

Quality management

Quality management is a method for ensuring that all the activities necessary to design, develop and implement a product or service are effective and efficient with respect to the system and its performance.

Quality Improvement

W. Edwards Deming is best known for his management philosophy establishing quality, productivity, and competitive position. He has formulated 14 points of attention for managers, some of these points are more appropriate for service management:

- Break down barriers between departments;
- Management should learn their responsibilities, and take on leadership;
- Improve constantly;
- Institute a programme of education and self-improvement.

The following diagram is the Shewhart cycle (PDCA) for quality improvement, made popular by Deming.



Shewhart Cycle

The philosophy is to keep improving the quality of an organization. It is defined by four keys:

- **Plan:** Design or revise business process components to improve results
- **Do:** Implement the plan and measure its performance
- **Check:** Assess the measurements and report the results to decision makers
- **Act:** Decide on changes needed to improve the process

The consolidation phase enables the organization to take stock of what has been taking place and to ensure made to processes that require documentation (both to allow processes to be repeatable and to facilitate recognition of the achievement of some form of quality standard).

Quality assurance

It is part of quality management focused on providing confidence that quality requirement will be fulfilled.

Productions quality starts with process capable of producing to design Specification and continuous with an inspection program arises if standards are being met. As said earlier the initial deviation concerning specification is based on precision sought by customers and accuracy attainable by production facilities. Given a process capable of obtaining the required precision unacceptable variations still occurs. Bluent tools, misalignment due to wear and tear of machinery, workers unless they can contribute to inferior output from a process inherently capable of acceptable quality. Coordinator controlled activities to prevent this and ensuring what customer wants they get.

Quality Inspections

The single act most costly associated with quality control is inspection (eg technicians testing concrete slabs in lab, food inspectors are also inspecting food grading tea, etc). In addition to maintaining quality inspectors provide information by which the performance of sorters, machines, departments, and plans can be evaluated.

Cost of Quality

- Prevention costs
 - Quality planning
 - Formal Technical Reviews
 - Test equipment
 - Training
- Appraisal costs
 - In-process and inter-process inspection
 - Equipment calibration and maintenance
 - Testing
- Failure costs
 - Internal failure costs
 - Rework
 - Repair
 - Failure mode analysis
 - External failure costs
 - Complaint resolution
 - Product return and replacement
 - Help line support
 - Warranty work

Evaluation of quality control

Part 1: The ancient Egyptians demonstrated a commitment to quality in the construction of their pyramids Greeks set high standards in arts and crafts. The quality of Greek architecture of the 5th century BC was the motivation behind subsequent architectural construction of Rome. Roman built cities; bridges and roads inspire us even today.

Part 2: up to 1800 production of goods and services was predominantly confirmed to single individuals/family responsible for quality of product (operator quality control period)

Part 3: Starting in early 1900 – 1920 . The second phase called former quality control period. With the industrial revolutions (steam engine-James watt-coal and iron) came the concept of mass production which was based on principle of specialization of labour .supervisor will be responsible for overall quality. (Companies with machine power in place of Human power alone came into existence

Part 4: Period from 1920- 1940. This is the inspection quality control period. Product and processes become more complicated and production volume increased. No. of workers reporting to a foreman increased. Inspectors were therefore designated to check the quality of the product item with those of standards. Non-conforming items were either reworked if feasible or were discarded.

During the period the foundations of statistical aspects of quality control were being developed. Bell labs proposed the concept of using statistical charts to control the variables of a product dodge and rowing proposed acceptance sampling

1930 saw the application of acceptance sampling plan in industrring .In 1929 Walter show hart got sponsorship of ASTM, ASME, ASA for creating a joint committee for the development of statistical applications in engineering and manufacturing

US Food Drugs and cosmetic Act 1938 came into existence-a quality measure.

Phase 5: the next phase in the evaluation process occurred between 1940-1960 and is termed as statistical quality control phase

American society for quality control was formed in 1946. Use of quality control procedures however no where close to the level that it should have been even in America. Japan although totally destroyed during World War II embraced the new philosophical whole-heartedly.

Quality assurance

- Analysis
- Auditing
- Reporting

Goal of quality assurance

- Provide management with the data necessary to be informed about product quality.
- Make confidence and be sure that product quality is meeting.

Quality Standards

The International Organization for Standardization (ISO) created the Quality Management System (QMS) standards in 1987. These were the ISO 9000:1987 series of standards comprising ISO 9001:1987, ISO 9002:1987 and ISO 9003:1987; which were applicable in different types of industries, based on the type of activity: designing, production or service delivery. The standards have been regularly reviewed every few years by the International Organization for Standardization. The version in 1994 and was called the ISO 9000:1994 series; comprising of the ISO 9001:1994, 9002:1994 and 9003:1994 versions. The last revision was in the year 2000 and the series was called ISO 9000:2000 series. However the ISO 9002 and 9003 standards were integrated and one single certifiable standard was created under ISO 9001:2000. Since December 2003, ISO 9002 and 9003 standards are not valid, and the organizations previously holding these standards need to do a transition from the old to the new standards. The ISO 9004:2000 document gives guidelines for performance improvement over and above the basic standard (i.e. ISO 9001:2000).

The Quality Management System standards created by ISO are meant to certify the processes and the system of an organization and not the product or service itself. ISO 9000 standards do not certify the quality of the product or service.

Recently the International Organization released a new standard, ISO 22000, meant for the food industry. This standard covers the values and principles of ISO 9000 and the HACCP standards. It gives one single integrated standard for the food industry and is expected to become more popular in the coming years in such industry.

The most elaborated and accepted concept of quality management is the model of the EFQM Excellence Model.

Process control

Process control is a statistics and engineering discipline that deals with architectures, mechanisms, and algorithms for controlling the output of a specific process. See also control theory.

A commonly used control device called a “programmable logic controller”, or a PLC, is used to read a set of digital and analog inputs, apply a set of logic statements, and generate a set of analog and digital outputs. Using the example in the previous paragraph, the room temperature would be an input to the PLC. The logical statements would compare the set point to the input temperature and determine whether more or less heating was necessary to keep the temperature constant. A PLC output would then either open or close the hot water valve, an incremental amount, depending on whether more or less hot water was needed. Larger more complex systems can be controlled by a Distributed Control System (DCS) or SCADA system.

In practice, process control systems can be characterized as one or more of the following forms:

- Discrete – Found in many manufacturing, motion and packaging applications. Robotic assembly, such as that found in automotive production, can be characterized as discrete process control. Most discrete manufacturing involves the production of discrete pieces of product, such as metal stamping.
- Batch – Some applications require that specific quantities of raw materials be combined in specific ways for particular durations to produce an intermediate or end result. One example is the production of adhesives and glues, which normally require the mixing of raw materials in a heated vessel for a period of time to form a quantity of end product. Other important examples are the production of food, beverages and medicine. Batch processes are generally used to produce a relatively low to intermediate quantity of product per year (a few pounds to millions of pounds).
- Continuous – Often, a physical system is represented though variables that are smooth and uninterrupted in time. The control of the water temperature in a heating jacket, for example, is an example of continuous process control. Some important continuous processes are the production of fuels, chemicals and plastics. Continuous processes, in manufacturing, are used to produce very large quantities of product per year (millions to billions of pounds).

Applications having elements of discrete, batch and continuous process control are often called *hybrid* applications.

Quality circle

A **quality circle** is a volunteer group composed of workers who meet together to discuss workplace improvement, and make presentations to management with their ideas. Typical topics are improving safety, improving product design, and improvement in manufacturing process. Quality circles have the advantage of continuity; the circle remains intact from project to project.

The determinants of quality

The degree to which a product or service successfully satisfying its intended purpose has four primary determinants

- 1) Quality of design
- 2) How well it conforms to the design
- 3) Ease of use
- 4) Service after delivery

Quality of design

Quality of design refers to the intentions of designers to include or exclude certain features in a product or service (eg: different automobiles with different size appearance, fuel economy, comfort, material used etc)

These differences reflect choices made by designers that determines the quality of design. Their design decisions take into account customer wants, production or service capabilities, safety, liability cost and similar other considerations. Designers may work closely with marketing and operations department. A poor design can result in difficulties in production or service. For example, materials might be difficult to obtain specifications to meet, procedure difficult to follow, similarly a superior design usually cannot offset poor workmanship.

Quality of conformance

Refers to the degree to which goods and services conform (ie to achieve) the intent of designers. This is affected by factors such as the capability of equipments, skills, training, taking prompt corrective action etc. (That is the reason we want designers to work in close coordination with manufacturing and inspection department during pilot job and procedures for manufacture developed accordingly.

Ease of Use

The determinants of quality does not stop once the product or service has been sold. Ease of use and user instructions are important. They increase the chances but do not

guarantee, that the product will be used for its intended purposes and in such a way that it will continue to function properly and safely. (ie user misused case)

Much of the same can be applied to services also. Customers, patients, clients must be clearly informed. Much of the instructions takes the form of printed instructions, labels and what to do if something goes wrong.

Service after delivery

For a variety of reasons products do not always perform as expected and services do not always yield the desired results. Through recall adjustment replacement, buyback etc this situation is remedied.

Quality of care should be defined in light of both technical standards and patients' expectations. While no single definition of health service quality applies in all situations, the following common definitions are helpful guides:

- ❖ Technical performance
- ❖ Access to services
- ❖ Effectiveness of care
- ❖ Efficiency of service delivery
- ❖ Interpersonal relations
- ❖ Continuity of services
- ❖ Safety
- ❖ Physical infrastructure and comfort
- ❖ Choice

Quality management principles

The following text is an integral reproduction of the content of the document "Quality Management Principles".

Introduction

This document introduces the eight quality management principles on which the quality management system standards of the revised ISO 9000:2000 series are based. These principles can be used by senior management as a framework to guide their organizations towards improved performance. The principles are derived from the collective experience and knowledge of the international experts who participate in ISO Technical Committee

ISO/TC 176, Quality management and quality assurance, which is responsible for developing and maintaining the ISO 9000 standards.

The eight quality management principles are defined in ISO 9000:2000, Quality management systems Fundamentals and vocabulary, and in ISO 9004:2000, Quality management systems Guidelines for performance improvements.

This document gives the standardized descriptions of the principles as they appear in ISO 9000:2000 and ISO 9004:2000. In addition, it provides examples of the benefits derived from their use and of actions that managers typically take in applying the principles to improve their organizations' performance.

Principle 1 Customer focus

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

Principle 2 Leadership

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

Principle 3 Involvement of people

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

Principle 4 Process approach

A desired result is achieved more efficiently when activities and related resources are managed as a process.

Principle 5 System approach to management

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

Principle 6 Continual improvement

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

Principle 7 Factual approach to decision making

Effective decisions are based on the analysis of data and information

Principle 8 Mutually beneficial supplier relationships

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value

BENCHMARKING

Benchmarking (also "best practice benchmarking" or "process benchmarking") is a process used in management and particularly strategic management, in which organizations evaluate various aspects of their processes in relation to best practice, usually within their own sector. This then allows organizations to develop plans on how to adopt such best practice, usually with the aim of increasing some aspect of performance. Benchmarking may be a one-off event, but is often treated as a continuous process in which organizations continually seek to challenge their practices.

A process similar to benchmarking is also used in technical product testing and in land surveying. See the article benchmark for these applications.

Advantages of benchmarking

Benchmarking is a powerful management tool because it overcomes "paradigm blindness." Paradigm Blindness can be summed up as the mode of thinking, "The way we do it is the best because this is the way we've always done it." Benchmarking opens organizations to new methods, ideas and tools to improve their effectiveness. It helps crack through resistance to change by demonstrating other methods of solving problems than the one currently employed, and demonstrating that they work, because they are being used by others.

Competitive benchmarking

Advantage of the benchmarking for a company:

1. A better understanding of the wants (expectations) of the customer because it is: based on the reality of the market estimated in an objectivist way
2. A better economic planning of the purposes and the objectives to achieve in the company because they are: centred on what takes place outside controlled and mastered.
3. A better increase of the productivity: resolution of the real problems Understanding of the processes and what they produce”
4. Better current practices Search for the change Many decisions practices of break

5. A better competitiveness thanks to: a solid knowledge of the competition a strong implication of the staff new ideas on practices and tried techniques

Benchmarking has consequences which are beyond the process itself: it reforms all the levels of the company.; modifies the process of manufacture of the product leads(drives) ; also reforms the hierarchical organization of the company, the product itself, and the state of mind of the employees.

Procedure

1. **Identify your problem areas** - Because benchmarking can be applied to any business process or function, a range of research techniques may be required. They include: informal conversations with customers, employees, or suppliers; exploratory research techniques such as focus groups; or in-depth marketing research, quantitative research, surveys, questionnaires, reengineering analysis, process mapping, quality control variance reports, or financial ratio analysis.
2. **Identify other industries that have similar processes** - For instance if one were interested in improving handoffs in addiction treatment s/he would try to identify other fields that also have handoff challenges. These could include air traffic control, cell phone switching between towers, transfer of patients from surgery to recovery rooms.
3. **Identify organizations that are leaders in these areas** - Look for the very best in any industry and in any country. Consult customers, suppliers, financial analysts, trade associations, and magazines to determine which companies are worthy of study.
4. **Survey companies for measures and practices** - Companies target specific business processes using detailed surveys of measures and practices used to identify business process alternatives and leading companies. Surveys are typically masked to protect confidential data by neutral associations and consultants.
5. **Visit the "best practice" companies to identify leading edge practices** - Companies typically agree to mutually exchange information beneficial to all parties in a benchmarking group and share the results within the group.
6. **Implement new and improved business practices** - Take the leading edge practices and develop implementation plans which include identification of specific opportunities, funding the project and selling the ideas to the organization for the purpose of gaining demonstrated value from the process.

Cost of benchmarking

Benchmarking is a moderately expensive process, but most organizations find that it more than pays for itself. The three main types of costs are:

- Visit costs - This includes hotel rooms, travel costs, meals, a token gift, and lost labour time.

- Time costs - Members of the benchmarking team will be investing time in researching problems, finding exceptional companies to study, visits, and implementation. This will take them away from their regular tasks for part of each day so additional staff might be required.
- Benchmarking database costs - Organizations that institutionalize benchmarking into their daily procedures find it is useful to create and maintain a database of best practices and the companies associated with each best practice now.

KAIZEN

Kaizen, a Japanese term that basically translates to 'continuous improvement' or 'change to become good', is a management concept originated by the Japanese in order to continuously effect incremental changes for the better, involving everybody within the organization from workers to managers. Kaizen is aimed at producing more and more value with less and less wastes (higher efficiency), attaining better working environment, and developing stable processes by standardization.

This never-ending process of achieving small improvements within the company everyday is in contrast to trying to achieve breakthrough results from a large improvement once in a while. Kaizen as a management technique is therefore more suitable for organizations with a collective culture that is trying to achieve long-term gains from a continuous supply of small and less radical contributions from its employees.

Kaizen implementation is said to operate on the following principles: 1) that human resources are the company's most important asset; 2) that success can not be achieved by some occasional radical changes alone, but more so by incremental yet consistently arriving improvements; and 3) that improvements must be based on a statistical or quantitative study of the performance of the process.

Thus, under Kaizen, everyone is a valued contributor to the company's success, and must therefore be given the necessary education and training in order to contribute in his or her own way on a continuous basis. Everyone in the organization must genuinely believe in the idea of Kaizen and strive to achieve one small goal at a time, each of which is considered a step towards the company's over-all success.

Every person must therefore be willing to: 1) learn; 2) communicate; 3) be disciplined; 4) get involved; and 5) change in order to maximize gains from Kaizen. Management must also be able to support this Kaizen structure by aligning resources, metrics, rewards, and incentives to Kaizen principles, encouraging all employees to contribute in their own ways.

Management programs that promote Kaizen include but are not limited to the following: 1) employee suggestion systems; 2) recognition systems for employees who exert effort for continuous improvement; 3) group-oriented suggestion or improvement systems like

Quality Circles (small groups that perform quality improvement activities); 4) [JIT](#); 5) [5-S](#); 6) [Total Productive Maintenance](#); and 7) [Total Quality Management](#).

Kaizen's Business Tenets:

- 1) Not a single day should pass without any kind of improvement anywhere in the company.
- 2) Improvement strategies must be driven by customer requirements and satisfaction.
- 3) Quality must always take a higher priority over profits.
- 4) Employees must be encouraged to recognize problems and suggest improvements to address these problems.
- 5) Problems must be solved by a collaborative and systematic approach through cross-functional teams.
- 6) Process-oriented thinking (as opposed to results-oriented thinking) must be practiced by everyone, so that every process gets continuously improved from time to time.

SIX-SIGMA

6-Sigma refers to a quality improvement and business strategy concept started by Motorola in the United States in 1987. In statistical terms, 6-Sigma is the abbreviated form of 6 standard deviations from the mean, which mathematically translates to about 2 defects per billion. Thus, strictly speaking, your process is said to have achieved 6-sigma if it is producing no more than 2 defects per billion parts produced.

No company is probably nearly perfect enough to achieve this quality level. Consequently, the term 6-Sigma in the industry has somehow taken on the equivalent defect rate of 3.4 ppm, which in reality corresponds to roughly 4.5 sigmas. Thus, in the industry today, a person speaking of 6-sigma is most likely referring to a quality level equivalent to 3.4 defects per million.

Regardless of how one wishes to use the term 6-sigma, though, it is apparent that its purpose when its concept was first incepted is to make processes as consistent as possible in order to reduce the defect rates of their outputs. Consistency of meeting customer specifications as well as the probability of meeting them consistently in the future is the essence of 6-sigma. To see how the number of sigmas relates to the process Cpk and the process ppm level, please refer to the [Cpk/ppm Table](#).

6-Sigma has evolved into a continuous, disciplined, and structured process of improving operations to make products that are consistently meeting customer requirements. In effect, 6-Sigma no longer simply means excellent finished products, but more importantly, excellent processes, services, and administration. When Motorola started 6-Sigma in the 80's, it was applied to repetitive manufacturing processes. Presently, however, the use of 6-Sigma is well-established in almost all aspects of doing business in a wide range of industries.

6-Sigma encourages leanness, simplicity, and doing things right the first time, so that wastes and corresponding costs are avoided. Statistics-based problem solving, results-orientation, and quantifiable top and bottom-line returns are also ingredients of 6-Sigma. Lastly, 6-Sigma is driven by the voice of the customer.

Total Quality Management

Total Quality Management is a structured system for managing the quality of products, processes, and resources of an organization in order to satisfy its internal and external customers, as well as its suppliers. Its main objective is sustained (if not progressive) customer satisfaction through continuous improvement, which is accomplished by systematic methods for problem solving, breakthrough achievement, and sustenance of good results (standardization).

Total Quality Management (TQM) is a management strategy aimed at embedding awareness of quality in all organizational processes. TQM has been widely used in manufacturing, education, government, and service industries, as well as NASA space and science programs.

Total Quality provides an umbrella under which everyone in the organization can strive and create customer satisfaction. TQ is a people-focused management system that aims at continual increase in customer satisfaction at continually lower real costs.

Definition

TQM is composed of three paradigms:

- **Total:** Organization wide
- **Quality:** With its usual Definitions, with all its complexities (External Definition)
- **Management:** The system of managing with steps like Plan, Organize, Control, Lead, Staff, etc.

As defined by the International Organization for Standardization (ISO):

"TQM is a management approach for an organization, centered on quality, based on the participation of all its members and aiming at long-term success through customer satisfaction, and benefits to all members of the organization and to society."

Principles of TQM

- 1) Quality can and must be managed.
- 2) Everyone has a customer to delight.
- 3) Processes, not the people, are the problem.
- 4) Every employee is responsible for quality.

- 5) Problems must be prevented, not just fixed.
- 6) Quality must be measured so it can be controlled.
- 7) Quality improvements must be continuous.
- 8) Quality goals must be based on customer requirements.

5S

Five related terms, beginning with an S sound, describing workplace practices conducive to visual control and lean production. The five terms in Japanese are:

1. Seiri: Separate needed from unneeded items-tools, parts, materials, paperwork-and discard the unneeded.
2. Seiton: Neatly arrange what is left-a place for everything and everything in its place.
3. Seiso: Clean and wash.
4. Seiketsu: Cleanliness resulting from regular performance of the first three Ss.
5. Shitsuke: Discipline, to perform the first four Ss.

Muda, Mura, Muri

Three Japanese terms often used together in the Toyota Production System (and called the Three Ms) that collectively describe wasteful practices to be eliminated.

- Muda: Any activity that consumes resources without creating value for the customer.
- Mura: Unevenness in an operation; for example, an uneven work pace in an operation causing operators to hurry and then wait.
- Muri: Overburdening equipment or operators.

CONTROL CHART

What is a Control Chart?

A control chart is a statistical tool used to distinguish between variation in a Process resulting from common causes and variation resulting from special causes. It presents a graphic display of process stability or instability over time.

Every process has variation. Some variation may be the result of causes which are not normally present in the process. This could be special cause variation. Some variation is simply the result of numerous, ever-present differences in the process. This is common cause variation. Control Charts differentiate between these two types of variation.

One goal of using a Control Chart is to achieve and maintain process stability. Process stability is defined as a state in which a process has displayed a certain degree of consistency in the past and is expected to continue to do so in the future. This consistency is characterized by a stream of data falling within control limits based on plus or minus 3 standard deviations (3 sigma) of the centerline.

Why should teams use Control Charts?

A stable process is one that is consistent over time with respect to the center and the spread of the data. Control Charts help you monitor the behavior of your process to determine whether it is stable. Like Run Charts, they display data in the **time sequence in which they occurred**. However, Control Charts are more efficient than Run Charts in assessing and achieving process stability.

Your team will benefit from using a Control Chart when you want to (Viewgraph2)

- Monitor process variation over time.
- Differentiate between special cause and common cause variation.
- Assess the effectiveness of changes to improve a process.
- Communicate how a process performed during a specific period.

What are the types of Control Charts?

There are two main categories of Control Charts, those that display attribute data, and those that display variables data.

Attribute Data: This category of Control Chart displays data that result from counting the number of occurrences or items in a single category of similar items or occurrences. These “count” data may be expressed as pass/fail, yes/no, or presence/absence of a defect.

Variables Data: This category of Control Chart displays values resulting from the measurement of a continuous variable. Examples of variables data are elapsed time, temperature, and radiation dose.

While these two categories encompass a number of different types of Control Charts (Viewgraph 3), there are three types that will work for the majority of the data analysis cases you will encounter. In this module, we will study the construction and application in these three types of Control Charts:

- X-Bar and R Chart
- Individual X and Moving Range Chart for Variables Data
- Individual X and Moving Range Chart for Attribute Data

Viewgraph 4 provides a decision tree to help you determine when to use these three types of Control Charts.

In this module, we will study only the Individual X and Moving Range Control Chart for handling attributes data, although there are several others that could be used, such as the np, p, c, and u charts. These other charts require an understanding of probability distribution theory and specific control limit calculation formulas which will not be covered here. To avoid the possibility of generating faulty results by improperly using

these charts, we recommend that you stick with the Individual X and Moving Range chart for attribute data.

The following six types of charts:

- X-Bar and S Chart
- Median X and R Chart
- c Chart
- u Chart
- p Chart
- np Chart

What are the elements of a Control Chart?

Each Control Chart actually consists of two graphs, an upper and a lower, which are described below under plotting areas. A Control Chart is made up of eight elements. The first three are identified in Viewgraphs 5; the other five in Viewgraph 6.

1. Title. The title briefly describes the information which is displayed.
2. Legend. This is information on how and when the data were collected.
3. Data Collection Section. The counts or measurements are recorded in the data collection section of the Control Chart prior to being graphed.
4. Plotting Areas. A Control Chart has two areas—an upper graph and a lower graph—where the data is plotted.

The **upper graph** plots either the individual values, in the case of an Individual X and Moving Range chart, or the average (mean value) of the sample or subgroup in the case of an X-Bar and R chart.

The **lower graph** plots the moving range for Individual X and Moving Range charts, or the range of values found in the subgroups for X-Bar and R charts.

5. **Vertical or Y-Axis.** This axis reflects the magnitude of the data collected. The Y-axis shows the **scale of the measurement** for variables data, or the **count (frequency) or percentage of occurrence** of an event for attribute data.

6. **Horizontal or X-Axis.** This axis displays the chronological order in which the data were collected.

7. **Control Limits.** Control limits are set at a distance of 3 sigma above and 3 sigma below the centerline [Ref. 6, pp. 60-61]. They indicate variation from the centerline and are calculated by using the actual values plotted on the Control Chart graphs.

8. Centerline. This line is drawn at the average or mean value of all the plotted data. The upper and lower graphs each have a separate centerline.

ISO 14000

The **ISO 14000** environmental management standards exist to help organizations minimize how their operations negatively affect the environment (cause adverse changes to air, water, or land), comply with applicable laws, regulations, and other environmentally oriented requirements, and continually improve on the above.

ISO 14000 is similar to ISO 9000 quality management in that both pertain to the process (the comprehensive outcome of how a product is produced) rather than to the product itself. As with ISO 9000, certification is performed by third-party organizations rather than being awarded by ISO directly. The ISO 19011 audit standard applies when auditing for both 9000 and 14000 compliance at once.

Standards

The material included in this family of specifications is very broad. The major parts of ISO 14000 are:

- **ISO 14001** is the standard against which organizations are assessed. ISO 14001 is generic and flexible enough to apply to any organization producing any product or service anywhere in the world.
- **ISO 14004** is a guidance document that explains the 14001 requirements in more detail. These present a structured approach to setting environmental objectives and targets and to establishing and monitoring operational controls.

These are further explicated by the following:

- **ISO 14040** discusses pre-production planning and environment goal setting.
- **ISO 14020** covers labels and declarations.
- **ISO 14030** discusses post-production environmental assessment.
- **ISO 14062** discusses making improvements to environmental impact goals.
- **ISO 14063** is an addendum to 14020, discussing further communications on environmental impact.
- ISO 19011 which specifies one audit protocol for both 14000 and 9000 series standards together. This replaces **ISO 14011** meta-evaluation—how to tell if your intended regulatory tools worked. 19011 is now the only recommended way to determine this.

ISO 14001 is an internationally accepted specification for an environmental management system. It specifies requirements for establishing an environmental policy, determining environmental aspects and impacts of products/activities/services, planning environmental objectives and measurable targets, implementation and operation of

programs to meet objectives and targets, checking and corrective action, and management review.

ISO 9000

ISO 9000 is a family of standards for quality management systems. ISO 9000 is maintained by ISO, the International Organization for Standardization and is administered by accreditation and certification bodies. For a manufacturer, some of the requirements in ISO 9001 (which is one of the standards in the ISO 9000 family) would include:

- A set of procedures that cover all key processes in the business;
- Monitoring manufacturing processes to ensure they are producing quality product;
- Keeping proper records;
- Checking outgoing product for defects, with appropriate corrective action where necessary; and
- Regularly reviewing individual processes and the quality system itself for effectiveness.

A company or organization that has been independently audited and certified to be in conformance with ISO 9001 may publicly state that it is "ISO 9001 certified" or "ISO 9001 registered." Certification to an ISO 9000 standard does not guarantee the compliance (and therefore the quality) of end products and services; rather, it certifies that consistent business processes are being applied.

Although the standards originated in manufacturing, they are now employed across a wide range of other types of organizations, including colleges and universities. A "product", in ISO vocabulary, can mean a physical object, or services, or software. In fact, according to ISO in 2004, "service sectors now account by far for the highest number of ISO 9001:2000 certificates - about 31% of the total" - source: the ISO Survey 2004

Advantages

1. Create a more efficient, effective operation
2. Increase customer satisfaction and retention
3. Reduce audits
4. Enhance marketing
5. Improve employee motivation, awareness, and morale
6. Promote international trade