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Quality Engineering and Management

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Abstract: All production processes employ materials, men and machines. Each of these elements has some *inherent variability* in addition to *attributable variability*, which can be controlled to an irreducible economic minimum. The subject of quality engineering and management is about reducing the variablity in products and processes, quality costs and to provide maximum satisfaction to the customers through improved product performance. The subject has grown considerably since 1930, when Shewhart first developed his statistical approach to quality. Several developments that have taken place since then are presented in this chapter along with quality planning, control, assurance and improvement, which form the backbone of any quality program.

12.1 Introduction

Quality is a world wide concern of manufacturers. However, the word quality has had different connotations when used by different people. The definition has also undergone changes and its meaning has been extended over time but it can be definitely called an attribute that is generally used to reflect the degree of perfection in manufacturing of a product. It is easy to realize that this degree of perfection is inversely proportional to the variability present in the process. All manufacturing processes involve materials, men and machines and they all have some element of *inherent variability* in addition to *attributable variability*, which can be controlled to an irreducible economic minimum. Reducing variability in production is synonymous with improving the quality of the product.

The reason for material variation can be traced to inadequate care taken in the purchase of material (quality assurance), or on account of poor material specifications or due to urgency of purchase compromising the quality specifications, *etc*.

The source of variation due to machines is the natural limits of capability that every process has, which is also known as *process/machine capability,* and any attempt to reduce this range would cost heavily in terms of money. If the process is incapable of acceptable operation within design limits, then we have the option of separating nonconforming from conforming products, using more precise process or change in the design of the product or system in order to achieve an optimum design at minimum total cost.

The third source of variation is man himself and this is the most important contributor to variability. In fact, man's decisions or actions directly influence the extent of variability to a very large extent.

It is not difficult to realize that quality is inversely proportional to the variability, and one must try to reduce all sources of variability if quality is to be improved.

12.1.2 Definition

The most widely accepted definition of quality is: quality of a product is a measure of the degree of conformance to applicable design specification and workmanship standards. Obviously, this definition concerns itself with the manufacturing phase of a product. Several other definitions of quality have been put forward by several eminent practitioners but the central concept remains the same: the quality of a product is considered satisfactory if the product is able to satisfy the requirements of the consumer. Alternatively, it is an attribute of a product, which if incorporated into a product meant for a specific purpose or use, will satisfy a consumer. However, it is definitely agreed that bad quality affects reliability because inferior workmanship is likely to shorten the life of a product and thus its reliability. Earlier, in western management ensuring quality was left to the quality inspectors. However, it was Deming's work using statistical tools and scientific management philosophies in Japan that gave quality effort an impetus, importance and respectability, it has been acquired over time and quality tends to become all pervasive. Deming's 14 points for management provided the roadmap for quality movement in Japan and elsewhere.

There are others, mostly engineers, who do not quite agree with statisticians and have the notion that it is an engineering design effort, by which the performance of a product can be increased. They may as well be called as proponents of reliability and see quality as a necessary but not sufficient characteristic. There are others (mostly statisticians) who consider reliability effort as a part of the quality program. We will discuss the difference in the definitions of quality and reliability a little later in this paper, but it can be said with certainty that quality professionals themselves have struggled with the definition of quality for quite some time.

Crosby [1] defines quality as conformance to requirements or specifications. Juran [2] provides a simple-looking definition of quality as the fitness for use.

Deming [3] defined two different types of quality, *viz.*, *quality of conformance* and *quality of performance*. Quality of conformance is the extent to which a firm and its suppliers surpass the design specifications required to meet the customer's need. Sometimes, another aspect of quality is added to the definition of quality, *i.e.,* quality of design, which implies that the product must be designed to meet at least the minimal needs of a consumer. *Quality function deployment* is a system of product design based on customer demands with participation from all concerned. The quality of design has an impact on the quality of conformance, since one must be able to produce what was designed.

Quality of performance, on the other hand, is a measure, arrived at through the research and sales/service call analysis, in assessing how well a product has performed when put to use. It signifies the degree to which the product satisfies the customer or the user. This measure, incidentally, is synonymous with the concept of reliability and leads to redesign, new specifications, and to a product improvement program on a continuous basis for any manufacturing concern through interaction with the user or the customer.

Feigenbaum [4] defines quality as: the total composite product and service characteristics of marketing, engineering, manufacture, and maintenance through which the product and service in use will meet the expectations of the customers.

Taguchi [5] defines quality as the loss imparted to the society from the time a product is shipped. He also divides quality control effort into two categories; online and off-line quality control. On-line involves diagnosis and adjustment of the process, forecasting and correction of problems, inspection and disposition of product and follow up on defective shipped to the customer. The off-line quality control is quality and cost control activities carried out at the product and process design stages during the product development cycle. Taguchi's concept of quality, relates to determining the ideal target values (parameter design) and evaluating losses due to variation from the target value. Thus the objective of a quality program is to minimize total losses to the society, which means both the producer and the consumer.

Therefore, it is not without confusion that one may want to settle for a practical definition of quality. However, whatever definition of quality one might settle for, no one can deny that to ensure the basic objective of high quality, a designer must be able to translate the needs of the consumer into an engineering design, including specifications and tolerances; the production engineer must be able to design a production process that will produce the product meeting these specifications and tolerances; of course while ensuring minimum waste, emissions or pollution of the environment.

12.1.3 Quality and Reliability

Obviously, the widely accepted definition of quality did not concern itself with the element of time and could not say whether a product would retain its quality over a period of time nor did it mention the product's performance under a set of given conditions of use or environment. Neither of these elements form a part of quality but are inherent in the definition of reliability, which is defined as the ability that a product will perform a specified function over a specified time without failure under the specified conditions of use. One proceeds to eliminate or minimize the failures during the product's mission time and their causes and to improve upon the design [6]. Moreover, quality definition does not make itself expressible in terms of a probability figure, which reliability does. However, the quality of performance comes closest to the definition of reliability as far as satisfying the user's requirement is concerned and the concept of quality of design can help build reliability at the design stage. However, whether reliability is a part of the quality effort or whether quality is reliability during the manufacturing phase is a question over which statisticians and engineers often differ.

12.2 Quality Control

Quality control (QC) is the most important activity during manufacturing and aims to provide and maintain a desired level of quality of a product. In fact, QC is the name given to a set of techniques and means [7]: used to manage, monitor, and control all those steps that are necessary in production of a product of desired quality.

Juran [2] provides the definition of control as "The process of measuring quality performance, comparing it requirements, and acting on difference". Feigenbaum [4] defines control as a "process for delegating responsibility and authority for a management activity while retaining the means of assuring satisfactory results". This definition is sufficiently generic to apply to any activity, which may include products or services, and involves four steps of control, *viz.*,

- setting standards
- appraising conformance
- acting when necessary
- planning for improvements

The activities that need control include workmanship, manufacturing processes, materials, storage and issue of parts and materials, engineering design changes and deviations, production and incoming material inspection and tests, vendor control and many related activities. The most important concern in quality control is workmanship, which can be achieved by good manufacturing methods and techniques, and through inspection of manufactured product. If performed during the manufacturing the inspection is called an *in-process* inspection and if it is performed on finished product is called the *final inspection.*

Off-line Quality Control

The procedures involved in off-line quality control deal with measures to select parameters of product and processes in such a way that the deviation between the product or process output and the standard is minimized. This is mainly achieved through product and process design in which the goal is to produce a design within the constraints of resources and environmental parameters.

Experimental design is an important tool for improving the performance of a manufacturing process in the early stage of process development as this can result in improved process yield reduced variability and closer conformance to target requirement reduced development time and thereby in reduced overall costs. The principles of design of experiments and the Taguchi method [7] help to come up with off-line process control procedures. Chapter 17 of this handbook on robust engineering deals with a certain aspect of the problem and illustrates it through an example.

On-line Quality Control

Instead of taking off-line quality control measures, it may be necessary to take online quality measures to correct the situation. When the output differs from a specified norm, the corrective action is taken in the operational mode on a real time basis for quality control problems. In fact, this forms the basis of online statistical process control methods. The most effective method of controlling the process is the most economic and positive method. It is for this reason that quality control engineers use control charts, as it is always better to control the method of doing things while the process is being performed, than to correct things after the job has been done. Since most processes are dependant on men and machines, inspection becomes a necessity to ensure that the product made is good. Quality control also concerns new design, control and change of specifications. Since QC affects the performance of a product over its lifetime, QC must be stringently implemented.

Classical quality control was achieved by observing important properties of the finished product and accepting/rejecting the finished product. As opposed to this technique, statistical process control uses statistical tools to observe the performance of the production line to predict significant deviations that may result in rejected products.

By using statistical tools, the operator of the production line can judge for himself if a significant change has been made to the production line, by wear and tear or due to other reasons, and even take measures to correct the problem – or even stop production – rather than producing a product outside specifications. The simplest example of such a statistical tool may be the Shewhart control chart.

12.2.1 Chronological Developments

Quality control has evolved constantly during the last century. The period between 1920 and 1940 was called the inspection quality control period by Feigenbaum [4], since the inspectors were designated to check the quality of a product by comparing it with a standard. If discrepancies were noticed, the deficient products were either rejected or reworked. The processes, however, were becoming more and more complex and side by side statistical aspects of quality control were also being developed. Shewhart [8] can be said to have laid down the foundation of using control charts to control the variables of a product. Acceptance sampling plans were developed to replace the 100% inspection and the 1930s saw the extensive use of sampling plans in industries. This gradually laid the foundation of statistical quality control and the period 1940–1960 was called the period of statistical quality control by Feigenbaum [4]. Statistical quality control became further popularized when W. Edwards Deming visited Japan in 1950 and taught Japanese industries the principles of SQC. Japanese were quick to embrace this new discipline and proved that a competitive edge can be achieved in the world market through SQC. J.M. Juran further helped strengthen Japanese management’s belief in quality programs when he visited Japan in 1954. Later, in 1980, he wrote his excellent text [2]. The next phase of *total quality control* started in the 1960s. The concept of *zero defects* was spawned during this period when the Martin Company of Orlando delivered a Pershing missile to Cape Canaveral with zero nonconformity. As the people started getting round the idea of the involvement of shop floor workers in the quality improvement programs, the impetus for TQC got a boost. Organizing *quality circles* in industries, an idea that originated in Japan, was keenly pursued the world over during this period. The next phase of implementation of total quality control started in the 1970s, beginning with the concept of involving everyone in the company right from top management to workers in the quality program; this laid the foundation of the concept of the *total quality system* pursued vigorously during 1980s. Taguchi [5, 9] introduced the concept of parameter and tolerance design and indicated the use of experimental design as a valuable quality improvement tool. Management saw the need and importance of giving training programs in statistical quality control to all levels of workers in the industry. Terms and concepts like quality management system (QMS), total quality management (TQM), total engineering quality management, product life-cycle management, Six Sigma, and ISO 9000 to promote quality consciousness and development of a distinct quality culture flourished between 1980 and the present. Around 2001, the concept of product life-cycle management (PLM) came into being; this is a holistic business activity addressing many things such as products throughout their life-cycles from cradle to grave, organizational structure, working methods, processes, people, information structures, and information systems.

12.2.2 Statistical Quality Control

The quality of a product can be assessed using the performance characteristics. Performance characteristics of a product are the primary quality characteristics that determine the product's performance in satisfying the customer's requirements. Performance variation can be best evaluated when a performance characteristic is measured on a continuous scale. The characteristics having randomness can be represented by statistical distributions. The quality of the product is defined using a target value, and upper and lower specification limits for each characteristic. We can compare the statistical distribution of each characteristic to decide whether the product should be accepted or rejected. This is called *statistical quality control* (SQC). As we have seen earlier, there are mainly two sources of variations in product characteristics, *viz.,* variability of materials and components and the variability of the production process. Statistical quality control can be applied to identify and control both sources of variability. However when SQC is applied to processes, it is referred to as *statistical process control* (SPC). Here online measurements of product performance characteristics can be made and compared with the specification limits. This will not only inform the operators of the off-specification product but should also identify the sources of variability in the process that need to be eliminated.

12.2.3 Statistical Process Control

Statistical process control (SPC) was pioneered by Walter A. Shewhart [8] and created the basis for control charts. Later on it was pursued by Deming [3], who was instrumental in introducing SPC methods to Japanese industry after World War II. A typical control chart is a graphical display of a quality characteristic that has been measured or computed from a sample versus the sample number or time. The chart contains a center line that represents the average value of the quality characteristic corresponding to the in-control state. Two other horizontal lines, called the upper control limit (UCL) and the lower control limit (LCL) are also drawn. These control limits are chosen so that if the process is in control, nearly all of the sample points will fall between them. As long as the points plot within the control limits, the process is assumed to be in control, and no action is necessary. Shewhart [8] concluded that while every process displays variation, some processes display controlled variation that is natural to the process, while others display uncontrolled variation that is not present in the process causal system at all times. However, a point that plots outside of the control limits on the control chart is interpreted as evidence that the process is out of control, and investigation and corrective action are required to find and eliminate the assignable causes responsible for this behavior. The control points are connected with straight line segments for easy visualization. Even if all the points plot inside the control limits, if they behave in a systematic or nonrandom manner, then this is an indication that the process is out of control.

The underlying assumption in the SPC method is that any production process will produce products whose properties vary slightly from their designed values, even when the production line is running normally, and these variances can be analyzed statistically to control the process. Today, we have a wide variety of control charts [11] for controlling different quality characteristics. In fact, one can find a discussion of several of these control charts and indexes in [11], and in this handbook, Chapter 14 deals with certain aspects of SPC and discusses some of the control charts and indexes.

12.2.4 Engineering Process Control

Engineering process control is a subject of statistics and engineering that deals with architectures, mechanisms, and algorithms for controlling the output of a specific process. Engineering process control (EPC) is used to control the continuous production processes and is a collection of techniques to manipulate the adjustable variables of the process to keep the output of the process close to the targetted value. This objective is achieved by generating an instantaneous response, opposing the changes to balance a process and take corrective action to bring the output as close to the target as possible. The approach involves forecasting the output deviation from the target that would occur if no control action were taken and then to take action to cancel this deviation. The control is achieved by an appropriate feedback or feedforward control that indicate when and by how much the process should be adjusted to achieve the objective.

In Chapter 15 of this handbook, we shall see how EPC can be applied to control the processes in a product industry.

12.2.5 Total Quality Control

In modern practice, QC begins with the design process and continues through manufacturing and product use. The sum of all these efforts is called *total quality control* (TQC). Quality control, therefore, can also be viewed as an aggregation of all activities directed toward discovering and controlling variations in performance.

According to Feigenbaum [4], TQC encompasses the entire product life-cycle, and involves activities such as:

- marketing
- engineering
- purchasing
- manufacturing engineering
- production
- inspection and tests
- shipping
- installation, maintenance and service

In fact, one can plan for quality during all the above activities, even before the product is produced.

12.3 Quality Planning

Quality planning is at the heart of TQC and is an activity aimed at preventing quality problems; it includes:

- establishing quality objectives
- building quality into the design
- procurement for quality
- control of nonconforming material
- ensuring in-process and finished product quality
- inspection and test planning
- handling and follow-up of customer complaints
- education and training for quality.

Quality guidelines are established by knowing the customer requirements and once these are clearly understood and it is determined that the company policies, procedures, and objectives are in conformity with these requirements, one may proceed to develop an effective quality plan. If necessary, these procedures and objectives can be revised. Comparing the proposed design with the customer requirements, including reliability and maintainability considerations, ensures design quality. A design is finally reviewed for *producibility* and *inspectability* since it is always possible to design a product that satisfies the customer's requirements but cannot be manufactured with the existing technologies. Design quality requires establishing specifications for all important quality characteristics and developing formal product standards. Work instruction and detailed procedures also form a part of this activity.

Inspection and test planning is always integrated with the design and production activities as they directly influence the quality of the product and involve fixing of inspection points, classification of characteristics according to their criticality, design and procurement of inspection and test equipment, and development of inspection, instructions and test procedures. The material control procedures are often incorporated into the purchase order or a contract.

Sampling [12] rather than inspecting 100% of the manufactured products reduces the cost of inspection and involves making decisions based on the results of limited inspection or tests. However, this is at the cost accepting a risk, usually known as the sampling risk. In fact, there are two types of risks and the first one is known as the product risk, and may result in a good product being incorrectly classified as nonconforming although it is not. The other is known as consumer risk, in which a nonconforming product may be incorrectly classified as conforming. For critical characteristics, there is no acceptable level of consumer risk and it is never sampled except to verify a previous 100% inspection. An exception occurs only when the inspection or test is destructive, where there is no option but to sample. Tests can either be classified as destructive or non-destructive depending upon whether or not they cause damage to the product or raw material. The nondestructive test includes eddy current, dye penetrant, magnetic particles, ultrasonic and X-ray tests, and is often used to check properties of a material or product such as cracks and porosity. The other problem in sampling is to resolve the question of how much to sample. All inspection and test activities involve some degrees of error, since no measuring instrument is perfect. However, there are statistical methods of assessing all kinds of inspection and tests errors. The known size is called a standard, and the process of adjustment of gauges is known as calibration. These form the routine activities of any quality planning.

12.4 Quality Assurance

Quality cannot be the concern of one person or one department, such as quality control department in a manufacturing concern; therefore a system has to be evolved that continually reviews the effectiveness of the quality philosophy of the company. All those who are directly or indirectly connected with the production department must be involved in the task. For example, this group may advise market department about the nature and type of information that may be helpful for the design team based on customer requirements. In fact, the quality assurance (QA) group must audit various departments and assist them to accomplish the company's goal of producing a quality product. The quality assurance department will ensure that means exist in terms of physical resources and manpower within the company to execute the quality plans. If any shortcomings are noticed, the quality assurance group may advise the concerned department to affect those changes. The quality assurance department actually acts as a coordinating agency for the quality needs of a company with respect to the products being manufactured. Thus the formal definition of a quality assurance activity involves all those planned actions necessary to provide confidence to the management and the customer that the product will eventually satisfy the given needs of a customer. Quality control is just a part of the quality assurance task. It is also true that all leading manufacturers depend on several vendors for incoming raw material or components and it will be incumbent on the quality assurance department to assist these vendors in maintaining and controlling the quality of parts supplied by them, since the quality of final product depends heavily on the quality of the parts supplied. In such cases, the quality assurance department's responsibility is also extended to include vendor product quality. In fact, vendors must be considered as partners in the quality program.

QA covers all activities from design, development, production, installation, servicing to documentation. It introduced the sayings "fit for purpose" and "do it right the first time". It includes the regulation of the quality of raw materials, assemblies, products and components, services related to production, and management, production, and inspection processes.

12.5 Quality Improvement

Quality improvement [13] is a continual process in any company and should be the objective of everyone in the company for increasing productivity and cost reduction and thereby increasing profitability. Since improvements are possible through reduction of variability of process and production of nonconforming items, quality improvement is possible by detection and elimination of common causes, in contrast with special causes that can be identified and eliminated through process control. Special causes are those having an identifiable reason, such as tool wear, poor raw material or operator fatigue, but common causes are inherent to the system and are always present, such as variability in characteristics caused by the inherent capability of a machine. Special causes can usually be controlled by an operator but common causes necessarily require the attention of the management.

In fact, there are three stages of the quality improvement program, *viz.*, the commitment stage, the consolidation stage, and finally the maturity stage. In the commitment stage, management accepts to undertake the quality improvement program, and plans and policies are drawn including the organizational structure to implement it. This phase usually concerns itself with identifying and eliminating special causes in the first instance. With the training and education of personnel and support from the management the quality improves and the percentage of nonconformities drops appreciably during this phase. In the consolidation stage, the main objective is to improve the quality of conformance and efforts are made to identify and eliminate common causes by improving process capabilities and investment is made to prevent defects. The causes of all defects must be traced to their origins and adequate measures be taken to prevent them in future. This exercise is likely to minimize the number of items for rework or scrapping, resulting in reduction of total cost. However, the percentage drop of nonconforming items is not as high as in the first stage of implementation. In the maturity stage, the processes are considered to have matured and process parameters are adjusted to create optimal operating conditions and the total cost reduces further as the number of scraps and reworked items reduces, but the rate is slower. The process of improvement continues and the quality improves asymptotically to a zero defect paradigm if the process performance keeps improving. However, one must bear in mind that the quality improvement program pays off only in the long run but the cost of improvement is immediate. This should not detract management or personnel engaged in the improvement program.

12.6 Quality Costs

Quality cost comprises four major components, *viz.*, prevention cost, appraisal cost, internal failure cost and external failure costs. Prevention costs are costs incurred in planning, implementing and maintaining a quality system, which include all the costs of making a product right the first time, such as the development costs of product design, process design and control techniques and salaries. Appraisal costs are the costs of measuring, evaluating and auditing products, components, incoming raw materials to determine the degree of conformance, as well as product inspection and testing and cost of calibration etcat the stage of final acceptance. Internal failure costs are all those costs incurred when products, components, materials fail to meet the quality requirements. These costs also includes the cost of rework, scraps, labour and other overheads associated with nonconformities, including loss of production and revenues. The external failure costs are the costs incurred when the product does not perform satisfactorily after it is delivered to the customer. Warranty and product liability costs are included in this component of the total cost. A quality system in place should reduce the total cost.

12.7 Quality Management System

A quality management system (QMS) is achieved by having an organizational structure, resources, procedure and programs, and processes to implement quality management. The major objective of QMS is to integrate all processes and functional units to meet the quality goal of a company. Planning is absolutely necessary for the success of a quality program. A strategic plan must be clearly defined. Quality policy and procedural manuals help in guiding the entire quality activity. An organizational structure should be created to establish a line of authority and responsibility.

Several companies are developing their quality systems to:

- reduce the first time failure,
- reduce the costs of customer claims,
- get things right the first time,
- improve service to the customer and to increase competitiveness.

Today, we need to pursue these goals more vigorously in order to minimize environmental pollution and wastes, besides affecting energy savings and conserving material resources.

In this handbook, Chapter 18 discusses how to build a quality management system.

12.8 Total Quality Management

Tobin [14] defines *total quality management* (TQM) as totally integrated effort for gaining competitive advantage by continuously improving every facet of organizational culture. Witcher [15] highlights important aspects of TQM using the following explanation:

Total signifies that every person in the firm must be involved (possibly even customers and suppliers)

Quality indicates the customer requirements are met fully.

Management represents that the senior executives are fully committed.

Feigenbaum [4] defines TQM as the organization-wide impact of TQC. The Department of Defense (DOD) of the US defines TQM as a philosophy and a set of guiding principles of a continuously improving organization. In fact, TQM [16, 17, 18, 19] entails the application of management techniques, quantitative methods and human resources to improve the material services supplied to an organization, all the processes within the organization, and the degree to which the requirements of its customers are met, now and in future. It stresses on optimal life-cycle cost and applies management methodologies to target improvements. A sound quality policy together with organization and facilities is a fundamental requirement for implementing TQM. The important elements of TQM philosophy are the prevention of defects and an emphasis on quality in design, elimination of losses and reduction of variability. It also stresses the development of relationships between employees, suppliers and customers.

TQM starts at the top and top management should demonstrate their commitment to quality and communicate it down to every one in the company through the middle level management. Developing and publishing clear corporate beliefs and objectives or mission statement helps motivating people. Every employee must be able to participate in making the company successful in its mission. This flows from empowerment of people at all levels to act for quality improvement and the efforts of all those who contributed to achieve good results must be recognized and publicized. The management should strive to remove barriers between the departments of the organization. Instead they should inculcate the spirit of team work and establish perfect communication between them. It often requires a mindset to change to breakdown the existing barriers. In fact, implementing TQM is like growing a new culture in the organization. The role of training and education cannot be underestimated and should back up the efforts of implementing TQM so that all employees clearly know what is at stake.

It is often believed that TQM is perhaps the only way of assuring customers what they want first time, each and every time. There is enough evidence to show that this is so. If it were not leading firms like American Express, IBM, Xerox, 3M, Toyota, Ricoh, Cannon, Hewlett-Packard, Nissan and many others may not be so successful. TQM is not just to meet customer requirements but to provide them satisfaction. Some companies, like Rover Cars, have extraordinary customer satisfaction as their corporate mission. Among other features, customer requirement may include delivery, availability, maintainability, reliability and cost effectiveness. While dealing with a supplier–customer relationship, the supplier must establish marketing activity charged with this task. The marketers must, of course, not only understand the requirement of the customer completely, but also their own ability to meet customer demands. Within organizations, and between customers and suppliers, the transfer of information regarding requirements is often very poor and sometimes totally absent. Therefore a continual examination of the customers' requirements and our ability to meet them is the price of maintaining quality. In fact, TQM philosophy very much relies on using the knowledge base as an asset in an organization. Everybody needs to be educated and trained to do a better job.

12.9 ISO Certification

The objective of International Organization for Standardization (ISO), which consists of representatives from several countries, comprised of more than 180 technical committees, covering many industry sectors and products, is to promote the development of standards, testing, and certification in order to encourage the trade of goods and services. Usually a standards body represents each country. There are two types of standards introduced by ISO, *viz.*, ISO 9000 for quality and ISO 14000 for environment.

ISO 9000 came into being in 1987 followed nearly by 10 years later by ISO 14000. ISO 9001 initially developed four standards (ISO 9000-9004) for different types of industries but in 1995 ISOs were revised and finally in the year 2000, there was only one standard, *i.e.*, ISO 9000-2000, which is the main stay of quality management system for all types of industries and organizations. Likewise, there is ISO 14000 for environment system management. ISO by itself does not audit or assess the management system of organizations to verify that they have been implemented in conformity with the requirements of the standards nor does ISO issue certifications. However, the auditing and certification done by ISO has approved more than 750 certification bodies active around the world.

The basic objective of the ISO 9000 quality standards is for a company to be able to establish quality systems, maintain product integrity, and satisfy customers.

ISO 9000 has become an international reference for quality management requirements in business-to-business dealings, which helps organizations to fulfil:

- customer quality requirements, and is
- applicable regulatory requirements, while aiming to
- enhance customer satisfaction, and
- achieve continual improvement of its performance in pursuit of these objectives.

ISO 14000 is primarily concerned with *environmental management*. This means what the organization does to:

- minimize the harmful effects on the environment caused by its activities, and to
- achieve continual improvement of its environmental performance.

For some firms, the first step in creating a total quality environment begins with the establishment of a quality management system such as enunciated by ISO 9000. For others, it is always debatable whether it is better to implement TQM or ISO 9000 first. However, if one views ISO 9000 as a route to TQM, they are complementary to each another. For companies already on TQM, installing ISO 9000 is comparatively straightforward. However, for companies planning towards TQM, the use of ISO 9000 can act as an instrument to achieve TQM. Nonetheless, it is true that, even with ISO 9000 certification, it cannot be guaranteed that the products and services are of high quality. To produce quality products and services, a company needs TQM to meet expectations.

12.10 Six Sigma

The term Six Sigma [20] was coined by Bill Smith, an engineer at Motorola, in 1986 and is actually a trademark of Motorola that resulted in a saving of US $17 billions by January 2006. It is a measure of process capability and is related to the defect rate and complexity of a process/ product. Six Sigma is a standard of excellence that allows less than four (or precisely 3.4) defects per million opportunities.

Some of the top companies that have embraced Six Sigma [21] as their company's strategy for quality improvement are: General Electric (GE), Honeywell International, Raytheon, Sony, Honda, Texas Instruments, Hitachi, Canon, Asian Brown Bovery, *etc*. In fact, GE is said to have made a gross annual profit of US $6.6 billion in the year 2000, which was 5.5% of their sales [22].

Six Sigma offers a proven management framework of processes, techniques and training that satisfies ISO 9000:2000 requirements with respect to:

- demonstrating top management commitment to continually improving the effectiveness of the quality management system;
- competence, awareness and training in statistical techniques and quality management;
- continual improvement of the quality management system;
- monitoring and measurement of customer satisfaction;
- monitoring, measurement and improvement of processes and products;
- analysis of data.

In fact, Six Sigma capitalizes on the good points of TQM with a sharp focus on customer satisfaction and thus combines good features of all earlier quality initiatives for quality improvement and does not have very many tools of its own. It is asking tougher and tougher questions until quantifiable answers are received. Through Six Sigma companies question every process, every number, every step along the way to creating a final product.

Six Sigma is a data-driven, systematic approach to problem solving, with a focus on customer impact. Statistical tools and analysis are often useful in the process. However, the Six Sigma project can be started with only rudimentary statistical tools.

For successful implementation of Six Sigma, a company requires the active role of the following:

- *Executive leadership* empowers the other role holders with the freedom and resources to explore new ideas for breakthrough improvements.
- *Champions* are responsible for the Six Sigma implementation in the company and are drawn from the upper management. Champions also act as mentor to black belts.
- *Master black belts* act as full time in-house expert coaches for Six Sigma and ensure integrated implementation of Six Sigma across various departments in the company.
- *Black belts* operate under master black belts to apply the Six Sigma methodology to specific projects.
- *Green belts* are common employees who help black belts implement Six Sigma along with their normal job responsibilities.

When 50% or more employees of a company embrace Six Sigma, the profitability of the company is bound to increase dramatically.

Design for Six Sigma (DFSS) is an important step in designing new products and/or processes and uses Six Sigma as a strategy. It is a way to implement the Six Sigma methodology as early in the product or service cycle as possible. It is a pathway to exceed customer expectations and a means to gain market share. It results in high ROI (return on investment) and reduces warranty costs.

Further, for services, a fusion of Lean and Six Sigma improvement methods is required. Lean Six Sigma is a business improvement methodology that maximizes shareholder value by achieving the fastest rate of improvement in customer satisfaction, cost, quality, process speed, and invested capital. The need for Lean Six Sigma arose from the fact that one cannot just have quality or speed, one needs a balanced process that can help an organization to focus on improving service quality, as defined by the customer within a set time limit.

Recent Six Sigma trends are in the development of a methodology by integrating it with TRIZ for inventive problem solving and product design. It was developed by the Russian engineer Genrich Altshuller [23] and his colleagues in 1946. TRIZ (the Russian acronym for the theory of inventive problem solving) is basically a collage of concepts and tools to solve manufacturing problems and create new products and has been used by companies like Procter & Gamble, Ford Motor Company, Boeing, Philips Semiconductors, LG Electronics, Samsung and many others.

In order to familiarize the reader with Six Sigma and to explore the future trends, Chapter 16 on Six Sigma has been included in this handbook.

12.11 Product Life-cycle Management

Product life-cycle management (PLM) is the activity of managing a company's products most effectively all through their life-cycles. This allows a company to take control of its products. With products becoming increasingly complex, customers becoming more demanding, the need to have shorter product development times, and the competitive product environment in the market, on-going globalization, outsourcing of product development, mass customization to meet customer requirements, end of life issues, product support over its long life, WEEE-like directives about disposal and recycling would make this job still more difficult. Losing control can have disastrous effects for a company. PLM [24] helps bring better products in the shortest possible time to the market, provides better customer support and reduces the cost of a product. In fact, PLM helps maximize the value of a product over its life-cycle. All companies need to manage communications and information with its customers through customer relationship management (CRM) and its suppliers through supply chain management (SCM)) and the resources within the enterprise through enterprise resource planning (ERP). In addition, a manufacturing engineering company should develop, describe, manage and communicate information about their products through PLM. PLM helps reduce the time to market, improves product quality, reduces prototyping costs, affects savings through the re-use of original data, reduces waste, and results in savings through the complete integration of engineering workflows and thereby provides a framework for product optimization.

The product life-cycle goes though many phases, involves many professional disciplines, and requires many skills, tools and processes. Product life-cycle management (PLM) is more to do with managing descriptions and properties of a product through its development and useful life, mainly from a business/engineering point of view; whereas product life-cycle management (PLC) is to do with the life of a product in the market with respect to business/commercial costs and sales measures.

Within PLM there are two primary areas:

- product data management (PDM)
- product and portfolio management

PDM is focused on capturing and maintaining information on products and/or services through its development and useful life. This is the activity that has the major influence on the time taken to get the product to market and on the cost of the product. Since the quality of the product delivered to the customer is in many ways a function of the quality defined during product development, it is here that major improvements in product quality must be made.

On the other hand, product and portfolio management focuses on managing resource allocation, tracking progress *vs*. plan for projects in the new product development projects that are in process (or in a holding status). Portfolio management is a tool that assists management in tracking progress on new products and making trade-off decisions when allocating scarce resources.

The core of PLM is in the creation and central management of all product data and the technology used to access this information and knowledge. PLM as a discipline emerged from tools such as CAD, CAM and PDM [25], but can be viewed as the integration of these tools with methods, people and the processes through all stages of a product's life. It is not just about software technology but is also a business strategy.

12.12 Other Quality Related Initiatives

There are several other initiatives related to quality improvement that have been introduced from time to time with the basic objective of improving quality of products, and productivity and profitability of the company.

Concurrent Engineering

Concurrent engineering can be defined as a strategy of employing a multi-disciplinary team consisting of specialists from business, engineering, production and customer support to conceptually conceive a product and to carry out its design and production planning all at one time. Inputs from all departments concerned, such as materials, purchase, marketing, finance, engineering design, production, quality, suppliers and customers, *etc*., are available simultaneously through brainstorming sessions to arrive at an agreed design. That is why sometimes it is also known as simultaneous engineering or parallel engineering. This is done to prevent problems with quality and productivity from occurring and eliminates the possibility of engineering changes at a later stage, which helps decrease the lead time and costs. This practice is at variance from sequential engineering followed earlier. Concurrent engineering designs the product within production capabilities so that statistical process control is effective and rework costs decrease. The main advantages of concurrent engineering are a substantial decrease in lead time to market, faster product development, better quality, and increased productivity. For example, the Chrysler Corporation used concurrent engineering to develop the Viper model from the concept stage to full production in less than three years with a budget of US $50 million. General Motors eliminated 900 parts from the 1995 Chevrolet Lumina model in comparison to its 1994 model and reduced assembly time by 33%. Westinghouse Electronic Systems decreased development lead times from 20 months to 9.

Kaizen

Kaizen is the Japanese term for *continuous improvement*. “Zen” in the word Kaizen emphasizes the learning-by-doing aspect of improving production. The Kaizen concept was pioneered by in Japan by Toyota as a daily challenge to all its employees to improve their processes and working environment little by little over time. Kaizen refers to a “quality” strategy and is related to various quality-control systems, including methods of W. Edwards Deming. Kaizen aims to eliminate waste or activities that add to the cost but do not add to the value. It is a rigorous and scientific method of using SQC and an adaptive framework of organizational values and beliefs that keeps workers and management focused on the objective of zero defects.

The Kaizen cycle has four steps:

- Establish a plan to change whatever needs to be improved.
- Carrying out changes on a small scale.
- Observe the results,
- Evaluate both the results and the process and determine what has been learned.

Masaaki Imai made the term famous in his book on Kaizen [26]. Kaizen methodology includes making changes and monitoring results, then adjusting. Large-scale pre-planning and extensive project scheduling are replaced by smaller experiments, which can be rapidly adapted as new improvements are suggested.

Quality Circles

One of the most publicized aspects of Japanese management is the *quality circles* or *Kaizen teams*. The quality circles concept first originated in the 1960s and became very popular around the world, partly due to the phenomenal Japanese success in improving the quality of their products. A quality circle is a voluntary group of workers doing a similar job, who meet regularly during the working hours under the leadership of their supervisor to identify, analyze and solve shop floor problems and possibly recommend solutions to management. These circles were successful in some countries but failed in others, partly due to a lack of enthusiasm in inculcating quality consciousness and understanding on the part of senior management and partly due to different cultural backgrounds.

Just in Time

Just in time (JIT) is an inventory strategy implemented to improve the return on investment of a business by reducing in-process inventory and its associated costs. The process is driven by a series of signals, or *Kanban* that tell production processes when to make the next part. Kanban are called “tickets” but can be simple visual signals, such as the presence or absence of a part on a shelf.

JIT [27] can lead to dramatic improvements in a manufacturing organization's return on investment, quality, and efficiency if implemented correctly.

Actually, the JIT inventory systems have a whole philosophy that the company must follow in order to avoid its downsides. The ideas in this philosophy come from many different disciplines including statistics, industrial engineering, production management and behavioral science. Inventory is seen as incurring costs, or waste, instead of adding value, contrary to traditional thinking. Under the JIT philosophy, businesses are encouraged to eliminate inventory that does not compensate for manufacturing issues and to constantly improve processes so that inventory can be removed. Secondly, by allowing any stock, management may be tempted to keep stock to hide problems within the production system, which include backups at work centers, machine reliability, process variability, lack of flexibility of employees and equipment, and inadequate capacity, among other things.

In short, the just-in-time is an inventory system that allows one to have the right material, at the right time, at the right place, and in the exact amount.

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