**Unit III**

Strategic tools for TQM – Bench Marking, Business Process Reengineering, Six sigma, JIT, QFD, Tagichi’s quality engineering, Failure mode and Effect analysis. Poka yoke.

**Strategic tools for TQM**

* Bench Marking,
* Business Process Reengineering,
* Six sigma,
* JIT,
* QFD,
* Tagichi’s quality engineering,
* Failure mode and Effect analysis.
* Poka yoke.

**What is benchmarking?**

Benchmarking is a way to go backstage and watch another company’s performance from the wings, where all stage actions and under pressure rearrangements are visible.

***What is that organizations do that gets result so much better than ours?***

The answer to this question opens door to benchmarking, an approach that is accelerating among many firms that have adopted the total quality management (TQM) philosophy.



**The Essence of Benchmarking**

The essence of benchmarking is the continuous process of comparing

* a company’s strategy,
* products,
* processes with those of the world leaders and
* best-in-class organizations.

The purpose is to learn how the achieved excellence, and then setting out to match and even surpass it. The justification lies partly in the question: “Why reinvent the wheel if I can learn from someone who has already done it?” However, Benchmarking is not a panacea that can replace all other quality efforts or management processes.

**The Evolution of Benchmarking**

The method may have evolved in the early 1950s, when W. Edward Deming taught the Japanese the idea of quality control. Other American management innovations followed.

The best example is Toyota Motor Corporation’s following the footsteps of Ford Motor Corporation albeit with the adaptation of the Ford’s Just-in-case system into Toyota’s Just-in-time system. The term “benchmarking,” however, was not coined by that time.

The term “benchmarking”  emerged when the idea took ground in US during 1980s when Xerox, Ford and Motorola became the pioneers of benchmarking in USA. Robert Camp, the logistics engineer who initiated Xerox’s benchmarking program and who is generally regarded as the guru of the benchmarking movement, defines it:

“Benchmarking is the search for industry best practices that lead to superior performance”.

**The Xerox Case**

The company invented the photocopier in 1959 and maintained a virtual monopoly for many years thereafter. “Xerox” became a generic name for all photocopiers. By 1981, however, the companies market shrunk to 35% as IBM and Kodak developed high-end machines and Canon, Richo and Savin dominated the low-end segment of market.

The company instituted the quality improvement plan, which resulted in tremendous progress and survival of the organization.  This quality improvement plan was later known to the world as Benchmarking Program. Xerox’s approach focused on key processes, rather than simply on finished products, and highlighted distinctive elements of those processes that accounted for product superiority.

Xerox’s benchmarking strategy recognized that many processes are not unique to a single industry and that comparisons need not be confined strictly to one’s competitors. Xerox and other bench markers now believe that break through advances are more likely to occur by adapting lessons learned from leaders operating in entirely different industries.

Xerox benchmarked companies both, in and  outside the industry. The particular example is L.L.Bean, catalog seller of outside equipment for improving distribution system based on the same. The benchmarking process resulted in: Quality problems cut by two-thirds, manufacturing costs cut in half, development task cut by two-thirds, direct labor cut by 50% and corporate staff cut by 35% while increase in volume.

It should be noted that all these improvements were not direct result of benchmarking rather it became the cause climate for change and continuous improvement followed as a natural result.

**What benefits have been achieved by the organizations that have successfully completed their benchmarking programs?**

There are three sets of benefits:

**1. Cultural Change**

**2. Performance Improvement**

**3. Human Resources**

**1. Cultural Change:** Benchmarking allows organizations to set realistic, rigorous new performance targets, and this process helps convince people of the credibility of these targets. It helps people to understand that there are other organizations who know and do job better than their own organization.

**2. Performance Improvement:** Benchmarking allows the organization to define specific gaps in performance and to select the processes to improve. These gaps provide objectives and action plans for improvement at all levels of organization and promote improved performance for individual and group participants.

**3. Human Resources:** Benchmarking provides basis for training. Employees begin to see gap between what they are doing and what best-in-class are doing. Closing the gap points out the need of personnel to be trained to learn techniques of problem solving and process improvement.

**What theoretical model would you suggest to implement a benchmarking program?**

Organizations that benchmark, adapt the process to best fit their own needs and culture. Although number of steps in the process may vary from organization to organization, the following six steps contain the core techniques:

1. Decide what to benchmark.
2. Understand the current performance of your organization.
3. Do proper planning of what, how and when of benchmarking endeavor.
4. Study others well (the practices or system you wish to benchmark)
5. Gather data and learn from it.
6. Use the findings.

**Some prominent beneficiaries of Benchmarking**

Within a decade following its introduction, benchmarking had distinguished itself as an important tool for performance improvement in corporate America.

In several highly publicized cases, benchmarking corporations were learning and benefiting from what would have seemed unlikely partnerships in the pre-benchmarking era.

* Xerox learned from L.L. Bean, a clothing store catalogue retailer
* Motorola from Domino’s Pizza
* Digital Equipment Corporation (DEC) from a seemingly illogical set of partners that included Scott Paper, Campbell Soup, Whirlpool,  Boeing, Hewlett-Packard, and Apple.

**WHAT IS BENCHMARKING?**

“Benchmarking is simply the process of measuring the performance of one's company against the best in the same or another industry. Benchmarking is not a complex concept but it should not be taken too lightly. Benchmarking is basically learning from others. It is using the knowledge and the experience of others to improve the organization. It is analyzing the performance and noting the strengths and weaknesses of the organization and assessing what must be done to improve.

**REASONS FOR BENCHMARKING**

There are several reasons that benchmarking is becoming more commonly used in industry;

* Benchmarking speeds up organization’s ability to make improvements.
* Compare business practices with those of world class organizations
* Challenge current practices and processes
* Create improved goals and practices for the organization
* Change the perspective of executives and managers.

**OBJECTIVES OF BENCHMARKING**

* Becoming competitive
* Improving industry best practices
* Defining customer requirement
* Establishing effective goals and objectives
* Developing the measures of productivity

**ADVANTAGES OF BENCHMARKING**

* It helps improve process effectiveness
* Helps in cost reduction
* It provides focus in planning operations
* The sharing of information may create opportunities for innovations
* It assesses the firms existing position and provides a basis for establishing standards of performance
* Cross comparison are more likely to expose different ways of doing things
* It provides evidence for additional resources
* Is practitioner led, so gives a sense of ownership
* Facilitates multi-disciplinary team building and networking
* Provides an avenue for change in clinical practices.

**DISADVANTAGES OF BENCHMARKING**

 Benchmarking is the danger of complacency and arrogance. Many organizations tend to relax after excelling beyond competitors' standards. The realization of having become the industry leader soon leads to arrogance, when considerable scope for further improvements remains.

* It implies there is only one best way of doing business
* The benchmark may be yesterday’s solution to tomorrow’s problems. If the operating environment is highly dynamic the solution will be dynamic.
* It depends on the accuracy of the information about the comparator company
* It may be difficult to decide which activities to benchmark
* It encourages the mentality of catching up rather than being innovative
* Lack of strategic relevancy

**TYPES OF BENCHMARKING**

* **Process benchmarking** –It’s where we go beyond performance measures and also compare how business processes are performed. The initiating firm focuses its observation and investigation of business processes with a goal of identifying and observing the best practices from one or more benchmark firms. Activity analysis will be required where the objective is to benchmark cost and efficiency; increasingly applied to back-office processes where outsourcing may be a consideration.
* **Financial benchmarking** - performing a financial analysis and comparing the results in an effort to assess your overall competitiveness.
* **Performance benchmarking** - allows the initiator firm to assess their competitive position by comparing products and services with those of target firms.
* **Product benchmarking** - the process of designing new products or upgrades to current ones. This process can sometimes involve reverse engineering which is taking apart competitors products to find strengths and weaknesses.
* **Strategic benchmarking** - comparison of strategic decisions and dispositions at a higher level. It involves observing how others compete. This type is usually not industry specific meaning it is best to look at other industries.

**Functional benchmarking** - comparison against organizations that are not necessarily competitors, but that performs related tasks within the same technological area. In the school analogy, this will be benchmarking against someone from another school, but of the same type. A company will focus its benchmarking on a single function in order to improve the operation of that particular function. Complex functions such as Human Resources, Finance and Accounting and Information and Communication Technology are unlikely to be directly comparable in cost and efficiency terms and may need to be disaggregated into processes to make valid comparison.

**Internal benchmarking**, comparison against the best within the same organization or corporation, often called benchmarking within your own class.

**Competitive benchmarking**, comparison against the best direct competitors, which then can be termed benchmarking against someone in the parallel class.

**External benchmarking**, it involves seeking outside organizations that are known to be best in class. It provides opportunities of learning from those who are at the leading edge, although it must be remembered that not very best practice solution can be transferred to others.

**International benchmarking**.  Is used where partners are sought from other countries because best practitioners are located elsewhere in the world and/or there are too few benchmarking partners within the same country to produce valid results.

**Business Process Reengineering**

The fundamental rethinking and radical redesign of the business process to achieve dramatic improvements in critical contemporary measures of performance such as cost, quality, service, and speed.

“BPR is the fundamental rethinking and radical redesign of business processes to achieve dramatic improvements in critical contemporary measures of performance, such as cost, quality, service, and speed.” Instead of starting with an activity flowchart, corporations are advised to start with a clean slate. They are then told to look into why they perform the tasks the way they do. A Process Engineer will look at the activities to be performed and how they can be engineered to invest minimum resources and get maximum returns.

To illustrate the point, let us consider the example of Apple iPod. Apple rethought the way music ought to be made available to the consumers. The changes it brought were:

* **Radical:** While all other music labels were selling music via brick and mortar stores, Apple developed its iTunes software to sell music digitally. (Napster had made digital music available through a P2P platform earlier, but was sued by music labels for copyright violation)
* **Fundamental:** Apple sold single tracks as opposed to whole albums being sold at brick and mortar shops.

Apple just kept in mind the end need of the consumer and reconsidered whether conventions were required.

**Basic characteristics of BPR are:**

* View business as a set of customer (both internal and external) oriented processes rather than a set of departmental functions.
* Processes must have clear cut ownership.
* Non value adding activities within a process should be eliminated..
* Gather information only once at the point of origin.

A successful BPR implementation brings significant improvement to productivity, customer service and bottom-line. There are pain and difficulties during implementation and instances where BPR efforts did not achieve desired result. Notwithstanding, the risk is worth taking. Otherwise, there will be grater risk of being overtaken by competitors who develop and progress rapidly through BPR.

**Implementation phases**

1. **Project kick off:** Project goal, project team and communication standards are agreed upon. A number of workshops are held where project scope, sponsors commitment, project risk, milestones and deliverables are discussed. A SWOT (strength, weakness, opportunities and threat) analysis is carried out with active participation of all.
2. **Process identification and data gathering:** “As is” processes are assembled through flow charts. Current practice of Interfacing with business partners is gathered. Bottlenecks, delays, complexity, internal blame games, idle assets etc. are brought forward. Use of existing technologies is comprehended. Major and strategic business processes to be reengineered, are identified. Stakeholders categorize the processes to be reengineered and agreed upon on the timeline of implementation.
3. **Process Reengineering:** In this phase, actual reengineering begins. A number of brain storming sessions are held with project team and other stakeholders, where current business processes are critically analyzed to determine non value adding activities and identify excess control and check, always with customer value as a focal point. Impact of new technologies on process improvement is also evaluated. New process ideas with reduced check and control and enabling technologies such as Workflow automation and ERP, are envisaged. Benchmarking is also done with best of breed industrial peers.
4. **Blueprint of new system:** Blueprinting involves modeling workflow and information requirement, of new business processes. “To be” processes are modeled using various modeling tools. New organization structures, human resource need, performance monitoring and compensation, technological needs, are also outlined. Normally, a first cut redesign scheme is produced which is modified after gathering actionable feedback from the stakeholders.
5. **Transformation:** A migration strategy and a migration plan is the first step of transformation. Migration strategy may decided as a pilot, phased or big bang implementation. The migration plan would include establishment of new organizational structure, detailed training and reallocation of workforce, and cut off dates for implementation. Change management and introduction of new technologies will form an important part and may need engagement of outside consultants for this specific purpose. There should be provision on the plan to tweak the implemented system so as to get maximum value out of it.

**BPR or ERP:** For successful of BPR implementation, Information Technology plays the role of a key enabler. Therefore, a question is raised whether it is logical to directly implement ERP and re-engineer business processes by adopting world class practices, contained in ERP packages. This approach would avoid embarking on BPR which is expensive, time consuming and often risky. Also reengineered process arising out of BPR exercise may not be best of class. On the other hand, there is a grave risk in this approach if a proper ERP package is not chosen. Process orientation and ownership will be lacking from employees which may lead to major implementation difficulties.

**Six Sigma**

**Six Sigma is a data-based methodology to improve performance by reducing variability**. It requires thorough understanding of product and process knowledge and is completely driven by customer expectations.

In other words, it is a methodology to achieve 3.4 defects per million opportunities. It can also be used to bring breakthrough improvements in the process. It focuses on the bottom-line and is a proven methodology for problem solving.

**Goals of Six Sigma**

* To reduce variation
* To reduce defects /rework
* To improve yield /productivity
* To enhance customer satisfaction
* To improve the bottom-line
* To improve top-line
* Shortening cycle-time

**Sigma Level Vs Number of Defects**

|  |  |
| --- | --- |
| **Sigma Level** | **Number of defects per Million** |
| 2 Sigma | 308537 |
| 3 Sigma | 66807 |
| 4 Sigma | 6210 |
| 5 Sigma | 233 |
| 6 Sigma | 3.4 |

**Evolution of Six Sigma**

The need for process improvements and a continuous improvement methodology like Six Sigma came into existence only due to

* rising customer expectations in terms of quality, delivery and cost,
* global competition - Japanese and Chinese threats,
* proven technique for quantum jumps in business results.

In the year 1980, Motorola started facing survival problems due fierce competition from Japanese companies. The CEO of Motorola - Bob Galvin was determined to overcome the competition. He challenged his organization to achieve a ten-fold improvement in performance over a period of five years. To achieve the same, strong emphasis was given to training of employees and also performing global benchmarking.

Bill Smith was a veteran engineer in Motorola and he wrote a research paper on product quality and its performance after delivery to customer. In his report he discovered that the products with fewer non-conformities (high quality) were the ones that performed well after delivery to the customer. It was accepted by everyone but the challenge that came in front of Motorola executives was to develop a solution to tackle this problem.

Mikel Harry having a doctorate from Arizona University worked with Bill Smith in developing a four-phase problem solving approach - Measure, Analyze, Improve and Control. A few years later Bob Galvin launched a long-term quality program called “The Six Sigma Quality Program” in Motorola.

Looking at the success of Motorola, many companies like Texas Instruments, Allied Signal etc started using Six Sigma methodology to bring organization-wide improvements.

In 1990’s Jack Welch launched Six Sigma in GE in a big way. He implemented Six Sigma in all areas and ensured that the entire organization participates in the initiative. He changed the performance incentives and made them based on individual’s ability and enthusiasm to take part in Six Sigma initiatives. He transformed GE to a state where Six Sigma had become the culture of the organization and not just a methodology for brining organization-wide improvements.

**Concepts of Six Sixgma**

**Types of Variables**

In the equation - Y = f(X), Y is the dependent variable and it is dependent on the variable X. In other words, when there is a change in value of X then value of Y will automatically change. The following are the characteristics of both types of variables:

|  |  |
| --- | --- |
| **Y** | **X** |
| Dependent variable | Independent variable |
| Output of the process | Input to the process |
| Effect | Cause |
| Symptom | Problem |
| It is monitored | It is controlled |

It is important to know that the variable or the factor that we want to improve is a Y or an X. If the variable under control is a Y then we should identify the Xs or the independent variables that affect Y and we should focus on improving the Xs and thereby improving the Y. There could be more one X that influences the Y and we should try to brainstorm along with the team to identify as many Xs as possible and then perform Pareto analysis or other prioritization tools to identify the critical Xs that impact our Y.

**Customer**

Customer is the person (whether internal or external to the organization) who uses the output that the organization produces. A customer could be

1. Internal to organization - Employees, other departments
2. Intermediate - person or department who uses the output to perform some operations on the output
3. External - People outside the organization who actually use the output to satisfy their needs

**Customer Requirements**

Customer requirements can be defined as the needs of the customer and his expectations from the output that the organization is producing and delivering. When the organization is able to meet all the customer requirements then it will lead to Customer Satisfaction. On the contrary, if the organization is unable to meet the customer requirements then the customers will be dissatisfied and over the period of time they will turn away from the organization’s product. Customer requirements are also called Voice of the customer - “VOC”.

**Tools for identifying Customer Requirements**

1. Customer one to one interview
2. Customer complaints - past history
3. Surveys
4. Focus groups

While performing the above the following questions should be asked:

* What are our customer’s needs?
* What is the Customer’s perception on our Process performance?
* How is Process Performance measured by Customer?
* What performance level of the Process does the Customer expect?
* What can we improve upon?

**Critical to Quality (CTQ)**

CTQ stands for ‘Critical to Quality’. In other words it represents the critical requirements of the output. CTQ’s could be derived from Customer requirements, Risks, Economics and Regulations. For eg a CTQ could be on-time delivery or accuracy etc. It is very critical to identify and define CTQs appropriately because it depicts the quality parameters that relate to wants and needs of the customer.

**VOC to CTQ Conversion**

Once we have collected the voice of the customer (VOC) we then will have to arrive at Critical to Quality (CTQ) elements so that the customer requirements can be incorporated into our process and the output can be produced as desired by the customer.

**Benefits of Six Sigma**

**Makes The Organization Systems Driven**

Six-Sigma efficiency is impossible to achieve if the mode of production used by the organization is craft production. To be efficient enough to run processes that have less than 3.4 defects per million, organizations need to be systems dependant. Thus Six Sigma mind set helps transform a people driven organization into a process driven one!

**Reduces Personnel Time and Skill Required**

Six Sigma results in massive cost savings to the organization involved. These cost savings are highlighted by the fact that after a Six Sigma project any organization has considerably less requirement for labour hours. Also the requirement of skilled labourers is also reduced. Hence, both these factors combined have an effect of drastically reducing the labour bill of the organization.

**Reduces Wastage**

Six Sigma projects realise a large amount of their financial value from their ability to eliminate or at least reduce wastage. Since the process is critically analysed for costs and corresponding value addition, measures are taken to eliminate wastage to a large extent.

**Reduces Inventory Needs**

An ancillary benefit of Six Sigma projects is that it creates a system which is much more efficient than the earlier one. Hence the organization can implement systems like Just In Time Inventory practices and cut still more costs.

**Reduces Reworks and Defects**

Organizations are plagued with defective processes which result in the manufacturing of defective products. Each defect has costs attached. The costs include material, time, overheads and loss of reputation for the firm. Implementing Six Sigma projects often pays for itself in the long run by providing the financial benefits of near zero defects to the firm that implements it.

**Increases Customer Satisfaction**

Customers do not like unreliable products or organizations. This can be verified by the fact that many companies that have implemented Six Sigma have not only found their costs reduced but their market share increased considerably. Hence, Six Sigma is also capable of positively impacting the marketing of the firm.

**JIT**

**Kanban: Just-in-time**

To Japanese managers, kanban or the just-in-time system is an approach for providing smoother production flows and making continual improvements in processes and products. Kanban attempts to reduce work in progress to an absolute minimum. In addition, the system constantly attempts to reduce lead times, work-in-process inventories, and setup times.

Kanban’s core objective is to obtain low-cost, high-quality, on-time production. To achieve this, the system attempts to eliminate stock between the successive processes and to minimize any idle equipment, facilities, or workers.

**Just In Time (JIT)**

Just In Time is set of strategic activities, which are formulated to achieve maximum production with minimal maintenance of inventory. JIT as philosophy is applicable to various types of organization but on implement side it is more relevant with manufacturing operations.

For JIT system to be successful, there are two critical elements, attitude of workers/management and practice.

**Fundamentals of JIT**

JIT is based on the following fundamentals:

* JIT manufacturing and ordering
* Elimination of waste
* Lean management
* Signal System (Kanban)
* Push-Pull System

With the above fundamentals in place, JIT delivers the following:

* Continuous improvement of production and order processing.
* Elimination of non-value added activities and procedures.
* Simplification and advancement of the existing systems.
* Creation of safety environment and ensuring total quality management.
* Creation crossed skilled workers.

**Elements involved in JIT**

**Continuous improvement:**

* Attacking fundamental problems and anything that does not add value to the product.
* Devising systems to identify production and allied problems.
* **Simplicity:** Simple systems are simple & easy to understand, easily manageable and the chances of going wrong are very low.
* **A product:** oriented layout for less time spent on materials and parts movement.
* Quality control at source to ensure every worker is solely responsible for the quality of their own produced output.

**Eliminating waste:**There are seven types of waste:

1. Waste from product defects.
2. Waste of time.
3. Transportation waste.
4. Inventory waste.
5. Waste from overproduction.
6. Processing waste.

Waste minimization is one of the primary objectives of Just In Time system. This needs effective inventory management throughout the whole supply chain. Initially, a manufacturing entity will seek to reduce inventory and enhance operations within its own organization. In an attempt to reduce waste attributed to ineffective inventory management, SIX principles in relation to JIT have been stated by Schniededans and they are:

1. Reduce buffer inventory.
2. Try for zero inventory.
3. Search for reliable suppliers.
4. Reduce lot size and increase the frequency of orders.
5. Reduce purchasing cost.
6. Improve material handling.

**Advantages & Disadvantages of Just-In-Time Systems**

**Advantages of Adopting Just-In-Time include:**

* Just-in-time approach keeps stock holding costs to a minimum level. The released capacity results in better utilization of space and bears a favourable impact on the insurance premiums and rent that would otherwise be needed to be made.
* The just-in-time approach helps to eliminate waste. Chances of expired or out of date products; do not arise at all.
* As under this management method, only essential stocks which are required for to manufacturing are obtained, thus less working capital is required. Under this approach, a minimum re-ordering level is set, and only when that level is reached, order for fresh stocks are made and thus this becomes a boon to inventory management too.
* Due to the abovementioned low level of stocks held, the ROI (Return On Investment? of the organizations be high in general.
* As this approach works on a demand-pull basis, all goods produced would be sold, and thus it includes changes in demand with unanticipated ease. This makes JIT appealing today, where the market demand is fickle and somewhat volatile.
* JIT emphasizes the ‘right-first-time’ concept, so that rework costs and the cost of inspection is minimized.
* By following JIT greater efficiency and High-quality products can be derived.
* Better relationships are fostered along the production chain under a JIT system.
* Higher customer satisfaction due to continuous communication with the customer.
* Just In Time adoption result in the elimination of overproduction.

**Disadvantages of Adopting JIT Systems**

* JIT approach states ZERO tolerance for mistakes, making re-work difficult in practice, as inventory is kept to a minimum level.
* A successful application of JIT requires a high reliance on suppliers, whose performance is outside the purview of the manufacturer.
* Due to no buffers in JIT, production line idling and downtime can occur which would have an unfavourable effect on the production process and also on the finances.
* Chances are quite high of not meeting an unexpected increase in orders as there will be no excess inventory of finished goods.
* Transaction costs would be comparatively high depending upon the frequency of transactions.
* JIT may have certain negative effects on the environment due to the frequent deliveries as the same would result in higher use and cost of transportation, which in turn would consume more fossil fuels.

**QFD**

Every organization has customers. Some have only internal customers, some have only external customers, and some have both. When you are working to determine what you need to accomplish to satisfy or even delight your customers, quality function deployment is an essential tool.

Quality Function Deployment (QFD) is a structured approach to defining customer needs or requirements and translating them into specific plans to produce products to meet those needs. The “voice of the customer” is the term to describe these stated and unstated customer needs or requirements. The voice of the customer is captured in a variety of ways: direct discussion or interviews, surveys, focus groups, customer specifications, observation, warranty data, field reports, etc. This understanding of the customer needs is then summarized in a product planning matrix or “house of quality”. These matrices are used to translate higher level “what’s” or needs into lower level “how’s” – product requirements or technical characteristics to satisfy these needs.

While the Quality Function Deployment matrices are a good communication tool at each step in the process, the matrices are the means and not the end. The real value is in the process of communicating and decision-making with QFD. QFD is oriented toward involving a team of people representing the various functional departments that have involvement in product development: Marketing, Design Engineering, Quality Assurance, Manufacturing/ Manufacturing Engineering, Test Engineering, Finance, Product Support, etc.

The active involvement of these departments can lead to balanced consideration of the requirements or “what’s” at each stage of this translation process and provide a mechanism to communicate hidden knowledge – knowledge that is known by one individual or department but may not otherwise be communicated through the organization. The structure of this methodology helps development personnel understand essential requirements, internal capabilities, and constraints and design the product so that everything is in place to achieve the desired outcome – a satisfied customer. Quality Function Deployment helps development personnel maintain a correct focus on true requirements and minimizes misinterpreting customer needs. As a result, QFD is an effective communications and quality planning tool.

**BACKGROUND**

QFD is a focused methodology for carefully listening to the voice of the customer and then effectively responding to those needs and expectations.

First developed in Japan in the late 1960s as a form of cause-and-effect analysis, QFD was brought to the United States in the early 1980s. It gained its early popularity as a result of numerous successes in the automotive industry.

**METHODOLOGY**

In QFD, quality is a measure of customer satisfaction with a product or a service. QFD is a structured method that uses the seven management and planning tools to identify and prioritize customers’ expectations quickly and effectively.

Beginning with the initial matrix, commonly termed the House of Quality (Figure 1), the QFD methodology focuses on the most important product or service attributes or qualities. These are composed of customer *wows, wants,*and *musts.*(See the Kano model of customer perception versus customer reality.)

Once you have prioritized the attributes and qualities, QFD deploys them to the appropriate organizational function for action, as shown in Figure 2. Thus, QFD is the deployment of customer-driven qualities to the responsible functions of an organization.

**Quality Function Deployment: Most Important Product/Service Attributes or Qualities**

**Quality Function Deployment of Customer-driven Qualities to Responsible Organizational Functions**


**Tagichi’s quality engineering**

**Taguchi methods** are statistical methods, sometimes called robust design methods, developed by Genichi Taguchi to improve the quality of manufactured goods, and more recently also applied to engineering, biotechnology, marketing and advertising. Professional statisticians have welcomed the goals and improvements brought about by Taguchi methods, particularly by Taguchi's development of designs for studying variation, but have criticized the inefficiency of some of Taguchi's proposals.

**Taguchi's work includes three principal contributions to statistics:**

A specific loss function

The philosophy of off-line quality control; and

Innovations in the design of experiments.

**Loss functions**

**Loss functions in the statistical theory**

Traditionally, statistical methods have relied on mean-unbiased estimators of [treatment effects](https://en.wikipedia.org/wiki/Design_of_experiments): Under the conditions of the Gauss–Markov theorem, [least squares](https://en.wikipedia.org/wiki/Least_squares) estimators have minimum variance among all mean-unbiased linear estimators. The emphasis on comparisons of means also draws (limiting) comfort from the [law of large numbers](https://en.wikipedia.org/wiki/Law_of_large_numbers), according to which the [sample means](https://en.wikipedia.org/wiki/Sample_mean) [converge](https://en.wikipedia.org/wiki/Convergence_%28mathematics%29) to the true mean. Fisher's textbook on the [design of experiments](https://en.wikipedia.org/wiki/Design_of_experiments) emphasized comparisons of treatment means.

However, loss functions were avoided by [Ronald A. Fisher](https://en.wikipedia.org/wiki/Ronald_A._Fisher)

**Taguchi's use of loss functions**

Taguchi knew [statistical theory](https://en.wikipedia.org/wiki/Statistical_theory) mainly from the followers of [Ronald A. Fisher](https://en.wikipedia.org/wiki/Ronald_A._Fisher), who also avoided [loss functions](https://en.wikipedia.org/wiki/Loss_function). Reacting to Fisher's methods in the [design of experiments](https://en.wikipedia.org/wiki/Design_of_experiments), Taguchi interpreted Fisher's methods as being adapted for seeking to improve the [mean](https://en.wikipedia.org/wiki/Mean) outcome of a [process](https://en.wiktionary.org/wiki/process). Indeed, Fisher's work had been largely motivated by programmes to compare agricultural yields under different treatments and blocks, and such experiments were done as part of a long-term programme to improve harvests.

However, Taguchi realised that in much industrial production, there is a need to produce an outcome *on target*, for example, to [machine](https://en.wikipedia.org/wiki/Machine) a hole to a specified diameter, or to manufacture a [cell](https://en.wikipedia.org/wiki/Electrochemical_cell) to produce a given [voltage](https://en.wikipedia.org/wiki/Voltage). He also realised, as had [Walter A. Shewhart](https://en.wikipedia.org/wiki/Walter_A._Shewhart) and others before him, that excessive variation lay at the root of poor manufactured quality and that reacting to individual items inside and outside specification was counterproductive.

He therefore argued that [quality engineering](https://en.wikipedia.org/wiki/Quality_engineering) should start with an understanding of [quality costs](https://en.wikipedia.org/wiki/Quality_costs) in various situations. In much conventional [industrial engineering](https://en.wikipedia.org/wiki/Industrial_engineering), the quality costs are simply represented by the number of items outside specification multiplied by the cost of rework or scrap. However, Taguchi insisted that manufacturers broaden their horizons to consider *cost to society*. Though the short-term costs may simply be those of non-conformance, any item manufactured away from nominal would result in some loss to the customer or the wider community through early wear-out; difficulties in interfacing with other parts, themselves probably wide of nominal; or the need to build in safety margins. These losses are [externalities](https://en.wikipedia.org/wiki/Externalities) and are usually ignored by manufacturers, which are more interested in their [private costs](https://en.wikipedia.org/wiki/Private_cost) than [social costs](https://en.wikipedia.org/wiki/Social_cost). Such externalities prevent markets from operating efficiently, according to analyses of [public economics](https://en.wikipedia.org/wiki/Public_economics). Taguchi argued that such losses would inevitably find their way back to the originating corporation (in an effect similar to the [tragedy of the commons](https://en.wikipedia.org/wiki/Tragedy_of_the_commons)), and that by working to minimise them, manufacturers would enhance brand reputation, win markets and generate profits.

Such losses are, of course, very small when an item is near to negligible. [Donald J. Wheeler](https://en.wikipedia.org/wiki/Donald_J._Wheeler) characterised the region within specification limits as where we *deny that losses exist*. As we diverge from nominal, losses grow until the point where *losses are too great to deny* and the specification limit is drawn. All these losses are, as [W. Edwards Deming](https://en.wikipedia.org/wiki/W._Edwards_Deming) would describe them, *unknown and unknowable*, but Taguchi wanted to find a useful way of representing them statistically. Taguchi specified three situations:

1. Larger the better (for example, agricultural yield);
2. Smaller the better (for example, [carbon dioxide](https://en.wikipedia.org/wiki/Carbon_dioxide) emissions); and
3. On-target, minimum-variation (for example, a mating part in an assembly).

The first two cases are represented by simple [monotonic](https://en.wikipedia.org/wiki/Monotonic_function) loss functions. In the third case, Taguchi adopted a squared-error loss function for several reasons:

* It is the first "symmetric" term in the [Taylor series](https://en.wikipedia.org/wiki/Taylor_series) expansion of [real analytic](https://en.wikipedia.org/wiki/Real_analytic) loss-functions.
* Total loss is measured by the [variance](https://en.wikipedia.org/wiki/Variance). For [uncorrelated](https://en.wikipedia.org/wiki/Uncorrelated) [random variables](https://en.wikipedia.org/wiki/Random_variables), as variance is additive the total loss is an additive measurement of cost.
* The squared-error loss function is widely used in [statistics](https://en.wikipedia.org/wiki/Statistics), following Gauss's use of the squared-error loss function in justifying the method of [least squares](https://en.wikipedia.org/wiki/Least_squares).

**Reception of Taguchi's ideas by statisticians**

Though many of Taguchi's concerns and conclusions are welcomed by statisticians and [economists](https://en.wikipedia.org/wiki/Economist), some ideas have been especially criticized. For example, Taguchi's recommendation that industrial experiments maximise some [*signal-to-noise ratio*](https://en.wikipedia.org/wiki/Signal-to-noise_ratio) (representing the magnitude of the [mean](https://en.wikipedia.org/wiki/Expected_value) of a process compared to its variation) has been criticized.

**Off-line quality control**

**Taguchi's rule for manufacturing**

Taguchi realized that the best opportunity to eliminate variation of the final product quality is during the design of a product and its manufacturing process. Consequently, he developed a strategy for quality engineering that can be used in both contexts. The process has three stages:

* System design
* Parameter (measure) design
* Tolerance design

**System design**

This is design at the conceptual level, involving creativity and innovation.

**Parameter design**

Once the concept is established, the nominal values of the various dimensions and design parameters need to be set, the detail design phase of conventional engineering. Taguchi's radical insight was that the exact choice of values required is under-specified by the performance requirements of the system. In many circumstances, this allows the parameters to be chosen so as to minimize the effects on performance arising from variation in manufacture, environment and cumulative damage. This is sometimes called robustification.

Robust parameter designs consider controllable and uncontrollable noise variables; they seek to exploit relationships and optimize settings that minimize the effects of the noise variables.

**Tolerance design**

Main article: Pareto principle

With a successfully completed parameter design, and an understanding of the effect that the various parameters have on performance, resources can be focused on reducing and controlling variation in the critical few dimensions.

**Design of experiments**

Taguchi developed his experimental theories independently. Taguchi read works following R. A. Fisher only in 1954.

**Outer arrays**

Taguchi's designs aimed to allow greater understanding of variation than did many of the traditional designs from the analysis of variance (following Fisher). Taguchi contended that conventional sampling is inadequate here as there is no way of obtaining a random sample of future conditions. In Fisher's design of experiments and analysis of variance, experiments aim to reduce the influence of nuisance factors to allow comparisons of the mean treatment-effects. Variation becomes even more central in Taguchi's thinking.

Taguchi proposed extending each experiment with an "outer array" (possibly an orthogonal array); the "outer array" should simulate the random environment in which the product would function. This is an example of judgmental sampling. Many quality specialists have been using "outer arrays".

Later innovations in outer arrays resulted in "compounded noise." This involves combining a few noise factors to create two levels in the outer array: First, noise factors that drive output lower, and second, noise factors that drive output higher. "Compounded noise" simulates the extremes of noise variation but uses fewer experimental runs than would previous Taguchi designs.

**Management of interactions**

**Interactions, as treated by Taguchi**

Many of the orthogonal arrays that Taguchi has advocated are saturated arrays, allowing no scope for estimation of interactions. This is a continuing topic of controversy. However, this is only true for "control factors" or factors in the "inner array". By combining an inner array of control factors with an outer array of "noise factors", Taguchi's approach provides "full information" on control-by-noise interactions, it is claimed. Taguchi argues that such interactions have the greatest importance in achieving a design that is robust to noise factor variation. The Taguchi approach provides more complete interaction information than typical fractional factorial designs, its adherents claim.

Followers of Taguchi argue that the designs offer rapid results and that interactions can be eliminated by proper choice of quality characteristics. That notwithstanding, a "confirmation experiment" offers protection against any residual interactions. If the quality characteristic represents the energy transformation of the system, then the "likelihood" of control factor-by-control factor interactions is greatly reduced, since "energy" is "additive".

**Inefficiencies of Taguchi's designs**

Interactions are part of the real world. In Taguchi's arrays, interactions are confounded and difficult to resolve.

Statisticians in response surface methodology (RSM) advocate the "sequential assembly" of designs: In the RSM approach, a screening design is followed by a "follow-up design" that resolves only the confounded interactions judged worth resolution. A second follow-up design may be added (time and resources allowing) to explore possible high-order univariate effects of the remaining variables, as high-order univariate effects are less likely in variables already eliminated for having no linear effect. With the economy of screening designs and the flexibility of follow-up designs, sequential designs have great statistical efficiency. The sequential designs of response surface methodology require far fewer experimental runs than would a sequence of Taguchi's designs.

**Analysis of experiments**

**Assessment**

Genichi Taguchi has made valuable contributions to statistics and engineering. His emphasis on loss to society, techniques for investigating variation in experiments, and his overall strategy of system, parameter and tolerance design have been influential in improving manufactured quality worldwide.

**Failure mode and effects analysis** (**FMEA**; often written with "failure modes" in plural) is the process of reviewing as many components, assemblies, and subsystems as possible to identify potential failure modes in a system and their causes and effects. For each component, the failure modes and their resulting effects on the rest of the system are recorded in a specific FMEA worksheet. There are numerous variations of such worksheets. An FMEA can be a qualitative analysis, but may be put on a quantitative basis when mathematical failure rate models are combined with a statistical failure mode ratio database. It was one of the first highly structured, systematic techniques for failure analysis. It was developed by reliability engineers in the late 1950s to study problems that might arise from malfunctions of military systems. An FMEA is often the first step of a system reliability study.

A few different types of FMEA analyses exist, such as:

* Functional
* Design
* Process

Sometimes FMEA is extended to FMECA (failure mode, effects, and criticality analysis) to indicate that criticality analysis is performed too.

FMEA is an inductive reasoning (forward logic) single point of failure analysis and is a core task in reliability engineering, safety engineering and quality engineering.

Basic terms[[edit](https://en.wikipedia.org/w/index.php?title=Failure_mode_and_effects_analysis&action=edit&section=6)]

The following covers some basic FMEA terminology.[[23]](https://en.wikipedia.org/wiki/Failure_mode_and_effects_analysis#cite_note-23)

**Failure**

The loss of a function under stated conditions.

**Failure mode**

The specific manner or way by which a failure occurs in terms of failure of the part, component, function, equipment, subsystem, or system under investigation. Depending on the type of FMEA performed, failure mode may be described at various levels of detail. A piece part FMEA will focus on detailed part or component failure modes (such as fully fractured axle or deformed axle, or electrical contact stuck open, stuck short, or intermittent). A functional FMEA will focus on functional failure modes. These may be general (such as No Function, Over Function, Under Function, Intermittent Function, or Unintended Function) or more detailed and specific to the equipment being analyzed. A PFMEA will focus on process failure modes (such as inserting the wrong drill bit).

**Failure cause and/or mechanism**

Defects in requirements, design, process, quality control, handling or part application, which are the underlying cause or sequence of causes that initiate a process (mechanism) that leads to a failure mode over a certain time. A failure mode may have more causes. *For example; "fatigue or corrosion of a structural beam" or "fretting corrosion in an electrical contact" is a failure mechanism and in itself (likely) not a failure mode. The related failure mode (end state) is a "full fracture of structural beam" or "an open electrical contact". The initial cause might have been "Improper application of corrosion protection layer (paint)" and /or "(abnormal) vibration input from another (possibly failed) system".*

**Failure effect**

Immediate consequences of a failure on operation, or more generally on the needs for the customer / user that should be fulfilled by the function but now is not, or not fully, fulfilled

**Indenture levels (bill of material or functional breakdown)**

An identifier for system level and thereby item complexity. Complexity increases as levels are closer to one.

**Local effect**

The failure effect as it applies to the item under analysis.

**Next higher level effect**

The failure effect as it applies at the next higher indenture level.

**End effect**

The failure effect at the highest indenture level or total system.

**Detection**

The means of detection of the failure mode by maintainer, operator or built in detection system, including estimated dormancy period (if applicable)

**Probability**

The likelihood of the failure occurring.

**Risk Priority Number (RPN)**

Severity (of the event) × Probability (of the event occurring) × Detection (Probability that the event would not be detected before the user was aware of it)

**Severity**

The consequences of a failure mode. Severity considers the worst potential consequence of a failure, determined by the degree of injury, property damage, system damage and/or time lost to repair the failure.

**Remarks / mitigation / actions**

Additional info, including the proposed mitigation or actions used to lower a risk or justify a risk level or scenario.

Example of FMEA worksheet[[edit](https://en.wikipedia.org/w/index.php?title=Failure_mode_and_effects_analysis&action=edit&section=7)]

|  |
| --- |
| **Example FMEA worksheet** |
| **FMEA Ref.** | **Item** | **Potential failure mode** | **Potential cause(s) / mechanism** | **Mission Phase** | **Local effects of failure** | **Next higher level effect** | **System Level End Effect** | **(P) Probability (estimate)** | **(S) Severity** | **(D) Detection (Indications to Operator, Maintainer)** | **Detection Dormancy Period** | **Risk Level P\*S (+D)** | **Actions for further Investigation / evidence** | **Mitigation / Requirements** |
| 1.1.1.1 | Brake Manifold Ref. Designator 2b, channel A, O-ring | Internal Leakage from Channel A to B | a) O-ring Compression Set (Creep) failure b) surface damage during assembly | Landing | Decreased pressure to main brake hose | No Left Wheel Braking | Severely Reduced Aircraft deceleration on ground and side drift. Partial loss of runway position control. Risk of collision | (C) Occasional | (V) Catastrophic (this is the worst case) | (1) Flight Computer and Maintenance Computer will indicate "Left Main Brake, Pressure Low" | Built-In Test interval is 1 minute | Unacceptable | Check Dormancy Period and probability of failure | Require redundant independent brake hydraulic channels and/or Require redundant sealing and Classify O-ring as Critical Part Class 1 |

**Probability (P)**[[edit](https://en.wikipedia.org/w/index.php?title=Failure_mode_and_effects_analysis&action=edit&section=8)]

It is necessary to look at the cause of a failure mode and the likelihood of occurrence. This can be done by analysis, calculations / FEM, looking at similar items or processes and the failure modes that have been documented for them in the past. A failure cause is looked upon as a design weakness. All the potential causes for a failure mode should be identified and documented. This should be in technical terms. Examples of causes are: Human errors in handling, Manufacturing induced faults, Fatigue, Creep, Abrasive wear, erroneous algorithms, excessive voltage or improper operating conditions or use (depending on the used ground rules). A failure mode may given a *Probability Ranking* with a defined number of levels.

|  |  |
| --- | --- |
| **Rating** | **Meaning** |
| A | Extremely Unlikely (Virtually impossible or No known occurrences on similar products or processes, with many running hours) |
| B | Remote (relatively few failures) |
| C | Occasional (occasional failures) |
| D | Reasonably Possible (repeated failures) |
| E | Frequent (failure is almost inevitable) |

For a piece part FMEA, quantitative probability may be calculated from the results of a [reliability prediction](https://en.wikipedia.org/wiki/Reliability_prediction_for_electronic_components) analysis and the failure mode ratios from a failure mode distribution catalog, such as RAC FMD-97.[[24]](https://en.wikipedia.org/wiki/Failure_mode_and_effects_analysis#cite_note-24) This method allows a quantitative FTA to use the FMEA results to verify that undesired events meet acceptable levels of risk.

**Severity (S)**[[edit](https://en.wikipedia.org/w/index.php?title=Failure_mode_and_effects_analysis&action=edit&section=9)]

Determine the Severity for the worst-case scenario adverse end effect (state). It is convenient to write these effects down in terms of what the user might see or experience in terms of functional failures. Examples of these end effects are: full loss of function x, degraded performance, functions in reversed mode, too late functioning, erratic functioning, etc. Each end effect is given a Severity number (S) from, say, I (no effect) to V (catastrophic), based on cost and/or loss of life or quality of life. These numbers prioritize the failure modes (together with probability and detectability). Below a typical classification is given. Other classifications are possible. See also [hazard analysis](https://en.wikipedia.org/wiki/Hazard_analysis).

|  |  |
| --- | --- |
| **Rating** | **Meaning** |
| I | No relevant effect on reliability or safety |
| II | Very minor, no damage, no injuries, only results in a maintenance action (only noticed by discriminating customers) |
| III | Minor, low damage, light injuries (affects very little of the system, noticed by average customer) |
| IV | Critical (causes a loss of primary function; Loss of all safety Margins, 1 failure away from a catastrophe, severe damage, severe injuries, max 1 possible death ) |
| V | Catastrophic (product becomes inoperative; the failure may result in complete unsafe operation and possible multiple deaths) |

**Detection (D)**[[edit](https://en.wikipedia.org/w/index.php?title=Failure_mode_and_effects_analysis&action=edit&section=10)]

The means or method by which a failure is detected, isolated by operator and/or maintainer and the time it may take. This is important for maintainability control (availability of the system) and it is especially important for multiple failure scenarios. This may involve dormant failure *modes* (e.g. No direct system effect, while a redundant system / item automatically takes over or when the failure only is problematic during specific mission or system states) or latent failures (e.g. deterioration failure *mechanisms*, like a metal growing crack, but not a critical length). It should be made clear how the failure mode or cause can be discovered by an operator under normal system operation or if it can be discovered by the maintenance crew by some diagnostic action or automatic built in system test. A dormancy and/or latency period may be entered.

|  |  |
| --- | --- |
| **Rating** | **Meaning** |
| 1 | Certain – fault will be caught on test – e.g. [Poka-Yoke](https://en.wikipedia.org/wiki/Poka-yoke) |
| 2 | Almost certain |
| 3 | High |
| 4 | Moderate |
| 5 | Low |
| 6 | Fault is undetected by Operators or Maintainers |

**Dormancy or Latency Period**[[edit](https://en.wikipedia.org/w/index.php?title=Failure_mode_and_effects_analysis&action=edit&section=11)]

The average time that a failure mode may be undetected may be entered if known. For example:

* Seconds, auto detected by maintenance computer
* 8 hours, detected by turn-around inspection
* 2 months, detected by scheduled maintenance block X
* 2 years, detected by overhaul task x

**Indication**[[edit](https://en.wikipedia.org/w/index.php?title=Failure_mode_and_effects_analysis&action=edit&section=12)]

If the undetected failure allows the system to remain in a *safe* / working state, a second failure situation should be explored to determine whether or not an indication will be evident to all *operators* and what corrective action they may or should take.

Indications to the operator should be described as follows:

* Normal. An indication that is evident to an operator when the system or equipment is operating normally.
* Abnormal. An indication that is evident to an operator when the system has malfunctioned or failed.
* Incorrect. An erroneous indication to an operator due to the malfunction or failure of an indicator (i.e., instruments, sensing devices, visual or audible warning devices, etc.).

PERFORM DETECTION COVERAGE ANALYSIS FOR TEST PROCESSES AND MONITORING (From ARP4761 Standard):

This type of analysis is useful to determine how effective various test processes are at the detection of latent and dormant faults. The method used to accomplish this involves an examination of the applicable failure modes to determine whether or not their effects are detected, and to determine the percentage of failure rate applicable to the failure modes which are detected. The possibility that the detection means may itself fail latently should be accounted for in the coverage analysis as a limiting factor (i.e., coverage cannot be more reliable than the detection means availability). Inclusion of the detection coverage in the FMEA can lead to each individual failure that would have been one effect category now being a separate effect category due to the detection coverage possibilities. Another way to include detection coverage is for the FTA to conservatively assume that no holes in coverage due to latent failure in the detection method affect detection of all failures assigned to the failure effect category of concern. The FMEA can be revised if necessary for those cases where this conservative assumption does not allow the top event probability requirements to be met.

After these three basic steps the Risk level may be provided.

**Risk level (P×S) and (D)**[[edit](https://en.wikipedia.org/w/index.php?title=Failure_mode_and_effects_analysis&action=edit&section=13)]

**Risk is the combination of End Effect Probability And Severity** where probability and severity includes the effect on non-detectability (**dormancy time**). This may influence the end effect probability of failure or the worst case effect Severity. The exact calculation may not be easy in all cases, such as those where multiple scenarios (with multiple events) are possible and detectability / dormancy plays a crucial role (as for redundant systems). In that case Fault Tree Analysis and/or Event Trees may be needed to determine exact probability and risk levels.

Preliminary Risk levels can be selected based on a Risk Matrix like shown below, based on Mil. Std. 882.[[25]](https://en.wikipedia.org/wiki/Failure_mode_and_effects_analysis#cite_note-25) The higher the Risk level, the more justification and mitigation is needed to provide evidence and lower the risk to an acceptable level. High risk should be indicated to higher level management, who are responsible for final decision-making.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Severity****Probability** | **I** | **II** | **III** | **IV** | **V** | **VI** |
| A | Low | Low | Low | Low | Moderate | High |
| B | Low | Low | Low | Moderate | High | Unacceptable |
| C | Low | Low | Moderate | Moderate | High | Unacceptable |
| D | Low | Moderate | Moderate | High | Unacceptable | Unacceptable |
| E | Moderate | Moderate | High | Unacceptable | Unacceptable | Unacceptable |

* After this step the FMEA has become like a [FMECA](https://en.wikipedia.org/wiki/FMECA).

**Timing**

The FMEA should be updated whenever:

* A new cycle begins (new product/process)
* Changes are made to the operating conditions
* A change is made in the design
* New regulations are instituted
* Customer feedback indicates a problem

**Uses**

* Development of system requirements that minimize the likelihood of failures.
* Development of designs and test systems to ensure that the failures have been eliminated or the risk is reduced to acceptable level.
* Development and evaluation of diagnostic systems
* To help with design choices (trade-off analysis).

**Advantages**

* Catalyst for teamwork and idea exchange between functions
* Collect information to reduce future failures, capture engineering knowledge
* Early identification and elimination of potential failure modes
* Emphasize problem prevention
* Improve company image and competitiveness
* Improve production yield
* Improve the quality, reliability, and safety of a product/process
* Increase user satisfaction
* Maximize profit
* Minimize late changes and associated cost
* Reduce impact on company profit margin
* Reduce system development time and cost
* Reduce the possibility of same kind of failure in future
* Reduce the potential for warranty concerns

**Poka yoke**

**Poka-yoke** (ポカヨケ, [[poka yoke]](https://en.wikipedia.org/wiki/Help%3AIPA/Japanese)) is a Japanese term that means "mistake-proofing" or "inadvertent error [prevention](https://en.wiktionary.org/wiki/prevention)". A poka-yoke is any mechanism in any process that helps an equipment operator avoid (*yokeru*) mistakes (*poka*). Its purpose is to eliminate product defects by preventing, correcting, or drawing attention to [human errors](https://en.wikipedia.org/wiki/Human_error) as they occur.[[1]](https://en.wikipedia.org/wiki/Poka-yoke#cite_note-1) The concept was formalised, and the term adopted, by [Shigeo Shingo](https://en.wikipedia.org/wiki/Shigeo_Shingo) as part of the [Toyota Production System](https://en.wikipedia.org/wiki/Toyota_Production_System).[[2]](https://en.wikipedia.org/wiki/Poka-yoke#cite_note-Shigeo-2)[[3]](https://en.wikipedia.org/wiki/Poka-yoke#cite_note-3) It was originally described as [*baka*](https://en.wikipedia.org/wiki/Baka_%28fool%29)*-yoke*, but as this means "fool-proofing" (or "[idiot-proofing](https://en.wikipedia.org/wiki/Idiot_proof)") the name was changed to the milder *poka-yoke*.

**MISTAKE PROOFING**

[Quality Glossary Definition: Mistake proofing](https://asq.org/quality-resources/quality-glossary/m)

Also called: poka-yoke, fail-safing

Mistake proofing, or its Japanese equivalent *poka-yoke* (pronounced PO-ka yo-KAY), is the use of any automatic device or method that either makes it impossible for an error to occur or makes the error immediately obvious once it has occurred. It is a common [process analysis tool](https://asq.org/quality-resources/process-analysis-tools).

**WHEN TO USE MISTAKE PROOFING**

* When a process step has been identified where human error can cause mistakes or defects to occur, especially in processes that rely on the worker’s attention, skill, or experience
* In a service process, where the customer can make an error which affects the output
* At a hand-off step in a process, when output (or for service processes, the customer) is transferred to another worker
* When a minor error early in the process causes major problems later in the process
* When the consequences of an error are expensive or dangerous

**MISTAKE PROOFING PROCEDURE**

1. Obtain or create a [flowchart](https://asq.org/quality-resources/flowchart) of the process. Review each step, thinking about where and when human errors are likely to occur.
2. For each potential error, work back through the process to find its source.
3. For each error, think of potential ways to make it impossible for the error to occur. Consider:
	* Elimination: eliminating the step that causes the error.
	* Replacement: replacing the step with an error-proof one.
	* Facilitation: making the correct action far easier than the error.
4. If you cannot make it impossible for the error to occur, think of ways to detect the error and minimize its effects. Consider inspection methods, setting functions, and regulatory functions expanded on below.
5. Choose the best mistake-proofing method or device for each error. Test it, then implement it. Three kinds of **inspection methods** provide rapid feedback:
	* Successive inspection is done at the next step of the process by the next worker.
	* Self-inspection means workers check their own work immediately after doing it.
	* Source inspection checks, before the process step takes place, that conditions are correct. Often it’s automatic and keeps the process from proceeding until conditions are right.

**SETTING AND REGULATORY FUNCTIONS**

**Setting functions** are the methods by which a process parameter or product attribute is inspected for errors:

* The contact or physical method checks a physical characteristic such as diameter or temperature, often using a sensor.
* The motion-step or sequencing method checks the process sequence to make sure steps are done in order.
* The fixed-value or grouping and counting method counts repetitions or parts, or it weighs an item to ensure completeness.
* A fourth setting function is sometimes added, information enhancement, which makes sure information is available and perceivable when and where required.

**Regulatory functions** are signals that alert the workers that an error has occurred:

* Warning functions are bells, buzzers, lights, and other sensory signals. Consider using color-coding, shapes, symbols, and distinctive sounds.
* Control functions prevent the process from proceeding until the error is corrected (if the error has already taken place) or conditions are correct (if the inspection was a source inspection and the error has not yet occurred).

**MISTAKE PROOFING EXAMPLE**

The Parisian Experience restaurant wished to ensure high service quality through mistake proofing. They reviewed the deployment chart (a detailed [flowchart](https://asq.org/quality-resources/flowchart) that shows who performs each step) of the seating process shown below and identified human errors on the part of restaurant staff or customers that could cause service problems.

**Mistake Proofing: Restaurant’s deployment chart**

The first potential error occurs when customers enter. The maitre d’ might not notice a customer is waiting if the maitre d’ is escorting other customers to their table, checking on table status, or conferring with kitchen staff.

The mistake proofing device is an electronic sensor on the entrance door. The sensor sends a signal to a vibrating pager on the maitre d’s belt to ensure that the maitre d’ always knows when someone enters or leaves the restaurant. Other mistake proofing methods replaced the process steps requiring the maitre d’ to leave the front door to seat customers.

A possible error on the customers’ part was identified at the step when diners are called from the lounge when their table is ready. They might miss the call if the lounge is noisy, if they are engrossed in conversation, or if they are hard of hearing.

The mistake proofing chosen by the team was to replace the step of the process in which the maitre d’ called the customer’s name over the loudspeaker. Instead, during the greeting step, the maitre d’ notes a unique visual identifier of one or more members of the party. When the table is ready, the table busser notifies the waiter, who comes to the maitre d’ and learns how to identify the customers. The waiter finds the customers in the lounge, escorts them to their table, gives them menus, and takes additional drink orders.

Not only does this mistake proofing method eliminate a customer-caused problem, it improves the restaurant ambiance by eliminating the annoying loudspeaker, keeps the maitre d’ at the front door to greet customers, creates a sense of exceptional service when the waiter “magically” knows the customers, and eliminates additional waiting time at the hand-off between maitre d’ and waiter.

**Unit IV**

Quality Education, process, quality system – quality objectives and quality policy – quality planning – quality information feedback. TQM Culture. Quality circles. Quality audits.

* Quality Education,
* process,
* quality system
* quality objectives and quality policy
* quality planning –
* Quality information feedback.
* TQM Culture.
* Quality circles.
* Quality audits.

**Concept of Quality Management (Total Quality Management) and Excellence in Education.**
Achieving quality education is possible only when educational services/products meet needs and expectations, give value for time and efforts and lead to true all-round development of the child – physical, mental, social, moral, spiritual, etc. For this we must follow Total Quality Management wherein the entire institution i.e. management, principal, supervisor, teachers, nonteaching staff, parents, pupil, all work as a harmonious unit to achieve results.

**PRINCIPLES**1) Child is the centre - Focus should be on the student and his needs, wants, way of life, goals, etc.

2) School is system-oriented - The school comprises of several inter-dependent factors that all work together in an integrated manner to achieve success.

3) Team Work - Cooperation and esprit de corps foster the spirit of oneness for harmonious working and better results.

4) Cooperative Management - The management must understand and empathise with issues faced by personnel at all levels. This creates a sense of belonging amongst the work force.

5) Human Resources Development - Constant training and extension services are needed to keep the staff up to date and proficient.

6) Future Planning - Think in terms of goal and objectives both longterm and short-term.

7) Leadership - The leader is the captain of the ship. He gives proper direction and holds all the threads together.

**The three pillars of quality education**

Quality education is based on three pillars:

1. Quality teaching – which  is ensured through the recruitment of high calibre candidates to teaching, the provision to them of high quality initial teacher education and the support throughout their career of continuous professional development. Teachers are the most important educational resource and a critical determinant of quality. They must be treated as respected professionals. Teaching must provide an attractive career choice, and must remain sufficiently attractive, in terms of salaries and conditions of employment, to retain the best teachers in the service.
2. Quality tools for teaching and learning – including appropriate curricula and inclusive teaching and learning materials and resources. These may be provided,  through the application of information and communication technology, that is, by harnessing the enormous power of the internet and the capacity and accessibility of modern technology to assist and support teaching and learning.
3. Quality environments for teaching and learning – supportive, comfortable, safe and secure, with the appropriate facilities to encourage student learning and to enable teachers to teach effectively. A quality environment also engages parents, students, teachers, school authorities and support staff in a community working together to achieve the goal of providing quality education for all of its students.

**I. Foundation**
TQM is built on a foundation of ethics, integrity and trust. It fosters openness, fairness and sincerity and allows involvement by everyone. This is the key to unlocking the ultimate potential of TQM. These three elements move together, however, each element offers something different to the TQM concept.

1. Ethics – Ethics is the discipline concerned with good and bad in any situation. It is a two-faceted subject represented by organizational and individual ethics. Organizational ethics establish a business code of ethics that outlines guidelines that all employees are to adhere to in the performance of their work. Individual ethics include personal rights or wrongs.

2. Integrity – Integrity implies honesty, morals, values, fairness, and adherence to the facts and sincerity. The characteristic is what customers (internal or external) expect and deserve to receive. People see the opposite of integrity as duplicity. TQM will not work in an atmosphere of duplicity.

3. Trust – Trust is a by-product of integrity and ethical conduct. Without trust, the framework of TQM cannot be built. Trust fosters full participation of all members. It allows empowerment that encourages pride ownership and it encourages commitment. It allows decision making at appropriate levels in the organization, fosters individual risk-taking for continuous improvement and helps to ensure that measurements focus on improvement of process and are not used to contend people. Trust is essential to ensure customer satisfaction. So, trust builds the cooperative environment essential for TQM.

 **II. Bricks**
Basing on the strong foundation of trust, ethics and integrity, bricks are placed to reach the roof of recognition. It includes:

4. Training – Training is very important for employees to be highly productive. Supervisors are solely responsible for implementing TQM within their departments, and teaching their employees the philosophies of TQM. Training that employees require are interpersonal skills, the ability to function within teams, problem solving, decision making, job management performance analysis and improvement, business economics and technical skills. During the creation and formation of TQM, employees are trained so that they can become effective employees for the company.

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5. Teamwork – To become successful in business, teamwork is also a key element of TQM. With the use of teams, the business will receive quicker and better solutions to problems. Teams also provide more permanent improvements in processes and operations. In teams, people feel more comfortable bringing up problems that may occur, and can get help from other workers to find a solution and put into place. There are mainly three types of teams that TQM organizations adopt:

A. Quality improvement teams or excellence teams (QITs) – These are temporary teams with the purpose of dealing with specific problems that often recur. These teams are set up for period of three to twelve months.
B. Problem solving teams (PSTs) – These are temporary teams to solve certain problems and also to identify and overcome causes of problems. They generally last from one week to three months.
C. Natural work teams (NWTs) – These teams consist of small groups of skilled workers who share tasks and responsibilities. These teams use concepts such as employee involvement teams, self-managing teams and quality circles. These teams generally work for one to two hours a week.

6. Leadership – It is possibly the most important element in TQM. It appears everywhere in organization. Leadership in TQM requires the manager to provide an inspiring vision, make strategic directions that are understood by all and to instill values that guide subordinates. For TQM to be successful in the business, the supervisor must be committed in leading his employees. A supervisor must understand TQM, believe in it and then demonstrate their belief and commitment through their daily practices of TQM. The supervisor makes sure that strategies, philosophies, values and goals are transmitted down through out the organization to provide focus, clarity and direction. A key point is that TQM has to be introduced and led by top management. Commitment and personal involvement is required from top management in creating and deploying clear quality values and goals consistent with the objectives of the company and in creating and deploying well defined systems, methods and performance measures for achieving those goals.

 **III. Binding Mortar**
7. Communication – It binds everything together. Starting from foundation to roof of the TQM house, everything is bound by strong mortar of communication. It acts as a vital link between all elements of TQM. Communication means a common understanding of ideas between the sender and the receiver. The success of TQM demands communication with and among all the organization members, suppliers and customers. Supervisors must keep open airways where employees can send and receive information about the TQM process. Communication coupled with the sharing of correct information is vital. For communication to be credible the message must be clear and receiver must interpret in the way the sender intended.

There are different ways of communication such as:
A. Downward communication – This is the dominant form of communication in an organization. Presentations and discussions basically do it. By this the supervisors are able to make the employees clear about TQM.
B. Upward communication – By this the lower level of employees are able to provide suggestions to upper management of the affects of TQM. As employees provide insight and constructive criticism, supervisors must listen effectively to correct the situation that comes about through the use of TQM. This forms a level of trust between supervisors and employees. This is also similar to empowering communication, where supervisors keep open ears and listen to others.
C. Sideways communication – This type of communication is important because it breaks down barriers between departments. It also allows dealing with customers and suppliers in a more professional manner.

**IV. Roof**
8. Recognition – Recognition is the last and final element in the entire system. It should be provided for both suggestions and achievements for teams as well as individuals. Employees strive to receive recognition for themselves and their teams. Detecting and recognizing contributors is the most important job of a supervisor. As people are recognized, there can be huge changes in self-esteem, productivity, quality and the amount of effort exhorted to the task at hand. Recognition comes in its best form when it is immediately following an action that an employee has performed. Recognition comes in different ways, places and time such as,

* Ways – It can be by way of personal letter from top management. Also by award banquets, plaques, trophies etc.
* Places – Good performers can be recognized in front of departments, on performance boards and also in front of top management.
* Time – Recognition can given at any time like in staff meeting, annual award banquets, etc.

**Quality System**

A quality system is formally described as 'the organisational structure, responsibilities, procedures, processes and resources for implementing the management of quality'. Said in a simpler way, a quality system concerns the way an enterprise goes about running its business to achieve its goals (effectively or otherwise!). The quality system would usually be documented and is often based around a quality manual that defines and embodies the system

**Elements of a Quality Management System**

Quality is a dynamic concept which is ultimately defined by customer expectations and satisfaction. QMS are designed to provide a framework for organizations to create and maintain customer relationships by understanding the customer’s preferences and needs. Customer satisfaction is achieved with QMS through the alignment of people, process, and technology throughout the product lifecycle.

One of the world’s most broadly adopted QMS, ISO 9001:2015, includes a series of quality principles which are frequently reflected in other QMS standards:

1. Customer focus
2. Leadership
3. Engagement of people
4. Process approach
5. Continuous improvement
6. Evidence-based decision making
7. Relationship management

Organizations must adopt an interdisciplinary series of quality controls to achieve these principles. The nine core elements of a QMS should include quality objectives, a quality manual, organizational responsibilities, data management, and other practices.

**1. Quality Objectives**

The creation of quality objectives is a common requirement of QMS standards, including ISO 9001. These objectives are designed to encourage organizations to define strategic goals and a purpose for the QMS. Objectives translate an organization’s vision into practice by creating a link between customer requirements and specific, measurable, and attainable goals. Well-written objectives lend purpose to a QMS initiative and establish a customer-centric culture in an organization.

A pharmaceutical startup in the research phase may have identified a customer need for affordable therapeutics to treat a common skin condition. Since the product is being developed, the organization may create a quality policy with a stated goal "To develop a safe, effective treatment for eczema patients which is available at a lower cost than alternatives."

Quality objectives for this organization could include:

* To obtain total compliance with staff training requirements and raise average assessment scores from 90% to 95%.
* To successfully implement a QMS software within three months and eliminate paper and spreadsheet-based record keeping methods within six months.
* To achieve a successful initial synthesis of the drug and complete all necessary processes for FDA initial review within 12 months.

Quality objectives should provide a clear vision for every member of the organization to understand the company's purpose and the value of a QMS. The objectives should provide a clear metric for measuring progress against strategic goals, including the timeline for achievement and a measurable parameter of improvement.

**2. Quality Manual**

A quality manual is defined as the first documentation of a QMS. It states the motivation for adopting a QMS framework and the role of quality within the organization. ISO 9000 requirements for a quality manual prescribe that this document should:

* Describe the scope of the QMS
* Detail the requirements of the QMS standard or framework
* List any elements of the QMS which are excluded from the implementation
* Reference specific quality procedures used within the organization
* Provide visual documentation of critical processes via flowchart
* Explain the organization’s quality policies and objectives

**3. Organizational Structure and Responsibilities**

A QMS should include a clear and updated model of the organization's structure and responsibilities of all individuals within the organization. Documentation of structure and responsibilities should include visual guides such as flowcharts and clear documentation.

Within the context of a QMS, the organization is broadly defined in World Health Organization guidance as both people and structure. For a life sciences company in the early phases of the product development lifecycle, initial efforts to identify organizational components may reveal a list similar to the following:

* Personnel
* Equipment
* Information Systems
* Tools for Assessment
* Facilities
* Purchasing & Inventory
* Process Controls
* Documents & Records

Documenting organizational structure should address the entire product lifecycle using techniques such as flowcharts which depict the “path of workflow.” Defining responsibilities requires an organizational chart with clearly defined roles which can be linked to standard operating procedures (SOPs).

**4. Data Management**

Data is at the core of modern approaches to total quality management. Data quality and availability are critical to the success of a QMS framework to drive continuous improvement and preventative quality control activities. Organizations with ineffective data management practices can experience inconsistent product quality, operating inefficiencies, compliance risks, poor customer satisfaction, and low profitability.

An organization must be able to provide meaningful data evidence of effective quality controls. Data management systems should support continuous improvement efforts and corrective actions by defining the types of data that are gathered by the organization and third-party sources. The policy for data management should address data types, sources, collection methods, responsibilities, storage, disposal, and analysis.

The types of data required to demonstrate effective QMS performance can vary significantly between organizations. However, at a minimum it should include the following sources:

* Customer Satisfaction
* Supplier Performance
* Product and Process Monitoring
* Non-Conformances
* Trends
* Preventative or Corrective Action

**5. Processes**

QMS are inherently process-driven approaches to quality control and assurance. Standards for quality management require organizations to identify and define all organizational processes which use any resource to transform inputs into outputs. Virtually every responsibility in the organization can be tied to a process, including purchasing.

Initial efforts to define processes should create a high-level picture of how processes serve the organization and intersect with resources such as employees, machines, or technology. After identifying processes, organizations can begin to define standards and success metrics:

* Identify organizational processes
* Define process standards
* Establish methods for measuring success
* Document a standardized approach to ensuring quality output
* Drive continual improvement

**6. Customer Satisfaction with Product Quality**

A core component of QMS is the requirement for organizations to monitor customer satisfaction to determine if quality objectives are achieved. Some standards do not prescribe specific methods for measuring customer satisfaction since the definition of product quality and available data can vary significantly between organizations.

A first step to establishing monitoring systems for customer satisfaction should be the definition of appropriate methods for measuring customer attitudes and complaints. This could include:

* Satisfaction Surveys
* Complaints Procedures
* Analytical Applications to measure satisfaction trends
* Management Review of customer satisfaction

**7. Continuous Improvement**

Continuous improvement and adaptation are necessary for organizations to drive benefits with the QMS and maintain customer satisfaction. QMS dictate that continual improvement is an organization-wide responsibility. However, ISO 9001 is clear that leadership should play a core role in implementing a quality-driven culture. Clause 5.1.1 states "top management shall demonstrate leadership and commitment with respect to the quality management system by taking accountability for effectiveness."

Designing organizational processes to meet QMS standards for continuous improvement requires clear documentation of controls across the organization. Improvement documentation should encompass, at a minimum:

* Quality Planning Procedures
* Compliance Requirements
* Safety Design
* Risk-based Thinking
* Corrective Action (CAPA)
* Gradual and Breakthrough Improvement
* Innovation
* Assessment of the QMS

**8. Quality Instruments**

The control and calibration of tools used to measure quality are integral to the success of a QMS. If machines or equipment are used to validate products or processes, this equipment must be carefully controlled and calibrated according to industry standards. Depending on the instrument, this could involve periodic calibrations or calibration before every measurement.

The QMS system design within an organization should dictate a clear policy for the maintenance of quality instruments based on nationally or internationally recognized standards for each piece of quality equipment.

This documentation should address:

* Intervals for instrument calibration
* Recognized Standards for instrument calibration
* Manufacturer Instructions for adjustment
* Procedures for identifying and documenting calibration
* Controls against tampering or adjustment post-calibration
* Methods to protect instruments and equipment from damage

In addition to these requirements, the QMS should address effective documentation of calibration results, including procedures for maintaining complete records of activities and calibration results.

**9. Document Control**

The definition of a document in a quality-driven organization is broad, according to ISO. It includes all records of:

* Communications
* Evidence
* QMS Conformity
* Knowledge Sharing

QMS dictate standards for the types of documentation which are necessary to support quality management at a minimum, which may not be reflective of all the documents needed for accurate quality control. This generally includes quality objectives, a quality manual, procedures, process documentation, and records keeping. Document management systems must contain all evidence necessary to prove QMS performance objectively.

# Quality Objectives

**Quality objectives** are goals for the value of products, services and processes. It is a basic quality management process to establish a set of quality objectives. Unlike a quality policy, that is set at the top level of an organization, quality objectives can be specific to a department, team, process or project. The following are common types of quality objective.

## Defects

A goal for conformance to specifications such as 0.1% of items failing quality control and 0% of products being shipped with a defect.

## Durability

A target for the minimum durability of a product such as 20,000 hours of use.

## Efficiency

The efficiency of products and services. For example, a conversion efficiency goal for solar panels.

## Performance

The performance of product and services as measured by a figure of merit.

## Timeliness

On-time performance such as a train line with a goal of less than 0.1% late arrivals.

## Stability

The stability of a service measured by incidents. For example, a software-as-a-service target to reduce production incidents by 30%.

## Reliability

Reliability goals such as a target of zero bugs in a software release.

## Availability

A target for the uptime of a service such as 99.99%.

## Accuracy

The accuracy of a process or service. For example, an inventory management process that seeks to reduce out of stock items by improving forecasting accuracy. Forecasting accuracy can be measured as the difference between forecast and actual results.

## Completeness

The variety offered by a service such as an ecommerce site with a target to offer the greatest variety of products. This can be measured by benchmarking product selection against competitors by product category.

## Customer Service

Customer service objectives are often phased as aspirational goals that paint a picture of the customer experience. Typically measured with customer satisfaction.

## Safety

Safety targets for a product, project or process. For example, a construction company with an objective of zero safety incidents.

## Usability

Usability goals such as software that customers find intuitive and pleasing to use. Measured with techniques such as surveys or by measuring customer inquiries. The latter is based on the assumption that intuitive user interfaces generate less questions.

## Sensory

Objectives related to visual appeal, taste, sound, touch and smell. For example, an airline with an objective to have the tastiest first class meals on a particularly competitive route. Measured with customer feedback such as surveys or ladder interviews.

**Quality Policies**

***Definition***

**Definition: *Quality Policy***

“Overall intentions and directions of an organization with regard to quality concerns, as formally expressed by the top management“

Source: ISO 9000

***Meaning and Synonyms***

Many find the term "policies" rather unfortunate. Policy could be understood as (quality) **strategy** or even as a (quality) **guideline**.

Referring to those synonyms, the meaning of quality policy becomes clearer. **Corporate philosophy**, **vision** and **mission** are also elements of quality policy. You can understand quality policy as the great, overarching vision, as the **appealing picture of the future** which is aspired by the company in the long term.

Often, companies define quality policies aiming at becoming "the leading provider" in a certain industry. However, this has little to do with quality in the sense of meeting customer requirements. You will find better examples below.

**Examples**

Two examples may help to better understand the term **quality policy**:

1. **Manufacturer of medical devices for diabetics**

The quality policy of this manufacturer is: We provide a comprehensive range of products and services due to which patients are impaired as little as possible by their diabetes. This quality policy addresses quality in its most original sense, namely the degree of fulfillment of a product's or service's characteristic which meets the real requirements.

1. **Johner Institute**

The Johner Institute expresses its quality policy in the form of a mission and its values:

* + **Mission**: The Johner Institute's mission is to support manufacturers of active medical devices in developing and approving secure products quickly and professionally while avoiding and reducing quality management bureaucracy respectively. [You can read the complete mission here.](https://www.johner-institute.com/articles/qm-system-iso-13485/quality-policy-objectives/)
	+ **Values**: The Johner Institute's values are the guidelines, the ethical corset for the implementation of the mission. These values include the constant strive for excellence and higher competence, taking care of customers, and the indispensable honesty and reliability.

Quality policy should be very specific to the company. Examples of typical formulation errors can be found below.

**A QUALITY PLAN**

Quality assurance or quality control plans evaluate and/or modify an organization’s procedures to help ensure they provide the desired results. Quality control plans are often viewed as a set of instructions that should be followed. They document the planning, implementation, and assessment procedures for a project, as well as any QA or QC activities.

Some areas may be more detailed than others, based on the project, process, or organization’s needs. It is important to note that each plan is unique based on the organization’s needs and their quality management system (QMS). However, quality control plans should always have a structure that permits improvements to the plan. This allows employees to offer input on how to improve efficiency and quality. In addition, the plan should be reviewed by others periodically, including stakeholders, to ensure the plan is comprehensive.

 **Three Elements of a Quality Plan**

Quality control plans generally include detailed information on:

* An overview or introduction of the project or process detailing the background, need, scope, activities, and important dates or deadlines
* The organizational structure or org chart detailing necessary team members, including external vendors
* Each team member’s responsibilities and qualifications necessary to fulfill stated duties
* Work verification (e.g., who is responsible for carrying out a task, as well as who is responsible for checking the work)
* Supplier standards (e.g., specify the standards the prospective suppliers must meet before they can bid on a contract, such as ISO 9001:2015)
* A list of qualified suppliers
* Testing parameters
* Performance standards and how performance will be documented
* Acceptance criteria
* Deliverables
* A feedback mechanism for internal and/or external customer feedback
* Quality control procedures
* Audits
* Training (e.g., overview, job-specific, or refresher training)
* Corrective action and preventive actions, including the person(s) responsible for CAPA
* Suggested corrective action
* Required notifications
* Any references or related materials, including performance ratings or performance reports

**QUALITY PLAN DOCUMENTATION AND DEPLOYMENT**

Quality plans result from both deployed strategic quality policies (which are linked to organizational strategic plans) and from the specific legal regulations, industry standards, organization policies and procedures, internal guidelines, and good practices needed to meet customers’ requirements for products or services.

Strategic-level quality plans are developed and deployed through the strategic planning process. These broad-based quality plans become the guideline for each function’s or department’s supporting quality plan. Where appropriate, each function or department may develop and internally deploy operating-level quality plans.

Operating-level quality plans often are the resulting document(s) from a production scheduling function. As such, this documentation often includes blueprints, a copy of the customer’s order, references to applicable standards, practices, procedures, and work instructions, and details on how to produce the specific product or service.

When the product or service is produced, the planning documents may be augmented by inspection documentation, statistical process control (SPC) charts, and copies of shipping documents and customer-required certifications. In the process, the plans are transformed from documents to records. In a fully computerized system, the documents mentioned may well be interactive computer screens accessed at operators’ workplaces and control points. These screens, internally, become records when operators, inspectors, shippers, and others make computer entries to the screens.

A completed set of matrices, developed by a quality function deployment (QFD) process, may fulfill a component of an organization’s quality plan. The purpose of QFD is to capture and deploy the customers’ needs and requirements throughout the organization.

Documenting the quality plan(s) has multiple uses, such as:

* Ensuring conformance to customer requirements
* Ensuring conformance to external and internal standards and procedures
* Facilitating traceability
* Providing objective evidence
* Furnishing a basis for training
* Together with multiple plans for the organization’s products, services, and projects, providing a basis for evaluating the effectiveness and efficiency of the quality management system (QMS).

**Quality Information Feedback**

Should be continually solicited and monitored: Customer Feedback should be continuously solicited as customer preferences keep on changing. Let us remember those days when the original red Lifebuoy was selling like hot cake. Now people’s preferences have changed. The organization has come up with many variations of Lifebuoy. The basic USP remains the same, ‘health and hygiene’ but concepts of, beauty and healthy skin is thrown in to satisfy the changed customer needs.

Purpose of Feedback:

**Discover Customer Dissatisfaction:** The feedback helps to know how satisfied or dissatisfied the customer is. A customer who does not complain and switches to another brand is more dangerous than a customer who complains. Customer dissatisfaction can be a big eye opener and help discover what more needs to be done for a product or service.

**Discover Relative Priorities of Quality:** Certain parameters of quality are more important than others. Whenever planning for a quality goal the organization should prioritize its goals.

**Compare Performance With Competition:** Watching competitor activity is a good learning tool for any organization. This is a way of benchmarking us vis-à-vis others.

**Identify Customer’s Needs:** There is a saying that salesman who discovers a customer need before everyone else is more likely to get the sales. The same logic holds for organizations as well. You can always reap the benefits of first mover advantage. Let us take example of Frooti. Probably Frooti is the first brand to identify the Indian taste and to make an effort to cater to that taste. No matter how many drinks with mango flavour has come Frooti remains the numero uno in its segment.

**Determine Opportunities for Improvement:** Customer feedback also helps an organization in determining about opportunities for improvement.

Tools of Customer Feedback:

1. **Comment Card:** This can have simple open questions so that customer can answer it quickly.
2. **Customer Questionnaire:** Design of questionnaire is of utmost importance to get timely and relevant information.
3. **Focus Groups:** Focus groups are mostly used in B2B set up. Especially in pharmaceuticals industry, key opinion makers are made part of the trial. Their opinion holds sway over doctors of hinterland. It helps them get a word to mouth publicity as well.
4. **Toll Free Telephone Numbers**
5. **Customer Visits**
6. **Report Cards**
7. **Social Networking Sites:** There are certain sites where visitors can share good or bad experience with a product or service. These sites give real insight into customer’s minds. On other social networking sites, like Twitter and Facebook, people share their experiences and sometimes, unknowingly may give opinion about a company. Now certain companies are having devoted teams to analyse these data.
8. **Employee Feedback:**
9. **Mass Customization:** Mass customization is another good tool to know about changed preferences. Levi’s gives a facility on its website which enables a potential customer to choose certain fabric, colour and design. Once the customer places an order Levi’s gets the jeans stitched and delivered at customer’s doorstep.

How to Use Customer Feedback:

* Thank for the feedback.
* Listen the complaint
* Solve the complaint
* Retain by solving the problem
* Regain lost customers

Service Quality

Organization Level

**Identify Each Market Segment:** Each market segment has its own dynamics, so customer needs tend to vary as per a market segment. For example in a diverse country like India, customers of north India will have different needs compared to those in south India.

**Write Down The Requirements:** A very good example of chalking out requirements of a particular market is shown during recent launch of a dark chocolate brand by Cadbury’s in India. India is hot country so selling dark chocolates has its own issue of logistics management. Cadbury’s is supplying these chocolates in insulated boxes to key retailers so that customer can get the right quality of chocolate.

**Communicate The Requirements:** Communicating your quality requirements is a way of convincing the front line people so that they will implement everything as per the original plan. Around 2000 the pharmaceuticals giant Pfizer launched a hepatitis-B vaccine. The product needed to be supplied through cold chain upto the vaccination point. All personnel in sales force were properly educated on this issue to ensure proper implementation of cold chain. This ensured that the product reached the end user at right temperature to provide desired efficacy.

**Organize Processes:** Every process should be well organized to ensure optimum output and resultant benefit to the customer.

Customer Care:

* Meet Expectations
* Get the customer’s point of view
* Deliver what is promised
* Make the Customer feel valued
* Respond to all complaints
* Over Respond to the customer
* Provide a clean and comfortable customer reception area

Communication

* Trade off between time and personal attention
* Minimize the number of contact points
* Provide pleasant, knowledgeable and enthusiastic employees
* Write documents in customer friendly language

Front Line People

* Hire people who like people
* Challenge them to develop better methods
* Give them authority to solve problems
* Serve them as internal customers
* Be sure they are adequately trained
* Recognize and Reward Performance

Leadership

* Lead by example
* Listen to the front line people
* Strive for continuous process improvement

**TQM Culture**

Total Quality management or TQM is a holistic approach in which quality is treated as extremely important by all individual at all levels. But creating a positive climate in which quality is taken seriously across an entire organization takes considerable hard work as well as lots of time and commitment. For an organization to be successful in this effort leadership is not just important but is the most critical factor. The leaders in any effort to introduce TQM or to make it work well therefore have very different roles to perform. Instead of expecting employees to report performance to them, leaders now spend the majority of their time in a support or coaching role where team performance becomes all important and it’s all about pulling together to remove any barriers that prevent the organization from meeting customer needs. In other words, this is a shift of culture, or the way things are generally done or expected to be done across the enterprise.

An organizational culture is typically most significantly shaped by the following elements:

* The enterprise vision and strategic goals
* The Organization’s values
* Cultural Role Models
* Organizational customs and practices
* The organizational communication system

A quality culture therefore has to recognize each one of the above elements and feature strongly in all of them. Hence the culture has to be conducive to the establishment a continuous improvement and Total Quality Mind-set.

Those organizations which can successfully develop and maintain a total quality culture will usually make considerable efforts to ensure that new and positive approaches which support the initiative are taken in all of the following areas:

* **Leadership** (which includes not only how leaders behave but also the Vision, Mission and values of the enterprise)
* **Strategic Planning** (and the extent to which the pursuit of Total Quality is built into it)
* **Customer Focus** (or the extent to which the customer’s voice and quality needs are continually heard and acted upon)
* **Measurement, Analysis, and Knowledge Management** (or how effective the organizational metrics are to measure quality)
* **Workforce Focus** (mainly focused on individual and team alignment and collaboration to ensure Total Quality is delivered across processes)
* **Operations Focus** (concerned essentially with quality of execution and follow through)
* **Results** (which concerns itself with measuring tangible gains in quality or better results for customers and the organization).

One way in which many organizations choose to adapt an existing culture to meet the above requirements is to use a total quality management framework or assessment model. There are several now available in different parts of the world. The Baldridge framework, which applies largely to US companies, for example, provides guidance on creating an optimal culture in all seven of the above categories and awards prizes every year to organizations that are most effective in their efforts.

In the final analysis, building a TQM culture cannot be done in a “cookie-cutter” kind of way, and each organization will have to determine how ready it is to undertake this often long and difficult journey and where it therefore best needs to invest its early efforts. However, the culture of the enterprise must be open and willing to undertake the change and this means that a focus on what leaders spend their time talking about is extremely important at the earliest possible stage.

**Meaning of Quality Circles:**

Conceptually Quality Circles can be described as a small group of employees of the same work area, doing similar work that meets voluntarily and regularly to iden­tify, analyse and resolve work related problems.

This small group with every member of the circle participating to the full carries on the activities, utilising problem solving techniques to achieve control or improvement in the work area and also help self and mutual development in the process.

The concept of the Quality Circle is based on “respect for the human individual” as against the traditional assumption based on suspicion and mistrust between management and its em­ployees.

Quality circles built mutual trust and create greater understanding between the manage­ment and the workers. Cooperation and not confrontation is the key element in its operation. Quality Circles aims at building people, developing them, arousing genuine interest and dedication to their work to improve quality, productivity, cost reduction etc.

Thus we can say that a quality circle is a group of 5 to 8 employees performing similar work, who volunteer themselves to meet regularly, to identify the cause of their on-the-job problems, employ advanced problem-solving techniques to reach solutions and implement them.

**Characteristics of Effective Quality Circles:**

1. The atmosphere should be informal, comfortable and relaxed. The members should feel involved and interested.

2. Everyone should participate.

3. The objectives should be clear to the members.

4. The members should listen to each other.

5. The group should feel comfortable even when there are disagreements.

6. The decisions should generally be taken by a kind of consensus and voting should be minimum.

7. When an action is required to be taken, clear assignments should be made and ac­cepted by all the members.

8. The leader should not dominate the group. The main idea should not be as to who controls but how to get the job done.

9. Until a final solution is found and results are attained feedback is necessary.

**Objectives of Quality Circles:**

**Some of the broad objectives of the Quality Circle are:**

(i) To improve quality, productivity, safety and cost reduction.

(ii) To give chance to the employees to use their wisdom and creativity.

(iii) To encourage team spirit, cohesive culture among different levels and sections of the employees.

(iv) To promote self and mutual development including leadership quality,

(v) To fulfill the self-esteem and motivational needs of employees.

(vi) To improve the quality of work-life of employees.

**Implementation of Quality Circles in an Organisation:**

**For the success of Quality Circle programme, following actions are necessary in the Organisation:**

(a) Few managers representing production, quality control, design, process planning form the Quality Circle (Q.C.) steering committee. This acts as a policy making body and will monitor the Q.C. in the Organisation.

(b) Top management must attend the orientation courses designed for them.

(c) A committed top and middle management is necessary.

(d) A facilitator must be appointed, who serves as a link between top management, Q.C., steering committee, middle management circle leaders and circle members. Facilita­tor will coordinate training courses; get the support from all concerned including top management Q.C., steering committee, circle leader and circle members to help the circle leader in conducting the meetings, and to provide necessary resources.

**Organisation and Working of Quality Circles:**

Q.C. was conceived in Japan in 1962 as a forum for training its work force for improving the quality of products. Q.C. is a voluntary one. Employees are free to join or not to join. In it, 8 to 10 employees including the Supervisor from same workshop doing similar work join together as a group. The Supervisor can become leader of the group, if the members of Q.C. so desire.

It is a part time activity; members of Q.C. are allowed to meet for an hour every week. During the various meetings, these groups progressively identify, select, analyse and solve the problems. Later they offer their proposed solutions to management for consideration, approval and implementation.

Additionally a senior officer from same workshop is nominated as facilitator who guides the activities of the group.

A Management Committee at senior level is also formed, which overview the progress of Quality Circles.

Training of members, leaders and facilitators is very important for the success of programme.

**Rules for Quality Circles:**

(a) Each member can contribute an idea on his turn in rotation.

(b) Each member offers only one idea per turn regardless of how many he or she has in mind.

(c) Not everyone has an idea during each rotation, when this occurs just say “Pass”.

(d) No criticism or comments should be passed on the ideas being contributed by the member whatever old it may look to be, welcome their ideas.

(e) During brain-storming, no evaluation of suggested idea should occur. This applies equally to leader, phrases such as “We have tried it before”, “Impractical”, “Well” “May be it would work”. “Doubtful”, “Very good” etc. should not be uttered.

(f) Members can vote by raising their hands.

(g) Only supporting votes are taken. Votes against the ideas are not allowed.

(h) The time allotted for brain-storming session should be variable. The length of time that can be spent profitably will vary widely with nature of problem and the group itself. As a general practice, one hour is probably the minimum.

(i) While members give their ideas, they are recorded by the Recorder on a large sheet.

(j) It is often helpful to set a goal originally, i.e. Let us start for 30 ideas.

(k) When all members say “pass” then the first phase of brain-storming session is over. This means all ideas have been exhausted.

(l) Now all the ideas recorded on the sheet are displayed.

(m) These massive number of ideas are then narrowed down by the process of voting. The voting technique works because the members are experts in their areas. Members vote on each idea. The leader records each vote next to the idea.

(n) Members can vote for as many ideas as they feel have value. Only supporting votes are taken.

(o) Leader draws a circle around those ideas that receive the most votes. The members thus find that many of the top ideas will be so identified.

(p) Now the members can focus on a few important ideas instead of being somewhat confused by a large number of them. These few important ideas are voted on to give ranking to the circle ideas. Leader writes the ranking number beside each idea that has been circled.

(q) A member can ask for voting on any idea and argue for or against it. Others can join, if they wish. Only when the discussion has finished then the voting take place.

Idea ranked in the session can then be taken up for analysis or solution later on.

**Duties of Circle Leader:**

**For the success of Quality Circles, circle leader must have following duties:**

(i) He must assume the responsibility of guiding the members.

(ii) He must make his members sure about what is going on.

(iii) He must channelise the discussions.

(iv) Every member is allowed equal opportunity.

(v) Specific task be assigned to each member.

(vi) He must work in coordination with facilitator.

**Steps for Setting up Quality Circles:**

**For starting Quality Circles in an organisation, following steps should be taken:**

(i) First of all Managers, Supervisors and Foremen must be made to understand the concepts and activities of Q.C.

(ii) Management’s total support and commitment should be made known to everyone in the organisation.

(iii) Steering committee is formed with the top management personnel to give direction to Quality Circle activities.

(iv) A facilitator (or sometimes known as promoter) is selected from the senior manage­ment level, who will serve as coordinator and advisor to the circle.

(v) Supervisor and foreman are then trained to act as Q.C. leaders.

(vi) Members of each circle must be selected from the persons who are doing similar type of work or belong to the same department or section.

(vii) Membership to the circle is voluntary.

(viii) First few meetings of the circle are held with a view to train them.

(ix) To start with, only one to two circles should be formed in an organisation, and then increase the number gradually as more and more experience is gained.

(x) Meetings must be held regularly, may be once in a week initially and once in a month on completion of basic training of members.

(xi) Everyone’s suggestion or problem matching with the circle’s objectives is discussed.

(xii) Total participation of team members must be encouraged.

(xiii) Recommendations of the circle must be considered and decisions should be taken without delay.

**Benefits of Quality Circles (Q.C.):**

1. Through the forum of Q.C. the chronic problems-of organisations which really create hurdles in work get resolved by the grass root employees of organisation, whose knowl­edge and experience otherwise is not fully utilized.

2. With such a capable work force, any organisation can easily undertake more difficult and challenging assignments for its growth and profit.

3. As the employees gain experience they take more challenging projects, in due course they undertake projects on cost reduction, material handling, quality improvement, preventing wastage, improving delivery schedule, improving customer service, im­proving inspection and test methods, preventing accidents improving design and pro­cess etc.

4. Cost reduction.

5. Increased productivity.

6. Improved quality.

7. Better communication.

8. Better house-keeping.

9. Increased team work.

10. Smooth working.

11. Better mutual trust.

12. Greater sense of belongingness.

13. Increased safety.

14. Better human relations.

**Launching of Quality Circle Programme:**

**The typical steps for launching programme are as under:**

(i) Orientation Programme for Senior Management Personnel.

(ii) Orientation Programme for Managers and Executives.

(iii) Orientation Programme for Selected Supervisors.

(iv) Orientation Programme for Workers (selected area).

(v) Formation of Circles (Minimum 2 and Maximum 4).

(vi) Training of Facilitators.

(vii) Training of Leaders.

(viii) Q.C. meetings for projects.

**Quality Audit**

A quality audit is a process by which you review and evaluate an element of your business to ensure that you're meeting certain standards. The standards vary—you can set them or you can follow standards set by your industry.

At a high level, quality audits are conducted to obtain objective evidence of operational compliance. There are several different types of audits that can be conducted to validate conformity. Audits can be performed internally, externally by a supplier, or by an independent third party. Audits can encompass processes, systems or products, but in all cases, they are measured against a defined set of standards.

***The following is a list of 10 commonly performed quality audit types:***

**Internal Quality System Audit**

This type of audit is an examination of the tool used to measure quality itself. An internal quality audit seeks to evaluate an organization’s Electronic Quality Management System (EQMS). The quality documentation and processes managed by the software solution are reviewed to ensure maximum efficiency and high-quality product outcomes. The software manual is audited to ensure all critical areas of the solution are covered and all key employees readily have access to the document. Work instructions are audited to ensure conformity to standard operating procedures and to confirm quality processes are meeting targets.

**Supplier Audit**

Supplier audits allow an organization to collaborate in real-time directly with its suppliers. By auditing the supply chain, companies can control the quality of its suppliers and sub-tier suppliers and introduce accountability for poor performers. Key performance indicators (KPIs) quickly identify areas for improvement. With this level of transparency, suppliers are able to view purchase order activity such as receipt and inspection history in order to collaborate on nonconformances and corrective actions.

**Production Team Audit**

Production team members usually get an examination (audit) when Operator Acceptance or Certified Operator programs are in place, or when skills management re-qualifications are required. Auditors evaluate changes to processes, evidence of training, past activity for escapes, nonconformance, and conformity inspections of operator accepted product as part of the re-qualification.

**Safety Audit**

A safety audit looks at the plans and procedures designed to protect the safety of company employees. This type of audit can include a review of equipment operation or an examination of organizational procedures to ensure routine safety. Successful safety policies prevent injuries and accidents from occurring and improve overall employee well-being.

**Facilities Audit**

A facilities audit addresses quality concerns of a corporation’s assets. Components of a facilities audit can include a review of building systems such as HVAC, manufacturing equipment or technology. Processes associated with these facilities are reviewed to ensure safety and identify improvements that could affect quality outcomes.

**Environmental Audit**

Environmental audits are designed to help companies create a safer work environment by helping to identify areas of workplace risk with an actionable plan to meet OSHA and other standards. An audit is conducted to ensure employees are adhering to regulatory standards and using appropriate personal protective equipment.

**Risk Assessment Audit**

A risk assessment is a process that identifies potential workplace hazards, then categorizes each risk so preventative measures can be put into place. An audit of this type helps companies put an effective risk mitigation strategy into action. When all risks have been identified, preventative measures can be prioritized, preventing adverse workplace and economic consequences.

**Design Control Audit**

Design control audits are conducted within highly regulated industries to ensure that manufacturers follow a formalized process that results in an end-product that meets acceptable quality and safety standards and adequately serves user needs. The design plan and design inputs and outputs are reviewed for proper acceptance criteria and a risk analysis is performed.

**Regulatory Audit**

Regulatory audits are conducted to verify compliance with a specific set of regulations or standards. Quality practices are examined, and the data collection process is systematically reviewed to identify possible areas of nonconformance. Examples of regulatory agencies include FAA, DARPA, DCMA, ISO, AS9100 as well as many others.

**Method Validation Audit**

A method validation audit is used by the FDA or other regulatory authorities to ensure that the analytical test methods used in the manufacturing process are standardized, reproducible and documented. This methodology is applied to testing that requires consistency and accuracy, usually in cases of products manufactured for human use.

An Electronic Quality Management System (EQMS) is key in helping a company build an effective audit management strategy. The system provides the flexibility to manage customer specific audit processes. An EQMS supports internal and external audits and allows auditors to get their job done more efficiently.

**Unit V**

The ISO 9000 SERIES, Need for ISO 9000- ISO 9000-2000 , Process of obtaining ISO Certification, Advantages of ISO certification, New version of ISO standards. Documentation, ISO 14000 – Concepts, Requirements and Benefits.

* The ISO 9000 SERIES
* Need for ISO 9000- ISO 9000-2000
* Process of obtaining ISO Certification
* Advantages of ISO certification
* New version of ISO standards
* Documentation
* ISO 14000 Concepts
* Requirements and Benefits

**ISO 9000 series of Standards**

The ISO 9000 family contains these standards:

* [ISO 9001:2015: Quality Management Systems - Requirements](https://asq.org/quality-press/display-item?item=T1040)
* [ISO 9000:2015: Quality Management Systems - Fundamentals and Vocabulary](https://asq.org/quality-press/display-item?item=T1039) (definitions)
* [ISO 9004:2018: Quality Management - Quality of an Organization - Guidance to Achieve Sustained Success](https://asq.org/quality-press/display-item?item=T1147E) (continuous improvement)
* [ISO 19011:2018: Guidelines for Auditing Management Systems](https://asq.org/quality-press/display-item?item=T1152E)

ASQ is the only place where organizations can obtain the [American National Standard Institute (ANSI)](https://asq.org/quality-resources/ansi-standards) versions of these standards in the ISO 9000 family.

**ISO 9000 history and revisions: ISO 9000:2000, 2008, and 2015**

ISO 9000 was first published in 1987 by the [International Organization for Standardization (ISO)](https://asq.org/quality-resources/standards-101#iso), a specialized international agency for standardization composed of the national standards bodies of more than 160 countries. The standards underwent major revisions in 2000 and 2008. The most recent versions of the standard, [ISO 9000:2015](https://asq.org/quality-press/display-item?item=T1039) and [ISO 9001:2015](https://asq.org/quality-press/display-item?item=T1040), were published in September 2015.

ASQ administers the [U.S. Technical Advisory Groups](https://asq.org/quality-resources/standards-101#tag) and subcommittees that are responsible for developing the ISO 9000 family of standards. In its standards development work, ASQ is accredited by ANSI.

**ISO 9000:2000**

ISO 9000:2000 refers to the ISO 9000 update released in the year 2000.

The ISO 9000:2000 revision had five goals:

1. Meet stakeholder needs
2. Be usable by all sizes of organizations
3. Be usable by all sectors
4. Be simple and clearly understood
5. Connect quality management system to business processes

ISO 9000:2000 was again updated in 2008 and 2015. ISO 9000:2015 is the most current version.

**ISO 9000:2015 principles of Quality Management**

The ISO 9000:2015 and ISO 9001:2015 standards are based on seven quality management principles that senior management can apply to promote organizational improvement.

 **ISO 9000 Quality Management Principles**

1. Customer focus
	* Understand the needs of existing and future customers
	* Align organizational objectives with customer needs and expectations
	* Meet customer requirements
	* Measure [customer satisfaction](https://asq.org/quality-resources/customer-satisfaction)
	* Manage customer relationships
	* Aim to exceed customer expectations
	* Learn more about the [customer experience](https://asq.org/quality-resources/customer-experience) and customer satisfaction
2. Leadership
	* Establish a vision and direction for the organization
	* Set challenging goals
	* Model organizational values
	* Establish trust
	* Equip and [empower employees](https://asq.org/quality-resources/employee-empowerment)
	* Recognize employee contributions
	* Learn more about [leadership](https://asq.org/quality-resources/leadership)
3. Engagement of people
	* Ensure that people’s abilities are used and valued
	* Make people accountable
	* Enable participation in [continual improvement](https://asq.org/quality-resources/continuous-improvement)
	* Evaluate individual performance
	* Enable learning and knowledge sharing
	* Enable open discussion of problems and constraints
	* Learn more about [employee involvement](https://asq.org/quality-resources/employee-empowerment)
4. Process approach
	* Manage activities as processes
	* Measure the capability of activities
	* Identify linkages between activities
	* Prioritize improvement opportunities
	* Deploy resources effectively
	* Learn more about a [process view of work](https://asq.org/quality-resources/process-view-of-work) and see [process analysis tools](https://asq.org/quality-resources/process-analysis-tools)
5. Improvement
	* Improve organizational performance and capabilities
	* Align improvement activities
	* Empower people to make improvements
	* Measure improvement consistently
	* Celebrate improvements
	* Learn more about approaches to [continual improvement](https://asq.org/quality-resources/continuous-improvement)
6. Evidence-based decision making
	* Ensure the accessibility of accurate and reliable data
	* Use appropriate methods to analyze data
	* Make decisions based on analysis
	* Balance data analysis with practical experience
	* See [tools for decision making](https://asq.org/quality-resources/decision-making-tools)
7. Relationship management
	* Identify and select suppliers to manage costs, optimize resources, and create value
	* Establish relationships considering both the short and long term
	* Share expertise, resources, information, and plans with partners
	* Collaborate on improvement and development activities
	* Recognize supplier successes
	* Learn more about [supplier quality](https://asq.org/quality-resources/supplier-quality) and see resources related to [managing the supply chain](https://asq.org/supply-chain-management/)

**Need for ISO 9000- ISO 9000-2000 Quality System**

**Basic Requirements of ISO 9001**

1. Procedure to cover all processes in the business

2. Monitoring process to ensure effectiveness

3. Keeping adequate record

4. Defect verification and appropriate correction

5. Regular review of individual processes

6. Facilitating continual improvement

**Benefits of ISO Registration**

1. Increase in internal quality – reduction of scrap, rework etc

2. Production reliability – measure of breakdowns, time and shift management etc

3. External quality – acceptance by customers, less claims, return of goods

4. Time performance – marketing, delivery, production time etc

Cost of poor quality – scraps and rework

**ISO 9000 Family**

-  ISO 9000:2000 QMS – Fundamental and Vocabulary

-  Basic QMS

-  Guidance document for certification

-  Revised in ISO 9000:2005

ISO 9001:2000 QMS – Requirements

-  Design, development and installation

-  Customer satisfaction through products and service

ISO 9004:2000 QMS – Guidelines for Performance

-  Continuous improvement

-  Enhance the mature system

**Process of obtaining ISO Certification**

**Steps to Achieve ISO 9000 Registration**

by Ron Kurtus (revised 29 November 2005)

The process for complying with the ISO 9000 standards and obtaining certification can be complex. From the experience of other companies, there are recommended steps to follow in order to facilitate the process.

Questions you may have on preparing for registration are:

* What steps must be taken with management?
* How is the documentation written?
* What is the registration process?

This lesson will answer those questions.

**Steps to follow**

These eight steps--along with their sub-steps--are based on what many major companies have followed to achieve their own ISO 9000 registration. These steps are also useful for companies simple seeking to conform to the ISO 900 standards, but not formally become certified.

These steps are a good guide for establishing a timeline, schedule, and potential costs for the process of becoming ISO 9000 certified.

(NOTE: Also see [*Simple Plan for ISO 9000 Certification*](https://www.school-for-champions.com/iso9000/isosimple.htm) for another outlook on this process.)

***1. Get top management commitment***

1. Top management considers ISO 9000 registration
2. Quality steering committee meets to evaluate process
3. Committee informs top management of ISO 9000 costs, schedule, etc.
4. Top management commits to pursue ISO 9000 registration

***2. Train personnel***

1. Hold basic quality and ISO 9000training for all employees
2. Select and train personnel to be internal auditors

***3. Prepare Quality Policy Manual***

1. Study and understand ISO 9000 requirements as they apply to your company
2. Write (or re-write) company Vision and Mission statements
3. Write basic Quality Policy Manual outline
4. Complete first draft of Quality Policy Manual
5. Send copy of  manual to customer desiring ISO 9000 compliance (if necessary)

***4. Prepare Operating Procedures***

1. Define responsibilities, using Quality Manual as a guide
2. Have those responsible for functions outline their procedures
3. Interview managers and fine-tune procedures
4. Compare Operating Procedures with Quality Manual for consistency

***5. Hold internal audit***

1. Hold internal audit of ISO 9000 manual vs. ISO 9000 compliance
2. Implement corrective action items from audit

***6. Select registrar***

1. Research registrars and their cost
2. Qualify possible registrars
3. Select third party registrar

***7. Go through registration process***

1. Apply for registration and audits
2. Agree to audit process etc. with registrar
3. Hold pre-assessment audit
4. Take any needed corrective action
5. Have ISO 9000 registration audit
6. Take any needed corrective action
7. Re-audit as needed
8. Take any needed corrective action

***8. Obtain ISO 9000 registration***

This verifies that you operate your business in compliance to the ISO 9000 requirements.

**Essential steps to becoming an ISO-certified business.**

**1. Develop your management system**

* Identify your core or [business processes](https://www.bdc.ca/en/articles-tools/business-strategy-planning/manage-growth/pages/business-processes-systematic-way-grow.aspx).
* Document processes with the involvement of employees.
* Review, approve and distribute the documents to those who need access to the information.

**2. Implement your system**

* Ensure procedures are being performed as they are described in your documentation.
* Ensure employees are trained properly for the tasks they are performing.
* Create effective reporting systems to cover inspection, testing, corrective actions, preventive actions, management review meetings, monitoring of objectives, statistical techniques and so on.
* Monitor the effectiveness of your processes through the use of measurable data, where possible.
* Review and take action to improve in the areas required.

**3. Verify that your system is effective**

* Conduct the audit and review the processes and system for compliance and effectiveness. Observe, interview people and look at sample records.
* Identify and report strengths and weaknesses of the management system.
* Take corrective or preventive action as required.

**4. Register your system**

* Select the appropriate auditing body for external registration.
* Submit your management system documentation for review to ensure it complies with the applicable standard.
* Prepare for review by an external auditor to confirm that the system’s requirements are being satisfied and that the management system is implemented effectively.

**Advantages of ISO certification**

**Benefits of ISO 9001:2008/ISO 9001:2015 to your business**

ISO 9001 aims to provide a practical and workable Quality Management System for improving and monitoring all areas of your business.

Achieving the ISO 9001 standard is not about establishing a set of procedures that are complicated and difficult to manage. The aim is to provide a workable management system that is suitable for your organisation. With the right support and the knowledge of your employees, you will end up with a system that will improve all areas of your organisation.
Implementing an effective and robust ISO 9001 Quality Management System (QMS) will help you to focus on the important areas of your business and improve efficiency. The management processes that are established throughout your business will provide a sound foundation, leading to increased productivity and profit. This in turn will improve your customer acquisition and retention.
Some of the main benefits of ISO 9001 certification include:

* Suitable for both small and large organisations
* Better internal management
* Less wastage
* Increase in efficiency, productivity and profit
* Improved customer retention and acquisition
* Consistent outcomes, measured and monitored
* Globally recognised standard
* Compatible with other ISO standards
* Accreditation by UKAS

A valid ISO 9001 certificate will be a prerequisite for some of your customers and a “nice to have” for others, when they are considering suppliers. It gives your customers confidence that you are working to standards and procedures that will provide them with a high standard of customer service.

**Benefits of ISO 9001 to your customers**

The ISO 9001:2008/ISO 9001:2015 standard is recognised worldwide and your customers will understand the benefits of working with companies that are ISO 9001 certified. In fact, some of your customers will only do business with certified companies because it gives them assurance that you management systems are constantly assessed and approved.

They will know from experience that working with ISO 9001:2008/ISO 9001:2015 certified companies provides many advantages:

* Minimises mistakes
* Improves reporting and communications
* Better quality products and service
* More reliable production scheduling and delivery
* Standards maintained by annual assessments

**New version of ISO standards**

**New version of the ISO 9001 standard is 9001:2015.**

**ISO 9001 is the international standard for a quality management system (“QMS”).**  In order to be certified to the ISO 9001 standard, a company must follow the requirements set forth in the ISO 9001 Standard. The standard is used by organizations to demonstrate their ability to consistently provide products and services that meet customer and regulatory requirements and to demonstrate continuous improvement.

**A few details about ISO 9001:**

There are several different documents in the ISO 9000 family of standards, but ISO 9001 is the only standard in the 9000 series that requires certification.  Typically, an entire organization will seek certification, but the scope of the QMS can be tailored to improve performance at a particular facility or department.  The current version is ISO 9001:2015, which was published in September of 2015 (thus the: 2015).

* It does NOT matter what size your organization is: 1 person or 1 million people. See ISO 9001 Implementation for Small Businesses
* It does NOT matter what industry you are in (service or manufacturing) – it can be a restaurant, consultancy, manufacturing company, government entity, etc. There are other standards based upon ISO 9001 for a few specific industries[.](https://the9000store.com/what-are-iso-9000-standards/standards-based-upon-iso-9001/)
* It is NOT a standard for products. It does not define product quality.  This is a process-based standard: you use it to control your processes, then your end product should meet the desired results.
* It is NOT a personal Standard – a person cannot get certified to ISO 9001, instead an organization or company becomes certified. Individuals, however, CAN become an ISO 9001 Certified Lead Auditor after a 5 day training course.  This then allows them to audit other companies.
* There is no such thing as “ISO Certification” or “ISO 9000 Certification”, only ISO **9001** certification.
* It is NOT a membership group – An organization cannot “join” ISO 9001. To become ISO 9001 certified, your organization must
	+ Follow the steps to implement an ISO 9001 quality management system.
	+ Then a Certification Body (CB or Registrar) audits the performance of your organization against the latest version of the ISO 9001 Requirements. If you pass this audit, the Registrar issues an ISO 9001 Certificate demonstrating that your organization is Registered to ISO 9001 for a three year period.
	+ Finally, the organization must be re-certified every three years in order to maintain their ISO 9001 certification status.

**Documentation ISO**

**ISO 9001 Requirements?**

As with any standardization or regulatory organization that awards certifications, you can expect that there are a lot of requirements to comply with — especially since this is an international standard.

All the ISO 9001 requirements are set out by ISO in [**ten clauses**](https://www.iso-9001-checklist.co.uk/iso-9001-requirements.htm#ISO-9001-Clauses).

**Mandatory requirements need to be complied with, while non-mandatory requirements may be submitted for documentation purposes.**To be certified compliant with ISO 9001:2015, the following documents must be submitted.

**ISO 9001 Mandatory Requirements — Documents and Records**

1. Monitoring and measuring equipment calibration records
2. Records of training, skills, experience and qualifications
3. Product/service requirements review records
4. Record about design and development outputs review
5. Record about design and development inputs
6. Records of design and development controls
7. Records of design and development outputs
8. Design and development changes records
9. Characteristics of product to be produced and service to be provided
10. Records about customer property
11. Production/service provision change control records
12. Record of conformity of product/service with acceptance criteria
13. Record of nonconforming outputs
14. Monitoring measurement results
15. Internal audit program
16. Results of internal audits
17. Results of the management review
18. Results of corrective actions

**Non-Mandatory Requirements — But Often Included**

1. Procedure for determining context of the organization and interested parties
2. Procedure for addressing risks and opportunities
3. Procedure for competence, training and awareness
4. Procedure of equipment maintenance and measuring equipment
5. Procedure for document and record control
6. Sales procedure
7. Procedure for design and development
8. Procedure for production and service provision
9. Warehousing procedure
10. Procedure for management of nonconformities and corrective actions
11. Procedure for monitoring customer satisfaction
12. Procedure for internal audit
13. Procedure for management review

**Concepts and Benefits of ISO 14000**

Focuses on environmental management system that will ensure all operational processes are consistent and effective and will achieve environmental objectives of the organization.

**Concepts of ISO 14000**

ISO - 14000 series

Focuses on environmental management system that will ensure all operational processes are consistent and effective and will achieve environmental objectives of the organization.

A company should review and continually improve its environmental management system, with the objective of improving its overall environmental performance

Section 3.5 of ISO 14001 defines an environmental management system as "the part of the overall management system that includes organizational structure, planning activities, responsibilities, practices, procedures, processes, and resources for developing, implementing, achieving, reviewing, and maintaining the environmental policy. " Although ISO 14001 was developed independent of ISO 9000 to fulfill environmental rather than quality needs.

An EMS is a structured plan to address the impacts a company or organization has on the environment. The EMS is implemented and checked to ensure that plan goals are being met.

With the plan being revised to meet new goals, the EMS can guide a company toward continual environmental improvement.

A basic condition for any EMS is compliance with applicable environmental laws, regulations, and permits. An effective EMS goes beyond compliance to provide an organization with a systematic approach to the development, implementation, and maintenance of an environmental policy.

Through planning, implementation, checking, management review, and continual improvement, organizations become more effective and efficient in the management of their activities and the impacts of those activities on the environment.

In response to widespread acceptance of the ISO 9000 quality management standards and to the proliferation of various environmental management systems, the International Organization for Standardization formed Technical Committee (TC) 207 to begin development of the ISO 14000 series of environmental management standards in 1992. As TC 207 carefully crafted the draft EMS standard (ISO 14001), companies around the world began to assess their existing environmental systems to learn what changes would be needed to meet ISO 14001.

**Benefits of ISO 14000**

The ISO 14001 standard provides specific requirements for an EMS and shares some common management system principles with the ISO 9000 series of standards, including the "plan-do-check-act model" mentioned above and the requirement for top management commitment. The basic focus of the ISO 14000 series of standards is environmental protection, while the ISO 9000 series of standards focuses on quality and customer needs.

It should be noted that ISO 9000 is not a prerequisite for ISO 14001, although companies that have both have successfully integrated the two management systems.

An effective EMS provides many benefits to the implementing organization, its customers and stakeholders, and to regulators, including:

•         Reduced environmental risk.

•         Proactive environmental management.

•         Improved employee environmental awareness and performance.

•         Increased operating efficiency and cost-effectiveness.

•         Enhanced relationships and communication with employees, regulators, and Stakeholders

**Benefits of Getting ISO Certification**

Based on the list of mandatory and non-mandatory requirements for certification, it seems that the task is too daunting! However**, data has shown that companies have greatly benefitted from getting ISO certified**.

* **Customer satisfaction** – To satisfy a customer’s needs, the company must first identify their market and its needs. By having insight regarding the needs of their market, companies are able to continuously deliver products and services that fulfill the needs of their market.
* **Integration of internal policies and procedures** – Collating all Quality Managements Systems (QMS) documents and having is certified as compliant by ISO aims to streamline the company’s processes and procedures.
* **Improved company image and reputation** – getting or even attempting to get ISO 9001:2015 certification is no easy feat. As mentioned earlier, having this certification puts a company in the ranks of other companies from around the world that follow the same quality standards.
* **Company culture that is aimed towards continuous improvement** – a company that complies with the ISO 9001:2015 have procedures that aim to improved products and services; it also aims to promote the professional development of its employees and the company culture.
* **Opportunities for partnerships** – because getting ISO-certified impels that they meet international standards of practice, there are certain companies that make ISO certification as a requirement to become an accredited supplier in their organization.

## Requirements

Introduction

* [Section 0.1 Background of the EMS](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-background/)
* [Section 0.2 The goal of the Environmental Management System](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-goal/)
* [Section 0.3 The Success of EMS](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-success/)
* [Section 0.4 Plan-Do-Check Act Model for EMS](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-pdca/)
* [Section 0.5 Contents of the International Standard](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-contents/)

Section 1: Scope

This section defines the scope of the 9001:2015 standard. In summary, the scope includes specifying requirements for a QMS of any organization.

Learn more about the ISO 14001:2015 Requirements

* [Section 1.0 Scope](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-scope/)

Section 2: Normative References

There are no normative references for ISO 14001:2015

Section 3: Terms and Definitions

Terminology used throughout this standard comes directly from *ISO 14001:2015, environmental management systems – Fundamentals and vocabulary.*

* [Section 3. Terms and Definitions of ISO 14001:2015](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-terms/)

Section 4: Context of the Organization

Determine external and internal issues, the needs and expectations of interested parties, environmental management system scope and its processes.

Learn more about the ISO 14001:2015 requirements for [Section 4 Context of the Organization](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-context/)

* [Section 4.1 Understanding the organization and its context in regards to ISO 14001:2015](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-context/iso-14001-2015-understanding/)
* [Section 4.2 Understanding the needs and expectations of interested parties in ISO 14001:2015 EMS](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-context/iso-14001-2015-understanding-needs/)
* [Section 4.3 How to determine the scope of the EMS ISO 14001:2015](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-context/iso-14001-2015-determine-scope/)
* [Section 4.4 Environmental Management System](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-context/iso-14001-2015-environmental-m-s/)

Section 5: Leadership

Top management to demonstrate leadership and commitment, establish and communicate a environmental policy, and ensure responsibilities and authorities are assigned, communicated and understood.

Learn more about [Section 5. Leadership ISO 14001:2015](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-leadership/)

* [Section 5.1 Leadership and commitment of EMS](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-leadership/iso-14001-2015-leadership-commitment/)
* [Section 5.2 Environmental Policy of the EMS ISO 14001:2015](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-leadership/iso-14001-2015-policy/)
* [Section 5.3 Organizational roles, responsibilities, and authorities](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-leadership/iso-14001-2015-organizational-roles/)

Section 6: Planning

Organizational Environmental Management System Planning to address organizational risks, opportunities, changes and quality objectives. <[**ISO 14001 Planning**](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-planning/)>

Learn more about ISO 14001:2015 Requirements [Section 6. Planning](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-planning/)

* [Section 6.1 Actions to Address Risk Associated with Threats and Opportunities](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-planning/iso-14001-2015-actions/)
	+ [ISO 14001:2015 Risk Management](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-planning/iso-14001-2015-actions/iso-14001-2015-risk/)
* [Section 6.2 Environmental Objectives and Planning to Achieve Them](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-planning/iso-14001-2015-objectives/)

Section 7: Support

Provide resource needs, ensure employees are competent and aware, and include documented information to support your environmental management system.

Learn more about ISO 14001:2015 Requirements [Section 7. Support for the EMS](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-support/)

* [Section 7.1 Resources for EMS](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-support/iso-14001-2015-resources/)
* [Section 7.2 Competence](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-support/iso-14001-2015-competence/)
* [Section 7.3 Awareness of the EMS](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-support/iso-14001-2015-awareness/)
* [Section 7.4 ISO 14001:2015 Communication](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-support/iso-14001-2015-communication/)
* [Section 7.5 Mandatory documents required by ISO 14001:2015](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-support/iso-14001-2015-mandatory-documents/)

Section 8: Operation

Plan and control processes needed to meet the requirements for products and services (Design and development, external providers, production and service provision, release of products and services, nonconforming outputs).

Learn more about [Section 8. Operation](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-operation/)

* [Section 8.1 Organization’s Operational Planning and Control for EMS](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-operation/iso-14001-2015-organization/)
* [Section 8.2 Preparing and responding to emergencies](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-operation/iso-14001-2015-preparing/)

Section 9: Performance Evaluation

Monitor, measure, analyze, and evaluate your environmental management system.

Learn more about ISO 14001:2015 Requirements [Section 9. Evaluating the ISO 14001:2015 Emergency Management System’s Performance](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-evaluating/)

* [Section 9.1 Monitoring, Measurement, Analysis and Evaluation ISO 14001:2015](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-evaluating/iso-14001-2015-m-m-a-e/)
* [Section 9.2 ISO 14001:2015 Internal Audit](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-evaluating/iso-14001-2015-internal-audit/)
* [Section 9.3 Effective Management Review](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-evaluating/iso-14001-2015-management-review/)

Section 10: Improvement

Select opportunities for improvement, take action against nonconformities, implement corrective actions as necessary, and continually improve your environmental management system.

Learn more about [Section 10.0 Improvement of the EMS](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-improvement/)

* [Section 10.1 General Requirements for Improvement](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-improvement/iso-14001-2015-general-requirements/)
* [Section 10.2 Nonconformity and Corrective Action](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-improvement/iso-14001-2015-nonconformity/)
* [Section 10.3 Continual Improvement ISO 14001:2015](https://14000store.com/iso-14000-2015-requirements/iso-14001-2015-improvement/iso-14001-2015-continual-improvement/)