the cheapest road to get a certificate on the wall and ignore problem areas uncovered in the audits.
2. How well the ISO system integrates into current business practices. Many organizations that implement ISO try to make their system fit into a cookie-cutter quality manual instead of creating a manual that documents existing practices and only adds new processes to meet the ISO standard when necessary.
3. How well the ISO system focuses on improving the customer experience. The broadest definition of quality is "Whatever the customer perceives good quality to be." This means that a company doesn't necessarily have to make a product that never fails; some customers will have a higher tolerance for product failures if they always receive shipments on-time or have a positive experience in some other dimension of customer service. An ISO system should take into account all areas of the customer experience and the industry expectations, and seek to improve them on a continual basis. This means taking into account all processes that deal with the three stakeholders (customers, suppliers, and organization); only

then will a company be able to sustain improvements in the customer's experience.

4. How well the auditor finds and communicates areas of improvement. While ISO auditors may not provide consulting to the clients they audit, there is the potential for auditors to point out areas of improvement. Many auditors simply rely on submitting reports that indicate compliance or non-compliance with the appropriate section of the standard; however, to most executives, this is like speaking a foreign language. Auditors that can clearly identify and communicate areas of improvement in language and terms executive management understands facilitate action on improvement initiatives by the companies they audit. When management doesn't understand why they were non-compliant and the business implications associated with non-compliance, they simply ignore the reports and focus on what they do understand.

Advantages

It is widely acknowledged that proper quality management improves business, often having a positive effect on investment, market share, sales growth, sales margins, competitive advantage, and avoidance of litigation. The quality principles in ISO 9000:2000 are also sound, according to Wade and Barnes, who says that "ISO 9000 guidelines provide a comprehensive model for quality management systems that can make any company competitive". Sroufe and Curkovic, (2008) found benefits ranging from registration required to remain part of a supply base, better documentation, to cost benefits, and improved involvement and communication with management. Implementing ISO often gives the following advantages:

1. Creates a more efficient, effective operation
2. Increases customer satisfaction and retention
3. Reduces audits
4. Enhances marketing
5. Improves employee motivation, awareness, and morale
6. Promotes international trade
7. Increases profit
8. Reduces waste and increases productivity
9. Common tool for standardization
10. Enables to meet the requirements of an internationally uniform quality system.
11. Motivates the employees and develops pride in them for achieving excellence.

2.10 Continual improvement process

A **continual improvement process**, also often called a **continuous improvement process** (abbreviated as **CIP** or **CI**), is an ongoing effort to improve products, services, or processes. These efforts can seek "incremental" improvement over time or "breakthrough" improvement all at once. Delivery (customer valued) processes are constantly evaluated and improved in the light of their efficiency, effectiveness and flexibility.

Some see CIPs as a meta-process for most management systems (such as business process management, quality management, project management, and program management). W. Edwards Deming, a pioneer of the field, saw it as part of the 'system' whereby feedback from the process and customer were evaluated against organisational goals. The fact that it can be called a management process does not mean that it needs to be executed by 'management'; but rather merely that it makes decisions about the implementation of the delivery process and the design of the delivery process itself.

A broader definition is that of the Institute of Quality Assurance who defined "continuous improvement as a gradual never-ending change which is: '... focused on increasing the effectiveness and/or efficiency of an organisation to fulfil its policy and objectives. It is not limited to quality initiatives. Improvement in business strategy, business results, and customer, employee and supplier relationships can be subject to continual improvement. Put simply, it means 'getting better all the time'.

2.11 Kaizen

Some successful implementations use the approach known as kaizen (the translation of kai ("change") zen ("good") is "improvement"). This method became famous from Imai's 1986 book *Kaizen: The Key to Japan's Competitive Success.*

- Feedback: The core principle of CIP is the (self) reflection of processes.
- Efficiency: The purpose of CIP is the identification, reduction, and elimination of suboptimal processes.
- Evolution: The emphasis of CIP is on incremental, continual steps rather than giant leaps.

Key features of kaizen include:

- Improvements are based on many small changes rather than the radical changes that might arise from Research and Development

- As the ideas come from the workers themselves, they are less likely to be radically different, and therefore easier to implement
- Small improvements are less likely to require major capital investment than major process changes
- The ideas come from the talents of the existing workforce, as opposed to using research, consultants or equipment – any of which could be very expensive
- All employees should continually be seeking ways to improve their own performance
- It helps encourage workers to take ownership for their work, and can help reinforce team working, thereby improving worker motivation.

The elements above are the more tactical elements of CIP. The more strategic elements include deciding how to increase the value of the delivery process output to the customer (effectiveness) and how much flexibility is valuable in the process to meet changing needs.

"Continuous" versus "Continual"

Continuous never stops until perfection is achieved. While continual presumes a set target is to be achieved at a certain point or time-frame, and when achieved, a new target is set and the cycle continues with no concept of perfection. Therefore, Continuous is Theoretical (the continuous improvement program of the company) while Continual is Practical (a specific project of the company). The standard refers to continual improvement in several clauses.

2.12 Let's sum-up

The implementation of a QMS according to the ISO 9001 standard has several advantages to the industry at large.

The pros could be summed up as:
- Focus on the satisfaction of customers and other relevant interested parties;
- Risk-based thinking applied to all relevant decisions, including (indirectly) technical decisions;
- Process approach matching the pre-analytical, analytical, and post-analytical phases;
- Context of the organisation, that includes the needs related to the pre-analytical and post-analytical phases;
- Indirectly, the trueness, measurement uncertainty and total error are utilized during method validation and internal QC/EQA/PT to determine if the test results are acceptable;
- Identification and traceability information of the different phases of the

production/ manufacturing process;
- Monitoring and measuring of devices that significantly contribute to the trueness and uncertainty of the reported results;
- Training and competence assessment of the staff which is critical to good management and good quality practices, and;
- Infrastructure to correctly support the operation practices.

Nevertheless, there are a few cons to the ISO 9001:

- The QMS assumed is only the basic cycle compared, for instance, to advanced models such as the total quality management cycle;
- It does not require sustainability;
- The operation specifications are generic;
- Procedures and allowable errors are not standardized, and;
- The safety specifications are basic.

2.13 Key Terms:

- **Quality Management System** (**QMS**) is a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction.
- **Business Process** is a collection of related, structured activities or tasks that produce a specific service or product (serve a particular goal) for a particular customer or customers.

- The International Standard for Quality management (**ISO 9001:2015**) adopts basically seven management principles that can be used by top management to guide their organisations towards improved performance. They are: Customer focus, Leadership, Engagement of people, Process approach, Improvement, Evidence-based decision making and Relationship management.
- **PDCA** (plan-do-check-act, sometimes seen as plan-do-check-adjust) is a repetitive four-stage model for continuous improvement (CI) in business process management. The**PDCA** model is also known as the Deming circle/**cycle**/wheel, Shewhart **cycle**, control circle/**cycle**, or plan–do–study–act (**PDSA**).
- **Third-party certification** involves an independent assessment declaring that specified requirements pertaining to a product, person, and process or management system have been met. In this respect, a Certification Body is a third-party, accredited body which is entitled by an Accreditation Body.
- **Continuous** improvement should be used for things that are continuous in a way literally or figuratively equal to the mathematical sense of the word.

- **Continual** improvement should be used for things that continue in discrete jumps (that is, quantum-wise). This is widely used in ISO 9001.

2.14 Self-Assessment Questions

Select the correct answer and justify

1. When a manager monitors the work performance of workers in his department to determine if the quality of their work is 'up to standard', this manager is engaging in which function?
   a. Planning
   b. Controlling
   c. Organising
   d. Leading

   Ans: (a) Controlling. Monitoring of workers' performance is a form of control.

2. What is the weakest form of control?
   a. Pre-control
   b. Simultaneous control
   c. Post control
   d. Dual control

   Ans: ((c) Post control. Post control is a case of shutting the barn door after horse has bolted. It is reactive and ineffective.

3. Where Total Quality Management was first developed?
   a. USA
   b. UK
   c. Japan
   d. Korea

   Ans: ((c) Japan. TQM is a Japanese innovation.

4. Improving quality through small, incremental improvements is a characteristic of what type of quality management system?
   a. Just-in-time
   b. Six Sigma
   c. Total Quality Management
   d. Kaizen

   Ans: (d) Kaizen. Kaizen is an incremental approach to improve quality.

5. The objective of ISO- 9000 family of Quality Management is
   a. Customer satisfaction
   b. Employee satisfaction

c. Skill enhancement
d. Environmental issues

Ans: (a) Customer satisfaction

6. How should we document the context of the organization? Is the Quality Policy a good place to describe the new context of the organization?

   Ans: No, the Quality Policy is not a good place for the context of the organization. The context of the organization can be documented, in the Quality manual, if the organization decides to keep it. While some documents and procedures will not be mandatory anymore they can be kept and serve as a good repository for evidence of compliance to new concepts brought by the new standard version.

2.15 References & Further Readings

1. "ISO 9000 - Quality management". International Organization for Standardization
2. *"Quality Management Principles" (PDF). International Organization for Standardization. 2015. ISBN 978-92-67-10650-2.*
3. ISO 9001:2015 - Just published!" ISO. Retrieved 2 October 2015.

2.16 Model Questions

1. What is Quality Management? Describe its evolution.

Ans: The history of total quality management (TQM) began initially as a term coined by the Naval Air Systems Command to describe its Japanese-style management approach to quality improvement. An umbrella methodology for continually improving the quality of all processes, it draws on a knowledge of the principles and practices of:

- The behavioral sciences
- The analysis of quantitative and non-quantitative data
- Economics theories
- Process analysis

Evolution during 1920s

- Some of the first seeds of quality management were planted as the principles of scientific management swept through U.S. industry.

- Businesses clearly separated the processes of planning and carrying out the plan, and union opposition arose as workers were deprived of a voice in the conditions and functions of their work.
- The Hawthorne experiments in the late 1920s showed how worker productivity could be impacted by participation.

Evolution made today

- QM is the name for the philosophy of a broad and systemic approach to managing organizational quality.
- Quality standards such as the ISO 9000 series and quality award programs such as the Deming Prize and the Malcolm Baldrige National Quality Award specify principles and processes that comprise TQM.

2. What are the characteristics of a business process?

   Ans: characteristics for a business process:

1. *Definability*: It must have clearly defined boundaries, input and output.
2. *Order*: It must consist of activities that are ordered according to their position in time and space (a sequence).
3. *Customer*: There must be a recipient of the process' outcome, a customer.
4. *Value-adding*: The transformation taking place within the process must add value to the recipient, either upstream or downstream.
5. *Embeddedness*: A process cannot exist in itself, it must be embedded in an organizational structure.
6. *Cross-functionality*: A process regularly can, but not necessarily must, span several functions.

3. What are the quality management principles of ISO 9001?

Ans: The ISO 9000 series are based on seven quality management principles (QMP)

The seven quality management principles are:

- QMP 1 – Customer focus
- QMP 2 – Leadership
- QMP 3 – Engagement of people
- QMP 4 – Process approach
- QMP 5 – Improvement
- QMP 6 – Evidence-based decision making
- QMP 7 – Relationship management

Unit- 3

Lean and Six Sigma

Learning Objectives

After completion of the unit, you should be able to:

- Explain the meaning of Lean
- Explain the meaning of Six Sigma
- Usage of Lean and Six-Sigma in Management
- Understand it's requirement in Management function

Structure

3.1 Introduction

The core idea is to maximize **customer value** while minimizing waste. Simply, lean means creating more value for customers with fewer resources.

A lean organization understands customer value and focuses its key processes to continuously increase it. The ultimate goal is to provide perfect value to the customer through a perfect value creation process that has zero waste.

To accomplish this, lean thinking changes the focus of management from optimizing separate technologies, assets, and vertical departments to optimizing the flow of products and services through entire value streams that flow horizontally across technologies, assets, and departments to customers.

Eliminating waste along entire value streams, instead of at isolated points, creates processes that need less human effort, less space, less capital, and less time to make products and services at far less costs and with much fewer defects, compared with traditional business systems. Companies are able to respond to changing customer desires with high variety, high quality, low cost, and with very fast throughput times. Also, information management becomes much simpler and more accurate.

Six Sigma at many organizations simply means a measure of quality that strives for near perfection. Six Sigma is a disciplined, data-driven approach and methodology for eliminating defects (driving toward six standard deviations between the mean and the nearest specification limit) in any process – from manufacturing to transactional and from product to service.

The **statistical representation** of Six Sigma describes quantitatively how a process is performing. To achieve Six Sigma, a process must not produce more than 3.4 defects per million opportunities. A Six Sigma defect is defined as anything outside of customer specifications. A Six Sigma opportunity is then the total quantity of chances for a defect. Process sigma can easily be calculated using a Six Sigma **calculator**.

3.2 Definitions

A popular misconception is that lean is suited only for manufacturing. Not true. Lean applies in every business and every process. It is not a tactic or a cost reduction program, but a way of thinking and acting for an entire organization.

Businesses in all industries and services, including healthcare and governments, are using lean principles as the way they think and do. Many organizations choose not to use the word lean, but to label what they do as their own system, such as the Toyota Production System or the Danaher Business System. Why? To drive home the point that lean is not a program or short term cost reduction program, but the way the company operates. The word **transformation or lean transformation** is often used to characterize a company moving from an old way of thinking to lean thinking. It requires a complete transformation on how a company conducts business. This takes a long-term perspective and perseverance.

The term "lean" was coined to describe Toyota's business during the late 1980s by a research team headed by Jim Womack, Ph.D., at MIT's International Motor Vehicle Program.

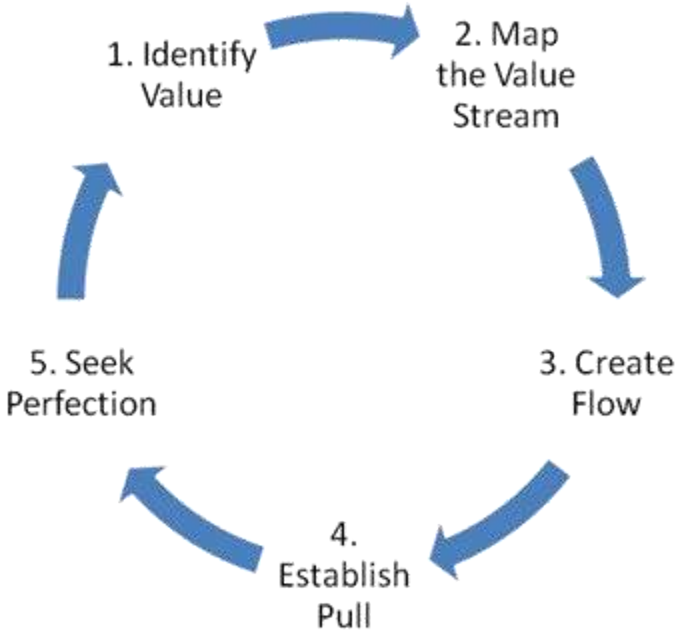
The characteristics of a lean organization and supply chain are described in *Lean Thinking*, by Womack and Dan Jones, founders of the Lean Enterprise Institute and the Lean Enterprise Academy (UK), respectively. While there are many very good books about lean techniques, *Lean Thinking* remains one of the best resources for understanding "what is lean" because it describes the *thought process*, the overarching key principles that must guide your actions when applying lean techniques and tools.

The fundamental objective of the Six Sigma methodology is the implementation of a measurement-based strategy that focuses on process improvement and variation reduction through the application of **Six Sigma improvement projects**. This is accomplished through the use of two Six Sigma sub-methodologies: DMAIC and DMADV. The Six Sigma DMAIC process (define, measure, analyze, improve, control) is an improvement system for existing processes falling below specification and looking for incremental improvement. The Six Sigma DMADV process (define, measure, analyze, design, verify) is an improvement system used to develop new processes or products at Six Sigma quality levels. It can also be employed if a current process requires more than just incremental improvement. Both Six Sigma processes are executed by Six Sigma Green Belts and Six Sigma Black Belts, and are overseen by Six Sigma Master Black Belts.

3.3 PRINCIPLES OF LEAN

The five-step thought process for guiding the implementation of lean techniques is easy to remember, but not always easy to achieve:

1. Specify value from the standpoint of the end customer by product family.
2. Identify all the steps in the value stream for each product family, eliminating whenever possible those steps that do not create value.
3. Make the value-creating steps occur in tight sequence so the product will flow smoothly toward the customer.
4. As flow is introduced, let customers pull value from the next upstream activity.
5. As value is specified, value streams are identified, wasted steps are removed, and flow and pull are introduced, begin the process again and continue it until a state of perfection is reached in which perfect value is created with no waste.



3.4 Difference between related concepts

Lean management and Six Sigma are two concepts which share similar methodologies and tools. Both programs are Japanese influenced, but they are two different programs. Lean management is focused on eliminating waste and ensuring efficiency while Six Sigma's focus is on eliminating defects and reducing variability.

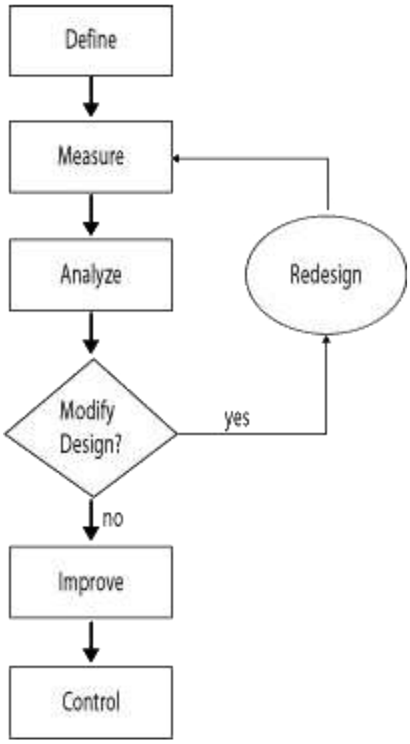
3.5 Methodologies

Six Sigma projects follow two project methodologies inspired by Deming's Plan-Do-Check-Act Cycle. These methodologies, composed of five phases each, bear the acronyms DMAIC and DMADV.

- DMAIC ("duh-may-ick") is used for projects aimed at improving an existing business process.
- DMADV ("duh-mad-vee") is used for projects aimed at creating new product or process designs.

3.6 DMAIC

DMAIC is an abbreviation of the five improvement steps it comprises: Define, Measure, Analyze, Improve and Control. All of the DMAIC process steps are required and always proceed in the given order.



Define

The purpose of this step is to clearly articulate the business problem, goal, potential resources, project scope and high-level project timeline. This information is typically captured within project charter document. Write down what you currently know. Seek to clarify facts, set objectives and form the project team. Define the following:

- A problem
- The customer(s)
- Voice of the customer (VOC) and Critical to Quality (CTQs) — what are the critical process outputs?

  The Define phase is about coming up with a focused problem statement and a supporting measure of success or failure.
  The deliverable for the Define phase is a team charter like the one below:

DMAIC Team Charter

Project Scope

Problem Statement
Warranty returns on the "Cedar Essentials" product line are at 2.6% of sales volume and increasing.

Overall Metric
Total Warranty Rate = (Returned Qty / Shipped QTY) x 100

Project Metric
Cedar Essentials Warranty Rate
(same metric as above, but for Cedar Essentials line)

Opportunities

- A 50% reduction in the Cedar Essentials warranty rate equates a $247K annual savings and a 2% increase in annual sales

Baseline Performance = 2.6%

Goal Performance = 1.4%

Project Status

- Historical and current warranty rate confirmed
- Initial feedback gathered from sales team on top problems
- Analysis of product returns scheduled for next week – meeting at returns center with engineering team
- Pareto chart and root cause analysis will follow product teardown session

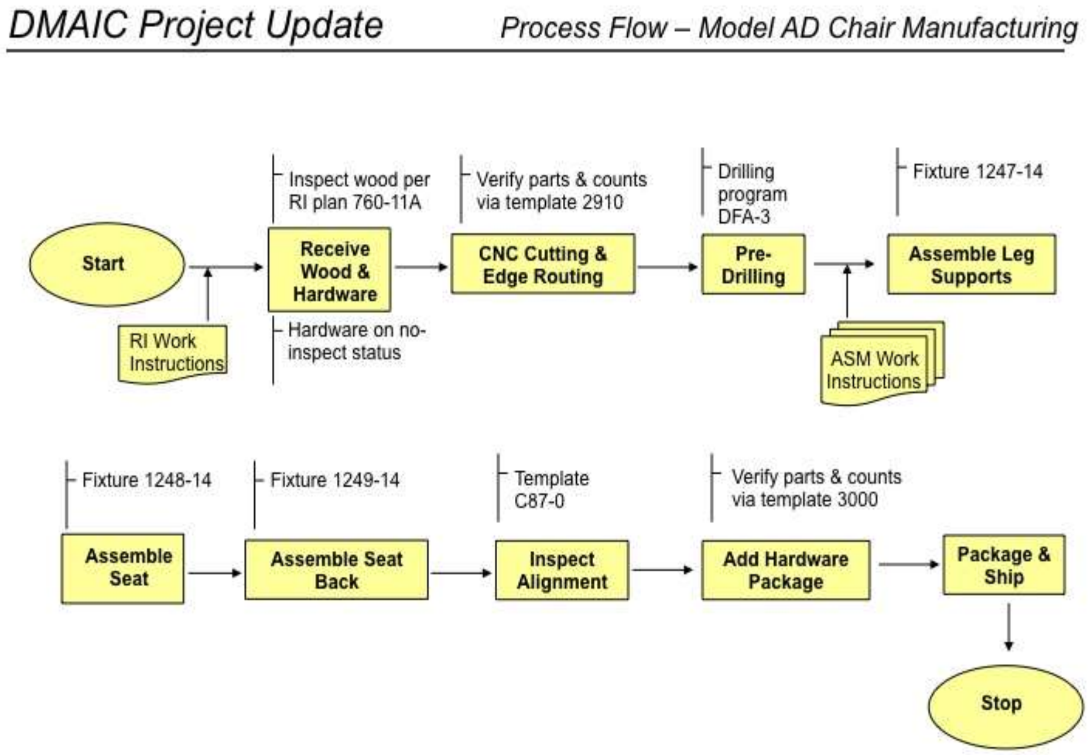
Actions / Open Issues

Action	Owner	Timing	Status
Confirm warranty numbers	JL	4-Mar	Complete
Obtain sales team feedback	RG	14-Mar	Complete
Schedule product teardown	JL	16-Mar	Complete
Conduct teardown	Team	25-Mar	On Track
Present pareto & root cause summary	Team	15-Apr	On Track

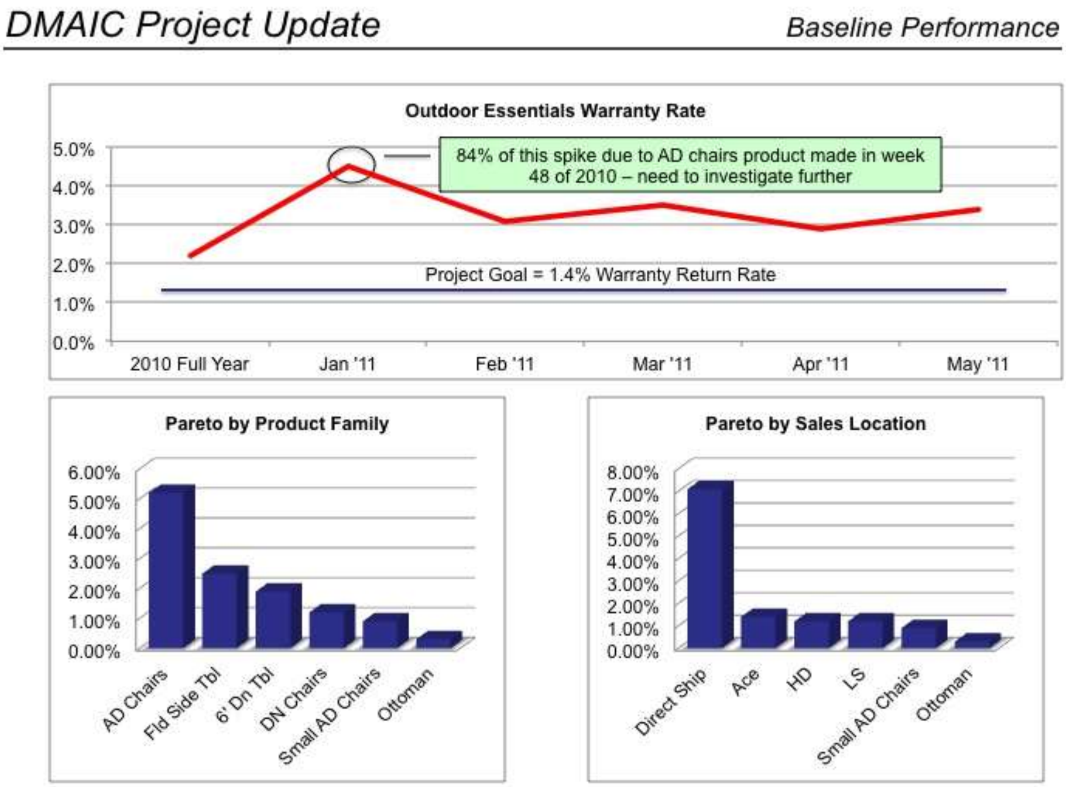
DMAICTools.com thanks our industry partners for sharing their forms
- use it, improve it, share it, send us back a better version! mailto::mike.walton@dmaictools.com

Measure

The Measure phase is about documenting the current process and assessing baseline performance. Some of the important tools in this phase include trend charts, basic Pareto charts, process flowcharts, Gage R&R, and process capability measurement (sigma level, also referred to as *process sigma*). Depending on the project scope, the team might hold off on the process flowchart and Gage R&R activities until primary focus areas are identified further into the project. In some cases, a macro flowchart is useful in providing all team members with an initial, high-level view of the process –



Oftentimes the Measure phase provides early clues that will direct team toward top problem areas and solutions, as shown in the following trend and Pareto charts for our outdoor furniture company example –



In the case of our furniture manufacturing company example, the project team also performs a Gage R & R study on a known critical measurement (screw torque) that affects a cracking condition on one of its chair lines – this will come in handy later in the project. The initial GR&R results show that the screw torque measurement method introduces far too much variation –

Gage R&R Study
Model 456-12 Digital Torque Wrench
Baseline Study

Gage R&R

Source	VarComp	%Contribution (of VarComp)
Total Gage R&R	1.14818	28.37
Repeatability	0.02858	0.71
Reproducibility	1.11959	27.66
Operators	0.90644	22.40
Operators*Parts	0.21315	5.27
Part-To-Part	2.89879	71.63
Total Variation	4.04697	100.00

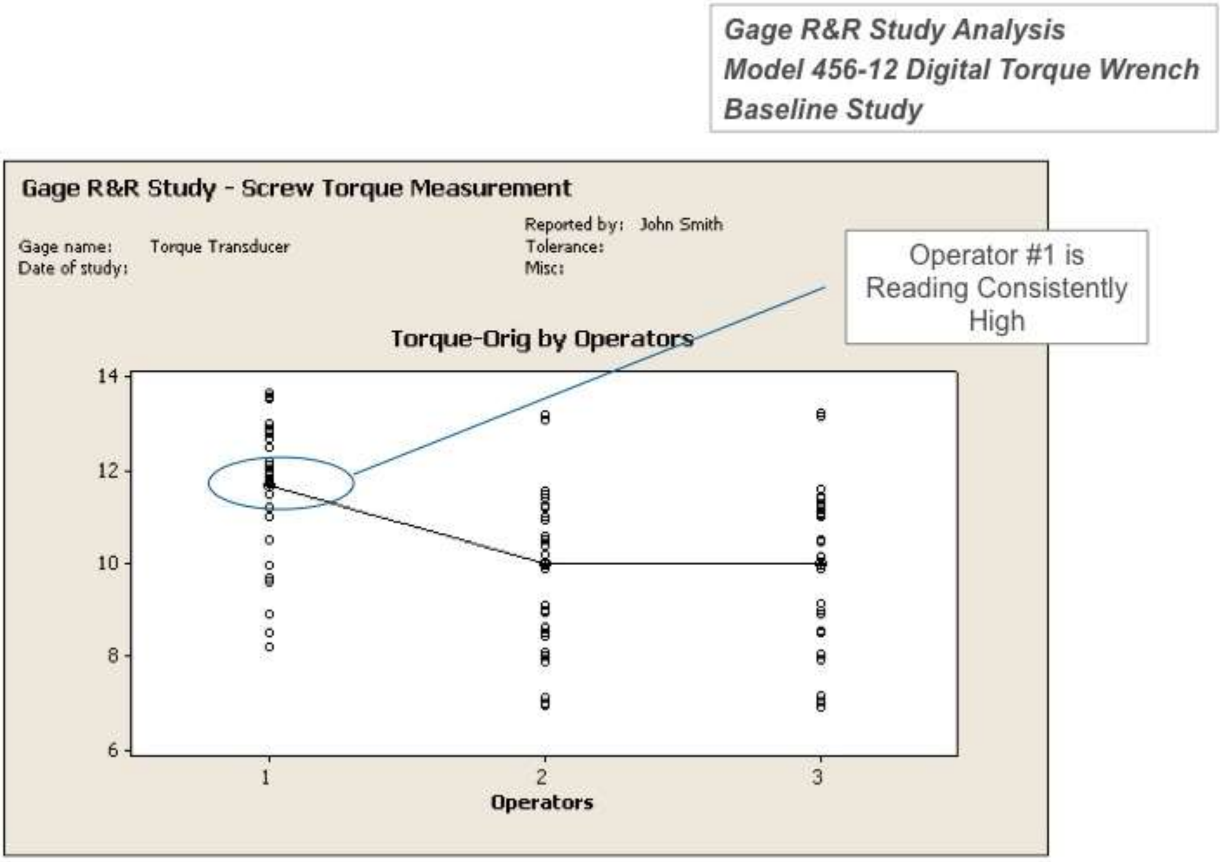
Process tolerance = 4

Source	StdDev (SD)	Study Var (6 * SD)	%Tolerance (SV/Toler)
Total Gage R&R	1.07153	6.43	160.73
Repeatability	0.16907	1.01	25.36
Reproducibility	1.05811	6.35	158.72
Operators	0.95207	5.71	142.81
Operators*Parts	0.46169	2.77	69.25
Part-To-Part	1.70258	10.22	255.39
Total Variation	2.01171	12.07	301.76

Overall GR&R of 161% exceeds 20% maximum

Reproducibility value is the major problem at 159%

Using a graphical technique learned in Gage R & R training, the team finds that the first operator in the study is recording consistently higher readings than the other two operators –



Finally, after correcting operator #1's measurement technique and updating the measurement procedure, the team conducts a follow-up Gage R & R study with much-improved results –

Gage R&R Study Analysis
Model 456-12 Digital Torque Wrench
Revised Study – Measurement Procedure Standardized

Gage R&R

Source	VarComp	%Contribution (of VarComp)
Total Gage R&R	0.00615	0.17
Repeatability	0.00615	0.17
Reproducibility	0.00000	0.00
Operators	0.00000	0.00
Part-To-Part	3.56042	99.83
Total Variation	3.56657	100.00

Process tolerance = 4

Source	StdDev (SD)	Study Var (6 * SD)	%Tolerance (SV/Toler)
Total Gage R&R	0.07843	0.47	11.76
Repeatability	0.07843	0.47	11.76
Reproducibility	0.00000	0.00	0.00
Operators	0.00000	0.00	0.00
Part-To-Part	1.88691	11.32	283.04
Total Variation	1.88854	11.33	283.28

Overall GR&R is now acceptable at 11.8%

Reproducibility value has been reduced to zero!

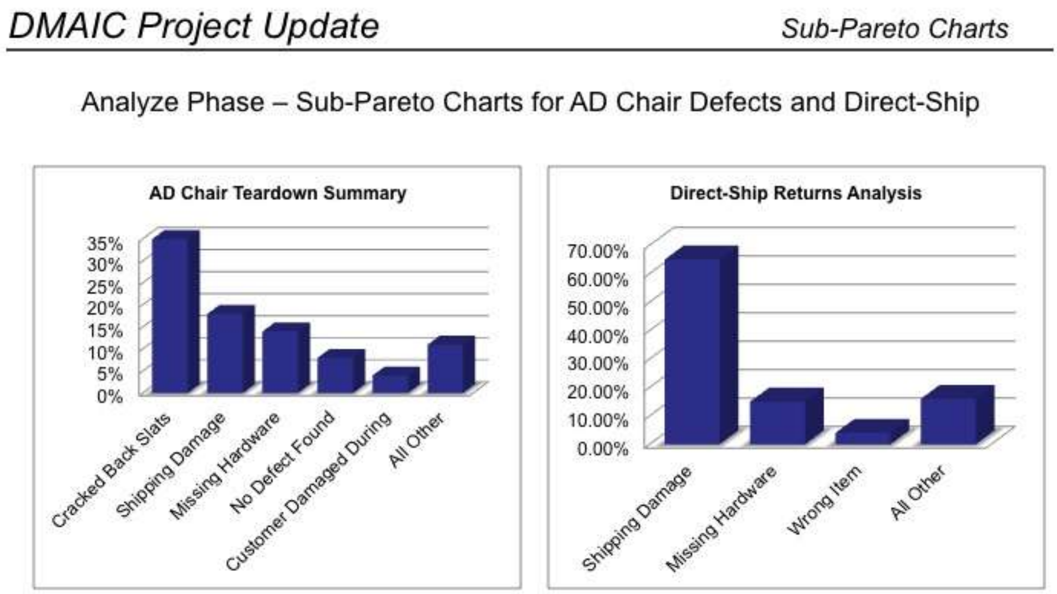
Finally, the baseline sigma level for the overall defect rate is estimated using a sigma conversion chart, providing a relative indicator of how close the current process is to delivering zero defects. A Six Sigma process has a sigma level of six, and for all practical purposes is considered a defect-free process over the long run, provided that adequate controls are in place to maintain capability. In the example above, an overall defect rate of 2.6% reflects a sigma level of 2.1.

Analyze

The Analyze phase in DMAIC isolates the *top causes* behind the metric or CTQ that the team is tackling. In most cases there will be no more than three causes that must be controlled in order to achieve success – if too many causes are identified, then the team has either not isolated the primary causes or the project goal is too ambitious to achieve success with a single project. There are always exceptions, but speed and results are key ingredients to building Six Sigma momentum inside an organization, and projects should be sized to assure team success and project closure inside reasonable time limits.

- The Analyze phase deploys a number of tools for collecting team input and conducting objective experiments to identify or confirm top causes.
- Not all tools are used on all projects.
- In our outdoor furniture manufacturing example, the team must understand the reasons behind two of the biggest Pareto items discovered in the Measure phase:
  (1) Returns on the "AD Chairs" product line and
  (2) Returns on Direct-Ship products.

A detailed analysis via product tear-downs produces the following sub-Pareto charts, which bring the team closer the primary causes that are driving high customer return rates



Improve

The purpose of this step is to identify, test and implement a solution to the problem; in part or in whole. This depends on the situation. Identify creative solutions to eliminate the key root causes in order to fix and prevent process problems. Use brainstorming or techniques like Six Thinking Hats and Random Word. Some projects can utilize complex analysis tools like DOE (Design of Experiments), but try to focus on obvious solutions if these are apparent.

However, the purpose of this step can also be to find solutions without implementing them.

- Create
- Focus on the simplest and easiest solutions
- Test solutions using Plan-Do-Check-Act (PDCA) cycle
- Based on PDCA results, attempt to anticipate any avoidable risks associated with the "improvement" using the Failure mode and effects analysis (FMEA)
- Create a detailed implementation plan
- Deploy improvements

Control

The purpose of this step is to sustain the gains. Monitor the improvements to ensure continued and sustainable success. Create a control plan. Update documents, business process and training records as required.

A Control chart can be useful during the Control stage to assess the stability of the improvements over time by serving as

1. A guide to continue monitoring the process and
2. Provide a response plan for each of the measures being monitored in case the process becomes unstable.

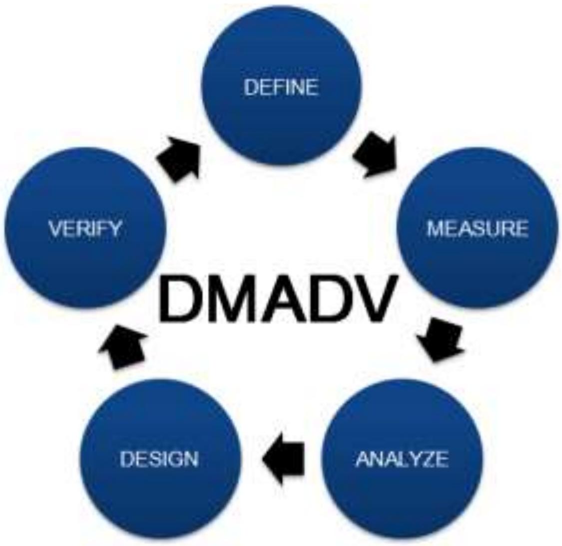
DMAIC's Control phase is about sustaining the changes made in the Improve phase. The best controls are those that require no monitoring (irreversible product or process design changes).
But oftentimes there are process settings, procedures, etc., requiring that employees follow specific requirements in daily operations – these items are typically documented in a control plan. In cases like this the Six Sigma team should do everything possible to error-proof the process, and should then add the appropriate checks and balances to the quality system for the long run.

3.7 DMADV Methodology

Some Six Sigma methodologies are aimed at reducing the errors in a product line by looking at all the processes contributing to the completion and delivery of an item or service. Improving the effectiveness of these processes and omitting redundancies are ways to make the entire manufacturing process more efficient. This leads to shortened lead times, improvements in gross margin and more reliable production lines.

Coupling improvements in the manufacturing processes with those that govern customer service can help to deliver a more complete and profitable product or service. The Six Sigma processes that look at the customer service aspects of a business are outlined in the acronym "DMADV" which refers to Define, Measure, Analyze, Design, and Verify.

An Overview of Six Sigma's DMADV processes:



The application of DMADVis used when a client or customer requires product improvement, adjustment, or the creation of an entirely new product or service. The application of these methods is aimed at creating a high-quality product keeping in mind customer requirements at every stage of the game. In general, the process can be outlined as:

Define

Project leaders identify wants and needs believed to be considered most important to customers. Wants and needs are identified through the historical information, customer feedback, and other information sources.

- Teams are assembled to drive the process
- Metrics and other tests are developed in alignment with customer information

Measure

The second part of the process is to use the defined metrics to collect data and record specifications in a way that can be utilized to help drive the rest of the process.

- All the processes needed to successfully manufacture the product or service are assigned metrics for later evaluation
- Technology teams test the metrics and then apply them

Analyze

The result of the manufacturing process (i.e. finished product or service) is tested by internal teams to create a baseline for improvement.

- Leaders use data to identify areas of adjustment within the processes that will deliver improvement to either the quality or manufacturing process of a finished product or service
- Teams set final processes in place and make adjustments as needed

Design

The results of internal tests are compared with customer wants and needs. Any additional adjustments needed are made.

- The improved manufacturing process is tested and test groups of customers provide feedback before the final product or service is widely released

Verify

The last stage in the methodology is continuous. While the product or service is being released and customer reviews are coming in, the processes may be adjusted.

- Metrics are further developed to keep track of continuous customer feedback on the product or service.
- New data may lead to other changes that need to be addressed, so the initial process may lead to new applications of DMADV in subsequent areas.

The applications of these methodologies are generally rolled out over the course of many months or even years. The end result is a product or service that is completely aligned with customer expectations, wants and needs.

Leadership opportunities are abound for Six Sigma professionals in today's competitive business environment. As an in-house expert or as an independent consultant, those with Green Belt, Black Belt, or Master Black Belt certification can be on their way to a more rewarding career path.

Career development is available through reputable third party accreditation bodies, providing professionals with flexible options designed to develop the leadership skills needed to edge above the competition and move into top Six Sigma positions across the industry.

3.8 DMAIC versus DMADV

We know that everything in business is a process, right? Sales people have a list of companies and contacts that they work in a certain fashion to produce a sale, production receives an order and schedules the manufacturing, and the product is built, packaged, shipped and invoiced. When the packing department has a problem with their process, though, should they fix it with a DMAIC or DMADV (also referred to as DFSS) type project?

The Similarities of DMAIC and DMADV

Let's first look at the DMAIC and DMADV methodologies and talk about how they're alike. DMAIC and DMADV are both:

- Six Sigma methodologies used to drive defects to less than 3.4 per million opportunities.
- Data intensive solution approaches. Intuition has no place in Six Sigma – only cold, hard facts.
- Implemented by Green Belts, Black Belts and Master Black Belts.
- Ways to help meet the business/financial bottom-line numbers.
- Implemented with the support of a champion and process owner.

The Differences of DMAIC and DMADV

DMAIC and DMADV sound very similar. The acronyms even share the first three letters. But that is about where the similarities stop.

DMAIC - Use this approach when the products or processes at our organization are not meeting customer demands or not performing accurately.

- Define - Define the goals and what the client wants. Look at both internal and external forces.
- Measure - Measure the current processes. Are they working?
- Analyze - By analyzing the current processes and finding out the root causes of the problems or defects we can then improve them.
- Improve - Improve the defects we've identified.
- Control - Set up good controls that can be implement and used on all processes. Use the areas we have identified and fixed.

DMADV - Use this approach when the products or processes at our organization don't even exist, at any level. Think of DMADV as our baby steps into Six Sigma.

- Define - Define the goals of a project both internal and external.
- Measure - Measure the client's needs and specifications.
- Analyze - Analyze how we are going to meet the customer's needs.
- Design - Design a good process that includes change management controls, project scopes, human resources, budgets and be very detailed on how each part of the process will be delivered or handled.
- Verify - Verify the Six Sigma approach. Did it work? Were there defects? If so, begin again.

When to Use DMADV

The DMADV methodology, instead of the DMAIC methodology, should be used when:

- A product or process is not in existence at our company and one needs to be developed
- The existing product or process exists and has been optimized (using either DMAIC or not) and still does not meet the level of customer specification or Six Sigma level

3.9 Integrating lean and Six Sigma

Lean and Six Sigma have the same general purpose of providing the customer with the best possible quality, cost, delivery, and a newer attribute, nimbleness. There is a great deal of overlap, and disciples of both disagree as to which techniques belong where.

The two initiatives approach their common purpose from slightly different angles:

• Lean focuses on waste reduction, whereas Six Sigma emphasizes variation reduction

• Lean achieves its goals by using less technical tools such as kaizen, workplace organization, and visual controls, whereas Six Sigma tends to use statistical data analysis, design of experiments, and hypothesis tests

Lean Six Sigma is a methodology that relies on a collaborative team effort to improve performance by systematically removing waste, combining **lean**manufacturing/**lean** enterprise and **Six Sigma** to eliminate the eight kinds of waste (muda): Transportation, Inventory, Motion, Waiting, Over production, Over processing.

3.10 The Five Principles of Lean Six Sigma

Company executives often call in Lean Six Sigma professionals when they are having trouble with the quality of the output their company has. The job of these professionals is to decrease waste and increase quality through the various tools and knowledge at their disposal.

When a company needs a Lean Six Sigma Professional, they may be having a problem with low job satisfaction among employees, creating a low morale and poor work production as a result. They may need to streamline their company processes, reducing and eliminating much of what they were doing wrong. The Six Sigma professionals would then use these methods to help them eliminate waste and streamline their processes while improving their output quality.

The training involved in learning the lean methods will provide a good overview of the tools that are used and how to apply them to Six Sigma projects. Some of these tools include process maps, affinity diagrams and value stream mapping. This process can be applied to any business or organization, no matter the size or the type of industry. Whether the business in question is in the manufacturing industry or it is a service provider, the processes can be used to streamline the procedures used within the company.

In lean Six Sigma, there are **five principles** that are used:

- The first of these is the law of the market. This signifies that the customer is always to be put first. The company must implement this immediately and make sure that all employees adhere to it. The company wants the employees to understand that without the customers, there would be no business.

- The second of these principles is the law of flexibility. If a process is easily maneuverable, it is easier to work with. A method of business that cannot be changed for any reason can cause problems.
- The third principle is the law of focus. This is meant to keep the focus on the problems within the company and not the entire company itself. Executives and employees should concentrate on just the portions of the company that are causing problems and fixing those problems, dismissing distractions by other areas of the business that are not having problems.
- The fourth principle is the law of velocity. This means that if a process has many, many details that have to be performed, it may be slowing down the process. The work put into the process should be proportional to the results the company sees.
- The fifth principle in lean Six Sigma is the law of complexity. Simply put, keep it simple. When a process is complex and difficult, it may have elements that are not necessary. More complexity does not necessarily mean more valuable or more important. In fact, it could mean just the opposite.

3.11 What are "Belts"?

A "Belt" signifies experience. Practitioners are given a "Belt" title (Black Belt, Green Belt, and Yellow Belt) that corresponds to their level of experience.
This roughly corresponds to their hierarchy in martial arts, with darker colored belts indicating more experience (more training, more knowledge and skills). For a visual example of what this looks like, visit our Belt comparison page.

3.11.1 Black Belt

A Black Belt has expert knowledge and skills related to the DMAIC methodology, Lean methods, and team leadership.
Black Belts should be able to lead any team across the organization in executing Lean Six Sigma projects. Black Belts may also conduct Lean Six Sigma training and act as coaches and mentors to other Belts-in-training.

Black Belt training can be obtained from a variety of sources but is typically between 140 and 160 hours in duration and includes instruction in the use of statistical data analysis, designed experiments, team leadership, and project management.

Black Belt *Certification* - the recognition of both knowledge and the practical application of skills - is offered by the American Society for Quality (ASQ) and other organizations and consulting firms.

3.11.2 Green Belt

A Green Belt has strong knowledge and skills related to the DMAIC methodology and Lean methods, but typically does not have experience with advanced statistical tools such as design of experiments (DOE).

Green Belts may lead simple projects under the guidance of a Black Belt or may work as a team member on a large project team.

Green Belt training can be obtained from a variety of sources, but is typically less than 100 hours in duration and includes instruction in the basic use of statistical data analysis, with emphasis on team problem-solving techniques.

Green Belt *Certification* - the recognition of both knowledge and the practical application of skills - is offered by the American Society for Quality (ASQ) and other organizations and consulting firms.

3.11.3 Yellow Belt

A Yellow Belt is trained in the general Lean Six Sigma concepts and basic tools.

A company deploying Lean Six Sigma may choose to designate project team members as Yellow Belts after completing a required training course, or may use the designation for employees responsible for data collection for a Green Belt or Black Belt project.

The Yellow Belt body of knowledge is defined quite differently by different organizations. In some cases, it may represent only the most basic concepts and language of Six Sigma, with an overview of the DMAIC process. In other cases, Yellow Belts are trained in a more complete set of basic tools, typically representing 15 to 25 hours of training.

3.11.4 Champion

A project Champion is a high-ranking manager who will work with a Black Belt to ensure that barriers to project success are removed and the project team has the organizational support it needs to be effective.

Champions are not expected to be experts in the statistical tools or even experts in the project's specific subject matter. Instead, they must possess a breadth of organizational knowledge to ensure that the project team's work is aligned with the organization's strategic objectives and interfaces effectively across the organization. A champion must also have the organizational clout to 'make things happen.'

3.11.5 White Belt

A White Belt has received a small amount (several hours) of awareness training. Enough to be dangerous!

Most White Belts are executives or staff who need to know the very basics of process improvement. White Belt training is used to assist change management and cultural buy-in from professionals who won't use the tools but may be impacted by projects.

3.11.2 Let's sum-up

Lean Six Sigma is a methodology that relies on a collaborative team effort to improve performance by systematically removing waste, combining lean manufacturing/lean enterprise and Six Sigma to eliminate the eight kinds of waste (muda): Transportation, Inventory, Motion, Waiting, Over production, Over processing, Defects, and Skills

Lean Six Sigma utilizes the DMAIC phases similar to that of Six Sigma. Lean Six Sigma projects comprise aspects of Lean's waste elimination and the Six Sigma focus on reducing defects, based on critical to quality (CTQ) characteristics. The DMAIC toolkit of Lean Six Sigma comprises all the Lean and Six Sigma tools. The training for Lean Six Sigma is provided through the belt based training system similar to that of Six Sigma. The belt personnel are designated as white belts, yellow belts, green belts, black belts and master black belts, similar to judo.

For each of these belt levels skill sets are available that describe which of the overall Lean Six Sigma tools are expected to be part at a certain Belt level. These skill sets provide a detailed description of the learning elements that a participant will have acquired after completing a training program. The level upon which these learning elements may be applied is also described. The skill sets reflects elements from Six Sigma, Lean and other process improvement methods like the theory of constraints (TOC) total productive maintenance (TPM).

3.13 Key Terms

Customer: Any internal or external person/organization who receives the output (product or service) of the process; understanding the impact of the process on both internal and external customers is key to process management and improvement.

Customer requirements: Defines the needs and expectations of the customer; translated into measurable terms and used in the process to ensure compliance with the customers' needs.

Cycle time: All time used in a process; includes actual work time and wait time.

Analyze: DMAIC phase where process detail is scrutinized for improvement opportunities. Note that: 1. Data is investigated and verified to prove suspected root causes and substantiate the problem statement (see also Cause and Effect). 2. Process analysis includes reviewing process maps for value added/non-value-added activities. See also Process Map; Value- Adding Activities; Non-Value-Adding Activities.

Control: DMAIC phase C; once solutions have been implemented, ongoing measures track and verify the stability of the improvement and the predictability of the process. Often includes process management techniques and systems including process ownership, cockpit charts and/or process management charts, etc. See also Cockpit Charts; Process Management A statistical concept indicating that a process operating within an expected range of variation is being influenced mainly by "common cause" factors; processes operating in this state are referred to as "in control." See also Control Charts; Process Capability; Variation.

Black Belt: A team leader, trained in the DMAIC process and facilitation skills, responsible for guiding an improvement project to completion.

DMAIC: Acronym for a Process Improvement/Management System which stands for Define, Measure, Analyze, Improve, and Control; lends structure to Process Improvement, Design or Redesign applications.

Efficiency: Measures related to the quantity of resources used in producing the output of a process (e.g., costs of the process, total cycle time, resources consumed, cost of defects, scrap, and/or waste); links primarily to company profitability.

Effectiveness: Measures related to how well the process output(s) meets the needs of the customer (e.g., on-time delivery, adherence to specifications, service experience, accuracy, value-added features, customer satisfaction level); links primarily to customer satisfaction.

Non-value-adding activities: Steps/tasks in a process that do not add value to the external customer and do not meet all three criteria for value-adding; includes rework, handoffs, inspection/control, wait/delays, etc. See also Value-Adding Activities.

Measure: DMAIC phase M, where key measures are identified, and data are collected, compiled, and displayed 2. A quantified evaluation of specific characteristics and/or level of performance based on observable data.

Quality: A broad concept and/or discipline involving degree of excellence; a distinguished attribute or nature; conformance to specifications; measurable standards of comparison so that applications can be consistently directed toward business goals.

Six Sigma or 6 Sigma: 1. Level of process performance equivalent to producing only 3.4defects for every one million opportunities or operations.

Term used to describe Process Improvement initiatives using sigma-based process measures and/or striving for Six Sigma-level performance.

3.14 Self-assessment Questions

Q. What is Lean Culture?

Ans: A Lean Culture (also known as Lean Management) is the foundation of Lean process improvement. When a Lean Culture exists, improvement is exponentially more likely to be sustained and an environment for continuous improvement is created. It is a combination of defining customer value, aligning around a common purpose, striving for perfection while at the same time respecting and developing employees.
Identify the correct answer (multiple choice).

Q. A bar chart that depicts the frequencies of numerical or measurement data.

a. Sample
b. Histogram
c. Check Sheet
d. Process map

Ans.: b

Q. Inputs to a process that can be manipulated during experimentation.

a. Factors
b. Hypothesis Testing
c. Control Plan
d. Population

Ans.: a

Q. Arithmetic average of a set of values.

a. Median
b. Sample
c. Mode
d. Mean

Ans.: d

Q. A methodology that provides businesses with the tools to improve the capability of their business processes.

a. Design of Experiments

b. Benchmarking
c. Six Sigma
d. Failure Mode and Effect analysis
Ans.: c

Q. The measure of the likelihood of a given event occurring.
a. Risk
b. Hypothesis Test
c. Cause and Effect Diagram
d. Probability
Ans.: d

3.15 Further Readings

1. *Lean Thinking* by James P Womack and Daniel T Jones

2. *The Certified Quality Engineer Handbook, Third Edition*, ed. Connie M. Borror,

3.16 Model Questions

Q. Differentiate between Lean and Six Sigma.

Ans.: Lean is the name given to the methods, tools and techniques that were developed by Toyota and used to dominate the automotive industry in the 1970's and 80's. These methods, tools and techniques are now copied by all automotive companies as well as many other industries for optimizing their Value-Streams, reducing non-valued added activities and removing waste. It is also about continuous improvement, a style of management and involvement of workers as problem solvers and in process improvement teams.

Six Sigma is the scientific approach to process improvement (DMAIC), data collection and data analysis (using statistical tools) that was started in the electronics industry in the late 1980's. It also has a framework for management and the use the 'Belt' structure within the organization.

Both Lean and Six Sigma emphasis the importance of understanding the customer for the output of each process, their needs and requirements.

Q. What is black belt in Lean Six Sigma?

Ans: A Black Belt has expert knowledge and skills related to the DMAIC methodology, Lean methods, and team leadership.

Black Belts should be able to lead any team across the organization in executing Lean Six Sigma projects. Black Belts may also conduct Lean Six Sigma training and act as coaches and mentors to other Belts-in-training.

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Q. What are the five basic phases of Lean Six Sigma?

Ans: The Five Basic Phases are:

1. **Define**: Define the problem and what is required to satisfy your customer.
2. **Measure**: Map the current process to collect data.
3. **Analyze**: Investigate and identify what causes the problem.
4. **Improve**: Implement a fix that will solve the problem.
5. **Control**: Sustain the improved results.

Simply put, Lean Six Sigma helps us identify the cause of a problem and implement a fix based on facts, rather than assumptions. This produces improved results and success that we and our team, managers and organization can be proud of.