PDHonline Course M482 (5 PDH)

Quality Management - ISO Audit & Performance Systems

Instructor: Jurandir Primo, PE

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PDH Online | PDH Center

5272 Meadow Estates Drive
Fairfax, VA 22030-6658
Phone: 703-988-0088
www.PDHonline.com

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Contents:

I. BASIC QUALITY CONCEPTS:

Everyone has had experiences of **poor quality** when dealing with business organizations. These experiences might involve an airline that has lost a passenger's luggage, a dry cleaner that has left clothes wrinkled or stained, a purchased product that is damaged or broken, or a pizza delivery service that is often late or delivers the wrong order.

The experience of poor quality is exacerbated when employees of the company either are not empowered to **correct quality inadequacies** or do not seem willing to do so. We have all encountered service employees who do not seem to care. The consequences of such an attitude are lost customers and opportunities for competitors to take advantage of the market needs.

Successful companies understand the powerful impact customer-defined quality can have on business. For this reason many competitive firms continually **increase** their **quality standards**. Quality may be difficult to define, such as airline services, child day-care facilities or college classes, and today, there is no single universal definition of quality. Some people view quality as "performance to standards", others view it as "meeting the customer's needs" or "satisfying the customer".

The basic assumption, here, is the knowledge of the quality management tools based on **production processes**, **quality methods** and scientific management approaches, such as, the traditional Total Quality Management (TQM) that is an integrated organizational effort to improve quality and customer expectations at every level, by involving everyone in the organization through an integrated effort.

1. Total Quality Management (TQM):

TQM is a philosophy and system for continuously improving the services and/or products offered to customers. Now that the technologies of transportation and communication have replaced national economic systems with a wide global economy, nations and businesses that do not practice a strong quality philosophy can become locally or globally non-competitive.

Total Quality Management is one of many other systems, defined as, a management method relying on the cooperation of all members of an organization that centers on Quality and on the long-term success, through the satisfaction of the Customers, as well as, the benefit of all its members and society.

1.1. Total Quality Management Evolution:

The concept of quality as we think of it now first emerged out of the Industrial Revolution. In the late 19th century pioneers such as Frederick Winslow Taylor and Henry Ford recognized the limitations of the methods being used in mass production at the time and the subsequent varying quality of output.

Birland established Quality Departments to oversee the quality of production and rectifying of errors, and Ford emphasized standardization of design and component standards to ensure a standard product was produced. Management of quality was the responsibility of the Quality department and was implemented by Inspection of product output to 'catch' defects.

The quality system, as is known worldwide, was defined by W. Edwards Deming (1900-1993), the "*father of the quality",* movement in Japan and then the United States. In the 1940s, quality became more statistical in nature and statistical sampling techniques were used to evaluate quality, using *quality control charts* to monitor the production processes, advanced with Deming, who was a statistician, after whom the Deming Prize for quality is named.

After W. Edwards Deming, Joseph Juran also had a great impact on quality management, focused more on *managing for quality*. The first edition of Juran's Quality Control Handbook was published in 1951. He

also developed the "*Juran's trilogy*," an approach to cross-functional management that is composed of three managerial processes: *quality planning, quality control and quality improvement*.

In the 1960s, with the help of so-called “quality gurus,” the concept took on a broader meaning. Quality began to be viewed as something that encompassed the entire organization, not only the production process. Since all functions were responsible for improving products and all shared the costs, quality was seen as a concept that affected the entire organization.

2. Quality Management System (QMS):

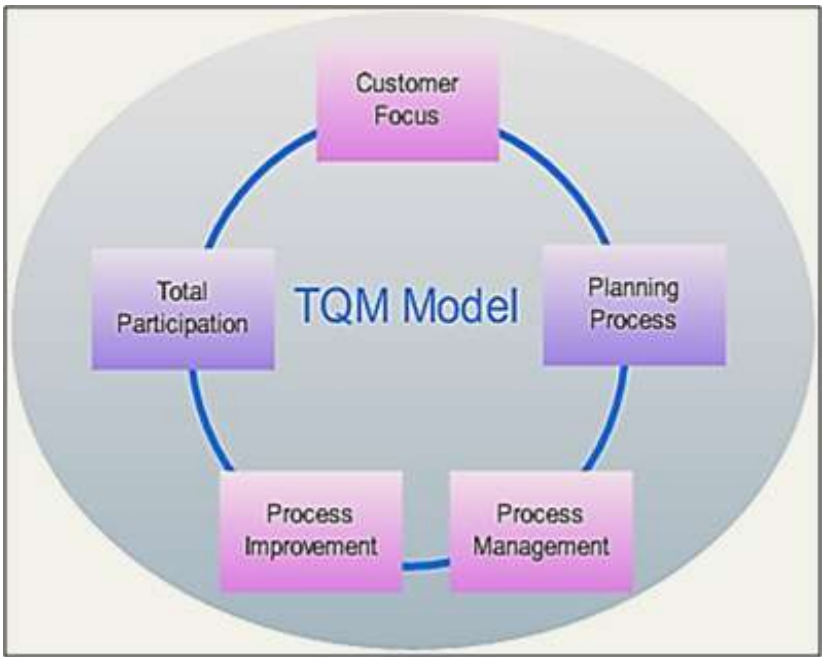
The Quality Management System (QMS) can be expressed as an organizational structure, procedures, processes and resources needed to implement quality management, as ISO 9000. Early systems emphasized many outcomes of an industrial production line, using simple statistics and random sampling.

Currently, 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 all 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 personnel integration.

Quality Management System is potentially "the way you do things" and normally reflects the ISO 9000 as the basis for the management system. The ISO 9001 is a set of requirements, nothing more, but provides a platform for standardization, commonly focused by customers to rely on products and services, QMS provides a framework for continual improvement, while TQM is a business strategy based on education, which tends to drive the customer to processes within a company.

2.1. TQM and QMS Relationship:

Total Quality Management: is **not a set of requirements**, it is an attitude, a way of working together for improving everything within the organization, much bigger than just a set of requirements. The TQM philosophy would break down barriers within a company, at functional level, and encourage people to support each other for the good of the organization.



2.2. Quality Gurus Main Contribution:

Walter A. Shewhart: Contributed to process variability. Developed concept of statistical control charts.
W. Edwards Deming: Stressed management's responsibility for quality. Developed "*14 Points*" to guide companies in quality improvement.
Joseph M. Juran: Defined quality as "*fitness for use*." Developed concept of cost of quality.
Armand V. Feigenbaum: Introduced concept of total quality control. In his book *Total Quality Control* (1961), he outlined quality principles in 40 steps.
Philip B. Crosby: Coined phrase "quality is free." Introduced concept of "*zero defects"*.
Kaoru Ishikawa: Developed "*cause-and-effect diagrams"*. Identified concept of "internal customer."
Genichi Taguchi: Focused on product design quality. Developed Taguchi loss function.

2.3. The Plan-Do-Study-Act Cycle (PDSA):

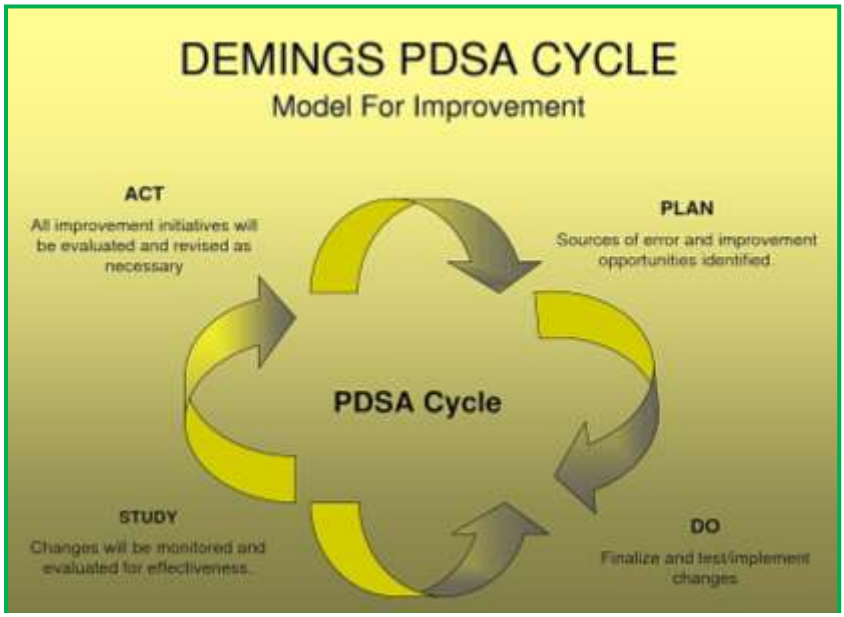
The plan-do-study-act cycle describes the activities a company needs to perform in order to incorporate continuous improvement in its operation. This cycle, is also referred to as the **Shewhart cycle or the Deming wheel.** The circular nature of this cycle shows that continuous improvement is a never-ending process.

Plan: The first step in the PDSA cycle is to plan. Managers must evaluate the current process and make plans based on any problems they find. They need to document all current procedures, collect data, and identify problems. This information should then be studied and used to develop a plan for improvement as well as specific measures to evaluate performance.

Do: The next step in the cycle is implementing the plan (do). During the implementation process managers should document all changes made and collect data for evaluation.

Study: The third step is to study the data collected in the previous phase. The data are evaluated to see whether the plan is achieving the goals established in the plan phase.

Act: The last phase of the cycle is to act on the basis of the results of the first three phases. The best way to accomplish this is to communicate the results to other members in the company and then implement the new procedure if it has been successful. Note that this is a cycle; the next step is to plan again.



2.4. TQM Failures:

The most important factor in the **success or failure** of TQM efforts is the complete organizations commitment. Often companies look at TQM as another business change that must be implemented due to market pressure without really changing the values of their organization. Recall that TQM is a complete **philosophy** that has **to be embraced** with true belief, not mere lip service. Looking at TQM as a short-term financial investment is surely a recipe for failure.

Another mistake is the view that the responsibility for quality and elimination of waste lies only over the employees, than top management. It is a "*let the workers do it*" mentality. A third common mistake is over-or under-reliance on Statistical Process Control (SPC) methods, but, SPC is not a substitute for continuous improvement, teamwork, and a change in the organization's belief system. Some common causes for TQM failure are:

- ✓ Lack of a genuine quality culture;
- ✓ Lack of top management support and commitment;
- ✓ Over-and under-reliance on statistical process control (SPC) methods.

3. Quality Assurance (QA):

Is all the activities associated with engineering design, construction, manufacturing, services, planning, training, execution, monitoring and documentation, site studies and environmental projects. For large or bigger projects, where safety of workers and the general public are major issues, the size and complexity of the QA program is commensurate with the intricacy of the project. The philosophy of a Quality Assurance (QA) program is based on three primary objectives:

1. Plan on doing it right: Is anyone intending to design and/or build a structure, manufacture a product, conduct site investigations or do environmental clean-up, which always plans to do it right.

2. Do it right the first time: Is a properly designed QA program which should allow identify problems in the very beginning, and take appropriate corrective actions before the problem grows to critical proportions. Doing it over again after a failure usually costs money, erodes goodwill and damages reputation, and may open the door to lawsuits and liabilities ranging from break of contract, delay of schedule, or, even worse, injury or loss of life.

3. Document what you did: Provides a critical documented tracking (paper or electronic) that allows to reconstruct what actually happened, and not rely solely on the often unreliable recollections and memories of the people involved. Formal QA activities and documentation assure that all procedures were implemented very well and avoid serious expenses and legal distractions down the road. However, Documentation takes time and effort, and therefore costs money.

3.1. Components of a QA Program:

The Federal Regulations that were originally developed to control the design, construction and operation of nuclear power plants identified a series of 18 "criteria" that need to be developed a comprehensive quality assurance program. The 18 criteria are formally published in Title 10, Part 50, Appendix B of the Code of Federal Regulations. The concepts formalized in these regulations provide an excellent framework within which to develop a quality assurance program for virtually any type of project.

The same principles apply to the engineering design and construction of structures, the manufacturing of products, providing professional services, and the implementation of site assessments and environmental projects such as hazardous waste clean-up. The **18 criteria** identified in the federal regulations are:

1. Organization;
2. Quality Assurance Program;
3. Design Controls;
4. Procurement Document Control;
5. Instructions, Procedures and Drawings;
6. Document Control;
7. Control of Purchased Material, Equipment and Services;
8. Identification and Control of Materials, Parts and Components;
9. Control of Processes;
10. Inspection;
11. Test Control;
12. Control of Measuring and Test Equipment;
13. Handling Storage and Shipping;
14. Inspection, Test and Operating Status;
15. Nonconforming Materials, Parts or Components;
16. Corrective Action;
17. Quality Assurance Records;
18. Audits Surveillance and Managerial Controls.

Each of these 18 criteria is addressed below. For each criterion, three questions are answered: "What does this criterion address?", "Why is this criterion important?", and "How is this criterion implemented?"

4. Quality Control in Civil Construction:

Many and assorted quality control tests in civil construction are conducted regularly in the quality control laboratories at various construction sites. The types and quantum of tests conducted depend on factors like the type of project, size of the project, the degree of importance laid on the quality domain, budget for the project and so on.

For example, the degree of **quality control (QC)** adopted for the construction of an ordinary road may be somewhat **different** from that of a highway project. Accordingly, the QC requirements for an ordinary waste water treatment project would presumably be more relaxed, as compared to the same for a nuclear power project, for obvious reasons.

A project supported by a healthy budget will have more space for the quality domain than one on a leaner budget. There can be a host of other factors also influencing the quality matters of a project, and are the reasons why the degree of QC tests may vary from project to project or place to place. Mentioned below, are some important **QC tests** commonly conducted in quality control laboratories at various construction sites:

Cement: initial & final setting time, compressive strength test (3, 7 & 28 days strength using mortar cubes), percent passing through 75 micron sieves, these tests are routinely conducted in a site QC laboratory. Tests which are not frequently performed are soundness test (Le chatelier or Autoclave expansion test), determination of specific surface (air permeability test), heat of hydration and chemical composition tests. These tests are often conducted in off-site labs very well equipped for all sorts of tests.

Fine aggregates (sand): particle size distribution (sieve analysis), specific gravity, water absorption, moisture content determination, etc. The zone of sand and fineness modulus are determined from sieve analysis. Tests for determining clay, silt contents and organic impurities are conducted occasionally, included during selection of the sand source. Bulking of sand is usually tested only when nominal concrete mixes are used for less important pours.

Coarse aggregate: sieve analysis, specific gravity, water absorption, moisture content determination, flakiness index, elongation index, aggregate impact value, aggregate crushing value, Los Angeles abrasion tests, etc. Petrographic examination of rocks is done initially to ascertain the quality of the quarry material. Aggregate impact value is the more useful test, as it indicates the quality of stone chips, unlike the aggregates crushing value test, which gives idea of the quality of the source material (rocks).

Reinforcing steel: determination of yield & ultimate stresses, % elongation test, bend & re-bend test, testing of nominal diameter and weight per unit length, etc. Tests like **ultrasonic** flaw detection, torsion test, fatigue test, chemical composition test, etc are also conducted (less frequently) usually in off-site approved labs in some projects.

Concrete: workability test (slump test, compaction factor test), compressive strength test (cube or cylinder), determination of total chloride and sulphate content in concrete, cement content in mix, temperature monitoring of concrete, especially for mass concreting work (with **infrared digital thermometer** or other device), etc. Testing of accuracy of **batching plant** is done by routine calibration of the same (once in 2 or 3 months).

Bricks: a compressive strength test, efflorescence test, dimensions test, water absorption test. Tests like soundness & warpage tests are also conducted sometimes.

Water: the pH value, determination of chlorides, sulphides and sulphates content, iron and Mn content, turbidity test, hardness test, determination of solids, determination of alkalinity, biochemical oxygen demand (BOD) and dissolved oxygen (DO), etc.

Grouting: Is a compressive strength test (for 1, 3, 7 & 28-day cubes), fluidity (immersion or cone method test), expansion test, bleeding test, volume change test, etc. Trial mixes are also prepared at initial stage to ascertain desired workability, strength, etc. Mock tests can be conducted at site lab to ensure proper grouting operation before actual execution at site.

Soil tests: Standard Proctor test to determine maximum dry density (bulk, dry densities & moisture content), core cutter or sand replacement method for bulk density, oven drying or calcium carbide method for moisture content, determination of Atterberg limits by Casagrande apparatus (LL, PL & SL), plasticity index, grain size analysis (sieve analysis & picnometer), California bearing ratio (CBR) test, etc.

Roadwork: sieve analysis for coarse aggregates for pavement & selected fill materials, flakiness index, sodium & magnesium soundness tests for coarse aggregates, aggregate impact value, LA abrasion loss test, water absorption by aggregates in bituminous base course, marshal stability test, retained stability test, bitumen penetration test, flash & fire point test, viscosity of coal tar, ductility test, etc.

Other civil construction tests: determination of sulphate, chloride & organic matter content for selected fill materials, sand equivalent, friable particles, bitumen stripping, extraction & grading analysis for asphaltic mix, degree of compaction for bituminous base course, Proctor test for maximum dry density, sand replacement method, calcium carbide method for moisture content, subgrade and selected fill, etc.

Note: Other common NDT´s are conducted at construction sites for testing quality of hardened concrete structures are: core test, Schmidt hammer or rebound hammer test and ultrasonic pulse velocity test.

4.1. Quality in Electrical Services:

Electrical engineering and services quality focus on understanding requirements and setting strategies for electrical power systems to satisfy business needs, from reduced costs to effective use of capital, with a qualitative portfolio of services for every stage of a power system's life cycle, design, build, and maintenance.

4.2. Civil, Mechanical and Electrical Relations:

The Electrical Quality Systems are commonly related to Civil, Mechanical and Electrical services including contracting, planned services and maintenance. The quality documentation always encompasses Engineering, Purchasing, Installation, Maintenance, Inspection, Testing and Commissioning activities, based on the International Standards Organization (ISO) 9000 series of quality standards. The main services are summarized below:

- ✓ Power quality and reliability;
- ✓ Safety and risk management;
- ✓ Continually maintenance services.

The main objectives should always comply with statutory obligations, standards, specifications and codes relevant to quality, continually improving a quality management system consistent with ISO 9001:

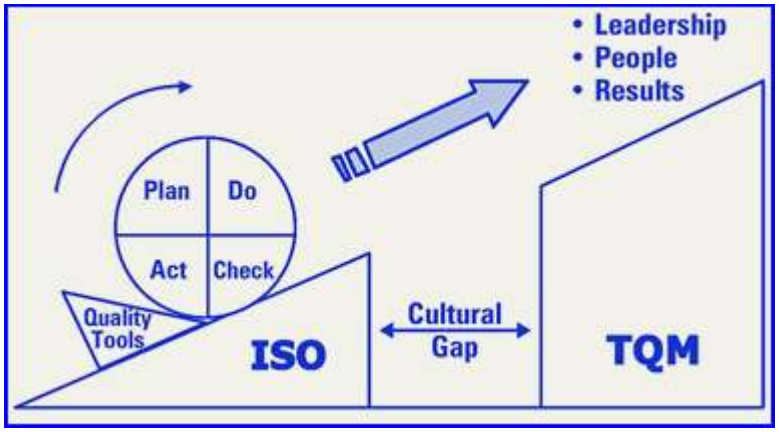
- ✓ Providing suitable resources to implement and maintain a Quality Management System;
- ✓ Employment of suitably qualified, skilled and experienced personnel;
- ✓ Educating and training in order to continually improve the skills of the staff;
- ✓ Ensuring to be conform the needs of customers.

The quality management development consists in formulating quality policies, developing quality manuals and quality assurance and control procedures, as shown below:

- **Process improvement:** provides recommendations for improvement of global services and supply chain according to existing standards and methodologies.
- **Audit:** performs internal or external audits according to international standards such as ISO 9001, EN 50126, EN 50128 or IEC 61508.
- **Quality training:** formal training in quality systems.

II. ISO 9000 BASIC STANDARDS:

The ISO 9000 was created in 1980 as a need for the development of universal standards of quality, seen as necessary in order for companies to be able to objectively document their quality practices around the world. In 1987 the International Organization for Standardization (ISO) published its first set of standards for **quality management** called **ISO 9000**.



The ISO 9000 family of standards is related to quality management systems and designed to help organizations ensure that they meet **the needs of customers** and other stakeholders. The ISO 9000 deals with the fundamentals of **quality management systems**, including the **eight management principles**

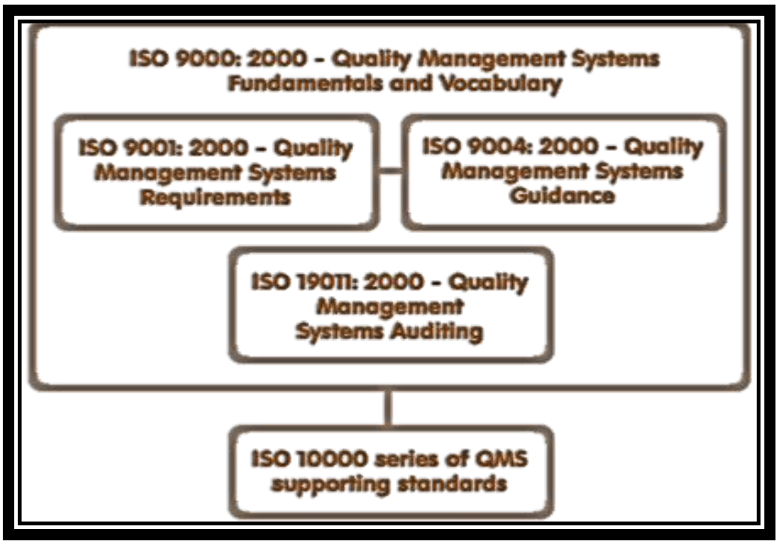
on which the group of standards is based. Third party certification bodies provide independent confirmation that organizations meet the requirements of ISO 9001.

1. ISO Quality Management Systems:

The International Organization for Standardization (ISO) is an international organization whose purpose is to establish agreement on international quality standards. It currently has members from **91 countries**, including the United States. ISO 9000 was created to develop and promote international quality standards, and consists of a set of standards and a certification process for companies.

The system can be applicable to all types of companies to demonstrate that have met the standards specified by the ISO, including government, and have gained global acceptance. In many industries ISO certification has **become a requirement** for national or international business, and also have been adopted by the European Community as a standard, for any business in Europe. In December 2000 the first major changes were made, introducing the following three new standards:

- **ISO 9000 - Quality Management Systems-Fundamentals and Standards**. Provides the terminology and definitions as the starting point for understanding the system of standards.
- **ISO 9001 - Quality Management Systems-Requirements**: This is the standard used for the certification of a firm's quality management system, used to demonstrate the conformity of quality management systems to meet customer requirements.
- **ISO 9004 - Quality Management Systems-Guidelines for Performance**: Provides guidelines for establishing a quality management system, and focuses not only on meeting customer requirements but also on improving performance.



1.1. ISO 9000 Latest Revision:

The ISO 9001:2000 combines the three standards **9001, 9002, and 9003 into one, called 9001**. Design and development procedures are required only if a company does in fact engage in the creation of new products. The 2000 version sought to make a radical change in thinking by actually placing the concept of process management front and center ("Process management" was the monitoring and optimizing of a company's tasks and activities, instead of just inspecting the final product).

The ISO 9000: 2008 version only introduced clarifications to the existing requirements of ISO 9001:2000

and some changes intended to improve consistency with ISO 14001:2004. There were no new requirements, for example, in ISO 9001:2008 Quality Management System as upgraded. ISO 9001 is supplemented directly by two other standards of the family:

ISO 9000:2005 - "Quality management systems. Fundamentals and vocabulary".
ISO 9004:2009 - "Managing for sustained success of an organization. A quality management approach".

Obs.: These three standards are the most widely used and apply to the majority of companies. However, ten more published standards and guidelines exist as part of the ISO 9000 family. To receive the **ISO Certification**, a company must provide extensive documentation of its quality processes.

1.2. ISO 9000 Audit:

Two types of auditing are required to become registered to the standard: auditing by an **external** certification body (external audit) and audits by **internal staff** trained for this process (internal audits).The aim is a **continual** process of review and assessment to verify that the system is working according to all written certified procedures, to find out where it can be improved and to correct or prevent identified problems, suggest solutions or emit a NCR (Non-conformance Report).

Auditors are expected to go beyond mere auditing for rote compliance by **focusing on risk**, status and importance. This means they are expected to make more judgments on what is effective, rather than merely adhering to what is formally prescribed. Under the 1994 standard, the auditing process could be adequately addressed by performing a "compliance auditing" as defined below:

- Tell me what you do *(describe the business process);*
- Show me where it says that *(reference the procedure manuals);*
- Prove that this is what happened *(exhibit evidence in documented records).*

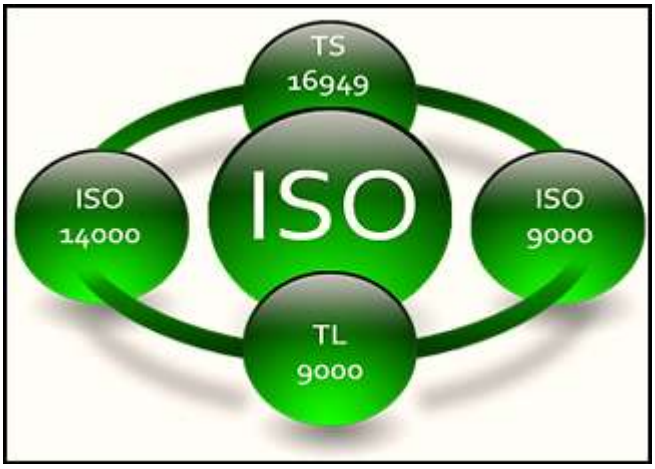
Only ISO 9001 is directly **audited** for third party control purposes. Other two standards are supplementary and contain deeper information on how to **sustain and improve** quality management systems. The ISO 9001 is a document of approximately 30 pages which is available from the national standards organization in each country. The **eight management** sections of ISO 9001 are as follows:

- ✓ Section 1: *Scope*
- ✓ Section 2: *Normative Reference*
- ✓ Section 3: *Terms and definitions* (specific to ISO 9001, not specified in ISO 9000)
- ✓ Section 4: *Quality Management System*
- ✓ Section 5: *Management Responsibility*
- ✓ Section 6: *Resource Management*
- ✓ Section 7: *Product Realization*
- ✓ Section 8: *Measurement, analysis and improvement*

Before the certification auditor can **issue or renew a certificate**, the auditor must review the requirements of sections 4 to 8. Sections 1 to 3 are not **directly audited against**, because provide context and definitions for the rest of the standards. The standard specifies the organization should issue and maintain the following six documented procedures:

- Control of Documents;
- Control of Records;
- Internal Audits;
- Control of Nonconforming Product / Service;
- Corrective Action.
- Preventive Action.

This includes methods used to monitor quality, methods and frequency of worker training, job descriptions, inspection programs, and statistical process-control tools used. High-quality documentation of all processes is critical. The company is then audited by an ISO 9000 accredited Auditor who visits the facility to make sure the company is very well-documented and the working processes meets the standards.



Companies have to be recertified by ISO every **three years**. One of the shortcomings of ISO certification is that it focuses only on the process used and conformance to specifications. In contrast to the Baldrige criteria, the ISO certification does not address questions about the product itself and whether it meets customer and market requirements. Today there are over 40,000 companies ISO certified. In fact, certification has become a requirement for conducting business in many industries.

Obs.: When the Audit Certifier finds that all is in order, the certification is received. Once a company is certified, it is registered in an ISO directory that lists all certified companies. The entire process can take 18 to 24 months and can cost anywhere from $10,000 to $30,000.

1.3. Non-conformance Report (NCR):

Is a standard procedure that documents the details of a non-conformance, commonly identified in quality audits, production system or work process review. The objective of the NCR report is to make an unambiguous, defensible, clear and concise definition of the process problem, so that corrective action can and will be initiated by management. The elements of an effective statement of non-conformance are:

Observation: A statement of the non-compliance (NCR).

Attribution: Standard, plan, procedure, work instruction, policy, documented social norms or organizational ethic violated by the target of the non-compliance.

Location: Where the non-compliance was identified. For example, department and geographical location.

Evidence: Physical evidence of non-compliance. For example, the absence of a required record or incomplete information on an existing record.

Obs.: Evidence is the most important record. Lack of physical evidence will often mean that the non-conformance **cannot be accepted** and no action shall be taken. For example, when an Auditor considers that a design process is inadequate, may open a dispute with workers performing the work. However, when there is a **real evidence** that a design description or a manufactured product does not comply with the company's procedures, clearly documented in registered standards, a NCR should be always triggered by internal staff audit and accepted by management.

III. ISO 10000 MAIN GUIDELINES SERIES:

The International Standards Organization (ISO) has many supporting standards which are used in conjunction with the ISO 9000 series. While some are more specific, the ISO 10000 Series give emphasis on many other standards to bring forth a business environment and best practices, as shown:

1. ISO 10001 - Codes of Conduct:

ISO 10001:2007 provides guidance for planning, designing, developing, implementing, maintaining and improving **customer satisfaction** and codes of conduct. It applies to an organization's promises to its customers regarding its behavior to improve customer satisfaction. The standard is not intended for certification or for contractual purposes, and it is not intended to change any rights or obligations provided by applicable statutory and regulatory requirements.

Improvement guidelines:

- ✓ Customer confidence in an organization;
- ✓ Customer expectations of your products and customer relationship;
- ✓ Annex A provides examples of codes for different organizations;
- ✓ Annex C gives guidance for small businesses.

2. ISO 10002 - Complaints in Organizations:

Provides guidance on the process of complaints handling and can be used as one of the processes of an overall quality management system. The standard is not applicable to **disputes referred** for resolution **outside** the organization or for employment-related disputes. It is also intended for use by organizations of all sizes and in all sectors, but Annex A provides guidance specifically for small businesses.

The improvement aspects of complaints handling are:

- Improve customer satisfaction by creating a customer-focused environment open to a feedback (including complaints),
- Promptness in resolving any complaints received, and enhancing the organization's ability to improve its product and customer service;
- Management commitment through adequate acquisition and deployment of resources, including personnel training;
- Recognize and addressing the needs and expectations of complainants;
- Provide an open, effective and easy-to-use complaints process;
- Analyze and evaluate complaints in order to improve the product and customer service quality;
- Audit of the complaints-handling process
- Reviewing the effectiveness and efficiency of the complaints-handling process.

3. ISO 10003 - External Dispute in Organizations:

The main benefit of ISO 10003 is a **transparent system**. You can upgrade and value your process the way your clients see that you have an open, effective and easy-to-use complaints process.

- ✓ **Customer Confidence**: A standardized commitment to complaint resolution shows them that any complaints will be addresses.
- ✓ **Improved Efficiency**: Continuous improvement allows root cause analysis to improve organization's operations.
- ✓ **Better Relationship**: System helps to adopt a customer-focused approach to handle, analyze and review complaints:

- ✓ **Auditable System**: Complaint management system is auditable to check that the requirements are being followed.

4. ISO 10004 - Measuring Customer Satisfaction:

It is a guidance standard. The Benefits are:

- ✓ **Implement:** Helps an organization to define and implement processes to monitor and measure customer satisfaction.
- ✓ **Organization**: Can be used by any organizations no matter what type, size or product. The focus is on customers outside of the organization.

5. ISO 10005 – Application/Revision of Quality Plans:

Provides guidelines for the development, review, acceptance, application and revision of quality plans. It is applicable whether or not the organization has a management system in conformity with ISO 9001, focused primarily on **product realization**, not a guide to organizational a quality management system.

The ISO 10005:2005 is applicable to quality plans for a process, product, project or contract, any product category (hardware, software, processed materials and services) and any industry.

6. ISO 10006 – Project Management Guidelines:

Released in the fall of 2003, this standard is creating the next wave in understanding of **project manament processes**. The ISO 10006 provides guidance for the improvement of project managements intended to maintain the process and product quality in design creation and to be used for registration purposes, therefore requiring a systematic approach that ensures:

- ➢ The stated and implied customers' needs are understood and met.
- ➢ The stakeholders' needs are understood and evaluated.
- ➢ The quality policy is incorporated into the organization's management.

This standard provides guidance on quality issues which impact projects, setting strategic objectives and driving results through tactical plans and continued improvements. Project management expertise is critical for any organization struggling with continual improvement compliance issues according to definitions shown below:

ISO:

- ➢ Document specifying which procedures and associated resources shall be applied to a specific project, product, process or contract.

PMBOK (Project Management Body of Knowledge):

- ➢ Identifies which quality standards are relevant to the project and determines how to satisfy them.
- ➢ Describes how the project management team will implement its quality policy.
- ➢ Stated and implied customers' needs are understood and met.
- ➢ Interested stakeholders needs are understood and evaluated.
- ➢ Quality policy is incorporated into the organization's management.
- ➢ Control of Documents.
- ➢ Control of Records.
- ➢ Internal Audits.

7. ISO 10007 - Configuration Management:

ISO 10007:2003 gives guidance on the use of **configuration management** within an organization, applicable to the support of products from concept to disposal. It outlines the responsibilities and authorities before describing the configuration management process that includes configuration management planning, configuration identification, change control, configuration status accounting and configuration audit.

8. ISO 10013 – Documentation System:

Provides guidelines for the development and **maintenance of the documentation** necessary to ensure an effective quality management system, tailored to the specific needs of the organization. The use of these guidelines will aid in establishing a documented system as required by the applicable quality management system standard.

Obs.: This Technical Report may be used to document management systems other than that of the ISO 9000 family, for example environmental management systems and safety management systems.

9. ISO 10014 - Financial and Economic Benefits:

The benefits are:

- ✓ **Financial**: provides guidelines for realizing financial and economic benefits from the application of the ISO 9000 quality management principles.
- ✓ **Complement**: is directed to top management of an organization and complements ISO 9004 for performance improvements.
- ✓ **Achievement**: It provides examples of achievable benefits and identifies management methods and tools that are available to assist with the achievement of those benefits.

10. ISO 10017 - Statistical Techniques Guidance:

Provides guidance on the selection of **appropriate statistical techniques** that may be useful to an organization in developing, implementing, maintaining and improving a quality management system, by examining requirements of ISO 9001 that involve the use of quantitative data, and then identifying the statistical techniques that can be useful, when applied to a proper production process.

However, the list of statistical techniques cited in this Technical Report is neither complete nor exhaustive, and does not preclude the use of any other techniques that are deemed to be beneficial to the organization. Nevertheless, this Technical Report does not attempt to prescribe which statistical technique are to be used, nor attempts to advise on how the technique(s) are to be implemented.

11. ISO 10019 - Quality Consultants Selection:

These guidance documents provide an understanding of the concepts, intent and the application of the "process approach" to the ISO 9000 family of Quality Management System standards. The guidance may also be used to **apply to the process approach** to any management system regardless the type or the size of organization.

IV. ISO ESSENTIAL EXTENDED GUIDELINES:

Beyond the standards just defined, ISO has a package of extended guidelines for the selection of quality management system consultants and the use of their services, intended to assist organizations when selecting a quality management system. These guidelines defined below, give better understanding on e-

very process for evaluating the competences of a quality management and provides confidence of what the organization needs and expectations for the ISO consultant´s services should meet.

1. ISO 13485 Medical Equipment Standards:

Published in 2003, represents the requirements for a comprehensive quality management system tailored to the industry's quality system and regulatory requirements to design and manufacturing of **medical equipment** or **their components**. This standard supersedes earlier documents, such as, ISO 13488 (1996), EN 46001 and EN 46002 (both 1997).

While it remains a stand-alone document, ISO 13485 is generally harmonized with ISO 9001. The principal difference, however, is that ISO 9001 requires the organization to demonstrate continual improvement, whereas ISO 13485 requires only that the certified organization demonstrate the quality system is effectively implemented and maintained. Other specific differences include:

- ✓ the promotion and awareness of regulatory requirements as a management responsibility.
- ✓ focus on risk management activities and design control activities during product development.
- ✓ specific requirements for inspection and traceability for implantable devices.
- ✓ specific requirements for documentation and validation of processes for sterile medical devices.
- ✓ specific requirements for verification of the effectiveness of corrective and preventive actions.

This method prove conformity to certification of the Quality Management System according to ISO 9001 and/or ISO 13485 and ISO 14971. This standard is adopted by the European medical device directives 93/42/EEC, 90/385/EEC and 98/79/EC, now considered to be the standard requirements for medical devices, even by the "Global Harmonization Task Force Guidelines" (GHTF). The GHTF guidelines are slowly becoming universal standards for design, manufacture, export and sales of various medical devices.

2. ISO 14000 Environmental Standards:

The ISO 14000/14001 standards specify requirements for establishing an **environmental policy** for monitoring the effects and impact of products and services over the environment. The methodology also plans implementation of programs to meet objectives, corrective actions and review of global management environments. In 1996 the International Standards Organization introduced standards for evaluating a company's **environmental responsibility**. These standards, designated as ISO 14000, focus on three major areas:

- ➢ Measure systems and integration of environmental responsibility into the overall business.
- ➢ Operations standards include the measurement of consumption of natural resources and energy.
- ➢ Environmental systems standards measure emissions, effluents, and other waste systems.

Included in the ISO 14000 series are the ISO 14001 EMS Standard and other standards, such as, environmental auditing, environmental performance evaluation, environmental labeling and life-cycle assessment. The ISO 14001 environmental standards are also being applied by automotive suppliers as a requirement from Ford and General Motors.

3. ISO/TS 16949 - Automotive Quality Certification:

The objective of this standard is to provide reliable quality systems within the **automotive supply chain**, based on the structure of ISO 9001 and specific requirements of the automotive quality standards, resulting in a focused and consistent approach. The ISO/TS 16949 was developed by the International Automotive Task Force (IATF), in cooperation with the International Standards Organization (ISO). The ISO/TS 16949:2009 aligns with ISO 9001:2008. The main key points include:

- Improved product and process quality and additional confidence for global sourcing;
- Common quality system approach in the supply chain and sub-contractors;
- Certification is rapidly becoming a condition of supply;
- Focused sector scheme allowing for a common approach;

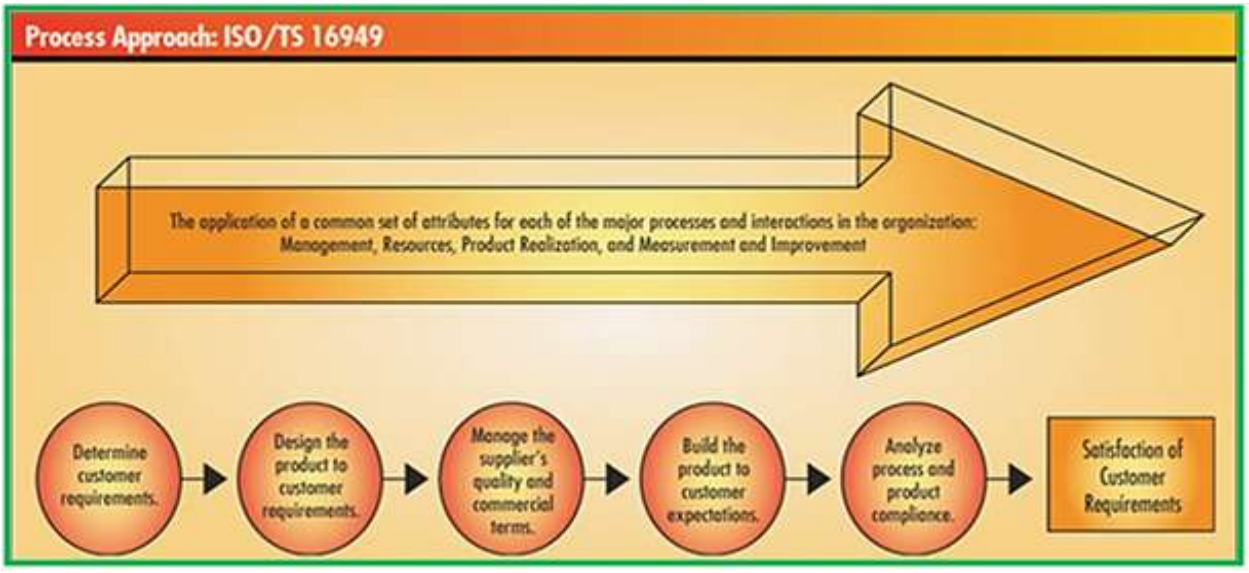
3.1. ISO/TS 16949 - Applicable Standards:

The ISO/TS 16949:2009, in conjunction with ISO 9001:2008, defines the quality management system requirements for the **design and development**, production and, when relevant, installation and service of automotive-related products. ISO/TS 16949:2009 is applicable to sites of the organization where customer-specified parts, for production and/or service, are manufactured.

Supporting functions, whether on-site or remote (such as design centers, corporate headquarters and distribution centers), form part of the site audit, but cannot obtain stand-alone certification to ISO/TS 16949:2009. The content and application of this quality manual makes reference to the following publications and documents:

- ISO/TS 16949:2009, Quality Management Systems - for automotive production.
- ISO 9000: 2000, Quality Management Systems - fundamentals and vocabulary
- ISO 9001: 2008, Quality Management Systems - requirements
- ISO 9004: 2000, Quality Management Systems - guidelines for performance improvement

Note: ISO/TS 16949, developed by the International Automotive Task Force, aligns existing American, German, French and Italian automotive quality standards within the global automotive industry.



4. QS 9000 - Automotive Suppliers Standards:

Is a quality management system developed by a joint effort of the "*Big Three*" automakers, General Motors, Chrysler and Ford, introduced to the industry in 1994 for **suppliers of production parts**, materials and services to automotive industry. It has been adopted by several heavy truck manufacturers in U. S. Essentially all suppliers to the domestic automakers need to implement a QS9000 system.

Note: On December, 2006 all QS9000 certifications were **terminated**. The middle certification, QS 9000, between ISO 9001 and ISO/TS 16949 is **no longer valid**, but companies have a choice between ISO 9001 or TS16949. QS9000 is considered superseded by ISO/TS 16949.

5. AS 9000 - Aerospace Quality Standards:

This Aerospace Basic Quality System Standard, was developed by a group of US aerospace prime contractors, including Allied-Signal. Allison Engine Company, Boeing, General Electric Aircraft Engines, Lockheed Martin, McDonnell Douglas, Northrop Grumman, Pratt Whitney, Rockwell Collins, Sikorsky Aircraft, and Hamilton Sundstrand.

Significantly, the US government was not actively involved in the AS9000 development, but was issued under the mentoring of the Society of Automotive Engineers. The intent and concept behind AS9000 are similar to Boeing's D1-9000 standard, based in ISO 9000, with 27 additional requirements unique to the **aerospace industry**. The intent is to standardize many of the other aerospace quality management standards. The current version is AS9100C.

6. TL 9000 - Telecom Quality Standards:

Designed in 1998 to focus on supply chain directives throughout the international **telecommunications** industry, including the USA domestically. TL 9000 specializes the generic ISO 9000 and ISO 9001 to the needs of the **telecom sector**, which is now the information and Industry Communications Technology (ICT), extending from service providers through equipment manufacturers through the suppliers and contractors and subcontractors that provide electronic components & software components. TL 9000 is defined by two documents:

- TL 9000 Requirements Handbook, release 5.0, includes the full text of ISO 9001-2008.
- TL 9000 Measurements Handbook, release 5.0.

Note: These reports are provided at no additional charges to TL 9000 member companies or members and non-members. Generally, these measurement data permit a service provider to compare **defect rates** among various equipment manufacturers and against each other.

7. ISO 26000 - Guidance on Social Responsibility:

The ISO 26000 essential objective is the social responsibility of any organization. The scope clearly states "*This International Standard is not a management system standard. It is not intended or appropriate for certification purposes or regulatory or contractual use***.** This statement includes that ISO 26000 **cannot be used as basis for audits**, conformity tests and certificates, or for any other kind of compliance statements.

This standard, released on November 2010, offers guidance on socially responsible behavior. As a guidance document the ISO 26000 is an offer, voluntary in use, and encourages organizations to discuss their **social responsibility issues** and possible actions with relevant stakeholders.

However, the practical value of this standard might be limited if it merely provided a common understanding of social responsibility instead of also facilitating management routines and practices leading to social responsibility.

8. ISO 26262 – Automotive Safety Standard:

Is a standard, adapted from the Functional Safety Standard IEC 61508 for Automotive Electric / Electronic Systems, due to the exponential increase of software integration into automotive systems and their **potential for catastrophic failure**. The electronic systems and software integration are a primary focus of this standard to ensure safety in the design of Electronic Systems for automotive applications.

The ISO 26262 provides guidelines and expectations to ensure a case for safety is included in new product planning from concept through decommissioning. This standard supplements the current APQP (Advanced Product Quality Planning) approach used in product and process quality planning. The standard consists of 9 normative parts and a guideline as the 10th part.

- ✓ **Automotive safety lifecycle**: provides supports tailoring the necessary activities during these life-cycle phases (management, development, production, operation, service, decommissioning);
- ✓ **Functional safety aspects**: covers the entire development process (including such activities as requirements specification, design, implementation, integration, verification, validation, and configuration).
- ✓ **Automotive risk-based approach**: provides determining risk classes (Automotive Safety Integrity Levels, ASILs), for specifying the necessary safety requirements for achieving an acceptable residual risk.

Like its parent standard IEC 61508, ISO 26262 is a risk based safety standard, where the risk of hazardous operational situations are qualitatively assessed and safety measures are defined to avoid or control systematic failures and to detect or control random hardware failures, or mitigate their effects. The standard details expectations and requirements to provide guidance for the following:

- Automotive safety life-cycle;
- Management, development, production, operation, service and decommissioning;
- APQP with specific electronic and software safety integration;
- Requirements and Specifications definition and design of product.

9. ISO 29001 - Oil & Gas Quality Standards:

The objective is the quality management system requirements for the design, development, production, installation and service of products for the petroleum, petrochemical and natural gas industries. Developed as a direct result of a partnership between ISO and the international oil and gas industry (led by the American Petroleum Institute - API), ISO 29001 specifically **focuses on the oil and gas** supply chain.

The ISO/TS 29001 standard is based on ISO 9001 and incorporates supplementary requirements emphasizing defect prevention and the reduction of variation and waste from service providers. These requirements have been developed separately to ensure progress and auditable services, providing global consistency and improved assurance in the supply quality of goods and services from providers.

This is particularly important when the failure of goods or services have severe ramifications for the companies and industries involved. The certification to ISO/TS 29001 ensures standardization and improvement within the sector. The utilization of this method can be through the following companies:

- ✓ Manufacturers of oil and gas industry equipment and material upstream and downstream.
- ✓ Service providers to the oil and gas industry.
- ✓ Purchasers of equipment, materials and services.

Benefits:

- ➢ **Safety**: oil and gas industry handles hazardous fluids and gases through a variety of processes, which makes considerations of the safety of personnel and the public of primary importance.
- ➢ **Integrity**: protection of the environment and of business continuity (maintenance of revenue streams, for companies and national economies) need a high level of operational integrity.
- ➢ **Integration**: incorporates the requirements of ISO 9001 and includes detailed, sector-specific requirements for design, development, production, installation and service of products.

- **Continual improvement**: Aims at the development of a quality management system for continual improvement, emphasizing defect prevention and the reduction of variation and waste.

10. ISO 39001 - Road Traffic Safety Management:

Is an ISO standard for a management system for **road traffic safety** (2008). The implementation of the standard is supposed to put the organizations, that provide the system "road traffic", into the position to improve the traffic safety and to reduce by that the number of persons killed or severely injured in road traffic, and is under the responsibility of the ISO Technical Committee ISO/TC241.

This International Standard is applicable to any organization that wishes to:

- Establish, implement, maintain and improve a management system;
- Evaluates the accident numbers, numbers of killed and injured persons;
- Provides a continuous improvement of the traffic safety;
- Observes and evaluates events, in connection with the road traffic safety;
- Traffic volume and traffic mileage by vehicle and road user type;
- Volume of product and/or service provided by the organization;
- The safe planning, design, operation and use of the road network;
- Use of personal safety equipment especially considering seat belts, motorcycle helmets, etc.;
- Use of appropriate roads depending on vehicle type, user, type of cargo and equipment;
- Using safe driving speed also considering vehicle type, traffic and weather conditions;
- Fitness of drivers especially considering fatigue, distraction, alcohol and drugs;
- The safe entry and exit of vehicles and road users to the road network;
- Appropriate authorization to drive/ride the class of vehicles being driven/ridden;
- Post-crash response and first aid, emergency, post-crash recovery and rehabilitation.

11. ISO 50001 - Energy Management System:

Is a specification created by the International Organization for Standardization (ISO) for the energy management system released in June 2011, suitable for any organization, whatever its size, sector or geographical location and specifies the requirements for establishing, implementing, maintaining and improving an **energy management system**.

The standard purpose is to enable a systematic approach in achieving continual improvement of energy performance, including energy efficiency, energy security, energy use and consumption and aims to help organizations to continually reduce their energy use, and therefore their energy costs and their greenhouse gas emissions.

The procedural details of the ISO Energy Management System and compares its procedures with those of the ISO 14001 - Environmental Management System (EMS). The main objective is to improve energy-related performance, energy efficiency and to identify energy reduction opportunities, to help organizations to establish systems and processes and realize untapped energy efficiency potential.

The main **benefit is cost savings** making a significant contribution to environmental and climate protection, for example by the permanent reduction of CO2 emissions. Organizations of all types and sizes increasingly want to reduce the amount of energy they consume. This is driven by the need or desire to:

- Reduce costs,
- Reduce the impact of rising costs,
- Meet legislative or self-imposed carbon targets,
- Reduce reliance on fossil fuels, and
- Enhance the entity's reputation as a socially responsible organization.

In tandem, governments increasingly want to reduce Greenhouse Gas Emissions of their citizens, and industries by imposing legislative mechanisms to compel carbon reduction more frequently. The ISO 50001 provides a framework of requirements that help organizations to:

- Develop a policy for more efficient use of energy;
- Fix targets and objectives to meet the policy;
- Use data to make decisions concerning energy use and consumption measure the results;
- Review the effectiveness of the policy;
- Continually improve energy management.

Note: ISO 50001 focuses on a continual improvement process to achieve the objectives related to environmental performance of an organization (enterprise, service provider, administration, etc.). The process also follows the Plan, Do, Control, Act (PDCA).

V. PERFORMANCE SYSTEMS:

Performance systems are used to easily **manage multiple environments**. Quality assurance teams use these types of tools to apply in test cases, defects and project tasks. Production management tools improve logistics, engineering, production processes and allow quick access to data analysis, simplifying internal structure with high levels of automation and easy communication across multiple teams.

Lean Manufacturing concepts are integral to Six Sigma initiatives. When combined, Lean Six Sigma integrates Lean production approaches with Six Sigma methodology. While Six Sigma focuses on the process, Lean focuses on the product. **Six Sigma initiatives** result in **minimizing** rework and scrap, while Lean reduces inventory levels and cycle time. Both are customer focused, with Six Sigma focusing on expected performance, while Lean responds to customer demand. Lean looks at the overall elements of the process, while Six Sigma has more of an individualized process view.

1. Six Sigma:

Is a set of tools and strategies for process and production improvement that can be introduced in any organization. The term "Six Sigma" comes from a field of process statistics, originally developed by Motorola in 1985. Six Sigma became well known after Jack Welch (CEO in General Electric) made it a central focus of his business strategy in 1995, and today it is used in different sectors of industry. Six Sigma also follows project methodologies inspired by Deming's - **Plan-Do-Check-Act Cycle (PDCA)**.

In fact, Motorola was one of the first companies to win the prestigious *Malcolm Baldrige National Quality Award* in 1988, due to its high ***focus on quality***. Both GE and Motorola have had a primary goal to achive total customer satisfaction, eliminating almost all defects from products, processes, and transactions. These companies consider quality to be the ***critical factor*** that has resulted in significant *increases in sales and market share*, as well as cost savings, in the range of *millions of dollars*.

Six Sigma seeks to improve the quality of process outputs by identifying and removing the causes of defects (errors) and minimizing variability in manufacturing and business processes. It uses a set of quality management methods, including statistical methods, and creates a special infrastructure of people within the organization as defined below:

Executive Leadership: includes the CEO (Chief Executive Officer) and other members of top management. They are responsible for setting up a vision for Six Sigma implementation. They also empower the other role holders with the freedom and resources to explore new ideas for breakthrough improvements.

Champions: are the personnel that take responsibility for Six Sigma implementation across the organization in an integrated manner. The Executive Leadership draws them from upper management. Champions also act as mentors to Black Belts.

Master Black Belts: identified by champions, act as in-house coaches on Six Sigma to assist the champions and guide Black Belts and Green Belts. Apart from statistical tasks, they spend their time on ensuring consistent application of Six Sigma across various functions and departments. They devote 100% of their time to Six Sigma.

Black Belts: operate under Master Black Belts to apply Six Sigma methodology to specific projects, by also devoting 100% of their time to Six Sigma. They primarily focus on Six Sigma project execution, whereas Champions and Master Black Belts focus on identifying projects/functions for Six Sigma.

Green Belts: are the employees who take up Six Sigma implementation along with their other job responsibilities, operating under the guidance of Black Belts.

Some organizations use additional belt colours, such as *Yellow Belts*, for employees that have basic training in Six Sigma tools and generally participate in projects and 'white belts' for those locally trained in the concepts but do not participate in the project team.

The **American Society for Quality**, for example, requires Black Belt applicants to pass a written exam and to provide a signed affidavit stating that they have completed two projects, or one project combined with three years' practical experience in the Body of Knowledge. The **International Quality Federation** offers an online certification exam that organizations can use for their internal certification programs; it is statistically more demanding than the ASQ certification, but many organizations provide certifications.

Therefore, the functions and general activities of management can be universally applied to managing any organization or activity. Recognition of these concepts are crucial to the propagation and utilization of software engineering projects, for it allows us to apply the wealth of research in management sciences and improvement of engineered installations.

IASSC IS a Professional Association dedicated to growing and enhancing the standards within the Lean Six Sigma Community. IASSC exclusively facilitates and delivers centralized universal Lean Six Sigma Certification Standards testing and organizational Accreditation's.

2. The Five W´s and One H:

The **Five W´s and one H**, or the **Six W´s** are questions whose answers are considered basic in information-gathering, often mentioned journalism (*cf.* news style) and can also be applied in research, quality systems, production processes, fabrication and construction engineering. This method constitute a formula for getting the complete story on a subject. According to the principle of the 5 W´s, a report can only be considered complete if it answers these questions starting with an interrogative word:

- **Who** is it about?
- **What** happened?
- **When** did it take place?
- **Where** did it take place?
- **Why** did it happen?

Some authors add a sixth question, “how”, or a seventh question, “how much”, to the list:

- **How** did it happen.
- **How** much did it cost.

The most important is that none of these questions can be answered with a simple "yes" or "no". In 19th century, the **American Prof. William C. Wilkinson** popularized the "*Three W´s*" - What? Why? What of it? - as a method of Bible study in the 1880, though he did not claim originality.

This became the **"*Five W´s*"**, though the application today is very different from this origin. The "What? Why? What of it?" is a plan of study of alliterative methods for the teacher emphasized by Professor Wilkinson not as original with himself, but as of venerable authority. "It is, in fact," he says, "an almost immemorial orator's analysis.

First the facts, **next** the proof of the facts, then the **consequences** of the facts, this analysis was also expanded into one known as "*The Five W´s*:" "When? Where? Who? What? Why?" Hereby attention is called, in the study of any lesson: to the date of its incidents; to their place or locality; to the person speaking or spoken to, or to the persons introduced, in the narrative; to the incidents or statements of the text; and, finally, to the applications and uses of the lesson teachings.

Nevertheless, the **"*Five W´s*"** and one *H* were introduced by **Rudyard Kipling** in his "*Just So Stories*" (1902), in a poem accompanying the tale of "*The Elephant's Child*" that opens with:

> *I keep six honest serving-men;*
> *They taught me all I knew;*
> *Their names are **What** and **Why** and **When**;*
> *And **How** and **Where** and **Who**.*

This is why the **"Five W´s and One H"** problem solving method is also called as the **"Kipling Method**", which helps to explore the problems by challenging them with these questions. By 1917, the "*Five W´s*" were being taught in high-school journalism classes, and by 1940, the "*Five W´s*" were characterized as old-fashioned. However, this old-fashioned method led to the five “*W´s and the one H”*, crystallized largely by the Pulitzer's "*new journalism*" and sanctified by the schools, widely giving way and guard to straight news stories and a form of management process.

2.1. 5 W’s and 1 H Applied in Six Sigma:

The 5W and 1H applied to Six Sigma explains the approach to be followed by exactly understanding and analyzing the process, project or a problem for improvement. Four of the W’s (who, what, where, when)

and one H is used to comprehend for details, analyze inferences and judgment to get to the fundamental facts and a guide to statements. The last W (why) is often asked five times so, some user can drill to get the core of a problem. The example below, shows how to apply the **5 W´s and One H"** including a checking question:

a. "What" in Six Sigma:

The "what" in Six Sigma is a concept and a level of quality applied to variations in any process. Sigma, (the Greek letter "σ") is the symbol in statistics used for standard deviation, a measure of variation in the distribution of values. Processes that operate with "six sigma quality" over the short term, are assumed to produce long-term defect levels, below 3.4 defects per million opportunities (DPMO).

b. "Why" in Six Sigma:

How to achieve the goals is accomplished in "why" context. Six Sigma requires practitioners to consider both the "voice of the customer" and the "voice of the process," it reduces the gap between the two voices. That leads to more satisfied customers, and that is what makes the Six Sigma initiative a profitable business proposition. Not only does the Six Sigma organization save costs, but it also has great opportunity to increase sales.

c. "Who" Is Involved with Six Sigma:

The Six Sigma eventually involves everyone in the organization, starting from the top management to the operator/staff level. It requires a companywide understanding of the processes, a commitment toward achieving the set goals and an involvement in projects that accompany those goals. The top levels of management appoint Sponsors, who are members of the leadership team who are responsible for selecting Six Sigma projects and are ultimately accountable for project results.

Under the Sponsors are the Champions, who typically have day-to-day responsibility for the business process being improved and their role is to ensure the Six Sigma project team has the resources required to successfully execute the project. Next are the Master Black Belts, who teach and mentor the Black-Belts, have been trained to manage Six Sigma projects and serve as leaders of project teams, consisting of Green Belts and other employees.

d. "Where" to Apply Six Sigma:

Six Sigma is applied to all business processes. To start with, it can be applied to key business processes which have the highest visible impact on the customers and shareholders. All business processes impacting customer satisfaction and profit growth of the organization need to undergo Six Sigma methodology implementation.

e. "When" to Apply Six Sigma:

In well-functioning Six Sigma deployments, everyone in the organization is involved in reducing defects, reducing cycle times and increasing customer satisfaction. As long as an organization has a strong desire to improve the business performance by identifying each and every key business processes for improvement, the starting point of Six Sigma does not matter. Organizations can implement Six Sigma:

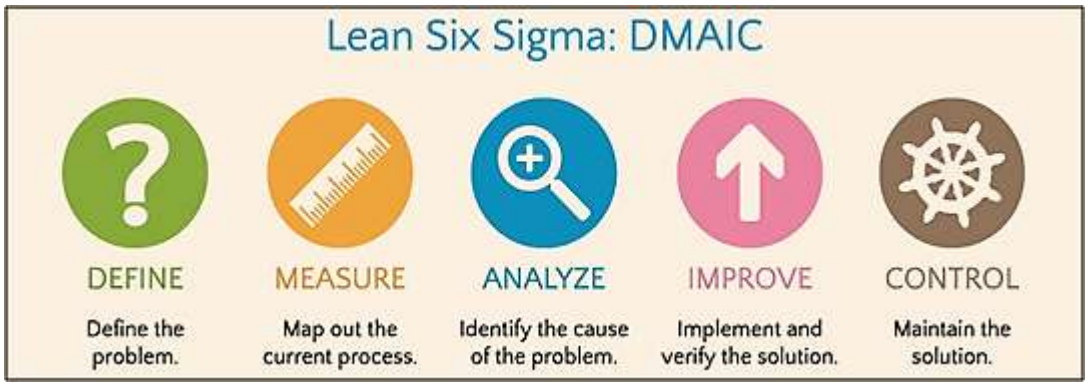
- When they find out that the customer satisfaction level is eroding.
- When they want to retain a leadership position through quality in the market.
- When there is a clear indication of losing market share due to quality.
- When their processes have not changed for a long time.
- When the quality of a product is dependent on skills instead of the production process.
- When they think their processes have all reached an improvement plateau.
- When they are required to improve performance in all areas of their business process.
- When they decide they want to survive and grow in today's competitive market.

f. "How" to Apply Six Sigma:

Depending upon the requirement of the organization and the type of organization different strategies are followed for Six Sigma implementation. The three main strategies followed in Six Sigma are:

- ✓ **Process Management:** An ongoing cross-functional ownership and measurement of core support processes.

- ✓ **Process Improvement:** Focused on problem solving, aimed at eliminating the vital few root causes. It is most common to use the **DMAIC** roadmap as explained below:

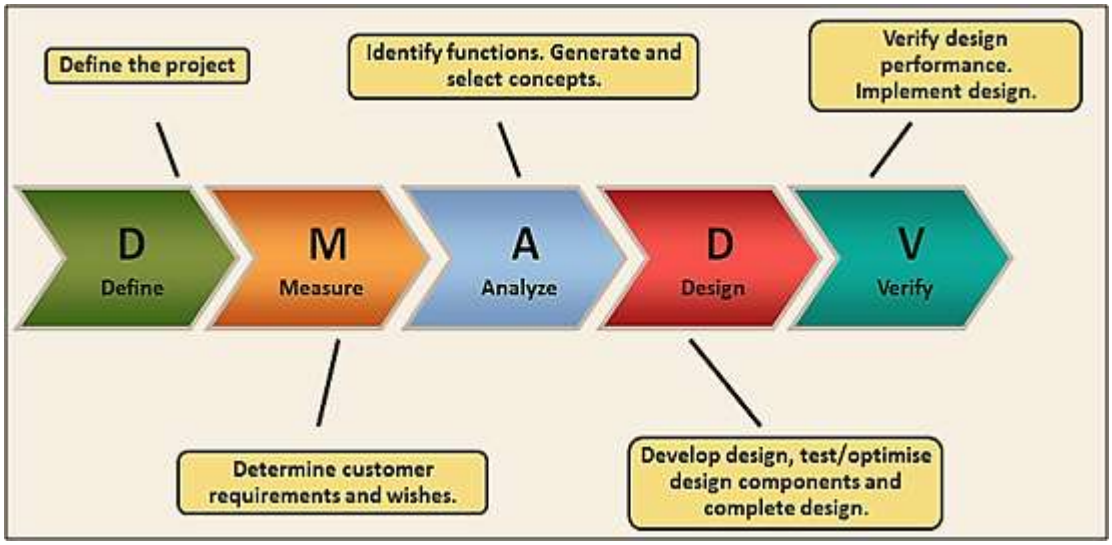


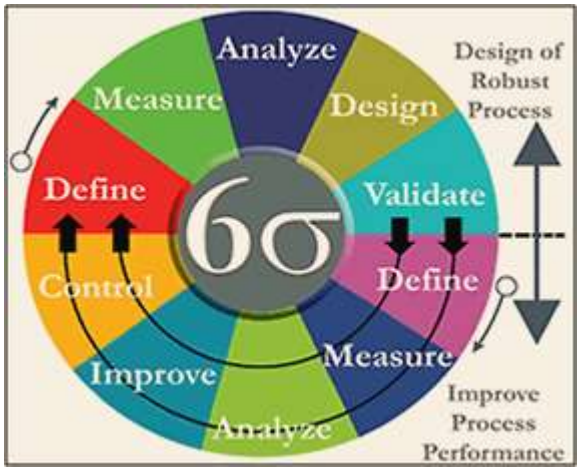
- **Define** - Select customer's critical-to-quality characteristics (CTQs). Define the process improvement goals that are consistent with customer demands and enterprise strategy.
- **Measure -** Create a measurement system and validate the system. Measure the current process and collect relevant data for future comparison.
- **Analyze -** Identify the sources of variation from the performance objectives. Analyze to verify relationship and causality of factors. Determine what the relationship is and attempt to ensure that all factors have been considered using one or more of the tools in the Six Sigma toolkit.

- **Improve -** Discover process relationships and establish new and improved procedures. Improve or optimize the process based upon the analysis.
- **Control -** Sustain the gain by implementing process controls, to ensure that any variances are corrected before they result in defects and continuously measure the control mechanisms.

✓ **Process Design/Redesign:** The creation of a new process to achieve exponential improvement and/or meet the changing demands of customers, technology and competition. It must handle totally dysfunctional processes and reengineer them. It is also known as Design for Six Sigma (DFSS). **DMADV** is the most common roadmap as defined below:

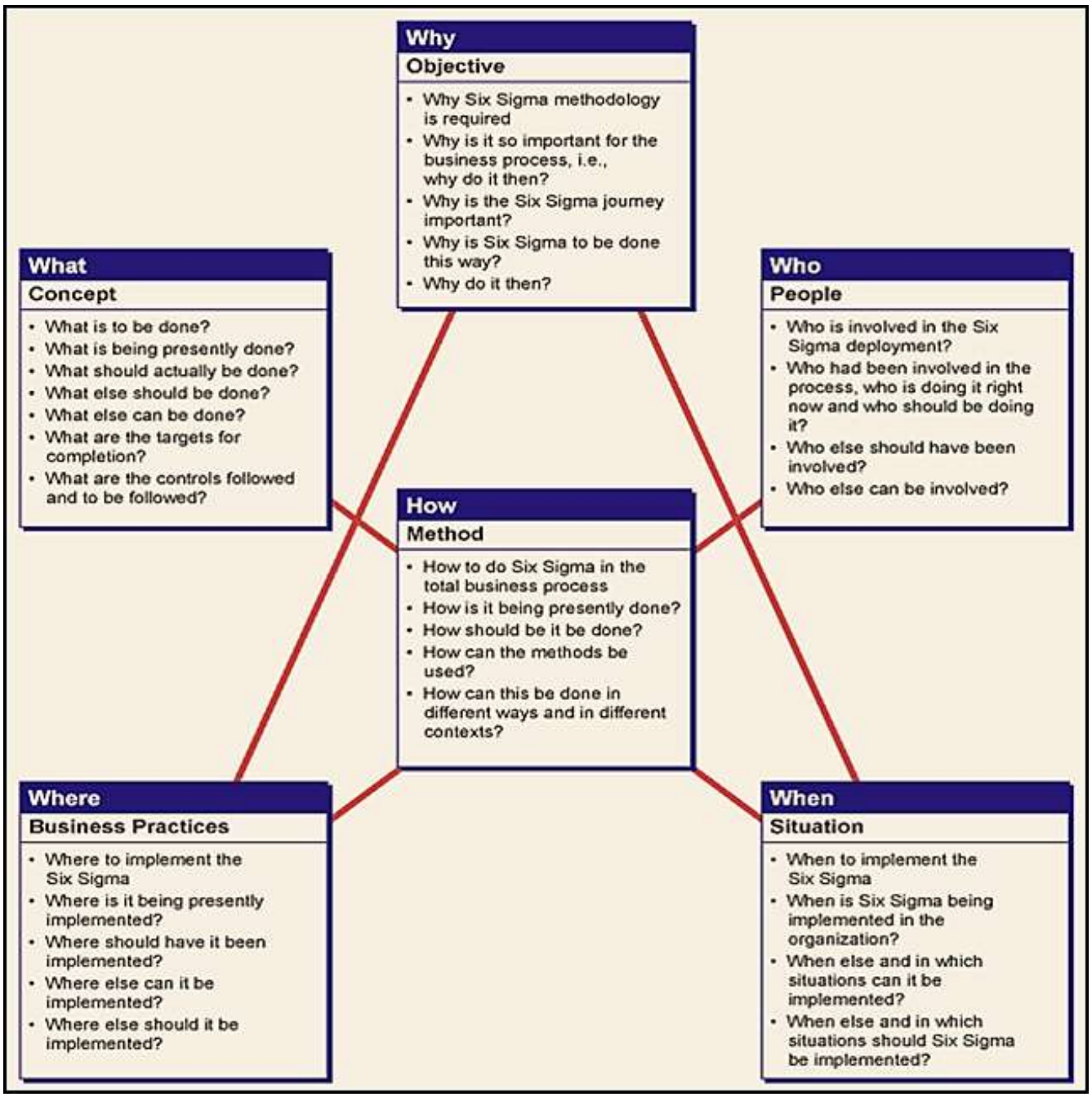
- **Define:** Define the goals of the design activity that are consistent with customer demands and enterprise strategy.
- **Measure:** Measure and identify CTQs, product capabilities, production process capability and risk assessments.
- **Analyze:** Analyze to develop and design alternatives, create high-level design and evaluate design capability to select the best design.
- **Design:** Design details, optimize the design, and plan for design verification. This phase may require simulations.
- **Verify:** Verify the design, set up pilot runs, implement production process and handover to process owners.





Six Sigma focuses on long and sustained success for every improvement projects, improving each and every process in the organization. That gives organizations a way to continue improving year after year and even provides a system that rewards "out of the box" thinking, which can accelerate the rate of improvement.

In the Six Sigma methodology, anything that **dissatisfies the customer** is a **defect**, and understanding the customer and customer requirements is the most important issue in establishing a Six Sigma culture. Six Sigma is a **problem-solving management methodology** that can be applied to any type of business process to identify and eliminate the root causes of defects, ultimately improving the key business processes and saving cost for the organization. In this regard, the main goal of Six Sigma is that any quality improvements in an organization need to be economically viable.



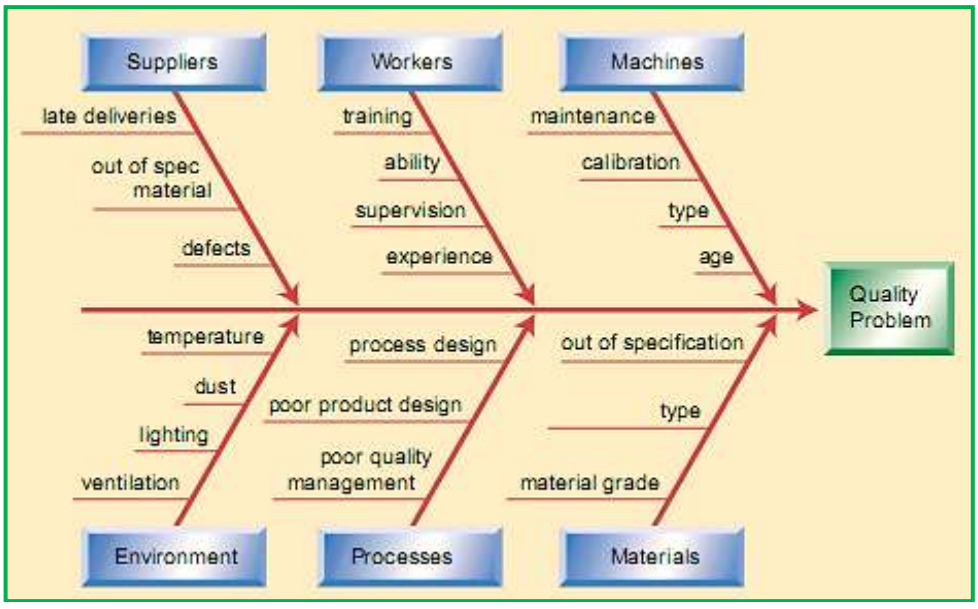
Since it is a data-driven approach to problem solving, Six Sigma **builds robustness** in daily management. This starts a set of chain reaction in strategic, tactical and operational improvements, which compels the organization to set a stretch target for every business performance and set goals for everyone in the organization.

The Six Sigma **creates a culture** in an organization aimed at learning to build processes that delivers the business output with flawless quality. Six Sigma also focuses on measuring and controlling the variation at each stage of business process. That sometimes creates a mistaken notion that Six Sigma is a set of statistical tools and a mere strategy for their use. The reality is Six Sigma is a blending of the wisdom of an organization with a methodology and an extensive toolkit to improve both the efficiency and effectiveness of the organization in meeting its the customer requirements.

3. Ishikawa Diagrams:

Also called **fishbone**, **herringbone**, **cause-and-effect** or **Fishikawa,** are causal diagrams created by Kaoru Ishikawa (1968) that show the causes of a specific event. Cause-and-effect or Ishikawa diagrams were popularized by in 1960s, who pioneered quality management processes in the Kawasaki shipyards, and in the process became one of the founding fathers of modern management.

The basic concept was first used in the 1920s, and is considered one of the seven basic tools of quality control. It is known as a fishbone diagram because of its shape, similar to the side view of a fish skeleton. Common uses of the Ishikawa diagram are product design and quality defect prevention, to identify potential factors causing an overall effect. Each cause or reason for imperfection is a source of variation.



Cause-and-effect diagrams: are usually grouped into major categories to identify these sources of variation. The categories typically include:

- **Suppliers**: Data generated from the process that are used to evaluate its quality.
- **Workers**: Anyone involved with the process.
- **Machines**: Any equipment, computers, tools, etc. required to accomplish the job.
- **Environment**: The conditions, such as location, time, temperature, and culture of the process.
- **Processes**: How the process is performed and the specific requirements for doing it, such as policies, procedures, rules, regulations and laws.
- **Materials**: Raw materials, parts, pens, paper, etc. used to produce the final product.

Cause-and-effect diagrams can reveal key relationships among various variables, and the possible causes provide additional insight into process behavior. Causes can be derived from groups brainstorming sessions, that can label the categories of the fishbone. Causes can be traced back to root causes with the **5 Whys** technique or causes in the diagram are often categorized, such as to the **6 M's**, described below. Typical categories are:

4. The 6 M´s Used by Toyota:

- Machine (technology);
- Method (process);
- Material (includes raw material, consumables and information);
- Man power (physical work)/mind power (brain work) - Kaizen suggestions;
- Measurement (inspection);
- Mother Nature (environment).

The original **6M´s** used by the **Toyota Production System** was expanded to include a following system referred to as **8Ms**. However, this was not globally recognized, then it was suggested to return to the roots of the tools and to keep the teaching simple since most programs do not address the 8Ms.

The 7 P´s (used in marketing industry): Product=Service; Price; Place; Promotion; People/personnel; Process; Physical Evidence.

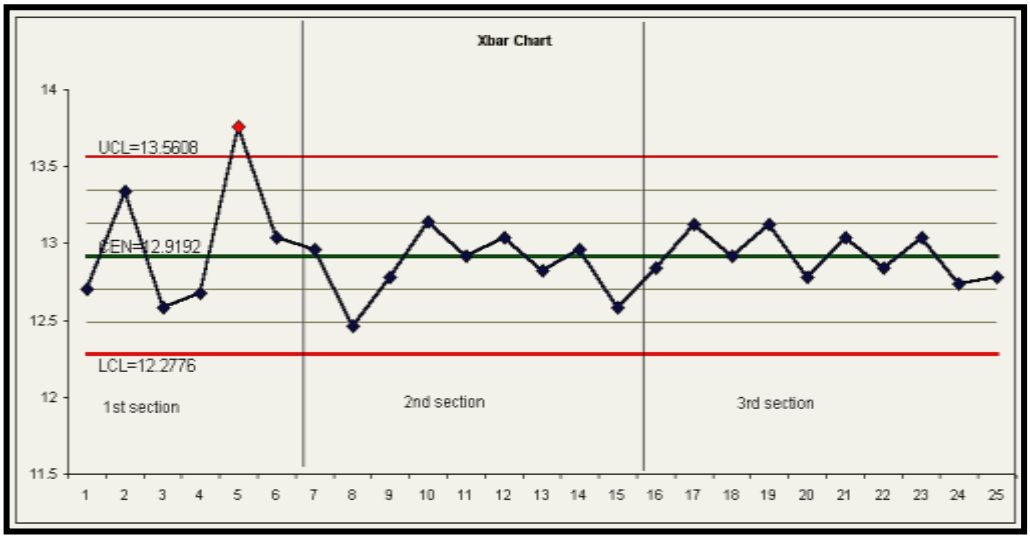
The 5 S´s (used in service industry): Surroundings; Suppliers; Systems; Skills; Safety.

The 5 W´s: Where; What; When; Who; Why.

5. Control Charts:

Also known as **Shewhart charts** was invented by Walter A. Shewhart while working for Bell Labs in the 1920. The company's engineers had been seeking to improve the reliability of their telephony transmission systems. In 1924 or 1925, Shewhart's innovation came to the attention of the statistician **W. Edwards Deming**, then working at the Hawthorne facility.

Deming later worked at the United States Department of Agriculture and became the mathematical advisor to the United States Census Bureau. Over the next half a century, Deming became the foremost champion and proponent of Shewhart's work.



5.1. Control Charts Definition:

The points represent a statistic (e.g., a mean, range, proportion) of measurements of a quality characteristic in samples taken from the process at different times [the data]. The mean of this statistics using all the samples is calculated (e.g., the mean of the means, mean of the ranges, mean of the proportions). A centre line is drawn at the value of the mean of the statistics. The standard error (e.g., standard deviation/sort(n) for the mean) of the statistic is also calculated using all the samples.

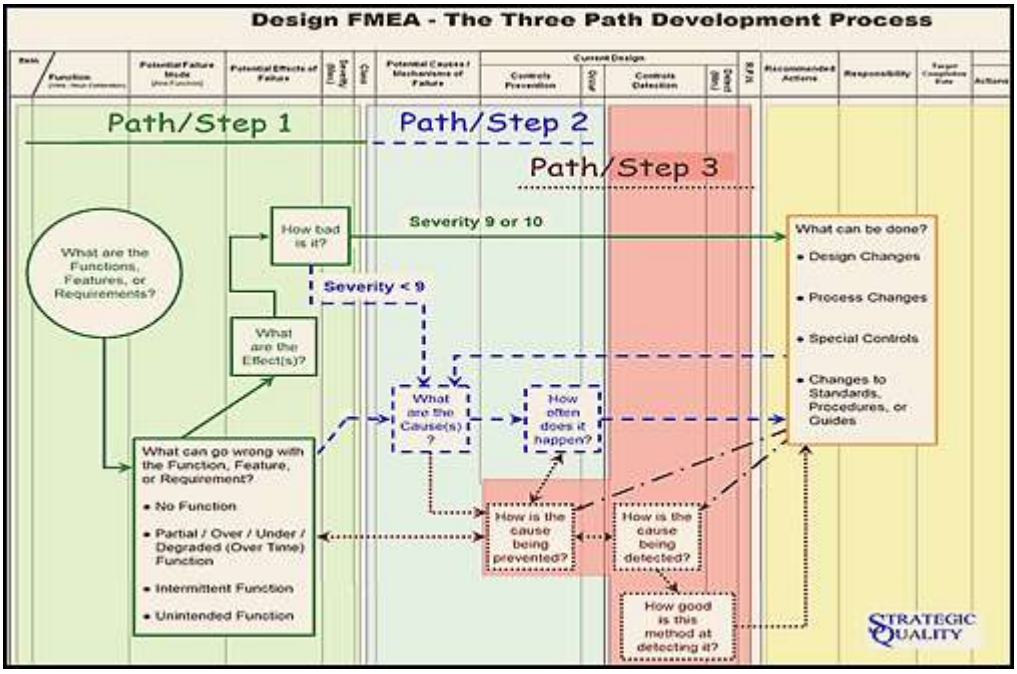
- **Upper and lower control limits**: Sometimes called "natural process limits" that indicates the threshold at which the process output is considered statistically 'unlikely' and is drawn typically at 3 standard errors from the centre line. The chart may have other optional features, including:
- **Upper and lower warning limits**: Drawn as separate lines, typically two standard errors above and below the centre line. Division into zones, with the addition of rules governing frequencies of observations in each zone. Annotation with events of interest, as determined by the Quality Engineer in charge of the process's quality.

6. Failure Mode and Effect Analysis (FMEA):

Is one of the first systematic techniques for failure analysis, developed by engineers in the 1950 to study problems that might arise from malfunctions of military systems. Currently, involves reviewing of many components, assemblies and sub-systems to minimum details, as possible, to identify failure modes, and their causes and effects. An FMEA is often the first step of a system reliability study.

For each component, the failure modes and their resulting effects on the rest of the system are recorded in a specific FMEA worksheet, which are numerous variations. A FMEA is mainly a qualitative analysis. A few different types of analysis exist, like the Functional, Design and Process FMEA.

A Design FMEA (DFMEA) is performed prior to the completion of the design of the product. A Process FMEA (PFMEA) is performed prior to the release of the design for the process. PFMEAs should ideally be conducted when DFMEAs provide special characteristics or when new process technology is planned. It is critical that a FMEA be performed with sufficient time to take counter measures against the risk and still capture the changes within the design before its release.



A successful FMEA activity helps to identify potential failure modes based on experience with similar products and processes or based on common physics of failure logic. It is widely used in development and manufacturing industries in various phases of the product life cycle. *Effects Analysis* refers to studying the consequences of those failures on different system levels.

The FMEA is in principle a full inductive (forward logic) analysis, however the failure probability can only be estimated or reduced by understanding the *failure mechanism*. Ideally this probability shall be lowered to "impossible to occur" by eliminating the *(root) causes*. It is therefore important to include in the FMEA an appropriate depth of information on the causes of failure (deductive analysis).

6.1. Critical Analysis - FMECA:

Sometimes the FMEA is called FMECA to indicate that **critical analysis** is performed also. An FMEA is an Inductive reasoning (forward logic) single point of failure analysis and is a core task in reliability engineering, safety engineering and quality engineering (Quality engineering is especially concerned with the "Process" ((Manufacturing and Assembly) type of FMEA.

The FMECA is a living document during development of a hardware design, scheduled and completed concurrently with the design. If completed in a timely manner, the FMECA can help guide design decisions. It is useful as a design tool and in decision making processes dependent on the effectiveness and timeliness with which design problems are identified.

6.2. FMEA Terminology:

- ✓ **Failure:** The loss of an intended function of a device under stated conditions. It shall at least clearly describe a (end) failure state of the item (or function in case of a Functional FMEA) under consideration. It is the result of the failure mechanism (cause of the failure mode).
- ✓ **Failure mode:** The specific manner or way by which a failure occurs in terms of failure of the item (being a part or (sub) system) *function* under investigation; it may generally describe the way the failure occurs. *For example; a fully fractured axle, a deformed axle or an fully open or fully closed electrical contact are each a separate failure mode.*
- ✓ **Failure cause and/or mechanism:** Defects in requirements, design, process, quality control, handling or part application, which are the underlying cause or sequence of causes that initiate a process (mechanism) that leads to a failure mode over a certain time.
- ✓ **Failure effect:** Immediate consequences of a failure on operation, function or functionality, or status of some item
- ✓ **Indenture levels (bill of material or functional breakdown):** An identifier for system level and thereby item complexity. Complexity increases as levels are closer to one.
- ✓ **Local effect:** The failure effect as it applies to the item under analysis.
- ✓ **Next higher level effect:** The failure effect as it applies at the next higher indenture level.
- ✓ **End effect:** The failure effect at the highest indenture level or total system.
- ✓ **Detection:** The means of detection of the failure mode by maintainer, operator or built in detection system, including estimated dormancy period (if applicable)
- ✓ **Severity:** The consequences of a failure mode. Severity considers the worst potential consequence of a failure, determined by the degree of injury, and/or time lost to repair the failure.
- ✓ **Remarks / mitigation / actions:** Additional info, including the proposed mitigation or actions used to lower a risk or justify a risk level or scenario.

Note: A failure mode may have more causes. *For example; "fatigue or corrosion of a structural beam" or "fretting corrosion in an electrical contact" is a failure mechanism and in itself (likely) not a failure mode. The related failure mode (end state) is a "full fracture of structural beam" or "an open electrical contact". The initial Cause might have been "Improper application of corrosion protection layer (paint)" and /or "(abnormal) vibration input from another (possible failed) system".*

7. Risk Levels:

Risk is the combination of end effect probability and severity, where probability and severity includes the effect on non-detectability failures in products and services. This may influence the end effect probability of failure or the worst case effect severity. The exact calculation may not be easy in multiple scenarios (with multiple events) due the difficult detectability/dormancy that plays a crucial role (as for redundant systems). In this case the manager should use the ***Fault Tree Analysis*** and/or the ***Event Trees*** to determine the exact probability of risk levels.

8. Statistical Quality Control (SQC):

Is the term used to describe the set of statistical tools used by quality professionals. The Statistical Quality Control can be divided into three broad categories:

- ✓ **Descriptive statistics:** used to describe quality characteristics and relationships. Included are statistics such as the mean, standard deviation, range, and a measure of the distribution of data.

- ✓ **Statistical process control (SPC)** involves 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 of whether the process is functioning properly or not.

- ✓ **Acceptance sampling** is the process of randomly inspecting a sample of goods and deciding whether to accept the entire lot based on the results. Acceptance sampling determines whether a batch of goods should be accepted or rejected.

All three of these statistical quality control categories are helpful in measuring and evaluating the quality of products or services. However, statistical process control (SPC) tools are used most frequently because they identify quality problems during the production process. For this reason, we will devote most of the chapter to this category of tools.

The quality control tools we will be learning about do not only measure the value of a quality characteristic. They also help us identify a *change* or variation in some quality characteristic of the product or process. We will first see what types of variation we can observe when measuring quality. Then we will be able to identify specific tools used for measuring this variation.

For example, if you look at bottles of a soft drink in a grocery store, you will notice that no two bottles are filled to exactly the same level. Some are filled slightly higher and some slightly lower. Similarly, if you look at blueberry muffins in a bakery, you will notice that some are slightly larger than others and some have more blueberries than others. These types of differences are completely normal.

No two products are exactly alike because of slight differences in materials, workers, machines, tools, and other factors. These are called **common, or random, causes of variation.** Common causes of variation are based on random causes that we cannot identify. These types of variation are unavoidable and are due to slight differences in processing.

The second type of variation that can be observed involves variations where the causes can be precisely identified and eliminated. These are called **assignable causes of variation.** Examples of this type of variation are poor quality in raw materials, an employee who needs more training, or a machine in need of repair. In each of these examples the problem can be identified and corrected.

Descriptive statistics can be helpful in describing certain characteristics of a product and a process. The most important descriptive statistics are measures of central tendency such as the mean, measures of

variability such as the standard deviation and range, and measures of the distribution of data. We first review these descriptive statistics and then see how we can measure their changes.

8.1. The Mean:

The arithmetic average, or the **mean,** is a statistic that measures the central tendency of a set of data. In the soft drink bottling example, we stated that the average bottle is filled with 16 ounces of liquid. To compute the mean we simply sum all the observations and divide by the total number of observations. The equation for computing the mean is:

$$\bar{x} = \frac{\sum_{i=1}^{n} x_i}{n}$$

Where:

$\bar{x}$ = the mean
x_i = observation i, $i = 1, \ldots, n$
n = number of observations

Another measure of variation is the **standard deviation.** The equation for computing the standard deviation is:

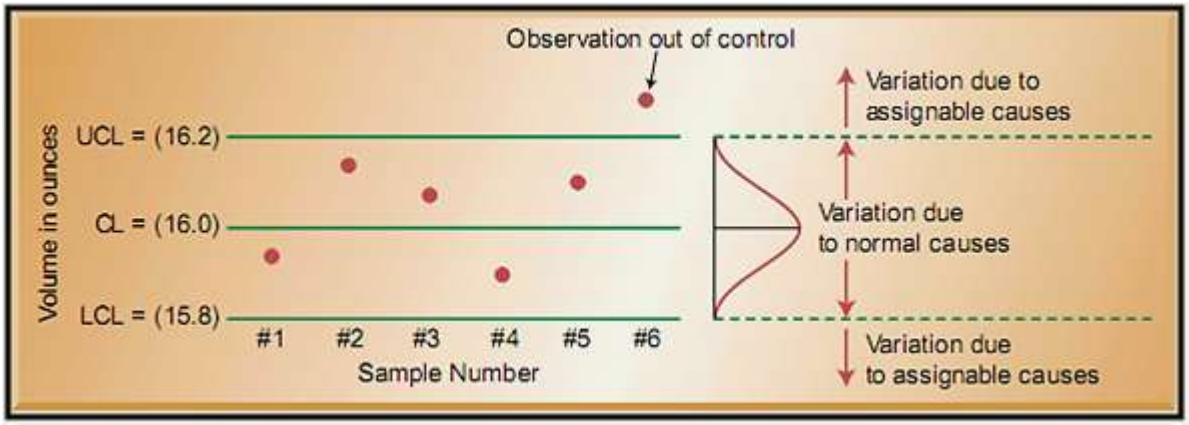
$$\sigma = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1}}$$

Where:

σ = standard deviation of a sample
$\bar{x}$ = the mean
x_i = observation i, $i = 1, \ldots, n$
n = the number of observations in the sample

a. Developing Control Charts:

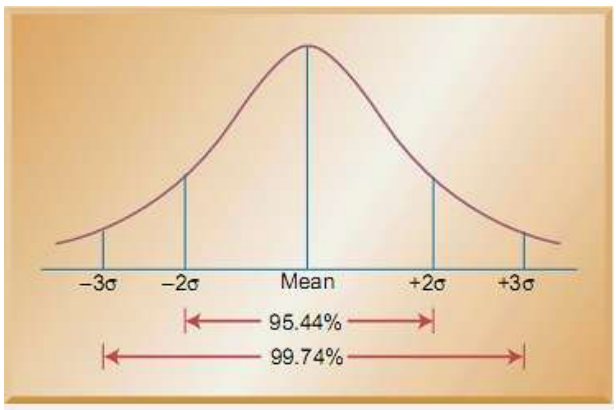
A control chart is a graph that shows upper and lower control limits that separate common from assignable causes of variation and the common range of variation is defined by the use of control limits. A **control chart** (also called process chart or quality control chart) shows whether a sample of data falls within the common or normal range of variation. We say that a process is **out of control** when a plot of data reveals that one or more samples fall outside the control limits.



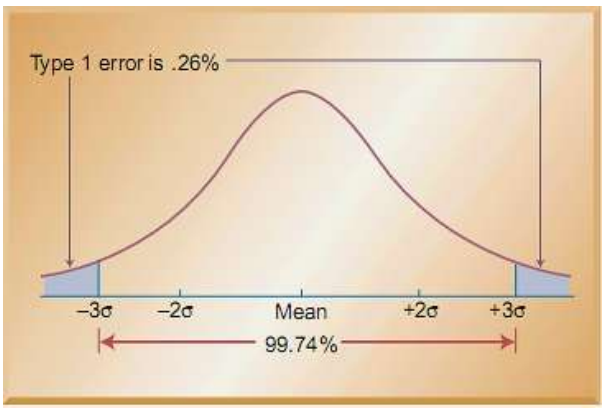
b. Types of Control Charts:

Control charts are one of the most commonly used tools in statistical process control. They can be used to measure any characteristic of a product, such as the weight of a cereal box, the number of chocolates in a box, or the volume of bottled water. The different characteristics that can be measured by control charts can be divided into two groups: **variables** and **attributes.**

A *control chart for variables* is used to monitor characteristics that can be measured and have a continuum of values, such as height, weight, or volume. A soft drink bottling operation is an example of a variable measure, since the amount of liquid is measured and can take on a number of different values.



Percentage of values captured by different ranges of standard deviation



Chance of Type I error for 3σ (sigma-standard deviations)

c. Mean (x-Bar) Charts:

A mean control chart is often referred to as an ***x-bar chart.*** It is used to change the meaning of a process. To construct a mean chart we first need to construct center line of the chart. To do this we take multiple samples and compute their means. Usually these samples have four or five observations.

$$\bar{\bar{X}} = \frac{\bar{X}_1 + \bar{X}_2 + \cdots \bar{X}_{\mathcal{K}}}{\mathcal{K}}$$

To construct the upper and lower control limits of the chart, we use the following formulas:

Upper control limit (UCL) =

$$\bar{\bar{X}} + z\sigma_{\bar{x}}$$

Lower control limit (LCL) =

$$\bar{\bar{X}} - z\sigma_{\bar{x}}$$

Where:

$\bar{\bar{X}}$ = the average of the sample means
z = standard normal variable (2 for 95.44% confidence, 3 for 99.74% confidence)
$\sigma_{\bar{x}}$ = standard deviation of the distribution of sample means, computed as $\sigma/\sqrt{n}$
σ = population (process) standard deviation
n = sample size (number of observations per sample)

d. Control Chart Variables:

Control charts variables monitor characteristics that can be measured and have a continuous scale, such as height, weight, volume, or width. When an item is inspected, the variable being monitored is measured and recorded. For example, if we were producing candles, height might be an important variable, so we could take samples of candles and measure their heights.

Two of the most commonly used control charts variables monitor both the central tendency of the data (the mean) and the variability of the data (either the standard deviation or the range). When observed values go outside the control limits, the process is assumed not to be in control.

One category of SQC techniques consists of **descriptive statistics tools** such as the **mean, range, and standard deviation**. These tools are used to describe quality characteristics and relationships. Another category of SQC techniques consists of statistical process control (SPC) methods that are used to monitor changes in the production process. To understand SPC methods you must understand the differences between common and assignable causes of variation.

e. Practical Example of a Mean *Chart*:

A quality control inspector at the Cocoa Fizz soft drink company has taken twenty-five samples with four observations each of the volume of bottles filled. The data and the computed means are shown in the table. If the standard deviation of the bottling operation is 0.14 ounces, use this information to develop control limits of three standard deviations for the bottling operation.

Sample Number	Observations (bottle volume in ounces) 1	2	3	4	Average $\bar{x}$	Range R
1	15.85	16.02	15.83	15.93	15.91	0.19
2	16.12	16.00	15.85	16.01	15.99	0.27
3	16.00	15.91	15.94	15.83	15.92	0.17
4	16.20	15.85	15.74	15.93	15.93	0.46
5	15.74	15.86	16.21	16.10	15.98	0.47
6	15.94	16.01	16.14	16.03	16.03	0.20
7	15.75	16.21	16.01	15.86	15.96	0.46
8	15.82	15.94	16.02	15.94	15.93	0.20
9	16.04	15.98	15.83	15.98	15.96	0.21
10	15.64	15.86	15.94	15.89	15.83	0.30
11	16.11	16.00	16.01	15.82	15.99	0.29
12	15.72	15.85	16.12	16.15	15.96	0.43
13	15.85	15.76	15.74	15.98	15.83	0.24
14	15.73	15.84	15.96	16.10	15.91	0.37
15	16.20	16.01	16.10	15.89	16.05	0.31
16	16.12	16.08	15.83	15.94	15.99	0.29
17	16.01	15.93	15.81	15.68	15.86	0.33
18	15.78	16.04	16.11	16.12	16.01	0.34
19	15.84	15.92	16.05	16.12	15.98	0.28
20	15.92	16.09	16.12	15.93	16.02	0.20
21	16.11	16.02	16.00	15.88	16.00	0.23
22	15.98	15.82	15.89	15.89	15.90	0.16
23	16.05	15.73	15.73	15.93	15.86	0.32
24	16.01	16.01	15.89	15.86	15.94	0.15
25	16.08	15.78	15.92	15.98	15.94	0.30
Total					398.75	7.17

Solution:

The center line of the control data is the average of the samples:

$$\bar{\bar{x}} = \frac{398.75}{25}$$

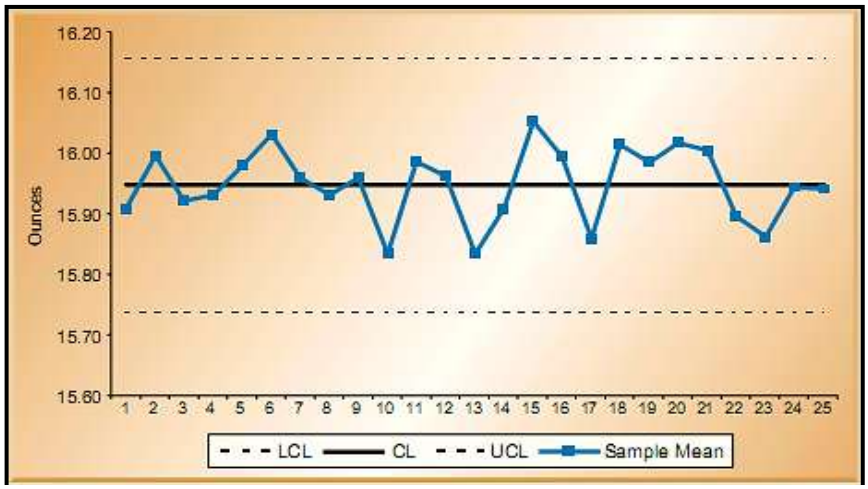
$$\bar{\bar{x}} = 15.95$$

The control limits are:

$$\text{UCL} = \bar{\bar{x}} + z\sigma_{\bar{x}} = 15.95 + 3\left(\frac{.14}{\sqrt{4}}\right) = 16.16$$

$$\text{LCL} = \bar{\bar{x}} - z\sigma_{\bar{x}} = 15.95 - 3\left(\frac{.14}{\sqrt{4}}\right) = 15.74$$

The **resulting control chart** is:



9. Histograms:

Is a graphical representation of the distribution of data. It is an estimate of the probability distribution of a continuous variable and was first introduced by Karl Pearson. A histogram is a representation of tabulated frequencies, shown as adjacent rectangles, erected over discrete intervals (bins), with an area equal to the frequency of the observations in the interval.

The height of a rectangle is also equal to the frequency density of the interval, i.e., the frequency divided by the width of the interval. The total area of the histogram is equal to the number of data. A histogram may also be normalized displaying relative frequencies. It then shows the proportion of cases that fall into each of several categories, with the total area equaling.

The categories are usually specified as consecutive, non-overlapping intervals of a variable. The categories (intervals) must be adjacent, and often are chosen to be of the same size. The rectangles of a histogram are drawn so that they touch each other to indicate that the original variable is continuous.

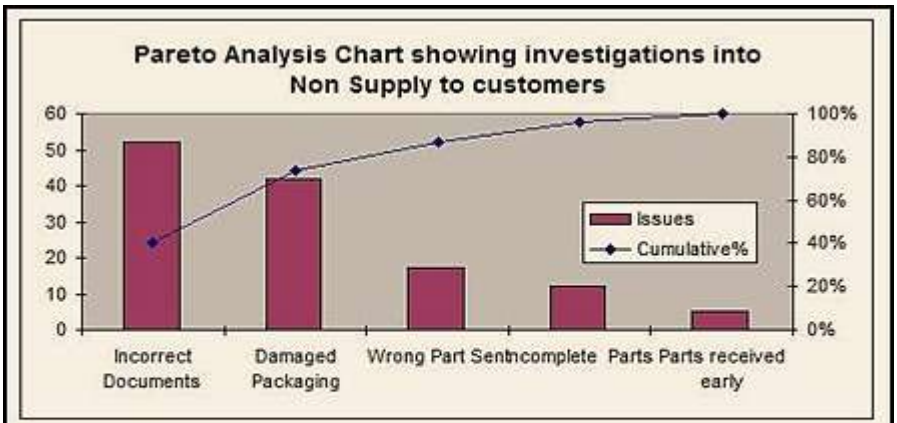
Histograms are used to plot the density of data, and often for density estimation: estimating the probability density function of the underlying variable. An alternative to the histogram is the kernel

density estimation, which uses a kernel to smooth samples. This will construct a smooth probability density function, which will in general more accurately reflect the underlying variable. The histogram is one of the seven basic tools of quality control.

10. Pareto Analysis:

Is a statistical technique in decision making that is used for selection of a limited number of tasks that produce significant overall effect. It uses the Pareto principle – the idea that by doing 20% of work, 80% of the advantage of doing the entire job can be generated. Or in terms of quality improvement, a large majority of problems (80%) are produced by a few key causes (20%).

Pareto analysis is a formal technique useful where many possible courses of action are competing for attention. In essence, the problem-solver estimates the benefit delivered by each action, then selects a number of the most effective actions that deliver a total benefit reasonably close to the maximal possible one. Pareto analysis is a creative way of looking at causes of problems because it helps stimulate thinking and organize thoughts.



	Incorrect Documents	Damaged Packaging	Wrong Part Sent	Incomplete Parts	Parts received early
Issues	52	42	17	12	5
Cumulative%	41%	73%	87%	96%	100%

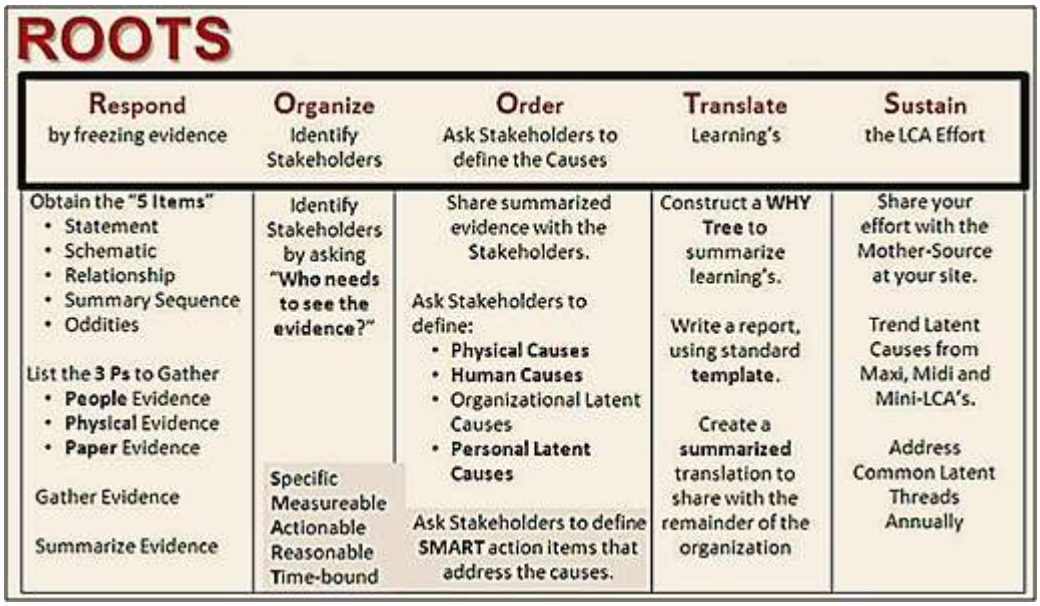
However, it can be limited by its exclusion of possibly important problems which may be small initially, but which grow with time. It should be combined with other analytical tools such as failure mode and effects analysis (FMEA) and fault tree analysis (FTA) for example. This technique helps to identify the top portion of causes that need to be addressed to resolve the majority of problems. Once the predominant causes are identified, then tools like the Ishikawa or Fishbone diagram.

Analysis can be used to identify the root causes of the problems. While it neither is common to refer to Pareto as "80/20" rule, under the assumption that, in all situations, 20% of causes determine 80% of problems, this ratio is merely a convenient rule of thumb and is not nor should it be considered immutable law of nature.
The application of the Pareto analysis in risk management allows management to focus on those risks that have the most impact on the project.

11. Root Cause Analysis (RCA):

Is a method of problem solving that tries to identify the root causes of faults or problems that cause operating events. RCA practice tries to solve problems by attempting to identify and correct the root causes of events, as opposed to simply addressing their symptoms. By focusing correction on root causes, problem recurrence can be prevented. RCFA (Root Cause Failure Analysis) recognizes that complete prevention of recurrence by one corrective action is not always possible.

Root cause analysis is not a single, sharply defined methodology; there are many different tools, processes, and philosophies for performing RCA. However, several very-broadly defined approaches or "schools" can be identified by their basic approach or field of origin: safety-based, production-based, process-based, failure-based, and systems-based, as defined below:



The primary aim of RCA is to identify the factors that resulted in the nature, the magnitude, the location, and the timing of the harmful outcomes (consequences) of one or more past events in order to identify what behaviours, actions, inactions, or conditions need to be changed to prevent recurrence of similar harmful outcomes and to identify the lessons to be learned to promote the achievement of better consequences. ("Success" is defined as the near-certain prevention of recurrence.)

Safety-based: descends from the fields of accident analysis and occupational safety and health.
Production-based: has its origins in the field of quality control for industrial manufacturing.

Process-based: a follow-on to production with a scope expanded to business processes.
Failure-based: rooted in practice of failure analysis employed in engineering and maintenance.
Systems-based: from fields such as systems analysis, change and risk management.

To be effective, the RCA must be performed systematically, usually as part of an investigation, with conclusions and root causes that are identified backed up by documented evidence. The purpose of identifying all solutions to a problem is to prevent recurrence at lowest cost in the simplest way. If there are alternatives that are equally effective, then the simplest or lowest cost approach is preferred.

12. 5S - Work Area Organization:

Is the name of a workplace organization method that uses a list of five Japanese words: ***seiri, seiton, seiso,*** **sei*ketsu,* and *shitsuke***. Translated into English, they all start with the letter "S" to describe how to organize a work space for efficiency and effectiveness by identifying and storing all items used in a work-place and sustaining the new order. The decision-making process usually comes from a dialogue about standardization, which builds understanding among employees of how they should do the work.

The essential objective behind the "***5S****"* is to maintain a safe, clean, organized, and a high-performance work environment. Although this should be a common sense, many work environments are un-organized, leading to safety and concerns, product mix-ups, difficulty in finding items (resulting in longer cycle times). The "*5S"* main elements are:

- ✓ **Sort**: Eliminate all unnecessary tools, parts keeping only essential items and eliminate what is not required, prioritizing things per requirements with easily-accessible places. Everything else is stored or discarded;
- ✓ **Set in order**: Arrange the work, workers, equipment, parts, and instructions in such a way that the work flows free of waste through the value added tasks with a division of labor necessary to meet demand. This is by far the most misunderstood and incorrectly applied S and has been responsible for many lean transformations failing to produce the benefits expected.
- ✓ **Shine**: Clean the workspace and all equipment, and keep it clean, tidy and organized. At the end of each shift, clean the work area and be sure everything is restored to its place. This step ensures that the workstation is ready for the next user and that order is sustained.
- ✓ **Standardize**: Develop standards for the first three 5's. Ensure uniform procedures and setups throughout the operation to promote interchangeability;
- ✓ **Sustain**: Follow the procedures and ensure disciplined adherence to rules and procedures to prevent backsliding.

13. Design of Experiments (DOE):

Is also a statistical technique and includes various aspects used in planning, design, data acquisition, as well as, analyzing and interpreting the data. The DOE determines "*X and Y factor*s" relationships through a structured and organized method, also helpful to best utilize resources.

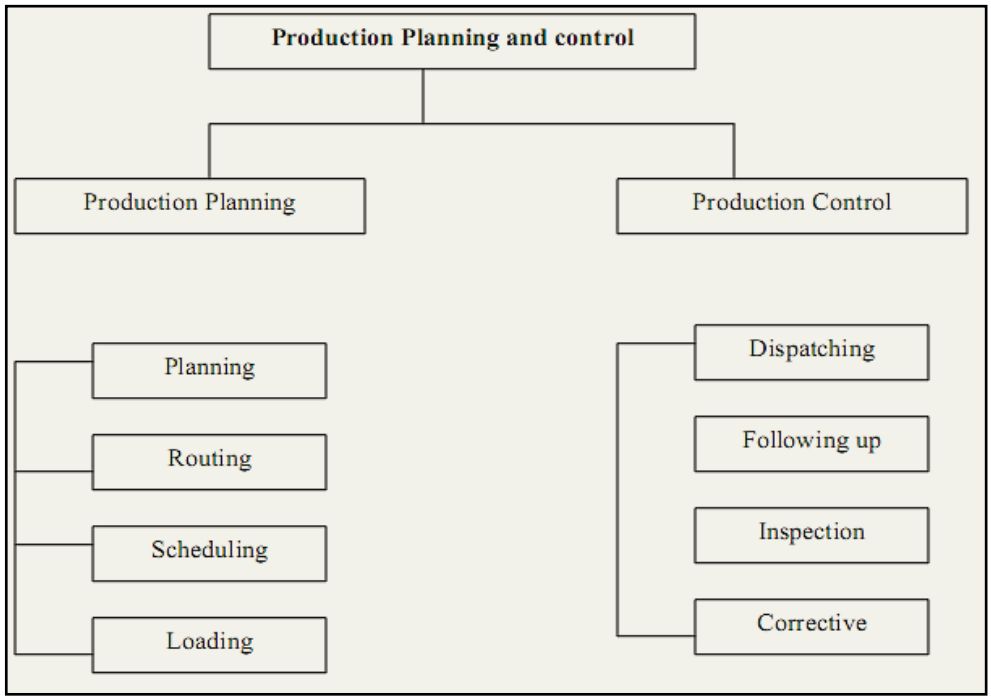
14. Quality Function Deployment (QFD):

Enables the design process to be developed with a customer focus. It includes a methodology with procedures to focus on customer requirements, including prioritization, after identifying and quantifying customer requirements, key critical parameters can be developed. In Six Sigma, the QFD also helps to prioritize actions to improve processes or products to meet customers' expectations. In summary, Six Sigma teams can better focus on what is really important to the customer by utilizing this approach.

15. Production Planning and Control (PPC):

Planned production is an important feature either in small and big industries. The companies possessing the ability to look ahead, organize and coordinate plenty of driving force and capacity to lead, supervise and coordinate work simulating associates by means of a programme of human relation and organization of employees, to be able to get the best out of an industrial unit.

Production, Planning and Control (PPC): Involve generally the manufacturing process. Especially it consists of the planning of routing, scheduling, dispatching inspection, and coordination, control of materials, methods machines, tools and operating times. The ultimate objective is the organization of the supply and movement of materials and labor, machines utilization and related activities, in order to bring about the desired manufacturing results in terms of quality, quantity, time and place.



15.1. Optimum Utilization of Capacity:

With the help of Production Planning and Control (PPC**)** the company can schedule his tasks and production runs and thereby, ensure that his productive capacity does not remain idle and there is no undue queuing up of tasks, via proper allocation of tasks to the production facilities. No order goes unattended and no machine remains idle.

- **Inventory control**: Proper PPC will help the company to resort to just-in-time systems and thereby reduce the overall inventory. It will enable him to ensure that the right supplies are available at the right time.
- **Economy in production time**: PPC will help the company to reduce the cycle time and increase the turnover via proper scheduling.
- **Ensure quality**: A good PPC will provide for adherence to the quality standards so that quality of output is ensured. PPC is of immense value in capacity utilization and inventory control. More importantly it improves his response time and quality. An effective PPC contributes to time, quality and cost parameters of entrepreneurial success.

15.2. Steps for Implementing PPC:

Production planning (PPC) may be defined as the technique of foreseeing every step in a long series of separate operations, each step to be taken at the right time and in the right place and each operation to be performed in maximum efficiency. It helps entrepreneur to work out the quantity of material manpower, machine and money requires for producing predetermined level of output in given period of time.

Scheduling: It means working out of time that should be required to perform each operation and also the time necessary to perform the entire series as routed, making allowances for all factors concerned. It mainly concerns with time element and priorities of a job. The pattern of scheduling differs from one job to another which is explained as below:

Production schedule: The main aim is to schedule that amount of work which can easily be handled by plant and equipment without interference. It´s not independent decision, as it takes into account following factors.

- Physical plant facilities of the type required to process the material being scheduled.
- Personnel who possess the desired skills and experience to operate the equipment and perform the type of work involved.
- Necessary materials and purchased parts.

Master Schedule: Means a weekly or monthly break-down of the production requirement for each product inside a definite time period commonly designated as **master schedule**. A master schedule is followed by the **scheduling** which fixes total time required to do a piece of work with a given machine or shows the time required to do each detailed operation of a given job with a given machine or process.

Manufacturing schedule: It is prepared on the basis of type of manufacturing process involved. It is very useful where single or few products are manufactured repeatedly at regular intervals. Thus it would show the required quality of each product and sequence in which the same to be operated.

Scheduling of Job order manufacturing: Scheduling acquires greater importance in job order manufacturing. This will enable the speedy execution of job at each center point.

Loading: The next step is the execution of the schedule plan as per the route chalked out it includes the assignment of the work to the operators at their machines or work places. So loading determines who will do the work as routing determines where and scheduling determines when it shall be done. Gantt Charts are most commonly used in small industries in order to determine the existing load and also to foresee how fast a job can be done.

Dispatching: Dispatching involves issue of production orders for starting the operations. Necessary authority and conformation is given for:

- Movement of materials to different workstations.

- Movement of tools and fixtures necessary for each operation.
- Beginning of work on each operation.
- Recording of time and cost involved in each operation.
- Movement of work from one operation to another in accordance with the route sheet.
- Inspecting or supervision of work

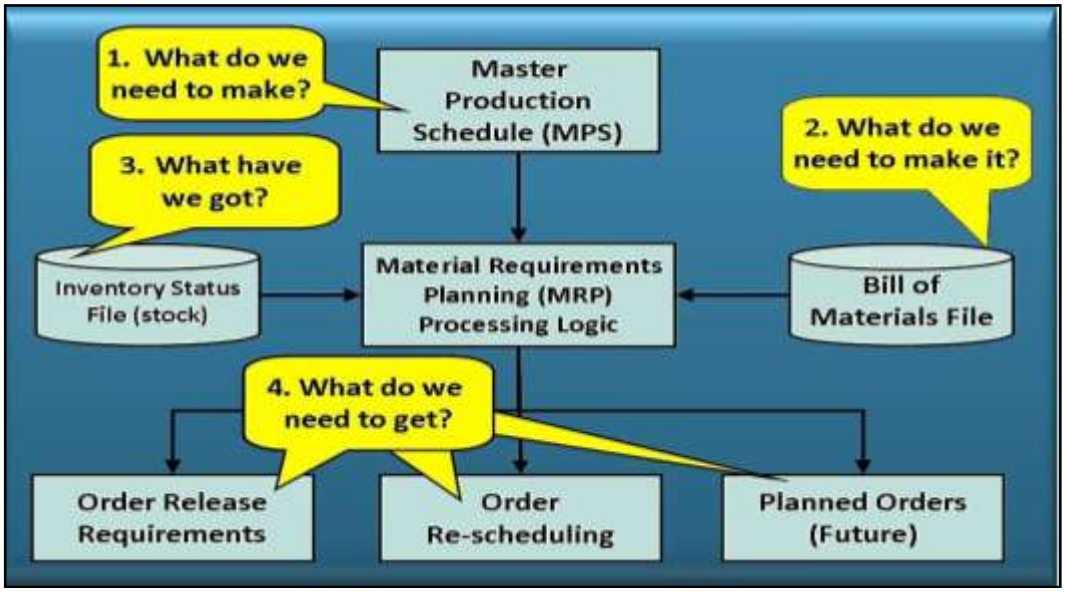
Follow up: means that the productive operations should take place in accordance with the plans and ensuring the flow of work. It spots delays or deviations from the production plans. Every production programme involves determination of the progress of work, removing the bottle necks

Inspection & Quality: This is mainly to ensure the quality of goods. It can be required as effective agency of production control.

Corrective measures: Corrective action may involve any of those activities of adjusting the route, rescheduling of work changing the workloads, repairs and maintenance of machinery or equipment, control over inventories of the cause of deviation is the poor performance of the employees. Certain personnel decisions like training, transfer, demotion etc. may have to be taken.

16. Enterprise Resource Planning (ERP):

ERP is a software architecture that facilitates the flow of information among the different functions within an enterprise. Similarly, ERP facilitates the communication sharing across organizational units, geographical locations and enables decision-makers to have an enterprise-wide view of the information they need in a timely, reliable and in a consistent fashion.



ERP facilitates internal and external management of information across an entire organization-embracing finance/accounting, manufacturing, sales, services, customer relationship, production schedule, materials, management and procurement. ERP also facilitates the communication flow between all business functions, starting inside the organization and with managers connections to outside stakeholders.

Enterprise system software is a multi-billion dollar industry that produces components that support a variety of business functions. IT investments have become the largest category of capital expenditure in United States-based businesses over the past decade. Enterprise systems are complex software packages that offer the potential of integrating data and processes across functions in an enterprise.

Organizations consider the ERP system their backbone, and a vital organizational tool because it integrates varied organizational systems, and enables flawless transactions and production. However, an ERP system is radically different from traditional systems development. ERP systems can run on a variety of computer hardware and network configurations, typically employing a database as a repository for information.

16.1. ERP Origin of:

In 1990, the Gartner Group first employed the acronym ERP as an extension of **Material Requirements Planning (MRP)**, later Manufacturing Resource Planning and Computer-Integrated Manufacturing. Without supplanting these terms, ERP came to represent a larger whole, reflecting the evolution of application integration beyond manufacturing.

Not all ERP packages were developed from a manufacturing core. Vendors variously began with accounting, maintenance, and human resources. By the mid-1990 ERP systems addressed all core functions of an enterprise. Beyond corporations, governments and non–profit organizations also began to use ERP systems.

16.2. ERP Expansion:

ERP systems experienced rapid growth in the 1990s because the year 2000 problem and introduction of the euro disrupted legacy systems. ERP systems initially focused on automating *back of office functions* that did not directly affect customers and the general public. Customer Relationship Management (CRM), dealt directly with customers, or e-business systems such as e-commerce, e-govern-ment, e-telecom, and e-finance, or supplier relationship management (SRM) became integrated later, when the Internet simplified communicating with external parties.

"ERP II" was coined in the early 2000s. It describes web–based software that provides employees and partners (such as suppliers and customers) with real–time access to ERP systems. The ERP II role expands traditional ERP's resource optimization and transaction processing. ERP II is more flexible than the first generation ERP. Rather than confine ERP system capabilities within the organization, it goes beyond the corporate walls to interact with other systems.

16.3. Two-tier Enterprise Resource Planning:

The Two-tier ERP software and hardware lets companies run the equivalent of two ERP systems at once: one at the corporate level and one at the division or subsidiary level. For example, a manufacturing company uses an ERP system to manage across the organization. This company uses independent global or regional distribution, production or sales centers, and service providers to support the main company's customers. Each independent center or subsidiary may have their own business model, worflows, and business processes.

16.4. Material Requirement Planning - MRP I:

Is a software specifically developed for the production industry, with the objective of keeping adequate stocks and the production lines in great activity. The use mathematical techniques related to industrial process engineering, knowledge through a default demand, make the future planning of raw materials and production steps. The MRP I system is intended to simultaneously meet three objectives:

- Ensure materials and products are available for production and delivery to customers.
- Maintain the lowest possible level of inventory.
- Plan manufacturing activities, delivery schedules and purchasing activities.

16.5. Manufacturing Resource Planning - MRP II:

Is the development of MRP I, where it was added to this resource several allocation tool resources and costing activity-based **costing product structure**, where the cost of raw material and resources are used for the production stages. Generally, MRP II refers to a system with **integrated financials**. An MRP II system can include finite or infinite capacity planning. But, to be considered a true MRP II, the system must also include the **financial tools**.

In the MRP II concept, fluctuations in forecast data are taken into account by including simulation of the master production schedule, thus creating a long-term control. A more general feature is its extension to purchasing, to marketing and to finance (integration of all the function of the company), where ERP has been the next step.

16.6. MRP I and MRP II Relationship:

Material Requirements Planning (MRP I) and Manufacturing Resource Planning (MRP II) are predecessors of Enterprise Resource Planning (ERP), a business information integration system. Both MRP I and MRP II are still widely used, independent and as modules of more comprehensive ERP systems, but the original version began with the development of MRP I and MRPII in manufacturing. The development of these manufacturing and integration methods and tools made the ERP systems possible.

16.7. Manufacturing Resource Planning - MRP III:

The 'M.R.P. III' process begins with an Accurate Demand Forecast, that drives the remainder of the business. Using the best possible demand forecast, a **Master Schedule** is developed. The total number of **master scheduled items** will be minimized, so that the M.R.P. system can appropriately generate build schedules for components and 'accessories' **automatically**, derived directly from the Demand Forecast with little or no changes.

The Master Schedule, the '*M.R.P. III*' system derives the individual component and assembly requirements, and recommends new purchase orders, just like a '*standard M.R.P.*', and also generates recommended purchase order and automatically re-schedules a non-master scheduled assemblies, based on the availability of components/resources and material requirements, like an MRP II system.

Finally, the '*M.R.P. III*' system bases its operating parameters on the principles of Bandwidth Management, dynamically adjusting parameters and 'ideal inventory' according to the historic data, measuring performance to a set of statistically derived 'control bands', rather than fixed parameters. A process such as '*M.R.P. III*' would help to eliminate certain kinds of errors that currently plague manufacturing businesses on a nearly universal level.

17. Advanced Product Quality Planning - APQP:

APQP (Advanced Product Quality Planning) is a structured method of defining and establishing the steps necessary to ensure that a product satisfies the customer involving 75% up front planning, and 25% implementation through production, to determine customer satisfaction and continuous improvement. Although APQP is generally associated with the **automotive industry**, this quality planning process can be applicable within all industries.

17.1. APQP Advantages:

The APQP facilitates communication between the supplier and the customer to clarify requirements that translate into more detailed specifications. Example of APQP - product activities communicating special characteristics to design activity, prior to design release, linking the DFMEA to PFMEA.

The first attempt of APQP is to ensure quality through the use of work practices, tools, and analytical techniques. The second attempt is to develop Quality controls if discovered risks have not been adequately mitigated. All activities within the APQP process must occur prior to the start of manufacturing or process start-up. The main steps are:

- ✓ **Plan**: acquire and install appropriate process equipment and tooling based on design tolerances provided by the customer.
- ✓ **Assembly**: better ways to assemble a product prior to the completion of the design of the product with personnel communicating suggestions.
- ✓ **Process Engineering**: establishes adequate Quality Controls for features of a product or parameters of a process, which still risk potential failure.
- ✓ **Performance**: special characteristics to understand the variation present and predict future performance.

17.2. APQP Relationship:

This process is never ending and it is also often illustrated with the Plan, Do, Study, Act Cycle (PDCA). Each section has analytical techniques and tools used to discover risk and weakness. The APQP team members should be able to review each risk, and take actions to reduce or eliminate the potential failure.

Aspects of pre-planning include, the scope of the project, team size and capability, methods for concern resolution, general rules, team structure, space and resources required, and timing of the project. The tools selected during the Product Assurance Plan are assigned and used within or collaboratively between sections. FMEA (Failure Mode and effects Analysis) provides a good example of a crossover or collaborative tool. The five main sections of APQP are:

- ➢ Plan and Define;
- ➢ Product Design and Development;
- ➢ Process Design and Development;
- ➢ Product and Process Validation;
- ➢ Feedback, Assessment and Corrective Action.

Each section has inputs, outputs and gateway reviews with management. Gateways are timed to coincide with key decisions impacting project Quality, Cost or Delivery. The APQP culminates in a sample submission, as evidence that the product quality has an achieved plan. This activity is called **PPAP** (Product Part Approval Process).

The **PPAP** highlights the proof or evidence collected and validated with results from the first trial run. The trial run cannot be a prototype. This trial must represent the production environment, with correct tools, machines, processes, personnel and conditions that may affect part quality. The PPAP and APQP **cannot be separated**, as PPAP documents the results, and provides evidence that the APQP has been successfully performed.

APQP is also related to **NPI** (New Product Introduction), **DFSS** (Design for Six Sigma) and other Product Development Processes are potentially the same development tools. The APQP is a Product Development Process designed to stand alone, as a default process or support supplier, engagement of a NPI activity. The DFSS is a highly focused effort reserved for high value requirements or specifications when a great deal of visibility is required for success.

18. Production Part Approval Process (PPAP):

The PPAP is the confirmation that the product meets the customer requirements for a production in series. Commonly used in the automotive supply chain to establish confidence in component suppliers and

their production processes designed to demonstrate that the component supplier has developed their design and production process to meet the client's requirements, minimizing the risk of failure by effective use of APQP.

18.1. The PPAP Package:

The PPAP package is various documents which need a formal approval by the supplier and customer. The form of this package is called PSW (Part Submission Warrant) to indicate that the supplier with his responsible person (usually the Quality Engineer) has reviewed this package and the customer has not identified any issues that would prevent its approbation.

The PPAP will be considered signed when a full PSW is approved by your customer and added to the PPAP folder to confirm that all suppliers have properly understood the design and specification requirements for the components they furnish, and that the provider´s process has the capability to consistently deliver products that comply with those requirements. The result is a series of documents gathered in one specific location called the "PPAP Package".

This documentation is closely related to APQP during the design and development of new vehicles and component systems to reduce the risk of unexpected failure due to errors in design and manufacture. Suppliers are required to obtain PPAP approval from the vehicle manufacturers whenever a new or modified component is introduced to production, or the manufacturing process is changed. Obtaining approval requires the supplier to provide sample parts and documentary evidences, showing that:

1) The client's requirements have been understood;
2) The product supplied meets those requirements;
3) The process (including sub suppliers) is capable of producing conforming product;
4) The production control plan and quality management system should prevent non-conforming products or compromising the safety and reliability of finished vehicles.

19. Measurement System Analysis (MSA):

Is a special designed process of obtaining measurements and data that seeks to identify the components of variation in the measurement and produce defects. This measurement system evaluates the test method, and the entire process of obtaining measurements to ensure the integrity of data used for analysis (usually quality analysis) and to understand the implications of measurement error for decisions ma- de about a product or process.

The MSA is an important element of Six Sigma and other quality management systems. This methodology analyzes the collection of equipment, operations, procedures, software and personnel that affects the assignment of a number to a measurement characteristics, and considers the following:

- Selecting the correct measurement and approach;
- Assessing the measuring device;
- Assessing procedures and operators;
- Assessing any measurement interactions;

Calculate the measurement uncertainty of measurement devices and measurement systems. The measurements may include:

- ✓ **Equipment**: measuring instrument, calibration, featuring, etc.
- ✓ **People:** operators, training, education, skills, safety, etc.
- ✓ **Process**: test method, specifications, procedures, etc.
- ✓ **Samples**: materials, items to be tested, sampling devices, sample preparation, etc.

- ✓ **Environment**: temperature, humidity, air conditioning, etc,
- ✓ **Management**: training programs, metrology, workers support, quality management systems, etc.

Note: The measured elements can be plotted in a "fishbone" Ishikawa diagram to help identify potential sources of measurement variation.

20. Poka-Yoke:

Is a Japanese term that means "mistake-proofing" that helps an equipment operator "*avoid"* (*yokeru*) "*mistakes"* (*poka*). The main purpose is to **eliminate product defects** by preventing, correcting, or drawing attention to human errors as they occur. The concept was formalized, and the term adopted, by Shigeo Shingo as part of the Toyota Production System, originally described as "*baka-yoke"*, but as this means "fool-proofing" the name was changed to the milder "*poka-yoke"*.

Defines an approach to prevent mistakes. "*Mistake-proofing"* are means built into a process to prevent errors from one stage of the process to another (such as automatic rejects, etc.) and also prevent the process from making a set of mistakes. The *Poka-yoke* is used where there are human interactions or interventions, with repetitive tasks, requiring physical manipulations and errors have previously occurred, as a tool for predictable mistakes.

20.1. Poka-Yoke in Service Companies:

Poka-yoke can also be implemented in service companies. *Call centers* have long had a challenge with compliance, poor training, fatigue, forgetfulness, and the limits on human consistency. All of these can add to agents skipping the main key steps in the working process. Disclosures are a good example. When a consumer makes a purchase of some kind, the *call center* agent is often required to provide the customer with key information. What the customer purchases dictates the disclosures that are required.

It can be hard to train the agents in all the required combination of disclosures or the agents can sometimes forget to read the disclosures. Using agent-assisted automation, the agents can provide the customers with all the required disclosures using pre-recorded audio files. By integrating the agent-assisted automation with the customer relationship management software, you can ensure that the agent cannot process/complete the order until the required disclosures are played.

21. Operational Equipment Effectiveness (OEE):

The OEE methodology focuses on improving the performance of equipment and machinery, as well as avoiding making the wrong purchases and focuses on the greatest areas of improvement that will have the greatest return. The OEE can be expressed by A, B, C, where A = Availability, B = Performance Rate, and C = Quality Rate used to illustrate how improvements will result in better change overs, reliability, quality, etc., based on production rates or schedule.

Note: The OEE production is equals the actual output (of an acceptable quality) divided by theoretical scheduled output, while the OEE schedule is equals the actual process time divided by theoretical process time.

22. Total Productive Maintenance (TPM):

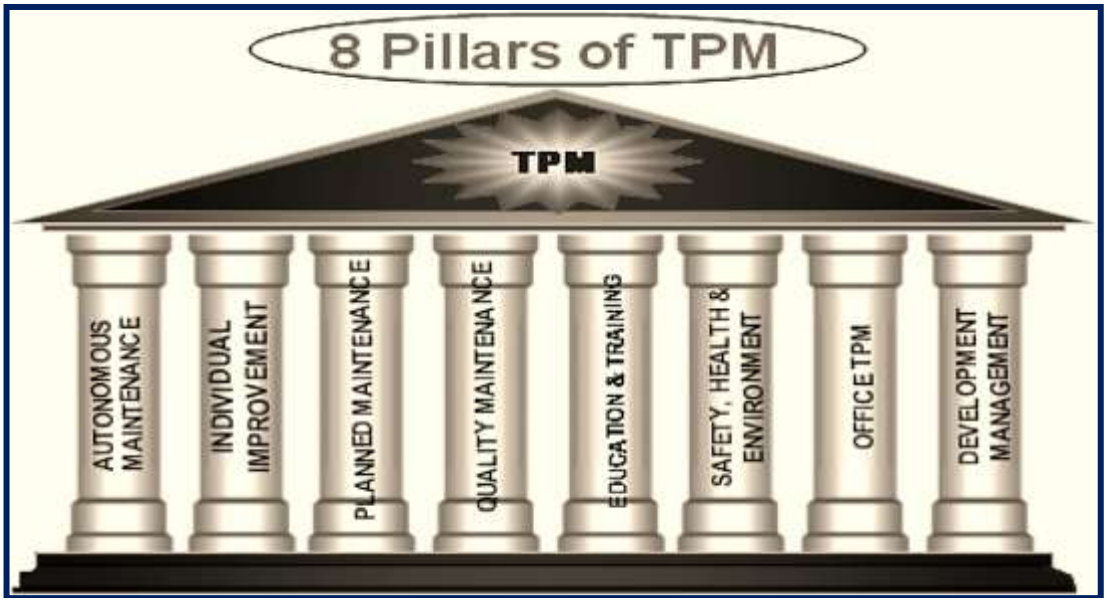
Was originated in Japan in 1971 as a method for improvement of machine availability through better utilization of maintenance and production resources. TPM includes Preventive and Predictive Maintenance. Preventive Maintenance includes intelligently performing necessary maintenance at appropriate intervals before failure occurs.

One way to think of TPM is "deterioration prevention": what happens naturally to anything that is not "taken care of". For this reason many people refer to TPM as "total productive manufacturing" or "total process management". TPM is a proactive approach that essentially aims to identify issues as soon as possible and plan to prevent any issues before occurrence.

In TPM the machine operator is trained to perform many of the day-to-day tasks of simple maintenance and fault-finding. Teams are created that include a technical expert (often an engineer or maintenance technician) as well as operators. In this setting the operators are enabled to understand the machinery and identify potential problems, righting them before they can impact production and by so doing, decrease downtime and reduce costs of production.

TPM is a critical adjunct to lean manufacturing. If machine uptime is not predictable and if process capability is not sustained, the process must keep extra stocks to buffer against this uncertainty and flow through the process will be interrupted. Unreliable uptime is caused by breakdowns or badly performed maintenance. Correct maintenance will allow uptime to improve and speed production through a given area allowing a machine to run at its designed capacity of production.

A CMMS (Computerized Maintenance Management System) is helpful in keeping track of work-orders, including recording and automatically issuing work-orders at the appropriate time. Predictive Maintenance is performed based on gathered data (such as vibration analysis, etc.).



23. General Quality Development:

- **Advanced Product Quality Planning (APQP)**
- Collaborative Product Process Design (CPPD)
- Control Plan Methodology
- Design for Assembly & Manufacturing (DFA/M)
- Design for Six Sigma (DFSS)
- Design Verification & Validation (DVP&R)
- Error / Mistake Proofing (Poka Yoke)

- Experimental Design / Design of Experiments (DOE)
- **Failure Mode & Effects Analysis (FMEA)**
- Failure Mode & Effects Criticality Analysis (FMECA)
- Failure Mode Avoidance (FMA)
- Fault Tree Analysis (FTA)
- Geometric Dimensioning & Tolerances (GD&T)
- **ISO 26262**
- New Product Introduction (NPI)
- Product Liability Overview
- Quality Core Tools
- Quality Function Deployment (QFD)
- Reliability Calculations of Systems
- Robust Engineering (Boundary Diagrams – Parameter Diagrams – Interface Analysis)
- Special Characteristics
- Systems Engineering
- Technical Kick-off (TKO)
- Tolerance Design / Root Sum Squares (RSS)

23.1 Improvement:

- Continuous Process Improvement (CPI)
- Control Plan Methodology
- Cost of Quality / Cost of Non Quality
- Failure Mode & Effects Analysis (FMEA)
- Gage Repeatability & Reproducibility (GR&R)
- Internal Auditing & Assessment
- Kaizen
- **Lean Operations**
- Life Cycle Costs (LCC)
- Measurement Systems Analysis (MSA)
- Organization & Standardization of the Work Area (5S)
- Process Kick-off (PKO)
- Process Mapping / Process Flow
- Production Part Approval Process (PPAP)
- Quality Core Tools
- Quality Function Deployment (QFD)

- Quality Management Systems
- Reliability & Maintainability (R&M)
- **Six Sigma (DMAIC)**
- **Six Sigma (DMADV)**
- Special Characteristics
- Standard Work Practices
- **Statistical Process Control & Process Capability (SPC)**
- Value Stream Mapping

23.2 Corrective Actions:

- **5 Why**
- Continuous Process Improvement (CPI)
- **Eight Disciplines of Problem Solving (8D)**
- Error / Mistake Proofing (Poka Yoke)
- Kaizen
- Process Mapping / Process Flow
- **Root Cause Analysis (RCA)**
- Standard Work Practices
- Value Stream Mapping

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