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**POLO TERRITORIALE DI COMO**

Integration of Six Sigma and ISO 9001 Quality Management System

Case Study: Wire Manufacturing Industry Ltd.

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## Abstract:

The Six Sigma concept alongside with the quality management system ISO 9001 would be the beneficial approaches to reduce or eliminate defects in the industrial processes. They are simplified and focused through using the simple tools and identifying the most critical issue in each process. The literature of Six Sigma, quality management system ISO 9001 is explained in detailed in this thesis. Company literature review done and a systematically approach designed to compare it with the different clause of the ISO 9001 and six sigma. Many companies, who have started with ISO 9000, have added the practices and principles of Six Sigma together, they have many synergies and Six Sigma is a natural step in the evolution of continues improvement at an ISO 9000 company. To know the opinions of the profession about our topic, we develop some question and did LinkedIn survey to find out synergies between six sigma and ISO 9001:2008.

In our cases we discovered that how the quality management system reacts with the nonconformities and DMAIC is very useful tool to improve the process in the manufacturing industry. Each DMAIC phase is totally interrelated with each other phases and the decisions that are taken in the beginning drives the rest of the project.

We observed that now it is the best and right time to integrate the Six Sigma and quality management system to boost the industry. With present economic conditions companies have to cut their bottom line costs to be remained profitable and this new concept gives a chance to firms not only stay alive but also become more powerful, efficient and competitive.

**KEYWORDS:** Six Sigma, ISO 9001, Quality Management system, Integration, Case

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For any errors or inadequacies that may remain in this work, of course, the responsibility is entirely my own.

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# Chapter 1

## WHAT IS QUALITY?

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### Definitions

We are likely to know what quality is when we see or experience it. We are also more likely to ponder the real meaning of the word when we buy something that fails to do what we originally bought it to do. We thus judge quality by making comparisons, based on our own experiences, but defining it in terms that convey the same meaning to others can be difficult. There are a number of definitions in use, each of which is valid when used in a certain context.

A degree of excellence (OED) – The meaning used by the general public.

Freedom from deficiencies or defects (Juran) – The meaning used by those making a product or delivering a service

Conformity to requirements (Crosby) – The meaning used by those designing a product or a service or assessing conformity

Fitness for use (Juran) – The meaning used by those accepting a product or service  
Fitness for purpose (Sales and Supply of Goods Act 1994) – The meaning used by those selling and purchasing goods

The degree to which a set of inherent characteristics fulfils requirements (ISO

9000:2005) – The meaning used by those managing or assessing the achievement of quality

Sustained satisfaction (Deming) – The meaning used by those in upper management using quality for competitive advantage.

There are other ways in which we think of quality. Masaaki Imai in his book on Kaizen writes that “when speaking of quality one tends to think first of product quality” and this is indeed the most common context for quality. But Imai goes on to write “when discussed in the context of KAIZEN strategy the foremost concern is with the quality of people”.

### Internationally Agreed Definitions

In 1987, ISO 8402 defined quality as the totality of characteristics of an entity that bear on its ability to satisfy stated or implied needs. Although superseded by the definition in ISO 9000:2005 below, in principle it remains relevant even if a little verbose.

### Introduction to ISO 9001 QMS

ISO 9000 series of standards, popularly known, as ‘Documented Quality Management Systems’ were amended and new guidelines for implementation of Quality Management Systems were released in November 2008, with slight changes from ISO 9001:2000. ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. All the certified companies and the companies to be certified a fresh, need to adopt the amended guidelines. This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.



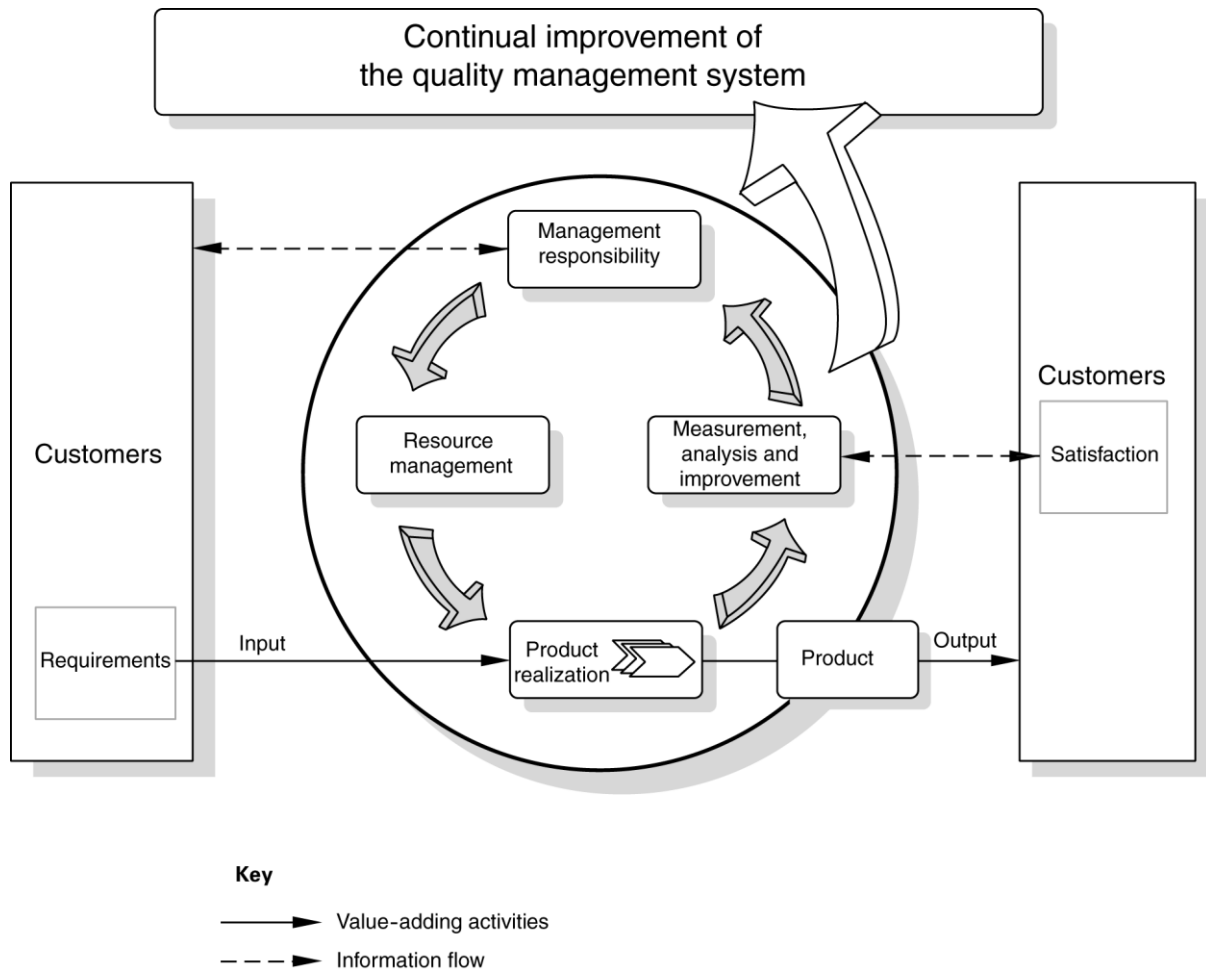


Figure 1 Quality management system ISO 9001 Model

## PDCA Cycle

The actual results of an action are compared with a target or a set point in the central process. The difference between the two is then mentioned, if the difference becomes large then corrective measures are adopted to reduce the variation. The repeated and continuous nature of continuous improvement follows this usual definition of control and is represented by the PDCA (Plan-Do-Check-Act) cycle. This is also referred to as the Deming circle, named after W. E. Deming.



Figure 2 PDCA Cycle

The application of the PDCA cycle has been found more effective than adopting “the right first time” approach. Using of the PDCA cycle means continuously looking for better methods of improvement. The PDCA cycle is effective in both doing a job and managing a programme. The PDCA cycle enables two types of corrective action – temporary and permanent. The temporary action is aimed at results by practically tackling and fixing the problem. The permanent corrective action, on the other hand, consists of investigation and eliminating the root causes and thus targets the sustainability of the improved process. The aspects of the PDCA cycle were applied to internal quality-assurance procedures. Figure 1 shows the PDCA cycle in detail. In the Do stage or implementation stage it is possible to involve a mini PDCA cycle until the issues of implementation are resolved.

The PDCA cycle is more than a tool, it is a concept of continuous improvement processes embedded in the organization’s culture. The most important aspect of PDCA lies in the “act” stage after the completion of a project when the cycle starts again for the further improvement.

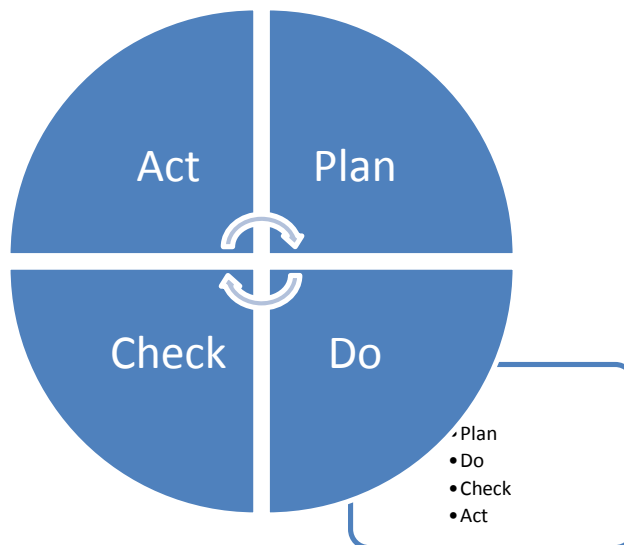


Figure 3 Advanced PDCA Cycle

While Deming's PDCA cycle has been extensively used in the development of quality policies, DMAIC (Six Sigma) and DMADV (DFSS) have added the rigor of project life-cycle (PLC) to the implementation and close-out of Six Sigma projects

## Relationship with ISO 9004

ISO 9001 and ISO 9004 are quality management system standards which have been designed to complement each other, but can also be used independently.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.

The standards have 8 clauses known as QMS requirements as follows:

1. Scope
2. Normative reference
3. Terms and definitions
4. Quality management system
5. Management responsibility
6. Resource management
7. Product realization
8. Measurement, analysis and improvement.

## Scope

The *scope* of the standard specifies the requirements of quality management systems, where an organization needs to demonstrate its ability to consistently provide the product and services that meets the customers and applicable statutory, legal and regulatory requirements, and aims to enhance customer satisfaction through the effective application of the system. This includes processes for continual improvement and assurance of conformity to customer and applicable regulatory requirements. Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion. Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

### 1. Normative reference

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document

(Including any amendments) applies.

ISO 9000:2005, Quality management systems — Fundamentals and vocabulary

### 2. Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 apply. Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

Statutory and regulatory requirements can be expressed as legal requirements.

### 3. Quality management system

#### *3.1 General Requirements*

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall determine the processes, sequence and interaction, criteria and methods, availability of resources and information, monitor, measure, control and analyse for the processes for quality management system requirements. If any of the processes is outsourced, shall be managed by the organization in accordance with the requirements of this International Standard.

### *3.2 Documentation Requirements*

#### *3.2.1 General*

The quality management system documentation shall include quality policy, quality objectives, quality manual, procedures and records and documents ensuring the effective planning, operation and control of its processes.

#### *3.2.2 Quality Manual*

The organization shall establish and maintain a quality manual that includes the scope of the quality management system, including details of and justification for any exclusions, documented procedures and interactions between the processes of Quality Management Systems.

#### *3.2.3 Control of documents*

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements as per requirements the use and need of the documents shall be controlled.

#### *3.2.4 Control of records*

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

## **4. Management responsibility**

### *4.1 Management commitment*

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by meeting customer and legal requirements, establishing the quality policy and Quality objectives, conducting management reviews and ensuring the availability of resources.

### *4.2 Customer focus*

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

### *4.3 Quality policy*

Top management shall ensure that the quality policy is appropriate to the purpose of the organization, meet the requirements of QMS, framework for establishing objectives, communicated and understood within the organization and is reviewed for continuing suitability.

## **4.4 Planning**

### 4.4.1 Quality objectives

Top management shall ensure that quality objectives are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

### 4.4.2 Quality management system planning

Top management shall ensure that the planning of QMS is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and integrity of QMS is maintained.

## **4.5 Responsibility, authority and communication**

### 4.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

### 4.5.2 Management representative

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority. Management representative is a key person in the implementation of ISO 9000 systems in any company.

### 4.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

## **4.6 Management review**

### 4.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

### 4.6.2 Review input

The input to management review shall include results of audits, customer feedback, process performance and product conformity, status of preventive and corrective actions, follow-up

actions from previous management reviews, changes that could affect the quality management system and recommendations for improvement.

#### 4.6.3 Review output

The output from the management review shall include improvement of the effectiveness of the quality management system and its processes, improvement of product related to customer requirements and resource needs.

## 6 Resource management

### 6.1 Provision of resources

The organization shall determine and provide the resources needed to implement and maintain QMS and for Customer satisfaction.

### 6.2 Human resources

#### 6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

#### 6.2.2 Competence, training and awareness

The organization shall determine the necessary competence for personnel performing work affecting conformity to product requirements, provide training, evaluate the effectiveness of the actions taken and maintain appropriate records of education, training, skills and experience.

### 6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, buildings, workspace and associated utilities, process equipment and supporting services.

### 6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

## 7 Product realization

### 7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system

## **7.2 Customer-related processes**

### **7.2.1 Determination of requirements related to the product**

The organization shall determine requirements specified by the customer, including the requirements for delivery and post-delivery activities, not stated by the customer, legal requirements and other requirements set by the organization.

### **7.2.2 Review of requirements related to the product**

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer and shall ensure that product requirements are defined and the organization has the ability to meet the defined requirements.

### **7.2.3 Customer communication**

The organization shall determine and implement effective arrangements for communicating with customers in relation to product information, enquiries, contracts or order handling, including amendments, and customer feedback, including customer complaints.

## **7.3 Design and development**

### **7.3.1 Design and development planning**

The organization shall plan and control the design and development of product and determine the design and development stages, the review, verification and validation the responsibilities and authorities for design and development.

### **7.3.2 Design and development inputs**

Inputs relating to product requirements shall be determined and records maintained these inputs shall include functional and performance requirements, legal and other R & D requirements.

### **7.3.3 Design and development outputs**

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall meet input requirements for design and development, provide appropriate information for purchasing, production and service provision, product acceptance criteria and specify the characteristics of the product that are essential for its safe and proper use.



#### 7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements to evaluate the ability of the results of design and development to meet requirements, and to identify any problems and propose necessary actions.

#### 7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.

#### 7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained.

#### 7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained.

### **7.4 Purchasing**

#### 7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

#### 7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, requirements for approval of product, procedures, processes, equipment, qualification of personnel and QMS requirements.

#### 7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

### 7.5 Production and service provision

#### 7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, the availability characteristics of the product, work instructions, the use of suitable equipment, monitoring and measuring equipment, the implementation of product release, delivery and post-delivery activities.

#### 7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

The organization shall establish arrangements for these processes including, defined criteria for review and approval of the processes, approval of equipment and qualification of personnel, use of specific methods and procedures, requirements for records and revalidation.

#### 7.5.3 Identification and traceability

The organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization. Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records.

#### 7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify,

verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records.

#### 7.5.5 Preservation of product

The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

### 7.6 Control of monitoring and measuring equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

## 8 Measurement, analysis and improvement

### 8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed conformity to product requirements, to ensure conformity and continually improve the effectiveness of QMS.

### 8.2 Monitoring and measurement

#### 8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

#### 8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system conforms to the planned arrangements to the requirements of Standard and to the QMS requirements established by the organization, and is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

#### 8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

#### 8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of product for delivery to the customer. The release of product and delivery of service to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

### **8.3 Control of nonconforming product**

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

The organization shall deal with nonconforming product by one or more of the ways by taking action to eliminate the detected nonconformity, by authorizing its use, release or acceptance under concession by a relevant authority, by taking action to preclude its original intended use or application, by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started. When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

### **8.4 Analysis of data**

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to customer satisfaction, conformity to product requirements, characteristics and trends of processes and products, including opportunities for preventive action and supplier.

## **8.5 Improvement**

### 8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

### 8.5.2 Corrective action

The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for reviewing nonconformities, determining the causes of nonconformities, evaluating the need for action to ensure that nonconformities do not recur, determining and implementing action needed, records of the results of action taken, reviewing the effectiveness of the corrective action taken.

### 8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for determining potential nonconformities and their causes, evaluating the need for action to prevent occurrence of nonconformities, determining and implementing action needed, records of results of action taken and reviewing the effectiveness of the preventive action taken.

## Chapter 2

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### 2.1. Introduction (6 $\sigma$ )

The rapid changing economic conditions such as demand for high quality product, product variety, reduced lead time, declining profit margin and global competition has major impact on manufacturing industries. To respond to these needs various industrial engineering and quality management strategies have been developed over the years, such as ISO 9000, Total quality management, Kaizen, Just-in-time manufacturing, Enterprise resource planning, Business process re-engineering, lean management etc. A new concept in this area of process strategies is six sigma. The six sigma approach has been increasingly adopted worldwide to enhance productivity and quality performance and to make process robust to quality variations.

Six sigma is originated at Motorola in early 1980s in response to achieving 10X reduction in product failure level in five years. Engineer Bill Smith of Motorola invented Six Sigma and dies in 1993 never knowing the massive scope of its implementations, success and controversies. Six sigma is based on various quality management theories such as Deming's 14 points for management, Juran's 10 steps on achieving quality etc.

The word sigma ( $\sigma$ ), is a Greek alphabet and used as a statistical term which measures that how far a given process deviated from perfection. In statistics sigma is the symbol of the Standard division (SD). Standard division is the process of measure the variation or desperation from the average, low value of sigma indicated that data point tend to be very close to the mean and high sigma value indicates that the data points spread over a large range of values. The principal idea behind six sigma is that if we can measure how many defects we have in a process, we can systematically figure out how to eliminate them and get close to zero defects as much as practically possible. The aim of six sigma strategy is to reduce the defects to as low as 3.4 occasion per million opportunities and in percentage 99.9997% perfection.

One Sigma ( $\sigma$ ), represents 34.134% of a data point. Six sigma is a rigorous and highly effective tool or methodology to eliminate the waste and inefficiency in the system, increases the customer satisfaction by delivering what the customer wants. Main goal of the six sigma is to identify, isolate and eliminate variation of defects in the product and services.

The process shown in the figure within one standard deviation from the mean will have the probability 68.26%. The probability is 95.44% that the same next value will fall within two standard divisions. The probability is 99.73% that it will be within three sigma and the 6 sigma covers the area of the 99.9997%.

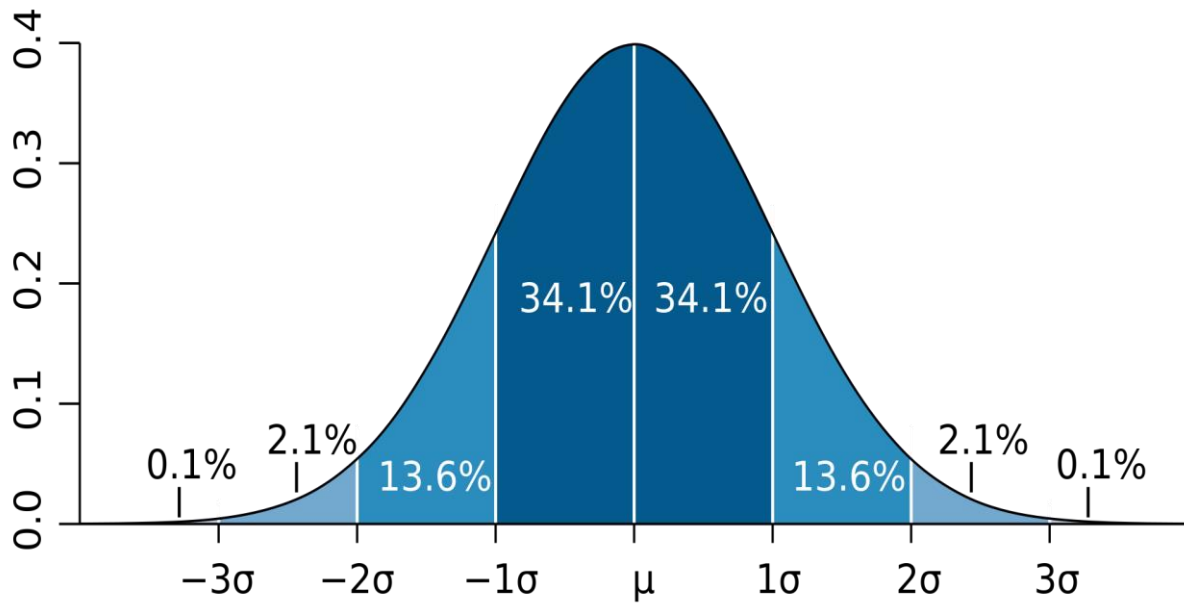


Figure 4 Six sigma Distribution curve

Six sigma strategy is the latest and most effective technique in the management scope and quality engineering. It enables organizations to make meaningful and considerable improvements in their bottom line by designing and monitoring everyday business activities in ways which minimizes all types of wastes and non-value added activities and maximizes customer satisfaction. Voelkel, J.G contents that six sigma blends correct management, financial and methodological elements to make improvements in process and products in ways that surpass other approaches. Six sigma is a strategic initiative to boost profitability, increase market share and improve customer satisfaction through statistical tools that can lead to breakthrough quantum gains in quality; Mark Harris (2000). Mostly led by practitioners, six sigma has acquired a strong perspective stance with practices often being advocated as universally applicable. Six sigma has a major impact on the quality management approach while still based in the fundamental methods and tools of traditional quality management (Goh and Xie, 2004). Park (1999) believes that six sigma is a new paradigm of management innovation for company's survival in 21<sup>st</sup> century, which implies three things: statistical measurement, management strategy and quality culture.

Six sigma is a business improvement strategy used to improve profitability, to drive out waste, to reduce quality cost & improve the effectiveness and efficiency of all operational processes that meets or exceeds customer's needs & expectations (Antony and Banuelas, 2001). Tomkins (1997) defines six sigma as a program aimed at the near elimination of defects from every product, process and transaction. Snee (2004) define six sigma as a business improvement approach that seeks to find and eliminate causes of mistakes or defects in business process by focusing on process outputs that are critical importance to customers.

At its simplest six sigma is: A program to accelerate profits and customer satisfaction by systematically eliminating the root causes of critical defects/errors in all processes, or by creating new, more effective processes.

## 2.2 History and evolution of six sigma:

The stem of six sigma as a measurement standard can go back to Carl Friedrich Gauss (1777-1855) who introduced the concept of the normal curve. In 1920's Walter Shewhart showed that three sigma from the mean is the point where a process require correction. Many measurement standards like zero defects, CpK etc came later but credit for the term "Six Sigma" goes to Motorola Engineer. Mikel Harry, who is called the "godfather" of six sigma has introduced this concept and is acknowledged as the leading authority on this theory and practice. Although he did not invent the concept, the way it is currently practiced but Harry's history footprints are followed here to reveal the evolution of six sigma. In 1986, Bill Smith introduced the concept of six sigma in response to the increasing complaints from the field sales personnel about warranty claims. It was new method for standardizing the way defects are counted, with six sigma near perfection. Smith developed a formula that were the beginnings of Motorola six sigma methodology. Traditional quality levels, measuring defects in thousands of opportunities didn't provide enough granularity. So In 1980s Chairman Bob Galvin and Motorola engineers decided to measure the defects per millions opportunities. Motorola develop this new standard and created new methodology and changed culture associated with it. Six Sigma helped Motorola realize powerful bottom line results in their organization and documented \$16 billion saving as a result of six sigma efforts. Six sigma became central approach to Motorola's strategy of delivering products that were fit to use by the customer. In 1988 Motorola became the first company to win the Malcolm Baldrige National Quality Award.

In 1996, Welch announced the launch of Six Sigma at GE, at that time he called Six Sigma the most ambitious undertaken the company had ever taken on. He stated: "Quality can truly change GE from one of the great companies to absolutely the greatest company in world business." Needless to say that when GE does something, it does it all the way. Welch said to GE's Corporate Executives: "Everyone in this room must lead the quality charge. There can be no spectators on this. What took Motorola ten years, we must do in five - not through shortcuts, but in learning from others". From that moment, Jack Welch became the global promoter of Six Sigma.

Since then, many companies around the world have adopted six sigma and six sigma has become the one of the most popular improvement initiatives, widely implemented around the world in a wide range sectors (by companies such as Allied signals, Kodak, Sony, Boeing, Toshiba, Texas Instrument Lockheed Martin) that all declared considerable financial savings (Harry, 1998; Antony and Banuclas 2001; Kwam and Anbari, 2006).

Six sigma has undergone a considerable evolution since the early manifestations (Folaron and Morgan, 2003; Abramowich, 2005). In the beginning six sigma was a quality measurement approach based on statistical principles, after that it transformed to a disciplined processes improvements technique. For example Snee (1999) defined six sigma as an approach that seeks to find and eliminate cause of mistake or defects in business processes by focusing on output that are critical importance to customer. In 1999 Harry and Schroeder (1999) also defines six sigma as a disciplined method of using extremely rigorous data gathering and statistical analysis to pinpoint source of errors and ways of eliminating them.



In its current incarnation it is commonly presented as a breakthrough strategy and even holistic quality philosophy (Pande, 2002; Eckes, 2001). It is now generally accepted that six sigma is applicable to various environments such as services, transaction or software industry regardless the size of the business (Pande, 2002; Lee, 2002) and being adapted six sigma may lead to nearly perfect products and services. Moreover six sigma is widening its areas of application very rapidly and there are examples of applying six sigma to predicting the probability of a company bankruptcy (Neagu and Hoerl, 2005) or finding opportunities for growth (Abramowich, 2005).

In the past few years, thousands of organization has indicated their interest in six sigma philosophy and want to implement six sigma properly just as General Electric did. It is worth nothing that the evolution of six sigma is continuing with, for example integration of lean principle, development of a product/Service variant (Design for six sigma) amongst others (De Mat, 2006).

### **2.3 Sigma Score:**

Sigma score is derived from the normal distribution, with a 1.5 standard deviation “off-set” chosen historically from custom and practice shown in the figure below. This offset is called the shift, a sigma score of 6 is actually 4.5 standard deviations from the mean value. Therefore to determine the proportion of the distribution. Remaining in the tail of the distribution, z is 4.5 using a standard normal distribution.

Six sigma focuses on the concept of defects per million opportunities (DPMO). It uses the standard normal distribution as its measurement system. When addressing variation it is important to remember the effects of special common cause variation. The normal distribution and DPMO cannot apply if special cause are dominant within the process.

Variation reduction is the key performance for six sigma to deliver business benefits. By focusing on product, services or process variation (depending on circumstances) projects create consistency of performance and improved conformance to customer requirements.

Six sigma uses the DPMO level of a process to generate a sigma level for the process. The idea of a six sigma level is that it compares the variation in process performance to acceptable levels set by the customer, the higher the sigma level the better, and a six sigma performance indicates 3.4 DPMO or 1.5 shift.

According to the standard normal distribution a process a six sigma performance would actually produce a DPMO of .002, but Sigma levels are calculated using an inbuilt 1.5 shift from the process average. This is effectively an allowance for the natural propensity of process to drift and although debate still rages as to the validity of the exact assumption this is the commonly used approach.

The basic idea is to create a process quality metric which comparison of any type of process; Goh (2010) described this as one of the six triumphs of six sigma. The DPMO are calculated first and then translated into a sigma value via a conversion table.

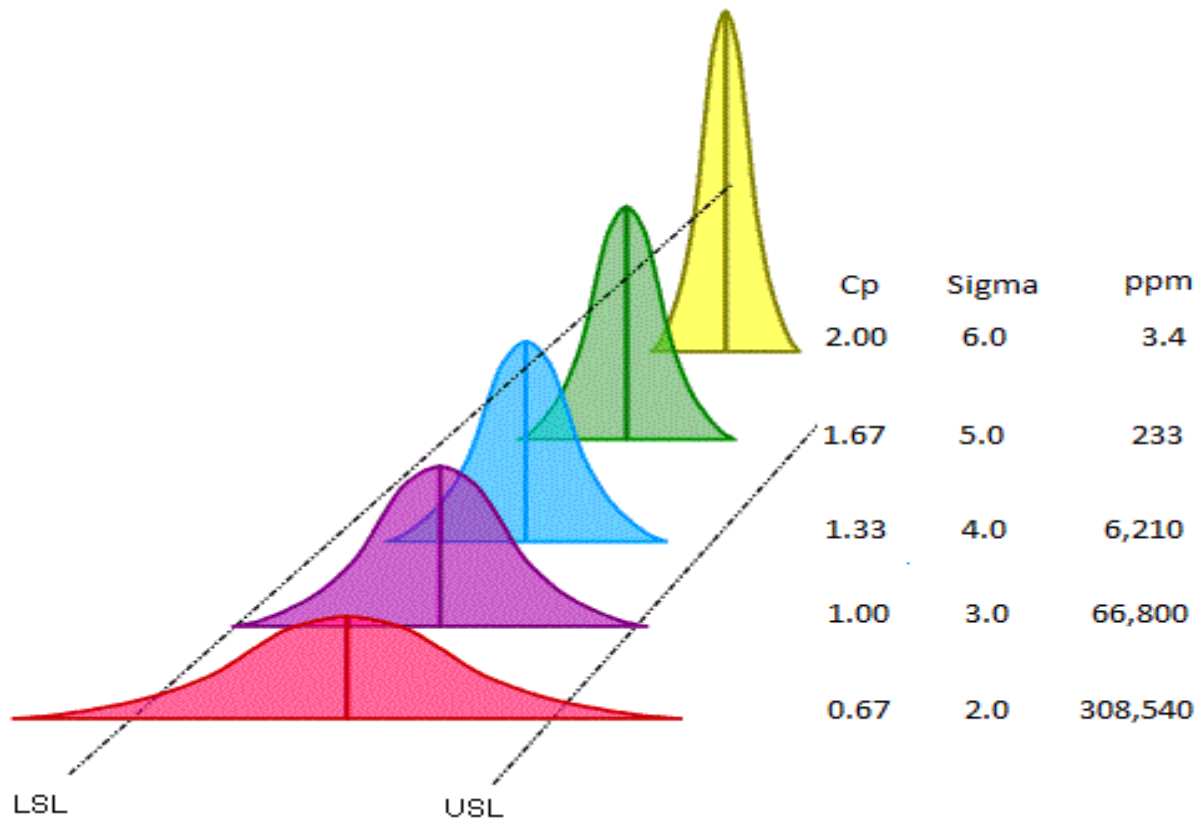


Figure 5 Sigma shift and its corresponds DPMO

## Six Sigma Today:

Today six sigma is,

- An object of quality of the processes or services that corresponds to a level of defectiveness of 3.4 errors per million units of the product.
- A methodology of the processes improvement
- A management tool or model to improve the business or system performance

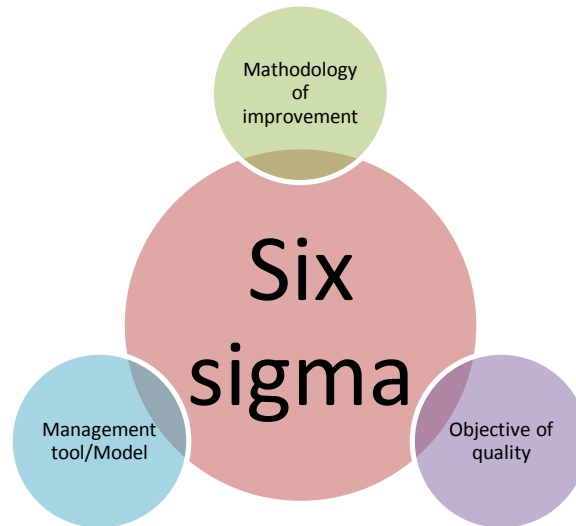


Figure 6 Six Sigma Today

## 2.5 Six Sigma Methodology:

### DMAIC:

“DMAIC” is a methodology used on Six Sigma improvement approach to solve problems and improve products or processes belonging to any kind of Organization. DMAIC is a five-step methodology “Define-Measure-Analyze-Improve and control” which drives unwanted variation from products and process. DMAIC is used when a project’s goal can be accomplished by improving an existing product, process, or service. This terms is refers to a data driven quality strategy for improving processes. DMAIC is such an integral part of Six Sigma that it is used to organize the material. It provides a useful framework for conducting six sigma projects. DMAIC is sometimes even used to create a “gated process” for project control. That is, criteria for completing a particular phase are defined and projects reviewed to determine if all of the criteria have been met. If so, then the gate (e.g. Define) is “closed.” By understanding and controlling underlying root causes, it is possible to achieve an excellent quality with a lower cost for a given process. As the backbone of the Six Sigma program, DMAIC delivers sustained defect-free performance and highly competitive quality costs over the long run.

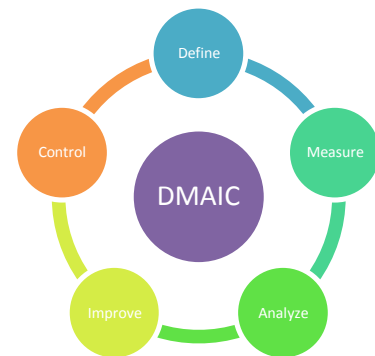


Figure 7 DMAIC

### 2.5.1 Define Phase:

In the define phase the main question is what problem would you like to fix? In this phase we will determine the project and organization goals, customer needs and process that needs to be improve to get the higher Sigma level. The most important goals are obtained from

customers. At the higher level the goals will be the strategic objectives of the organization, a higher ROI or increased market share, such as greater customer loyalty, or greater employee satisfaction. At the operations level, a goal might be to increase the throughput of a production department. At the project level goals might be to reduce the defect level and increase throughput for a particular process. Obtain goals from direct communication with customers, shareholders, and employees. In the define phase we have to consider the following main points,

- Define customer requirements that are critical to quality
- Develop problem statement
- Define Goals and benefits
- Define resources
- Develop process Map
- Evaluate key organizational support

DMAIC Phase	Tools used in corresponding to the DMAIC phase
Define	<ul style="list-style-type: none"> <li>• Project Charter: Define all the interaction of the project and sets the stage for the successful completion</li> <li>• Process Flowchart</li> <li>• SIPOC Diagram: That identify the following elements, Supplier, Input, Process, Output, and Customer. SIPOC is a tool used by a team to identify or highlight relevant elements of a process improvement project before works begins.</li> <li>• Voice of the Customer</li> <li>• Critical to Quality</li> <li>• Affinity Diagram</li> <li>• Pareto Diagram</li> <li>• Kano Model</li> </ul>

*Table 1 Tools used in six sigma Define phase*

### 2.5.2 Measure Phase:

The measure phase involves more numerical studies and data analysis. During measurement phase overall performance of the process or system is to be evaluated. This phase is time consuming and most likely used software for statistical calculation. Data collection is often encounter resistance and takes time from operators and management. The reason to collect data is to identify areas where current processes need to be improved. There are three primary sources input, process and output to collect data. The input source is where the process is generated. For example, a sales representative delivers orders to the Marketing Department. That is one form of input. Process data refers to tests of efficiency: the time requirements,

cost, value, defects or errors, and labour spent on the process. Output is a measurement of efficiency. To evaluate how a process is working, you will want to next arrive at the current baseline Sigma. To do this, you need to calculate the approximate number of defects. That is divided by the sum of units multiplied by the number of opportunities. To evaluate how a process is working, you will want to next arrive at the current baseline Sigma. To do this, you need to calculate the approximate number of defects. That is divided by the sum of units multiplied by the number of opportunities. The sum of this calculation is then multiplied by one million to find Sigma. Collecting as much information as possible without consuming excessive resource is a key to success in this phase. Accuracy and validity of data is more important in measurement phase. During the measure phase we have to follow the following main steps,

- Define Detected defects and opportunities
- Map the whole process in detail
- Plan the data collection
- Measure the data
- Develop relationship between the measurement activities
- Determine processes capability

Main tools used in the measure phase is mention below table,

DMAIC Phase	Tools used in corresponding to the DMAIC phase
Measure	<ul style="list-style-type: none"> <li>• 5 WHY's</li> <li>• Fishbone Diagram/ Ishakawa Diagram/ Cause and effect Diagram</li> <li>• Measurement system Analysis/ Gage R&amp;R</li> <li>• Rout cause Analysis</li> <li>• Data collection And Data classification</li> <li>• FMEA- Failure Mode effects and Analysis</li> <li>• DPU- Defects per Units</li> <li>• DPO- Defect per Opportunity</li> <li>• DPMO- Defects per Million Opportunities</li> </ul>

*Table 2 Tools used in Six Sigma Measure Phase*

### 2.5.3 Analyse Phase:

The purpose of the six sigma is to define the causes of the defects, measure that and analyse those defects so that they can be reduced. In analyze phase, involves array of complex mathematical formulas, diagrams and other forms of analysis. This assume to achieve the desired result with fewer defects and greater efficiency and effectiveness, without develop a series of mathematical analysis. For that purpose we will consider five specific types of analysis that will help to promote the goals of the project are explained below,

**1. Source analysis.** Also called “root cause” analysis, this procedure attempts to find defects that are derived from the sources of information or work generation.

**2. Process analysis.** The source analysis is often difficult to distinguish from process analysis. The process refers to the precise movement of materials, information, or requests from one place to another.

**3. Data analysis.** The data may be flawed as well, further adding to the complexity of the problem and generating defects.

**4. Resource analysis.** We also need to ensure that employees are properly trained in all departments that affect the process. If training is inadequate, you want to identify that as a cause of defects. Other resources include raw materials needed to manufacture, process, and deliver the goods.

**5. Communication analysis.** One problem common to most processes high in defects, is poor communication. The classic interaction between a customer and a retail store is worthy of study because many of the common communication problems are apparent in this case. The same types of problems occur with the internal customer as well, even though we may not recognize the sequence of events as a customer service problem.

The analysis phase is the beginning of the problem statistical analysis, in this phase we reviews all the data or the families of variation that gathered in the measure phase, to determine that which significant contribution to the output.

DMAIC Phase	Tools used in corresponding to the DMAIC phase
Analyze	<ul style="list-style-type: none"> <li>• Pick chart</li> <li>• Control Charts</li> <li>• Hypothesis testing</li> <li>• Histogram</li> <li>• Regression Analysis</li> <li>• Time series/ Run charts</li> <li>• Process mapping review and analysis</li> <li>• Analysis of Variance (ANOVA)</li> </ul>

*Table 3 Tools used in six sigma Analyze*

### 2.5.4 Improve Phase:

In the Improve phase, team will identify the cause of the problems and proceeds research to find out all possible solutions by carrying out the experiments. Team will also identify the validation of the solution. The whole process in this phase take 1-8 weeks.

Followings are the main steps we will consider in the improve phase,

- Define monitoring and control, also validate it
- Implement statistical process control and determine processes capability
- Develop new standard and procedures

- Develop transfer plan, verify outcomes and profit growth
- Close project, Finalized documentation

DMAIC Phase	Tools used in corresponding to the DMAIC phase
Improve	<ul style="list-style-type: none"> <li>• Design of experiment (DOE)</li> <li>• Quality function deployment (QFD)/ House of quality</li> <li>• Failure Mode and effect analysis (FMEA)</li> <li>• Brainstorming</li> <li>• SMED: Single Minute exchange of Die</li> <li>• ANOVA: Analysis of variance</li> </ul>

*Table 4 tools used in six sigma Improve phase*

### 2.5.5 Control Phase:

Last part of the DMAIC is control in which we ensure that the processes is going well or in other words we can say that this phase is the conclusion of the different DMAIC phase. In this phase we will consider the four aspects which are:

**Quality control:** six sigma is the tool to improve the quality of the processes by reducing defects, quality control is the essential method to keep the process on track and assure that high quality standards are achieving.

**Standardization:** Develop standard to enable processes as smooth as possible and to assure that the majority of the work is managed in standardized manner.

**Control methods:** Development of the new processes and methods to control the work flow.

**Respond to defect:** the final step in the control phase is how to response the defect when it occurred and height the defect and fix it before process continues.

DMAIC Phase	Tools used in corresponding to the DMAIC phase
Control	<ul style="list-style-type: none"> <li>• Processes sigma calculation</li> <li>• Control charts</li> <li>• Control plan</li> <li>• Mistake proofing</li> <li>• TPM (Total productive maintenance)</li> <li>• Revised FMEA</li> </ul>

*Table 5 Tools used in Six Sigma Control phase*

## 2.6 DMADV:

This term is refers to a data driven strategy for designing product and processes. This methodology is used to create new products or processes design in such a way that its results are more predictable, mature and defect free performance. There is one more methodology called DFSS (Design for Six Sigma) is data driven quality strategy for the redesign of the product and services from the ground up. DFSS is an alternative abbreviation of DMADV and like DMADV is a central to six sigma.

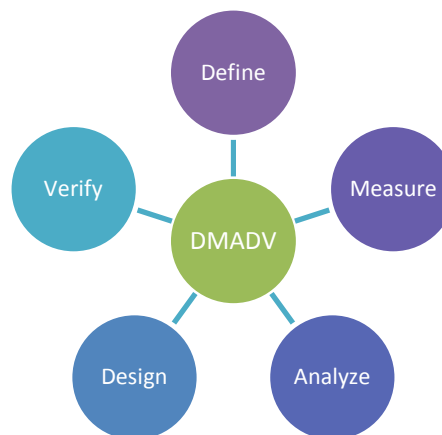


Figure 8 DMADV

Sometimes DMAIC project may turn into DFSS project because it requires complete redesign to bring about the desire degree of improvement.

## 2.7 Design for Six Sigma (DFSS):

Design for six sigma can be applied in two situation,

- When design a new product or services.
- When desire results are not achieved by applying traditional Six Sigma.

Design for six sigma does not mean to replace the existing new product introduction process, it mean to support the process by ensuring the same focus on process, as is evident in standard six sigma.

The DFSS methodology begin during the analysis of the negatively affecting new product performance. It also focus on the customer response to the product, once it has been completed to tackle the problem can be established.

### 2.7.1 DFSS Tools:

Number of tools are associated with DFSS. Many are the same standard six sigma like QFD quality function deployment, Design of experiment DOE, process capability where as others are specially used in design (Failure Modes. Effect and criticality analysis, Pugh Matrix), in most cases DFSS tools are more challenging and require more effort.



## 2.8 Implementation of Six sigma:

The implementation of six sigma is not a short term, quick improvement process. Implementation of six sigma in manufacturing and service industries is becoming a fashion now after several decades of success the industries has seen through it. To successfully implement the six sigma, one should understand the company performance. Initiatives in six sigma focus on company profitability rather than simply improving quality. The starting point of the six sigma implementation is the cost of the poor quality and how much money I wasted in a company. Most of the companies do not even have measurements for the tracking the cost of the poor quality. The internal failures components of the Cost of poor quality are Scrap, rework and lost capacity, external failures are field failure, warranty cost, complaints, returned material and lost business, appraisal (inspection testing and audit) and prevention (quality planning, process control, improvement and training)

Six sigma initiatives are for the company that want to be the best in the market and more profitable. The executives who are looking at the average and satisfactory performance, would achieve average results. For the higher performance executives must plan to eliminate or extra ordinary reduce waste stream and to recognize competitive advantages. Identifying an area or division for piloting the Six Sigma initiative is a good way to develop a successful program. Having in-house success stories can be a great way to gain interest in other departments, divisions and management sectors

In the present world the steps of successful implementation of six sigma are well documented. Researchers have found that successful deployment of six sigma involves focusing on small number of items, which are mentioned below:

- Providing training in the philosophy, principles and tools to the senior leadership, they must begin the successful performance improvements in the organization. Senior leaders develop a management infrastructure to support six sigma by using their acquired knowledge, cultivate an environment in the organization where innovation and creativity can flourish. This involves reducing the hierarchy level and barriers to experimentation and change in the organization, and make it easier to try new things without fear of reprisal.
- Develop a system for establishing closed communication with the customers, employees, suppliers and owner and evaluate their inputs. Conduct base line studies to identify cultural, policy and procedural obstacle and to determine the starting point.
- Arrange trainings to all employees to assure that they have adequate knowledge to handle problems in the organization. Conduct top to bottom trainings in system improvement tools and techniques.
- Develop a continuous process improvement framework, along with a system indicators for monitoring progress and success. Focus of the six sigma matrices is on company strategic goals and key business processes.
- At all levels of organizations business processes are to be improved through chosen by management and by people with intimate process knowledge. The projects of six

sigma are conducted to improve business performance linked to measurable financial results. Organization's constraints knowledge are required for this step.

- Lead by Green belts and assisted by black belts six sigma projects are conducted by individual employees.

This seems to be a simple approach but it is no means easy. Six Sigma initiatives can be perceived as expensive unless implemented correctly. Results and research justify the firms that successfully implement six sigma perform well in every business category. After implementing the correct performance measurements, executives need to reward and recognize employee's success through profit shearing and promotion.

## **2.9 Six Sigma Roles and Responsibilities:-**

A structure format is required in order to implement six sigma in an organization, although the moto quality is everyone's responsibility is correct but six sigma add some focus in assigning specific roles to certain job titles. Eckes (2001) experience of six sigma deployment says that "the companies which did the best job of changing how they selected and developed their people had the best results. It is also recognized as probably the most variable aspects of six sigma implementation (Fleming et al, 2005; Jones et al 2010).

There are seven specific roles area in the six sigma,

### **2.9.1 Leadership:-**

Generally consists of the senior team member led by CEO. The team is responsible for the strategic cycle the need to:

- Generate vision and mission that explain how the results is going to benefit the customer, linking the program in the visible manner and lead the six sigma transformation.
- Set work schedule and deadlines
- Monitor the work progress and motivate the personnel
- Cross functional activities like trainings on six sigma
- Six sigma must be implemented from top to bottom.

### **2.9.2 Champion and sponsors:**

- Champion is a non-executive role in the project and senior manager.
- A bridge between the leadership and the staff
- High level individuals who understand six sigma and are committed to its success.
- Six sigma will be led by full time, high level champion.

- Champions are responsible to address barriers that are beyond the team authority.
- Sponsors are the owner of processes who initiate six sigma improvement activities in there are of responsibilities.

### **2.9.3 Master Black Belt:**

- The role of the Master Black Belt is to provide the leadership and project mentoring to the Black Belts running project.
- Liaison with champions to provide effective support.
- MBB is responsible to resolve the technical issues in the project
- Provide progress report to upper management

### **2.9.4 Black Belts:**

- Black belt holders are usually team leader
- Responsible for implementing or execution and scheduling of the six sigma project
- Lead the project team in improvement processes and deliver the project outcomes and facilitating the team.
- Self-confident, optimistic and active member of the team.
- Black belt person has highest skill level and are expert in various techniques.
- In six sigma program, Black belt will have completed a through training program and have experienced on several projects.

### **2.9.5 Green Belts:**

- Green belts are team members, their responsibility is to maintain the regular jobs but are assigned one or more team according to their background on selected projects.
- Green belt training consist of three days of classroom training on statistical tools and is conducted in conjunction with six sigma projects to enhance their particular area of expertise.
- Training consists of quality management tool, quality control tools, problem solving project management and data analysis.
- Six Sigma help Green belt in defining their project prior to the training and assist them with their project after training.

### 2.9.6 Yellow Belt and White Belt:

- Yellow Belts participates as a core team member on a project.
- Yellow belts personnel may often be responsible for running small process improvement using PDCA methodology.
- A Yellow Belt has a basic knowledge of six sigma, they cannot lead project on their own.
- Yellow belts are responsible for development of process maps to support six sigma projects that are often get accelerate to Green or Black Belts where DMAIC methodology is used to reduced cost by using statistical processes control.
- White belt is not fully recognized in the six sigma community
- White belt is an introductory six sigma awareness or started journey for participating on six sigma Yellow Belt project execution team.

## Chapter 3

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### **Q#1: I actually want suggestions on how to integrate or link the ISO 9001 and six sigma.**



#### **Bob Alisic**

Consultant, trainer, auditor and key-note speaker at ActinQ  
(quality, change mgt. & innovation)

Eindhoven Area, Netherlands • Professional Training & Coaching

To show the link is very simple, to implement it is another story.

a) Especially in the coming version of ISO 9001:2015, Process Management is mentioned many times as one of the very crucial quality management principles ISO 9001 is based on. In simple words: Success of an organization depends very strongly on the "quality" of management of processes organization has reached.

b) Six Sigma is an excellent tool organization could use to improve performance of processes and advance the level of maturity of the processes used, including the way how processes are managed. But, to really implement Six Sigma, it is a question of commitment, culture and training; .....as mostly....it depends....on people involved.



#### **Andy Nichols**

Regional Sales Manager at NQA-USA Inc  
Greater Detroit Area • Information Services

Easy: ISO 9001 requires continuous improvement. 6 Sigma is a tool box and methodology of continuous improvement! Simples!



#### **Richard Bowden**

Don't judge each day by the harvest you reap but by the seeds you plant - Robert Louis Stevenson.

Cardiff, United Kingdom • Management Consulting

You Cant link them Like you can by combining ISO 9001 with ISO 14001 and 18001 into an integrated management system. That said like the other people have said they do live very well together like peas and carrots.



#### **Isabella Isaac**

Customer Service Specialist at  
ElderSource [www.myeldersource.org](http://www.myeldersource.org)

Jacksonville, Florida Area • Philanthropy

To achieve Six Sigma a process must not produce more than 3.4 defects per million opportunities. The fundamental objective of the Six Sigma methodology is the implementation of a measurement-based strategy that focuses on process improvement and variation reduction through the application of Six Sigma improvement projects. This is accomplished through the use of two Six Sigma sub-methodologies: DMAIC and DMADV. The Six Sigma DMAIC process (define, measure, analyze, improve, control) is an improvement system for existing processes falling below specification and looking for incremental improvement. The Six Sigma DMADV process (define, measure, analyze, design, verify) is an improvement system used to develop new processes or products at Six Sigma quality levels. It can also be employed if a current process requires more than just incremental

improvement. Both Six Sigma processes are executed by Six Sigma Green Belts and Six Sigma Black Belts, and are overseen by Six Sigma Master Black Belts. As mentioned earlier ISO 9001 standard requires continuous improvement hence applying Six Sigma would get you connected. Hope this helps.



**Les Murphy**  
Quality Management Specialist  
Newfoundland And Labrador, Canada • Management Consulting

Wow, implementing Six Sigma as part of a new QMS is like going squirrel hunting with a cruise missile. It will do the job but the pieces will be tough to find.

As some of the contributors have said 6 Sigma is great for a very mature, well informed, and committed QMS/Management Team. I'm not saying don't use some aspects of 6 Sigma, but be very careful as you chance complete rejection from the general workforce. Just my opinion from someone who worked on the Honeywell campus in Morristown.



**Andy Nichols**  
Regional Sales Manager at NQA-USA Inc  
Greater Detroit Area • Information Services

Of course you can't link them like ISO 9001 with 14001, that because 6 Sigma isn't a management system requirement! It's simply a set of tools to improve a process.



**Ajay Parelkar**  
Consultant- ISO 9001-2008, FSSC 22000, Undertaking Six Sigma  
Projects for Capability Study & Performance Improvement..  
Mumbai Area, India • Food & Beverages

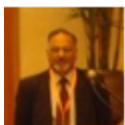
You can use this tool to show continual improvement in ISO 9001



**Jimmy Hashem**  
Global Service Quality Lead at Halliburton  
Dallas/Fort Worth Area • Oil & Energy

I dont know the straight answer to this but can try.

QMS has a requirment for data analysis. Six sigma is a data collection and analysis methodology. Any tools out of the six sigma tool bag fullfill the requirement for analysis of data



**Dhurjati Chhaya**  
Experienced Multifunctional Leader  
Vadodara Area, India • Professional Training & Coaching

Before going in for six sigma, you would have listed all the problems. Some may not need rigour of six sigma and are called low hanging fruits. Make sure you have plucked all low hanging fruits before applying rigour of six sigma to problems that merit six sigma. ISO 9001 goes by incremental improvements as a process of continual improvement. Six sigma requires quantum jump. You can claim results of improvements in ISO 9001 also.



**Andy Nichols**  
Regional Sales Manager at NQA-USA Inc  
Greater Detroit Area • Information Services

ISO 9001 simply requires improvement - doesn't matter which method the organization chooses!



**Ranganath Manadayam Anandampillai**  
 Freelance Consultant at TQM Management  
 Bengaluru Area, India • Professional Training & Coaching

It requires a focussed attention. While, ISO 9001 focusses on Overall Systems Management with a Process Approach, Six Sigma helps in improving the processes reducing Waste and helps in overall benefit to the organization. I have been actually associated with such a situation during my active career and it really works wonders.



**Subramanya V Ravi**  
 Vice President at VENKODIS Consultants  
 Chennai Area, India • Management Consulting

ISO 9001 is to ensure 'consistency' in product quality.  
 Quality is consistently meeting or exceeding customer expectations.  
 CONSISTENCY is the key word.

Six sigma is a tool for variability reduction i.e contributory factor for CONSISTENCY

Understand your current level of non conformance (in process / product / material etc etc)  
 set a target for reducing the non conformance  
 use six sigma as a tool ( As Andy said it is one of the improvement tools - nothing prevents you from selecting six sigma as a tool for improvement, if it is suitable for the organization)



**Abraham Dunmade**  
 Dumex business consulting Bt & Hermon Quality Solutions  
 Hungary area • Automotive

Andy Nichols you are right in your opinion :ISO 9001 requires continuous improvement. 6 Sigma is a tool box and methodology of continuous improvement! thats all .



**Leif Svensson**  
 Lecturer in production and qaaiity management at Jönköping  
 University  
 Skovde, Sweden • Higher Education

Well Ladies and gentlemen.  
 The most important things in this topic is brought up already but I any how like to put attention to the fact that the ISO 9001 is a set of requirements telling you which areas you should focus and be able to show progress in. The standard does not neither tell you how to create and formulate your targets nor how to reach the wanted progress in each specific area. The ISO 9001 does not include such things due to it's a standard with a set of requirements. The organization has to decide what specific targets to set up and which kind of tools to be used in the internal improvement process. There you can use 6Sigma, Lean, PDCA or whatever you find applicable for your own company. Based on my experience as responsible for a QMS the set up of tools needed will be a combination of tools from different tool boxes available. You have to pick appropriate ones to be used in the specific situation





### Tomáš Mintál

Quality Assurance Specialist in ENEL, project K3 and K4 in  
Mochovce  
Slovak Republic • Machinery

ISO 9001 is the international standard, which are including the single parts, from which every part is addressing to another part of the process. It means, that this is the standard, which is like a guide for establishing the quality process, which will be controlled, analysed, measured and improved by some quality tools.

Six sigma is the set of tools, and when these tools are implemented into the processes, material purchasing, quality control, manufacture, storing, packaging, ... you will upgrade the quality to the highest level, because your material stock will be minimalised, also the times for new machine set-up. Every method from six sigma is for another one part of the process,



### Orlando Petini

VP of Quality & NPI at First Source Electronics  
Baltimore, Maryland Area • Consumer Electronics  
Similar

Six Sigma, as we all know, is a scientific methodology for reducing variation in processes. It is easy to link Six Sigma to ISO 9001 simply by its use as an improvement methodology. However, as has been pointed out in previous posts, it is the implementation of the Six Sigma culture that can be difficult. It has been my experience that a lack of commitment from the top down is a sure fire path to failure. I have found that a structured implementation plan which includes training is the best way to ensure six sigma implementation success. It is imperative that Upper Management supports any Six Sigma initiatives from beginning to end.



### Leif Svensson

Lecturer in production and quality management at Jönköping  
University  
Skovde, Sweden • Higher Education

I completely agree with Orlando when he states that lack of commitment from Top Management is a sure path to failure. This statement is valid not only for 6 Sigma but also valid for implementation and management of a QMS as well. All activities in an enterprise needs full Top Management support to get a fair chance for success.

Going back to the initial question if it is possible to integrate 6Sigma into the QMS I would like to answer this by saying that an integration is not necessary. You have to interpret the requirements in the ISO-standard into things that are valid for your company and then set targets in specific areas and choose appropriate tools for analyse and improvement in the field of the targets.



### alan Roberson

Corporate HSEQ Manager Aker Solutions  
Guildford, United Kingdom • Oil & Energy

another interesting topic. For me 6 sigma is not just a set of tools but also a way of thinking that supports redesign, optimisation of a process and continuous improvement. Its just not that great without some sort of system or process in which to nestle. A QMS against ISO 9001 is one of a number of systemic process based approaches that need to be in place to support a process improvement approach such as 6 sigma. The two are not mutually exclusive, they support each other; if of course you want them to.





### **Christo Wiid**

**Head of Hardgoods Operations at Afrox, a member of The Linde Group**  
South Africa • Mechanical or Industrial Engineering

Back to the original request ...integrate or link ISO9001 and 6 sigma: I have considered that idea as well. Here's a tip: when you develop your process documentation (SOPs or whatever), structure them in the "form" recognized by 6 sigma, i.e. SIPOC, VOC/CTQ's etc. Any resolution of a process non-conformance then becomes a structured 6 sigma process improvement that the team can handle itself - "punching above its belt"... Off course the staff needs training to make the most of the effort that went into the process documentation...



### **Subramanya V.Ravi**

**Vice President at VENKODIS Consultants**  
Chennai Area, India • Management Consulting

Remember to include sis sigma in your 6.2 (Competence, training, Awareness). I also support SIPOC. Good luck!



### **Leif Svensson**

**Lecturer in production and quaiity management at Jönköping University**  
Skovde, Sweden • Higher Education

A quick comment!  
Why link ISO 9001 and 6 Sigma?  
The QMS is built upon requirements described in the ISO 9001.  
When putting up the QMS it is up to the organization to choose the appropriate tools to reach their own targets.



### **Devarajan Rajagopalan**

**Proprietor of Jupiter Business Excellence**  
Chennai Area, India • Management Consulting

In your ISO implementation strengthen SPC deployment. SPC must penetrate deep into your systems, manufacturing process & product. Through these organization can attain a stability (no special cause). At this point you can start measuring your present sigma level & try to improve it to six sigma levels.



### **Simon Alexander**

**TQM Manager at Tridonic**  
Darlington, United Kingdom • Management Consulting

Six sigma projects are an excellent way to achieve the continual improvement requirements of ISO 9001.

You set up a project charter (which involves setting improvement objectives, ergo quality objectives), then set up an action plan and allocate resources. Then you go ahead and improve and save money! There is no incongruence between that and any part of ISO 9001.

The only problem some people have had is that DMAIC does not fit seamlessly with PDCA (the sequence is not entirely the same). It's an epistemic issue that us users of the standards need not worry about, and can be bracketed off as an academic irrelevance.

I've been citing lean six sigma projects as our way of fulfilling the continual improvement activities of several management systems standards. Every auditor who has looked at what the team has done has not only accepted the situation, but has complemented us on how thoroughly we've got ISO 9001 as a living, breathing part of our business

## Q#2 How QMS ISO 9001 and Six sigma addresses CTQ?



Mawardi,

**Mawardi, S.T.**

Social Compliance Audit (Freelance)

How QMS ISO 9001 and Six sigma addresses CTQ? I think..

Six Sigma is a new breakthrough in solving problems of organization and management of the process in helping companies to improve product quality and to the failure rate of zero (zero defect) to save and avoid the same mistakes. Where Six Sigma is a measurement tool to identify some of the vital factors, the factors most crucial to improve the quality of the process and make a profit

In conjunction with the CQT (Critical To Quality), which saw the production process, it can be determined CTQ key. With the key CTQ has been described in, then the critical point concerns the production process is more easily identified.

So expect the products meet the standards of Quality Management System

## Filippo Rejna

Professor added, Senior Consultant, former CEO

Como Area, Italy | Chemicals

Current Politecnico di Milano and MIP (School of Management), Synopsis Srl

Previous Synopsis Srl, Akzo Nobel Coatings SpA, Akzo Nobel Coatings

Education Politecnico di Milano

Six Sigma tends to listen the CTQ, to satisfy the customer requirements; the customer and the customer's requirements are the focus of Six Sigma activity. In QMS ISO 9001 the focus is much more on the process and on its efficiency.



Ahmed  
EL

**Ahmed EL Khamlichi**

Directeur - Consultant ASQSYSTEM

I think ISO 9001 as well as Six Sigma are both treating the CTQ. Six Sigma is a statistical approach which is focussing mainly on the quality of the product or the service: not all the features of a product are critical; for this reason I think the terme CTQ is used in the aim to focus on what's most important in the product quality. How Six Sigma is addressing this? all the approach is doing it.

But ISO 9001 is also an approach and a management system with a set of requirements that you know. How ISO 9001 addresses CTQ (for quality products or customer requireemnts) see §7.1 to §7.6.



Remi

**Remi Aubry**  
Industrial Processes & Environment Manager at SNFS

As a quality management system standard, ISO 9001 can be envisaged as a device to integrate more sophisticated quality tools such as Six Sigma. Furthermore, it also may be used to help the user's choices regarding these tools in order either to use the ones that are required in their activities, or to use the ones that are most suitable for them. Again "fitness for use" is the "quality" guidance.



Remi

**Remi Aubry**  
Industrial Processes & Environment Manager at SNFS

Quality tools, with the proper "i" at the proper place.  
Once we could edit our messages to correct such typing errors...  
Regards to all and thank you for fruitful exchanges.

### Q#3 What does “C” and “A” has in PDCA of QMS ISO 9001 and “C” of DMAIC of six sigma, what they have common for process control?

## Filippo Rejna

Professor added, Senior Consultant, former CEO  
Como Area, Italy | Chemicals

Current Politecnico di Milano and MIP (School of Management), Synopsis Srl  
Previous Synopsis Srl, Akzo Nobel Coatings SpA, Akzo Nobel Coatings  
Education Politecnico di Milano

In PDCA, “C” means “Check”, i.e control that the planned action is producing the expected result, and “A” means “Act” consequently, i.e decide the next action to be implemented with the following loop. In DMAIC, “A” means “Analyze”, i.e use the statistical analysis (and eventually other analytical method) to understand the problem and the causes that have originated it, while “C” means “control” that the planned results and quantified benefits have been achieved.



HS

**HS Anand**  
Master Trainer 3rd Party Automotive & Aerospace CB Auditors

C in PDCA and C in DMAIC are not one and the same thing for sure.

C in PDCA means CHECKING the status followed by A for ACT appropriate to the status identified at C.

On the other hand C in DMAIC means to combine the C & A of PDCA. C in DMAIC means Control and not simply CHECKING. Control means taking all those actions which could be helpful in bringing the status back to original or intended action.



Mawardi,

**Mawardi, S.T.**  
**Social Compliance Audit (Freelance)**

Meaning of "C" and "A" has been in the PDCA QMS ISO 9001 and "C" of the six sigma DMAIC, according to my knowledge in general are as follows:

In the management science in both the ISO 9001 and DMAIC on LEAN SIX SIGMA, there is the concept of problem solving that can be applied in the workplace we are using PDCA approach as a problem-solving process. In the language of quality control, PDCA can be defined as the process of settlement and control problems with cascading and systematic pattern. Associated with the meaning of "C" and "A" meaningful outline is

**C (Check = Evaluation)**

This means evaluating and PROCESS TARGETS and report any results. We checked back what we already do, have according to existing standards or there are still shortcomings.

- Monitor and evaluate the processes and results against objectives and specifications and report the results.
- In checking there are two things that need to be considered, namely to monitor and evaluate the process and results against objectives and specifications.
- The technique used is the observation and surveys. If still find weaknesses, then drafted a plan to implement further improvements. If it fails, then look for another implementation, but if successful, performed routines.
- Referring to verify whether the application in accordance with the plan of improvement and refinement desired.

**A (Act = Follow-up)**

This means that the total evaluating the results of TARGET and PROCESS and follow up with improvements. If it turns out what we've done there are less or not perfect, immediate action to fix it. ACT process is very important before we go further into the process of further improvement.

- Following up the results to make the necessary repairs. This means also review all the steps and modify the process to fix it before the next implementation.
- Following up the results mean standardizing changes, such as considering any area that may be applied, revise the process that has been repaired, make modifications standards, procedures and policies exist, communicate to all staff, customers and suppliers over the changes made, if necessary, develop a plan clear, and documenting the project. In addition, it is also necessary to monitor changes in the measurement and control processes on a regular basis.

After the implementation process (do) is executed, the next process is the examination (check) the results obtained and the determination of the action (act) required for repair. In this process:

- Organization of monitoring and measuring customer satisfaction;
- Conduct internal quality audits (internal quality audits);
- Monitor and measure processes and products;
- Exercise control over mismatches (non-conformity) that occurred;
- Analyze all the data obtained, including the tendency of processes;
- Then perform corrective and preventive actions.



Peter

**Peter Krafft**

–

Plan, Do, Check, Act  
Define, Measure, Analyze, Improve and Control

I would use DMAIC to come up with the plan for PDCA



**Nomikos (Mike) Trikoilis AMIMechE**  
Senior Manufacturing Engineer at Edwards

Nomikos  
(Mike)

Plan-Do-Check-Act and Define Measure Analyse Improve Control are both methods of continuous improvement and they use a structured methodology. Both they put controls in place to ensure the continuous improvement either by audits, validations or verifications and sharing the lessons learned.

## Q#4 How we consider the term “Continual Improvement of the process” specifically in DMAIC methodology of Six sigma and PDCA of ISO 9001.

### Filippo Rejna

Professor added, Senior Consultant, former CEO  
Como Area, Italy | Chemicals

Current Politecnico di Milano and MIP (School of Management), Synopsis Srl  
Previous Synopsis Srl, Akzo Nobel Coatings SpA, Akzo Nobel Coatings  
Education Politecnico di Milano

In PDCA, as recommended by ISO 9001, you tend to repeat several times the Deming cycle which is meant to solve problematic situations, and after having reached the planned benefits, you start again another loop planning actions, doing what you have planned, checking the results obtained and acting consequently. Improvement is reached as sequence of single step improvement actions. Also in Six Sigma you again reach the Continuous Improvement, but the approach is meant more to improve continuously the efficiency and the effectiveness of what you do, because you look more to what it can be improved and not that much what need to be fixed.



**Pretesh Biswas**  
Quality Consultant at APB Consultant  
Pune Area, India • Outsourcing/Offshoring

The ISO 9000 definition of Continual Improvement is “recurring activities to increase the ability to fulfil requirements. “NOTE: The process of establishing objectives and finding opportunities for improvement is a continual process through the use of audit findings and audit conclusions, analysis of data, management reviews or other means and generally leads to corrective action or preventive action.”

Thus continual improvement is a set of recurring activities that an organization carries out in order to enhance its ability to meet requirements. Continual improvements can be achieved by carrying out, self-assessments, management reviews, and benchmarking projects. Continual improvements can also be realized by collecting data, analyzing information, setting objectives, and implementing corrective and preventive actions. Continuous improvement is an ongoing effort to improve products, services or processes. These efforts can seek “incremental” improvement over time or “breakthrough” improvement all at once.

Among the most widely used tools for continuous improvement is a four-step quality model—the plan-do-check-act (PDCA) cycle, also known as Deming Cycle:

Plan: Identify an opportunity and plan for change.

Do: Implement the change on a small scale.

Check: Use data to analyze the results of the change and determine whether it made a difference.

Act: If the change was successful, implement it on a wider scale and continuously assess your results. If the change did not work, begin the cycle again.





**Bharti Anand**  
 Associated with Sidwal Refrigeration  
 New Delhi Area, India • Automotive

Very well said by Pretesh "The process of establishing objectives and finding opportunities for improvement is a continual process" it is similar to PDCA cycle, similarly in DMAIC methodology after finding the opportunities for improvement we need to follow the same steps of DMAIC.



**SURESH ABADE**  
 Free Lance consultant for Quality Management System.  
 Pune Area, India • Management Consulting

Just go through the graphs you plotted for last years objectives measured, without having implemented and monitored system. And vice versa check the graphs where well established system is in place. Where all corrective actions and preventive actions are taken for every process considering improvements. You will find gradual definite improvement.



**Eddie Oguing**  
 Experienced Manufacturing Quality Manager  
 NCR - National Capital Region, Philippines • Electrical/Electronic Manufacturing

Six Sigma DMAIC is a problem-solving technique, some tools used in the Measure and Analyze stage can also be utilized to address continual improvement of the process. However, you need to define your base standard in order to determine your target. When you reached that target, make it your base standard then define another target, this is a continuous process that measures how well you improve your process.



**Mohit Dhawan**  
 Senior Manager Quality at Aricent  
 Gurgaon, India • Telecommunications

Continual Improvement term means the same in both PDCA and DMAIC. Though I see a difference in the approach followed. In DMAIC the approach followed is more meticulous and there is lot of emphasis on statistics and it's by design. In PDCA the approach is more of brainstorming, discussions leading to a possible improvement, it's not that meticulous/statistics driven.



**Santosh Shelke**  
 Sr. Quality Engineer at Digital Circuits P L  
 Pune Area, India • Automotive

Continual Improvement term means = improvement and its monitoring / sustenance.



**Jim Dent**  
 Corp. Supplier Quality Engineer at Zimmer  
 Phoenix, Arizona Area • Automotive

To identify opportunities for continuous improvements, go on daily Gemba walks in different departments. Continuous Improvement (CI) does not necessarily need to apply to a single improvement project; but that you are continually improving processes throughout your organization. Depending on the size of the organization and the priorities you establish will determine how many CI projects you can work on at one time - all at different phases of their cycle.

If your solution to a 6-Sigma project within a process still has room for more improvement, than start

another DMAIC project immediately after finishing the first. Don't try to fix everything within a process at once, break the multiple opportunities down into individual and manageable projects ased on each project's scope and/or benefit.

I've seen many 6-Sigma project fail because the scope is like trying to solve world hunger



**Ranganath Manadayam Anandampillai**  
Freelance Consultant at TQM Management  
Bengaluru Area, India • Professional Training & Coaching

DMAIC is normally a SIX SIGMA approach adopted for any project / process improvement. The outcome normally is for a STEP IMPROVEMENT. Any step by step improvement is a part of continual Improvement. When applied to Processes & Projects as a part of SYSTEMS APPROACH leading to Small improvements leads to Continual Improvement.



**RE: Need comments on my Project work**  
Carlos Conejo, Lean Six Sigma Master Black Belt  
March 8, 2015, 5:21 PM

1. Define the current state of you ISO  
Measure how successfully you are implementing and complying  
Analyze "Gaps" - Why- Do root  
Implement new counter-measures  
Place under statistical control and come up with plan to get back to desired state of ISO compliance  
The PDCA- is the method you will use. PPlan what you will do, Check your facts/collect meaningful data. Act- Andiamo! Do it, tweak it, do it, tweak it...etc.

#### **Q#4 How important a Customer is in QMS and Six sigma.**



**Jim Dent**  
Corp. Supplier Quality Engineer at Zimmer  
Phoenix, Arizona Area • Automotive

The purpose of the QMS should be Customer Satisfaction in everything your company does - specifically exceeding your customers' expectations of you as their supplier to the point where they think of you more as a partner than a supplier.



**Jane Bennett**  
Quality Management Consultant; DIY ISO 9001 Kit author  
Melbourne Area, Australia • Management Consulting

Not important at all, unless you want to stay in business. And thrive.

## Filippo Rejna

Professor added, Senior Consultant, former CEO

Como Area, Italy | Chemicals

Current	Politecnico di Milano and MIP (School of Management), Synopsis SrL
Previous	Synopsis SrL, Akzo Nobel Coatings SpA, Akzo Nobel Coatings
Education	Politecnico di Milano

The customer is the central point of any Six Sigma project, because you develop the project to satisfy the customer, and on the basis of the customer requirements (The voice of the customer); so you focus on customer requirements and not that much on process performances



### Murli KN

Head-Quality & MR (QMS/AS 9100C) at Astra Microwave Products Ltd

Bengaluru Area, India • Defense & Space

Customer is the business for which organization exists, unless you yourself is the buyer.



### Mark Lepiten

CE, Materials Engineer, ASQ CMQ/OE, PMP

Qatar • Construction

Just imagine without them for one second and you will be surprised of what you will see.. Everything starts with them.



### Karen Boyd

QMS Consulting - ISO 9001 / ISO 13485 - Seeking Opportunities!

West Palm Beach, Florida Area • Management Consulting

Everything; input through output and back again.



### Devarajan Rajagopalan

Proprietor of Jupiter Business Excellence

Chennai Area, India • Management Consulting

On a comparative note, they are equal to brain in a human system w.r.t importance. Brain dead is the real death as-per science. Once brain is dead & every other organ is functioning well is of no use!!



### Senthil Kumar

Supplier Quality Manager at Philips Lighting India Ltd

Noida Area, India • Consumer Electronics

Well said, Mr.Devaraj.

In a speech in South Africa in 1890 Mahatma Gandhi said this:

“A customer is the most important visitor on our premises. He is not dependent on us. We are dependent on him. He is not an interruption of our work. He is the purpose of it. He is not an outsider of our business. He is part of it. We are not doing him a favour by serving him. He is doing us a favour by giving us the opportunity to do so.”

This is a philosophy well worth absorbing and putting at the heart of all business.



**Q#6: When a Major or Minor NCR (Non-conformance) is raised how six sigma and QMS (ISO 9001) are helping to find out Root causes and CAPA (Corrective Actions and Preventive Actions)?**



**RE: Need comments on my Project work**

Carlos Conejo, Lean Six Sigma Master Black Belt

March 8, 2015, 5:21 PM

Six Sigma does not help. YOU have to do some heavy lifting and conduct proper root cause, collect data, get out to your gemba and see. You do not solve in the office or conference room. You have to go and get dirty and SEE!

## Filippo Rejna

Professor added, Senior Consultant, former CEO

Como Area, Italy | Chemicals

Current Politecnico di Milano and MIP (School of Management), Synopsis SrL

Previous Synopsis SrL, Akzo Nobel Coatings SpA, Akzo Nobel Coatings

Education Politecnico di Milano

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My interpretation of this question is that in both cases 6S and QMS you need to identify the Root Cause that must be eliminated if you want to fix your problem, or to remove the NCR, but (and I repeat, it is my interpretation) in QMS you need to remove the Root Cause to prevent the re-occurrence of the NCR, while in Six Sigma you aim to continuous improvement, and to reach it you approach NCR as an opportunity for improvement. The difference is conceptual, and in the methodology used.

## Chapter 4

### 4.1. Relationship between ISO 9001:2008 and Six Sigma:

The common elements and interrelationship of ISO 9001:2008 standards and Six Sigma DMAIC Methodology (Define, Measure, Analyze, Improve, and Control) can be seen in diagram below. A deep look is taken at the various stages of the DMAIC Methodology and the specific clauses out of ISO 9001:2008. By analyzing clause 4.1 (General Documents) of the ISO 9001:2008 standard it is possible to identify five main steps shows in the figure below, to be followed in order to develop a quality management system based on both process and systems approach principles.



Figure 9 Five steps to develop a quality management system based on ISO 9001:2008

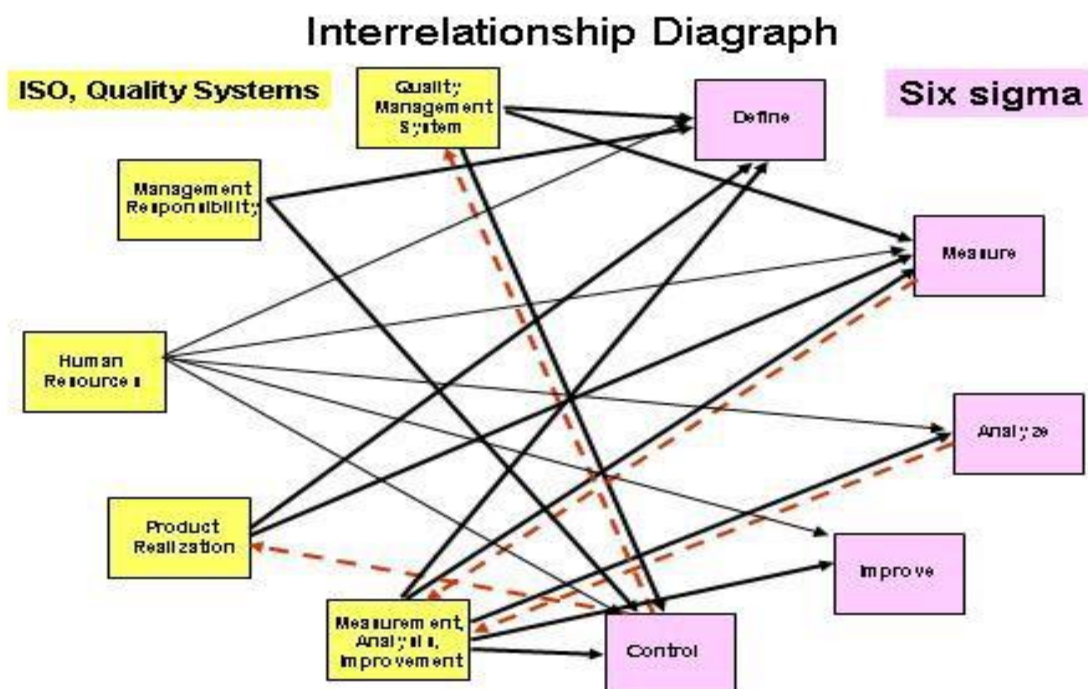


Figure 10 Interrelationship Diagram

#### **4.1.1. Define Phase- Six Sigma and ISO 9001:2008**

Voice of the customer is the focus point in the six sigma, whether this is an external or internal. In the Six sigma define phase we define key Critical to Quality (CTQ) and Critical to service (CTS) characteristics. Both critical to quality (CTQ) and Critical to service (CTS) found in the same way in quality management system ISO 9001:2008, Clause 5.2 as focus on the customer requirement, to improve customer satisfaction and ISO 9001:2008 clause 8.2.1 is customer satisfaction.

We identify core business process, and map the process flow in six sigma define and measure phase. In ISO 9001:2008 clause 4.1 define the same thing that identify the quality processes their sequence and interaction, criteria and methods. ISO 9001:2008, clause 7.2 it is mention that develop a standard for Customer Related Processes for products and services with 2 elements 1) Determine requirements that related to the products and 2) Determine statutory and regulatory requirements. For our project we set performance objectives, project priorities identified, and financial impact determined by using the collected data and all key measures. This is driven in ISO 9001:2008, clause 5.4, that is related to the planning of the quality system and defined quality objective.

Management review is core element of the of the six sigma phases that is called gate review. In gate review, management reviewed all the deliverables and schedules to meet the criteria of the project. This gate review take place at DMAIC methodology phases. This corresponds to ISO9001:2008 clause 5.6 where management review is required.

#### **4.1.2. Measure Phase- Six Sigma and ISO 9001:2008:**

ISO 9001:2008 clause 4.1, that requires to quality processes and their interaction with each other. This relates to six sigma measure phase, in which we measure the input and output of the process on the bases of the collected data.

Six sigma focus on the improvement of the process and analysis of the system on basis of the measured data, also determines the variability and stability of the system. This is also found in ISO 9001:2008 clause 7.8, that you have to control and monitor the measuring equipment's.

#### **4.1.3. Analyses Phase- Six Sigma and ISO 9001:2008:**

In Analyses phase, we identify the gaps or mistakes that prevents us from getting our goal by doing advanced data analysis. Identification of the root cause of failure and their influence on the system, understanding the relationship of the input and output of the system is the key aspects of the analysis phase. At the end we identify the corrective and preventative action to maintain the system and get better results that is also required in ISO 9001:2008, clause 8.5.2 corrective action and 8.5.3 preventive action. In Analysis we also identify the operating tolerance for our system and this is also requirement of the ISO 9001:2008.

#### **4.1.4.Improve Phase- Six Sigma and ISO 9001-2008:**

After doing DOE and all other process that we have done in the above process, we find out the best solution. We implement the best solution that we found out by performing the DOE and all other producers in the above steps (Define, Measure, Analyses) by changing work process and optimizing critical parameters. The results we get are verified through short term capability analysis, with the focus on continuous improvement. This also require in ISO 9001:2008 clause 8.5.1, that focus on the continual improvement.

#### **4.1.5.Control Phase- Six Sigma and ISO 9001-2008:**

In ISO 9001:2008 clause 8.2.3: it is required to monitor and measure processes, this is also the underpinned in the six sigma control phase that monitor and measure the new process through ongoing monitoring in the six sigma project. We implement a flexible change process by setting new operating baseline, and standardized processes change that is well documented in the procedures documents and also in the organization quality policy. It is also requirement of the ISO 9001:2008 clause 4.2: which stated documentation requirement, quality policy and quality manual.

Many companies, who have started with ISO 9000, have added the practices and principles of Six Sigma together they have many synergies and Six Sigma is a natural step in the evolution of continues improvement at an ISO 9000 company. To find out synergies between six sigma and ISO 9001:2008, we develop some question to get experts opinion. We visited Wire Manufacturing Industry Limited they have issue of lead time, we found some nonconformities in the quality work. How quality management system and six sigma deals with those nonconformities we will discuss this below.

## Case Study

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### **Company Introduction**

Wire Manufacturing Industry Limited is situated 45 KM, Multan Road, Lahore – Pakistan. Wire Manufacturing Industry Ltd. (WMIL) was incorporated on 31st October 1992. The company has installed a brand new state-of-the-art plant imported from Europe/South Korea, which is the only plant of its kind in Pakistan. WMIL has been accorded ISO 9001 certification by world-renowned quality certification agency BVQI. Mr. M. Iqbal (C.F.O / M.R) is the main resource person for communicating and sharing of information The Company consists of 100 employees and operating in two shifts.

### **Products and Production Capacity:**

The main products are Pre-stressed Concrete Wire/Strand (P.C. Wire/Strand) conforming to ASTM A-416, A-421 or B.S. 5896 in Grade 250/270-K (Normal Relaxation) which are used for bridges, storage tanks and silos, high pressure concrete pipes, railway sleepers and concrete poles; other products include drawn wire in medium and High Carbon from 1.60 mm to 16 mm. We also manufacture H.T. Steel Wire for Railway Concrete Sleepers. Apart from Pre-stressing Industry, we are also major suppliers of Spring Wires.

Pre-stressing of concrete by using P.C. Strand is the introduction of desirable compressive forces into Concrete member. These compressive forces are designed to offset or neutralize any subsequent tensile forces, which occur when concrete member is loaded. Since, concrete has very little tensile strength, pre-stressing permits the concrete member to withstand tensile forces without cracking.

The said project is designed to manufacture 12000 M.tons per annum of P.C. Wires/Strands, Spring Wires etc.

### **1. Audit Objectives**

The objectives of this audit are to confirm that the management system conforms to all the requirements of the audit standard ISO 9001:2008; to confirm that the organisation has effectively implemented its planned arrangements and to confirm that the management system is capable of achieving the organisation's policies objectives.

### **3. Basic Inputs and Initial Planning:**

Activities/locations/processes/functions of the organization based on the audit plan which was submitted and agreed with the auditee prior to the audit were covered which are listed in Audit Summary section (Audit Matrix) of the report.

#### 4. Key people interviewed / involved

Name	Department/Process
Mr. Muhammad Iqbal	Chief Financial Officer / M.R
Mr. Mukhtar Hussain	Quality & Lab Incharge
Mr. Muhammad Mushtaq	Production Manager

#### 5. Audit Findings

The audit against ISO 9001:2008 standards was performed on 16th March to 20th March 2015. The audit team conducted a process-based audit focusing on the ISO 9001:2008 standards requirements. The audit methods used were interviews, observations of activities and review of documentation and records.

The onsite audit was started with an opening meeting which attended by the senior management of the organization.

During audit noted Wire Manufacturing Limited has established, documented and maintained Quality management system based on the requirements of ISO 9001:2008 Standards. The documentation of the organization's management system was reviewed and found in compliance with the requirements of the above mentioned standards.

It was found that the company has incorporated all requirements of the ISO 9001:2008 standards in an effective manner, the relevant documentation has been developed accordingly and effectively implemented throughout the organization.

The organization objectives were reviewed for the various requirements against the requirements of Quality Management System in order to establish decision for Certification against ISO 9001:2008 Standards.

During closing meeting 4 minor nonconformities were communicated and handed over to the management of the organization. It was shared after acceptance of corrective actions; recommendation for certification will be given to organization.

#### **Quality Manual Adequacy: (WMI/QSM/01)**

The Organization has established quality manual and the scope of quality management system found established and documented procedures have been developed. It was verified that the quality manual has addressed all the requirements as per the standard and was available at relevant locations. The interaction between the processes has been defined in manual. It is noted that the manual was not updated and auditor raised the NCR.

## **NCR 4: Manual was not updated as per current version (ISO 9001:2008)**

### **5.2 Validation of Scope & Exclusions**

During site tour observed organization is engaged in manufacturer of wires

Exclusions were defined in manual clause reference scope is clear and exclusions justified. Exclusions were comprehensively discussed and defined

### **7.3**

The company is not carrying design & development work as product is being manufactured as per the specification / standards of ASTM.

### **7.5.2**

There is no process which requires validation or where the output cannot be measured by any subsequent mean.

### **7.5.4**

No customer property in system therefore this clause is excluded

## **5.3 Level of Integration (in case of Integrated Management System Audit)**

Not applicable. The organization has only Quality Management System.

## **5.4 Achievement of Policy commitments and Objectives**

Wire Manufacturing Limited has established a Quality management system policy. The policy is authorized and signed by top management. Quality management system policy found displayed throughout the facility, translated into local language and communicated to employees, visitors and contractors. Policy found available to public as well as interested parties. Quality Policy found well defined and appropriate to the nature of organizations & Quality impacts of organization's activities.

Wire Manufacturing Limited has established QMS objectives and targets for the year 2015. Management programs are established, which illustrate actions to achieve objectives. Target

dates and responsibilities for achieving these objectives found clearly established within management programs. The following objectives were reviewed and found measurable

- 1- To maintain the supply of 0% defective products to the customers
- 2- To install and operate new accounting software by the end of November 2015
- 3- To automate store activities

## **5.5 Description of system conformance & Capability**

### **Internal Audit: (WMI/QSP/11)**

Procedure for planning, conducting, recording results and reporting the audits on Quality management system found established and implemented. The mechanisms of investigating and taking actions on audit findings are also described in the procedure. The internal audit was conducted on 25/01/2015. During the internal audit process, 6 internal audit nonconformities found and the organization has not taken the action in some of them as mentioned target dates on NCR's (observation). It is also noted that M.R conducted the audit his own department and the auditor raised the minor nonconformity.

### **Minor Nonconformity – 01**

**Though the audit was conducted on 25/01/2015 but in case of M.R, he conducted the audit his own department**

### **Management Review (WMI/QSP/03)**

Last management review found conducted on 12/11/2014. The input requirements of the Quality Management System standard were adequately covered in MR report and decisions and actions arising from the management review process were documented in Minutes of Management Review. Information found clearly communicated through minutes of meeting also detailing action items, responsibilities and target dates. As per procedure, quarterly management review is being conducted but it is noted that targets dates not given to responsible person by given by top management in last management review (observation).

### **Corrective and Preventive Action: (WMI/QSP/15)**

Procedure addresses the corrective and preventive action including control of nonconformance. It was verified and found that the new requirements of ISO 9001:2008 standards were addressed adequately. CPA's are being raised and suitable corrective actions were taken on audit/system NCRs and customer's complaints to avoid recurrence of non-conformities. In this regard, the CPA # 07 was reviewed which is raised by production department to purchase department. It is noted that properly action has been taken and closed.



### **5.5.1 General**

Wire Manufacturing Limited has established a well-documented Quality Management System by adopting Quality aspect impacts based approach. The organization has identified all manufacturing activities, SOP, methodologies and criteria defined in relevant procedures and observed through physical practices. It was observed that the top management is committed to the effective establishment, implementation, maintenance and its continual improvement of Quality management system. Management Representative was appointed with clearly defined responsibilities and authorities.

Wire Manufacturing Limited has also complied with the documentation requirements through establishing documented quality policy, quality objectives, and quality manual, mandatory procedures of document control, record control, internal audit, and control of nonconforming product, corrective and preventive actions. Other procedures and work instructions related to process and operations were also found established and documented during the audit of relevant departments. The organization also maintains a substantial amount of records for processes, operation and quality management system related activities to provide evidence of on-going implementation of the quality management system.

As per the scope of activities the organization is not involved in any outsourcing activities.

### **5.5.2 Planning**

#### **Documentation, Control of documents and records: (WMI/QSP/01)**

The Control of Document & Record procedure was established and maintained and it was found that changes were made in the manual. It was also found that updated version of documents were available at relevant locations. Master list of controlled documents was verified and found that all documents were listed with current revision status, review and approval authorities, and distribution records. List of external origin documents was also verified. Master list of records was reviewed and found that all records were identified and listed on the index with defined retention periods and disposition authorities. External origin documents found well maintained. Different records were checked quality checklist, receiving inspection, Purchase requisitions, Purchase Orders, minutes of last management review, internal audit & trainings etc. And found adequately maintained.

Computer generated records are stored regular basis into cd's. These Cd's are located at the C.E.O office for proper keeping and storage of records were found in good shape and their retention time found established and maintained.

#### **Policy:**

Wire Manufacturing Limited has established a Quality management system policy. The policy is authorized and signed by Top Management. The policy was found to be appropriate to the activities detailing commitments continual improvement of the Quality Management System Performance. The Quality Objectives found derived from the policy as it provides

framework for establishing and reviewing objectives. Understanding of policy within the organization was verified and observed as adequate. Quality management system policy found displayed throughout the facility and communicated to employees.

### **Objectives and Programs:**

Wire Manufacturing Limited has established QMS objectives and quality achievement plan for the year 2015. Quality Plan illustrates actions to achieve objectives. Target dates and responsibilities for achieving these objectives found established. Performance against objectives covered in management review meeting. The following objectives were reviewed and found measurable

- 1- To maintain the supply of 0% defective products to the customers
- 2- To install and operate new accounting software by the end of November 2015
- 3- To automate store activities

### **Roles, Responsibility and Authority:**

Organization has established an organogram which identifies reporting and communication channels, job descriptions have been documented which define responsibilities and authorities. Job Descriptions of Management Representative, Production Manager & Printing Supervisor were reviewed and found adequate.

## **5.5.3 Implementation & Operation**

### **Planning of Product Realization:**

It was observed that the organization is planning and Producing Product in a controlled manner. Availability of suitable equipment's, monitoring and measuring devices / equipment's, monitoring and measurement of services at different processes stages and implementation of proper work instruction and Procedures are being ensured.

Batch wise Production plans are being issued by the Sales department which is approved by Director. The plan can be further classified as:

- Pickling Plan
- Wire drawing and Stranding Plans.

Here,

Pickling means treating the raw coil in HCl Solution so that all rust or any adherent particle can be removed

Wire drawing means to stretch the mother roll to decrease the diameter and increase the length of mother roll.

Stranding means to twist two or more wires to make one roll. Normally six wires are being twisted together to form one final roll.

However, this plan can be revised time to time by considering any new requirement specified by the client or sometime un-availability of Pickled coils. In such case plan is approved from General Manager Marketing.

It was seen that production is being carried out as per the plan; the plan is reviewed on daily basis that clearly explains the deviations in the planning. In some cases deviations from planned product were also observed, however the revision of planning was approved by the competent authorities.

**Production of the following Product was verified during the audit:**

**Planning Date: 10/03/2015**

**Item: ½ P.C Strands**

**Product coil No. 10770**

**Batch No. 687/12**

**Quantity: 07 Coils**

**Weight: 14400 KGS**

**Customer: TTC & ZKA (JV)**

The auditors verified Production schedule is not proper for the current month and maintained, production control procedure was developed, operating process developed, different standards used to test the product.

It was observed that the organization is planning and producing product in a controlled manner. Availability of raw material, monitoring and measurement of its installation at different proces stages and implementation of proper work instruction and procedures are being ensured.

**Customer Related Process:**

Marketing departments received the queries from customer and determines and reviewed the requirements related to products including legal & regulatory requirements. Manager Sales is primarily responsible for determining requirements related to product and communicating necessary information to customers. The communication is being done through email, telephonic and fax. The company provides product to its existing customers (like construction companies etc), Export the product and supplies product to industries. All type of inquiries are logged in Sales and Marketing department. Manager Sales makes an Inquiry review and forward to Production Manager for further processing. However, in some cases Export inquiries are reviewed by General Manager Marketing and Director:

Following sale inquiry was reviewed and found done as per the defined procedure:

Purchase Order #: 765-Consutraction Div

Customer: Frontier Works Organization (FWO)

Inquiry date: 23/02/2015

Product: Strands, 0.5 mm

Quantity: 02 Coils

Delivery Date: 28/02/2015

Outward Gate pass: 7422

Purchase Order #: 02-11-07-006

Customer: Pakistan Cycle

Inquiry date: 5/07/2013

Product: Steel Wire 4.5 mm

Quantity: 07 Coils

Delivery Date: 04/05/2014

Outward Gate pass: 7413

### **Customer Communication:**

Customer communication is done through email, fax and phone and found to be effective. The Organization was found analyzing the customer satisfaction level, customer complaint and customer feedback form in a satisfactory manner.

### **Purchasing Process**

Purchase department is responsible of all activities related to purchase. Purchase Officer gets the queries from different department and purchase officer discussed with store incharge about the stock level. If stock is not available or not enough, he gets the quotations from approved vendors and makes the comparison sheet. After getting the all information, he sends comparison sheets to Director / G.M for approval. After approval he formally raises the purchase order to the selected vendors. In this regard, the following records were verified and found according to define in procedure

Dated – 02-03-2014

Supplier – Sitar Chemicals, Faisalabad

Item – Hydro Choleric Acid (HCL)

PO # 859

Order Qty – 1000 KGS

Received Date: 3/3/2014

GRN#: 7263

Date: 24-01-2015

Supplier – Meta Prep (Pvt.) Limited

Item: Meta Phos for Pickling Plant

Order Qty – 240 KGS

PO # 931

Received Date: 27/01/2015

GRN#: 7312

### **Verification of Purchased Product**

Purchased product/service is verified by concern department and the goods receiving note was established. After receiving the product/service quantity is normally verified by the concern / purchase department and quality by QA. In addition, receiving inspection report for verification of product is also generated and verified for above mentioned Pos and found satisfactory.

Generally, the organization purchased the goods from approved suppliers. In this regard, the auditor reviewed the records of supplier's evaluation.

The Organization has established the selection criteria for suppliers; list of approved suppliers was available. The following supplier's evaluation records were verified and found adequate

- Umer Usman Traders
- Maqsood Ali
- Waheed Brothers
- Shahid & Sons

Performance of suppliers is being monitored regularly and analyzed and recorded. They have developed the criteria for selection like quantity, cost effectiveness, timely delivery, quality checks etc. Supplier's re-evaluation is done on annually basis. It is noted that no date mentioned on few supplier's evaluation form (observation)

## **Control of Production and Service Provision:**

Wire Manufacturing Industry Limited has established a procedure and process flow chart for production and for product realization. Product information was available throughout the realization process. Work instructions were reviewed and found compliant with the requirements. Organization develop quality plan for process follow and process verification areas are clearly define. Production Manager is responsible to develop the activities plan as per provided the information by marketing department. During the audit following records were verified in production area.

During the reviewing of production record, the following noncompliance was found

### **Minor Nonconformity – 02**

**Internal Production order (WMI/QR/10) is not being issued to production as mentioned in procedure for production and service provision (WMI/QSP/07)**

During the factory tour and reviewing of records of maintenance, it is noted that corrective maintenance is not being done in the defined period and the maintenance record was also not maintained after 05/07/2013 moreover preventive maintenance records not available

### **Minor Nonconformity – 03**

**Maintenance records was not maintained after 05/07/2013 moreover preventive maintenance records (WMI/QR/21) not available as per procedure (WMI/QSP/07)**

## **Identification & Traceability:**

Identification & Traceability has been maintained through tags and board displayed at different work stations. Traceability is made through product traceability report:

Traceability is maintained by the following way:

- Each mother coil / roll has been given a unique roll number by the supplier.
- Mother roll after pickling is traceable by Pickling report
- New rolls after the drawing of mother roll are traceable to their mother rolls.
- Workers involved in drawing, stress reliving, pickling etc are traceable by their respective log reports.

It is noted in pickling section that chemicals drum, steel wires and were not identified

### **Preservation of Product:**

Store and Execution departments are responsible to ensure that the handling of materials and equipment's have been done properly. Adequate storage and preservation of the final product (PC Coils) were observed, the warehouse is weather protected to avoid any corrosion on the product.

### **Control of Monitoring and Measuring Equipment:**

During the review of records related to calibration, the organization has calibrated the all instruments which are critical with respect of product quality. The following calibration records were reviewed and found satisfactory.

- 1-WIM-001 Vernier Caliper (20-12-2014)
- 2- WIM-002 Digital Micro Meter (20-12-2014)
- 3- WIM-003 Extension Meter (20-12-2014)
- 4- WIM-004 Universal Tensile Tester Machine (31-12-2014)

### **Provision of Resources:**

The Organization has established a system to determine the resources required to implement, maintain and continually improve the effectiveness and give awareness of customer requirement throughout the organization to enhance customer satisfaction. Effective tooling and other resources has been provided in order to achieve the organization's goals.

### **Human Resources:**

System for Hiring, Criteria for the evaluation and selection of human Resources has been established. Job descriptions were verified of Production Manager, Mechanical Engineer, Supervisor, M.R & Helper found adequately.

### **Competence, Training and Awareness:**

System for training, awareness and competence found developed. The Training plan for the year 2015 was reviewed and in this regard, the record of following training was reviewed and found compliant as per mentioned in training plan

Training Date: 21/02/2015

Training Related to: Quality Control Activities

Trainer: Mr. M. Mukhtar

Duration: 10:30 AM to 12:30 PM

It is noted in records that competency criteria was also defined and reflected this criteria in personal files.

## **Infrastructure:**

Necessary infrastructure has been provided in terms good equipment, qualified personnel, buildings, work space and necessary support services throughout the organization.

The work environment of organization is considered an important process to manage the quality system. In this regard, the top management has provided the all necessary resources. Company has determined and manages the work environment needed to achieve conformity to product requirements. This includes healthy and safety conditions, and ambient working conditions. It is noted that exposed/naked wires found in production and the auditor communicated to the management with respect of observation

## **5.5.4 Monitoring and Measurement:**

### **Monitoring and Measurement of Processes & Products:**

Noted organization applies suitable methods for monitoring and measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. Inspections were carried out according to the quality plan describes type of inspection, test, responsibility for inspection, reference checklist, reference standard. The acceptance criteria as per product requirement were identified in the records and the procedures. The following data was reviewed and verified according to the defined specifications while visiting of the site

Following are the main process parameters which are recorded during product realization:

- Pickling time (residence time of mother roll in HCl solution)
- Drawing Efficiency
- Wire breaking

Raw Product like mother rolls in each lot has also been inspected and verified against set ASTM standards, besides supplier like, sends a compliance certificate along with each consignment.

Testing of the following Material was verified:

Coil No. 10657

Item: ½ P.C Strand

Batch #: 685/12

Dia: 12.71

Lay Length: 170

Breaking Load: 20292

Yield Load: 17248



Elongation: 3.6%

Unit Weight: 776

Each coil of PC wire / Final product is tested against the following specifications.

- Nominal diameter
- Breaking Load
- Linear Density
- Load @ 1 % extension
- Ultimate breaking load
- Gauge length
- Mass / km
- Elongation
- Yield Load.

Testing of Batch no 687 /12 was also verified and found adequate.

### **Internal Audit: (WMI/QSP/11)**

Procedure for planning, conducting, recording results and reporting the audits on Quality management system found established and implemented. The mechanisms of investigating and taking actions on audit findings are also described in the procedure. The internal audit was conducted on 25/01/2015. During the internal audit process, 6 internal audit nonconformities found and the organization has not taken the action in some of them as mentioned target dates on NCR's (observation). It is also noted that M.R conducted the audit his own department and the auditor raised the minor nonconformity

### **Minor Nonconformity – 01**

**Though the audit was conducted on 25/01/2015 but in case of M.R, he conducted the audit his own department**

### **Customer Satisfaction:**

Organization has also established a mechanism to entertain customer complaints. According to procedure, complaints are received through phone/ fax, email etc. After receiving the complaints, corrective and preventive action form generated so that the proper root cause analysis, corrective and preventive action can be found but it is noted that during the last one year no customer complaint received. Customer feedback is taken from customers/buyers on completion/ regular basis. MR has developed the analysis.

### **Control of Nonconforming Product:**

The company has established a documented procedure for the control of Non-Conforming Products. The procedure was found adequately describing the methods for identification, segregation, disposition and taking actions against Non-conforming products.

Raw Coils that are out of internal specs are being treated as Non-conforming products which are either returned to supplier or accepted with some concessions and used in for some other purposes. Records of such Non-conforming coils are kept with GM Procurement

During the process, following can be the possible Non-conformities:

- Pickling rejection (recorded on Pickling report)
- Size change in case of wrong drawing (records are kept in drawing report)

Records of stage Non-conforming products were verified and found adequate.

### **5.5.5 Improvement**

#### **Analysis of Data:**

Appropriate data was found collected i.e. Customer feedback, Supplier's performance, Process and product performance analysis, Production efficiency, internal audit results and customer complaint etc were reviewed and found satisfactory.

#### **Continual Improvement:**

The organization has established a system for continual improvement and effectiveness of the quality management system through the use of the quality policy, objectives, audit results, analysis of data, corrective and preventive actions and management review, which was found working satisfactorily.

#### **Management Review (WMI/QSP/03)**

Last management review found conducted on 12/11/2014. The input requirements of the Quality Management System standard were adequately covered in MR report and decisions and actions arising from the management review process were documented in Minutes of Management Review. Information found clearly communicated through minutes of meeting also detailing action items, responsibilities and target dates. As per procedure, quarterly management review is being conducted but it is noted that targets dates not given to responsible person by given by top management in last management review (observation).

#### **Corrective and Preventive Action: (WMI/QSP/15)**

Procedure addresses the corrective and preventive action including control of nonconformance. It was verified and found that the new requirements of ISO 9001:2008 standards were addressed adequately. CPA's are being raised and suitable corrective actions were taken on audit/system NCRs and customer's complaints to avoid recurrence of non-conformities. In this regard, the CPA # 07 was reviewed which is raised by production department to purchase department. It is noted that properly action has been taken and closed.

### **5.6 System strengths**

The conformance level of following processes observed as highly consistent:

- Top management commitment to Quality management system
- Teamwork and involvement of employees at various levels
- Work instruction displayed at relevant locations

## 5.7 Nonconformities

### **NCR 1:**

#### **Minor Nonconformity – 01**

**Though the audit was conducted on 25/01/2015 but in case of M.R, he conducted the audit his own department**

### **NCR 2:**

**Internal Production order (WMI/QR/10) is not being issued to production as mentioned in procedure for production and service provision (WMI/QSP/07)**

### **NCR 3:**

**Maintenance records was not maintained after 05/07/2013 moreover preventive maintenance records (WMI/QR/21) not available as per procedure (WMI/QSP/07)**

### **NCR 4:**

**Manual was not updated as per current version (ISO 9001:2008)**

## 5.8 Observations

Ref. #	Grade	Status	Summary of Finding	Sector/Division/Location	Date	Standard	Clause
GMD 1	OB S	Ne w	Few internal audit nonconformities not closed despite of mentioning target date on NCR	M.R	16/06/2012	9K	8.2.2
GMD 2	OB S	Ne w	Target dates not given to responsible person in last management review	M.R	16/06/2012	9K	5.6.3

MAN 3	OB S	Ne w	Items were not identified in pickling section	Production	16/06/20 12	9K	7.5. 3
GMD 4	OB S	Ne w	Dates are not mentioned on supplier's evaluation forms	Purchase	16/06/20 12	9K	7.4. 2

*Table 6 Quality Management System ISO 9001 Observation*

## **5.9 Opportunities for Improvement**

### **6. Uncertainty / obstacles that could affect the reliability of audit conclusions**

None

### **7. Unresolved diverging opinions between the audit team & auditee**

None

### **8. Agreed follow-up actions**

The management has agreed to take action against minor nonconformities and observations.

### **9. Conclusion:**

The Quality management system documentation demonstrated conformity with the requirements of the audit standards and provided sufficient structure to support implementation and maintenance of the Quality management system,

Wire Manufacturing Limited has demonstrated the establishment and tracking of appropriate key Quality performance objectives and targets and monitored progress towards their achievement,

### **10. Recommendation**

The audit team conducted Quality Management System audit focusing on objectives required by the standard ISO 9001:2008 Standard. The audit methods used were interviews, observations, sampling of activities and review of documentation and records.

The structure of the audit was in accordance with the audit plan and audit planning matrix included in the Appendices to this summary report.

The audit team concludes that Wire Manufacturing Limited has established and maintained its Quality management system in line with the requirements of the standard ISO 9001:2008 and demonstrated the ability of the system to achieve requirements related to QMS within the scope and the organization's policy and objectives.

Therefore the audit team recommends certification of this Quality Management System, based on acceptance of corrective actions against raised minor NCRs.

COMPANY SUMMARY REPORT FOR ISO 9001:2008																								
Company / Site:			Processes																					
Wire Manufacturing Industry Limited			A	B	C	D	E	F	G	H	I	J	K	T O T A L S										
Auditor:			Management Representative	Sales & Marketing	Production Process	Quality Assurance / Lab	Warehouses	Purchase	Administration & HR															
A																								
B																								
Exclusions / Justifications:																								
7.3, 7.5.2, 7.5.4																								
Shifts Audited: Check all that apply																								
First	Second	Third																						
X																								
															1	1	1	1	1	1	1			
	Auditor -A, -B													A	B	A/B	B	A	B	A				
	Period (10:00 A.M. / 5: 30 P.M.)																							
4.1	General Requirements		X	X	X	X	X	X	X															
4.2	General Documentation Requirements		1	X	X	X	X	X	X				<b>1</b>											
5.1	Management commitment		X	X	X	X	X	X	X															
5.2	Customer Focus		X	X	X	X	X	X	X															
5.3	Quality policy		X	X	X	X	X	X	X															
5.4	Planning		X	X	X	X	X	X	X															

5.5	Responsibility, authority and communication	X	X	X	X	X	X	X					
5.6	Management Review	X											
6.1	Provision of resources	X	X	X	X	X	X	X					
6.2	Human resources	X						X					
6.3	Infrastructure	X	X	X	X	X	X	X					
6.4	Work environment			X	X								
7.1	Planning of Product Realization			X									
7.2	Customer-related processes	X											
7.3	Design and or development	EXCLUSION											
7.4	Purchasing						X						
7.5 .1	Control of Production and Service			<b>2</b>	X								<b>02</b>
7.5 .2	Validation of Service	EXCLUSION											
7.5 .3	Identification and Traceability		X	X	X	X	X	X					
7.5 .4	Customer Property	EXCLUSION											
7.5 .5	Preservation of Product					X							
7.6	Control of measuring and monitoring equip				X								
8.1	General	X	X	X	X	X	X	X					
8.2 .1	Customer Satisfaction	X											
8.2 .2	Internal audit	1											<b>1</b>

8.2 .3	Measurement and monitoring of processes			X	X								
8.2 .4	Measurement and monitoring of product			X	X								
8.3	Control of Non-conforming Products			X	X								
8.4	Analysis of Data	X	X	X	X	X	X	X					
8.5 .1	Continual improvement	X	X	X	X	X	X	X					
8.5 .2	Corrective action	X	X	X	X	X	X	X					
8.5 .3	Preventive action	X	X	X	X	X	X	X					
	Use of Logo's	X											
		MAJOR			NIL			MINOR			04		

Table 7 COMPANY SUMMARY REPORT FOR ISO 9001:2008

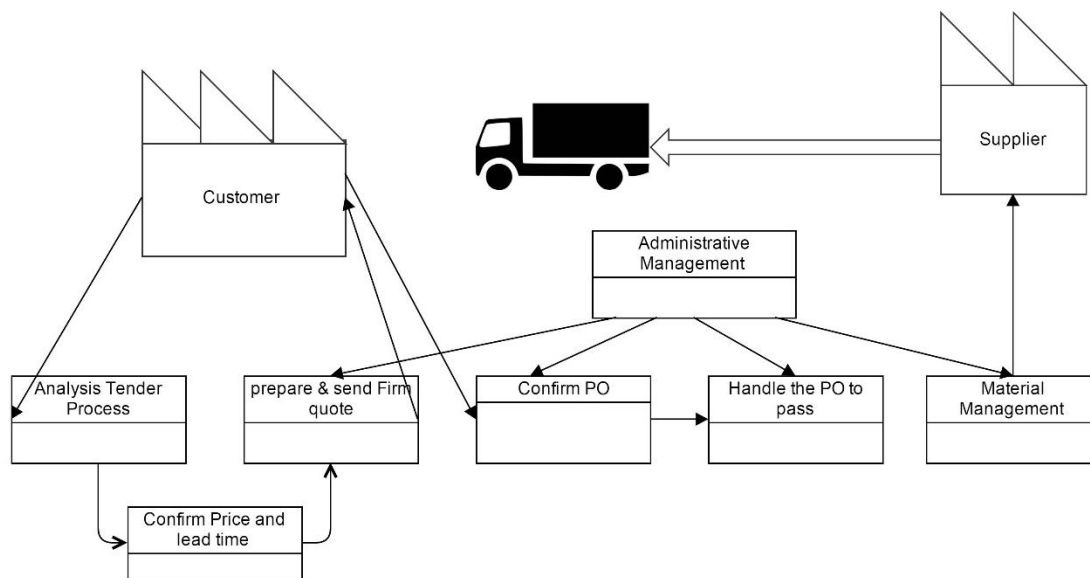
## Six sigma Methodology:

Wire Manufacturing Industry Limited facing problems due to non-conformities that is mention above. One of the main problem is the long lead time, and there is no up to date system to handle the production according to the customer demand. Therefore company is facing issue of the delay customer order. We can improve this process by applying the Make to order (MTO) and proper documentation. Six sigma methodology is an important tool to overcome this problem.

### Define Phase:

In this phase develop the value stream map of the process and the CTQ characteristics are established.

**a) Construction of the value stream Map,**



*Figure 11 Value stream Map*

**b) Identify the Critical to Quality (CTQ) characteristics:**

The CTQ characteristics were collected as follow,

**Critical to Process:** As a result of the VSM analysis the team identified the following KPIs that are critical to process. Percentage of Gross margin for each project and process long lead time.

**Critical to Customer:** It was found that “Delivery on time as mentioned in the Purchase Order” is the most critical measure.

**Critical to Compliance:** It was found that the availability of a standard quotation template that the sales department can use to deal with all customers is a very important measure.

**c) Identify Problem:** By analyzing all the process and the critical to the quality it is decided that most critical problem that is effecting the system is the long lead time and the main cause of this problems are maintenance of the system in order keep the system smooth, internal production order, relationship with supplier and update of the manual up to the standards to attain the desire quality level. Therefore the management needs to find the causes of the problem and a way to solve it.

**Measure Phase:**

In this phase the relevant KPIs will be identified according to the BSC methodology, linked them and then measured.



Four balance score card perspective and their relevant KPI's are identified that are given in the table below. The reason for the chosen of these KPI's are that they represent the problem that need to fix in a direct and indirect relationship.

BSC Perspective	KPI's
Financial	Gross Margin
customer	<ol style="list-style-type: none"> <li>1. Number of Milestone delivered before date</li> <li>2. Quotation done before planned date</li> <li>3. Order delivered on Time</li> </ol>
Processes	<ol style="list-style-type: none"> <li>1. Continuous or smooth process without any break down</li> <li>2. Number of working hour on each processes</li> </ol>
Learning and Growth	<ol style="list-style-type: none"> <li>1. Number of actual man hours on the process training</li> <li>2. Number of employees who reached 85% capability</li> </ol>

*Table 8 KPI Corresponding to BSC Perspective*

As shown in the table, order delivery on time, man hour in working on the process and continuous operation without break down are highly connect KPI's that can affect the system.

**Analysis phase:**

In this phase cause of the problem is identified. We used cause and effect analysis to identify the root cause of the problem. The current process state is manual there is a communication gap between the production department and other departments. ERP system need to be introduced. The analysis of the whole process showed that the long lead time was due to following causes,

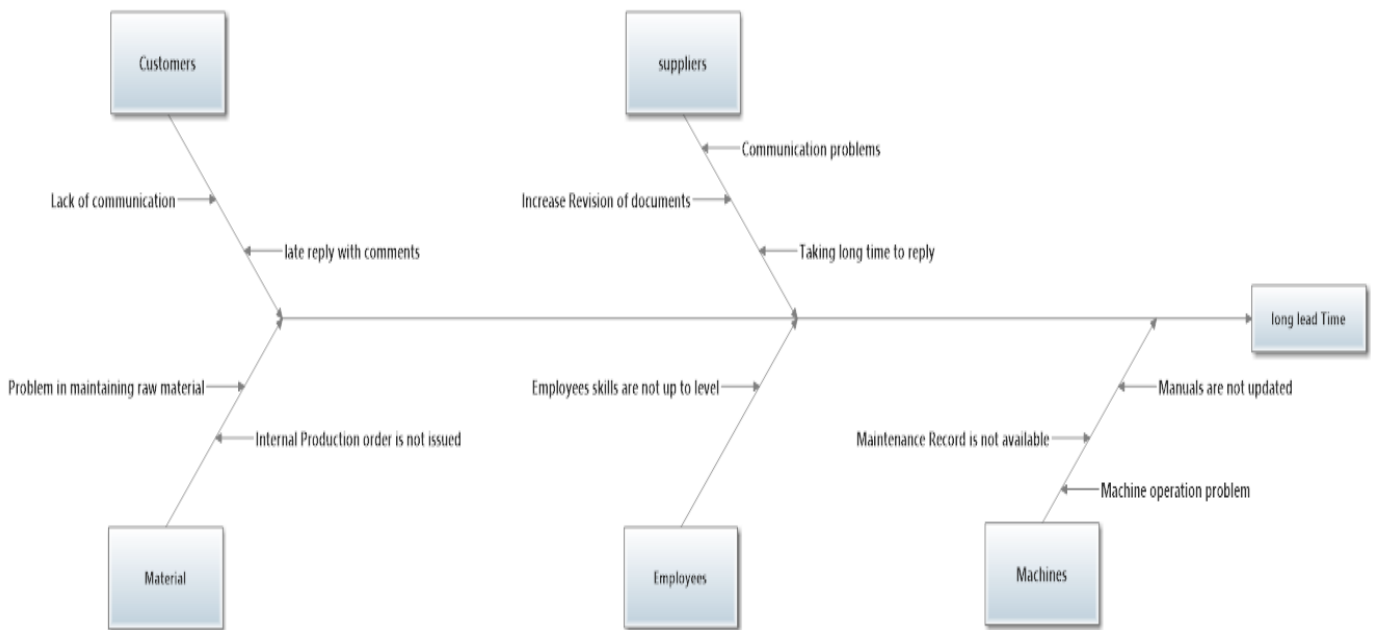


Figure 12 Fishbone Diagram

### Improve:

From the Analyse phase the material supplier, preventative maintenance, updated manuals and proper documentation appeared to have the most influence on the long lead time, and for that a solution must be found. The team suggested following solutions for the problem:

1. Improve the relationship with the current suppliers
2. Find new suppliers.
3. Keep the Manual and maintenance record up to date

For each scenario the necessarily changes will make for the input data in a way that reflects what has been changed in the system. To “Improve the relationship with the current suppliers average time reduced. To find “a new supplier”. All the delays caused by the suppliers are eliminated. And the waiting time also reduced. For “on time maintenance and keeping the manuals up to date” has great impact on the overall system and it increases the efficiency of the processes. It will also reduce the lead time. After implementation of new updated accounting software and automated store and production activities that will reduce the lead time.

The production area did not seem as neat and tidy as it should be. To address this, we introduce the concept of 6S, which is work management philosophy that refers to the following,

Sort: Eliminate unnecessary items from the work space, leaving only tools, equipment, components and machines that are required on the ongoing processes

Set in order: Identify and organize everything in the work space, such as tools, equipment's,

Shine: conduct regular cleaning and maintenance which is main drawback in weir manufacturing Industry.

Standardize: Do the above in standard and consistent manner

Sustain: Maintain what has been accomplished

Safety: concentrate on a safety aspects of our initiative, reviewing every action and each are to ensure that we have not overlooked any potential hazards

Through 6S we can gain the highest level of employee engagement.

### **Control:**

In this phase the company must do something that will enable it to have control on continues improvement process. This tool contains the current and the future value stream, and how the team is going to reach this future value stream map. The company can establish any process or method that will enable it to have a continuous improvement to the process. Also the KPI's are listed with the target the company expects by the end of the fiscal year. Also, the action plan and who will be responsible to implement this action is listed under the future value stream map.

## Conclusion:

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The Six Sigma concept alongside with the quality management system ISO 9001 would be the beneficial approaches to reduce or eliminate defects in the industry. They are simplified and focused through using the simple tools and identifying the most critical issue in each process. The literature of Six Sigma, quality management system ISO 9001 is explained in detailed in this project. Company literature review done and a systematically approach designed to compare it with the different clause of the ISO 9001 and six sigma. Many companies, who have started with ISO 9000, have added the practices and principles of Six Sigma together, they have many synergies and Six Sigma is a natural step in the evolution of continues improvement at an ISO 9000 company. To find out synergies between six sigma and ISO 9001:2008, we develop some question to get experts opinion. Different people gave their opinion on that questions e,g you can use six sigma to show continual improvement in ISO 9001. In coming version of ISO 9001:2015, Process Management is mentioned many times as one of the very crucial quality management principles ISO 9001 is based on. It requires a focused attention. While, ISO 9001 focusses on Overall Systems Management with a process approach.

It is a fact that the ISO 9001 is a set of requirements telling you which areas you should focus and be able to show progress in. The standard does not neither tell you how to create and formulate your targets nor how to reach the wanted progress in each specific area. The ISO 9001 does not include such things due to it's a standard with a set of requirements. The organization has to decide what specific targets to set up and which kind of tools to be used in the internal improvement process. There you can use 6Sigma, Lean, PDCA or whatever you find applicable for your own company.

We visited Wire Manufacturing Industry Limited through their audit report we found some nonconformities due to that company is facing problem of lead time. We tried to solve those issue according to the available data and gave some suggestions. We realized that there is a lack of simulation usage in projects; hence we propose to use the simulation method in the implementation of DMAIC. Simulating the real process on computer with all possible variables helps to change parameters at the same time and the effects of each change could be seen and compared immediately.

The framework can be used to integrate quality management system and six sigma techniques with lean concept into one strategy. It is a generalized framework that enables the decision-maker to first measure, holistically, the company performance with respect to customer requirements. It then enables the company to analyse potential performance problems, propose solutions, evaluate the suggested solutions, and make a cost-effective decision according to the Six Sigma systemic process improvement methodology.

In our cases we discovered that how the quality management system reacts with the nonconformities and DMAIC is very useful tool to improve the process in the manufacturing industry. Each DMAIC phase is totally interrelated with each other phases and the decisions that are taken in the beginning drives the rest of the project.

Day by day in the current market conditions, customer expectations are increasing and there is an increase in customized products. In order to produce more customized products in affordable prices there must be reliable and sustainable production systems. In exploring the synergies of Quality management system and Six Sigma with the lean concept would provide a reliable and sustainable production system with continuous improvement.

We observed that now it is the best and right time to integrate the Six Sigma and quality management system to boost the industry. With present economic conditions companies have to cut their bottom line costs to be remained profitable and this new concept gives a chance to firms not only stay alive but also become more powerful, efficient and competitive.

To sum up we can say that in some aspects integration of Six Sigma and ISO 9001 is helpful in improving the processes reducing Waste and helps in increase overall benefit to the organization.

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