

Guide to ISO 9000

An explanatory guide to various
aspects related to ISO 9000:2000 standards

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General Issues About ISO 9000:2000

When we are speaking of ISO 9000 standard, certain things should be clearly stated. ISO 9000 is a family of standards, divided as follow:

- **ISO 9000:2000** - which is focused on vocabulary and principles;
- **ISO 9001:2000** - the main item in the family, which states the requirements for the quality management systems;
- **ISO 9004:2000** - which is a guide for improvement the quality management systems.

ISO 9000:2000 section named Quality Management Systems - Fundamentals and Vocabulary is intended to help the beginners and not only to understand the basic terms and principles used in the family of standards. The main sections of this standard are: fundamental principles of quality management systems, definitions of the most important terms, and methodology used in preparing the vocabulary.

As stated above, the most important standard of the family is ISO 9001:2000 named Quality Management Systems - Requirements, which state the requirements for the quality management system. This is the only standard that the company must comply to, also is used as reference by external bodies, usually those that are undertaking the assessment of the quality management system for issuing and maintaining the certificate. All the other standards in the family are optional, being used as guides; therefore no one can issue a nonconformance against any of these. You may pass or fail a certification, surveillance or re-assessment audit only against the ISO 9001:2000 standard! This is the reason for which the company has to focus especially on this standard.

Going to the third section of the standard family, we reach the ISO 9004:2000 standard, named Quality Management Systems - Guiding Lines for Improvement of Performances. As the title suggests, the standard is focused on setting guides for improvement of the system, based on the clauses stated in the ISO 9001:2000 standard. Examples of the chapters contained in the standard are: process approach of the system, compatibility with other management systems, guiding lines, a self evaluation guide with a classification of maturity levels of performances of quality management system, links between the benefits of ISO 9002:2000 and the results of self evaluation, and the continual improvement process.

Having the above explanation about how is structured the ISO 9000 standard family, is easier now to understand "technical discussion" when these word comes up. However, pay attention that in many cases people usually refers to ISO 9001:2000 standard simply saying ISO 9000, or ISO standard, etc. Keep in mind all the time that there are three section each one having its very specific role...

ISO 9000:2000 Explained

The main issues addressed by ISO 9000:2000 standard, named Quality Management Systems - Fundamental Principles and Vocabulary are: fundamental principles, definition of most important terms and methodology used for preparing the vocabulary. The basic principles that are taken into consideration in ISO 9000 standard family are:

Orientation towards client - the central point of this principle is that companies depend on their customers, therefore understanding their needs and also their expectation would lead to an increased satisfaction, equal to solid future of the companies.

The principle of leadership is used with the purpose of increased internal environment for the processes and relations between personnel. Leaders should be followed by their subordinates based on trust and confidence in their capabilities, not by constrictions and fear. Enthusiast workers may achieve established objectives in a shorter time, with improved efficiency.

Involvement of personnel is also an essential part for gaining benefits for both of personnel and the company. As an example, allowing an employee to establish his or her own objectives, based on company's vision and mission, may allow the ease of work, better control, better product or service, reduction of consumption. After all, each of us is dreaming of getting its own life in own hands, deciding what would be best for satisfying the own needs and expectations, in correlation with the extended community interests.

Process approach of every aspect that exists in the company may lead to improved performance. As long as some inputs are transformed into some outputs, within the process, is more easy to understand it, control it and decide either if planned objectives has been reached or not.

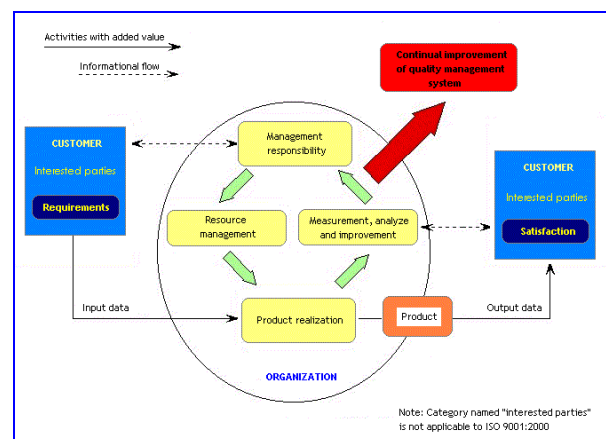
Continual improvement should be a constant concern of every company. It not important to have small or large improvements; it's important for them to exist. Areas for improvements can be established simply by following the rule: if you don't measure it, you can't control it, therefore you can't improve it. Having the result of a measurement, it's very easy to observe if there is something good or not. Either way, the managers may decide if some improvements are needed. Setting new objectives, providing necessary resources, measuring again the result of the process and comparing observed results with initial objectives is a usual practice to apply what is called continual improvement.

How you will know that an improvement was made? Quite simple. Are there happier customers, does the processes flows easier, are resources used more efficient, are the employee happier, is the local or regional community happier? If the answer is yes to either of these questions, then improvement exists.

The principle approach based on facts should be a guiding light for managers. This means that a good decision is possible when is based on objective evidences, in an adequate amount. Less information or inaccurate is most of the time a chance of establishing wrong decision with all the consequences that arise from implementation of it.

Understanding of processes and their interrelation, managing of each process and of all of them as an entire have to lead to more effectiveness and efficiency. The **management is seen as a system**.

Suppliers are a key factor for every company. Because the quality of products and services provided by suppliers directly affects the quality of products or services supplied by organization, it is important to exist a mutual good relation with suppliers. Developing this concept, is reached the concept of positioning the company in chains of suppliers in which every link of the chain (meaning supplier) has a high value in terms of quality, reputation, relations, etc.



These principles described above represents the base of ISO 9000 standard family. Understanding these principles and judging the existing situation of the company will help to identify which of these principles will be applied on a larger scale initially. However, it's important to apply all of them, achieving this way a high value of the company, seen as an entire.

Because of the requirement of continual improvement under clause 8.5.1 of ISO 9001:2000, this family of standards may be seen as an instrument dedicated especially to companies which seeks to improve themselves. Improvement has to reach the objective of increased customer satisfaction, first of all, and, for companies who wish to go beyond of ISO 9001:2000 requirements, the goal is extended to interested parties, like shareholders, local and/or regional community, employees, etc.

The management system has to be on a spiral, in terms of understanding what the customers is asking from the company. There has to be a honest relation with the client, meaning that when the company is confirming the request, it has the capability of fulfill it. On the spiral comes then the management of needed resources (all resources needed to fulfill customer requirements). The spiral continues with product or service realization and then the measures needed to determine if what was made comply to specified requirements. If conformity is achieved, the product or the service is delivered to customer, followed by monitoring of customer feedback regarding how well the requirements were fulfilled. From every step of this spiral, the management has to learn, in terms of avoiding previous mistakes, also to prevent potential problems. This way is achieved the continual improvement in increased customer satisfaction.

As you can see, the customer is the most important element: it starts from the customer and it ends with it.

The vocabulary section

The vocabulary section of the standard addresses terms that are used within ISO 9000 standards and quality management systems. Reading these terms, we shall explain some of the most important ones, critical for understanding quality management systems and application of the standard.

Client: the beneficiary of a product or service supplied by the company. Based on this definition, companies may be seen each time as suppliers and clients, depending on the side they are. This concept may be extended for instance to employees. An employee receives something from someone else, playing in this case the role of a client, and this employee is supplying something to someone else, playing in this case the role of a supplier.

Process: transformation of inputs into outputs under correlated activities. Understanding previous definition and linking it to the current one, we may reach the conclusion that processes may be seen as supplier processes and client processes. Extending this concept, we can understand that an overall process is an assembly of smaller processes.

Product: is the output of a process. Usually, the term product is used for tangible things like a car, furniture, pen, etc. However, the ISO 9000:2000 standard identifies four classes of products such as services (communication services), software (computer program), hardware (car, furniture, pen), and processed materials (paint thinner). Understanding these classes, it's easy to find out that many products contains incorporated some of these classes.

Quality Management System: a management system in which an organization is oriented and controlled regarding quality. Quality management system is part of the overall management system of the company, along with other management systems like human resource management system, supplier management system, environmental management system, health and safety management system, etc. In every single company such system exists, even if they are not well known or defined. As an example, every company has some sort of prevention methods for safety of employees, also is concerned of reducing the consumptions. A certain level of product quality is achieved most of the time, either is lower or higher. This is an example of co-existence of three management systems in a company.

Requirement: the need or expectation which is declared to be achieved. Most of the time requirements are mandatory. When a customer says that wants a metal bar with a certain metal specification, having certain dimensions, we understand what a requirement is. It's unlikely that the customer with accept a metal with other specification or with other dimensions. In this example is possible however that alternate materials or dimensions to be accepted by the client, but the goal of the client is to get something that is useful for further use.

Quality Assurance: is part of the quality management system which is concerned with the supplying of full confidence that requirements related to quality will be achieved. As an example, the quality control intention is to determine either if a product is within specification limits or not.

Conformity: is the fulfillment of a requirement. Returning to that example with metal bar, if the client will be provided by the company with the exact specification of material and requested dimensions, is obviously that the company achieved the conformity in supplying that product, in accordance with requirements stated initially.

Nonconformance: non fulfillment of a requirement. Once again we go back to the example given in the requirement definition. If the company accepted the client order initially and will fail to deliver the metal bar with that specification and dimensions, there is a nonconformance. The client is provided with a product that is for no further use for him. Please note that nonconformance is a wide term, which refer to product especially (non fulfillment of a requirement). But for instance, when an objective was set for a process, like x% rejection rate and that percentage is exceeded, there is a nonconformance related to that initially set objective. Another example of nonconformance may be encountered when a process is operating without complying with the documentation set for it. In this case, the requirement is: the process must follow the applicable documentation.

Corrective Action: is the action taken to eliminate the cause of the nonconformance. Every problem has a cause that lead to emergence of the problem. Identifying the primary cause is the aim of analyze, for fully solving a problem. It's not enough just to rework the product for instance; is needed also a method for preventing the recurrence of the problem. Usually, the Analyze of Multiple Cause method should be used in order to determine the primary cause of a problem. It's useless to apply a corrective action to an apparent cause. The main cause still exists, and will generate the same problem again, meaning that resources were provided without a good result. Valuable companies understands the true value of the corrective action and spends quite amounts of time to identify the primary cause of problems.

Preventive Action: it's similar in concept with the corrective action but in this case is applied to potential nonconformance. The first difference comes from the apparition or not of the nonconformance. Corrective action is strictly applied to nonconformances which appear, while preventive action is applied to problems that might appear, in order to prevent them. As an example, many preventive actions comes in the design and development phase of a product, when are analyzed the characteristics of the product and is made an analyze regarding what might go wrong. Another difference in our opinion regarding

corrective and preventive action comes up usually from the amount of information needed to establish adequate actions. While usually for corrective action is needed a smaller amount of information, for a good preventive action is needed a lot of information and valuable, too.

Correction: action needed to eliminate a nonconformance which occurred. Based on this definition, the following example will clarify this term. When a product is found as nonconforming, let's say the length of a metal bar is exceeding given specification, the correction needed for that is to cut the bar to specified length. Correction is the action needed to comply with stated requirement. Some time a correction may be applied, other times is not possible.

Document: is the information along with its support, which may be a paper or electronic format. Various documents are used daily. Examples of documents are: a standard, a drawing, a written procedure, etc.

Record: a document that states the achieved results. Correlating these two definitions, result that a record may be on paper or in electronic format. A good quality management system contains enough amounts of records which prove the conformance with stated requirements. This should not lead to an extended bureaucracy, however.

Effectiveness: it's simply the achievement of established objectives.

Efficiency: is the level of resources used to achieve established objectives. Having these definitions is clear that in good quality management systems, these two terms has to be used in conjunction. Obviously, it's important to discuss about achievement of objectives; a company which achieved planned objectives is happy, but it has also to take into consideration how much resources were used for that. Achieving a small objective with high amounts of resources can't lead the company to good performance (most of the time when such situations occur there are only few steps left until bankruptcy). Valuable companies achieve important objectives managing needed resources in an intelligent manner. After all, every company has a goal of maximizing the profit, by cutting down the costs and to be better compared to previous moments.

Quality Policy: is the orientation of the company regarding the quality. Quality policy is decided by the top

management of the company, in accordance with its vision and mission.

Quality Objectives: more precise identification of what is to be achieved within quality policy. These two definitions shouldn't be used separately. Valuable companies have very good visions for the future and adequate missions. As part of the vision and mission, quality policy usually set the long term orientation of the company regarding quality. Setting the path (needed steps) to fulfill the policy is made using quality objectives. As an example, a company decides to achieve an increased solidity of the quality of the products, within next 3 years, so that to beat the competition. This is a quality policy. To achieve that, the company will constantly monitor competitor's performance regarding quality and will set, from time to time, new quality objectives such: in the first year, the maximum number of defective products returned to us will

be that amount, in the second year will be that amount, and so on. These are quality objectives. The above example is a very simple one. Just think to quality of a product: is influenced by many, many factors, like supplier performance, adequacy of processes inside the company, the quality of human resource, the quality of managers, the infrastructure used to make the product, etc. For each of these items quality objectives may be set, which will be in concordance with the quality policy. New example for quality objective: periodical training of workers so that the capability of process to increase from actual 1.21 to minimum 1.44. As you can see, the quality policy is more general, setting a main target for quality. The quality objectives set to approach the policy are focused on more detailed items and are quantified, so that to allow comparison of results with established objectives.

ISO 9001:2000 Explained

The most crucial part of ISO 9000 family is the ISO 9001:2000, named Quality Management Systems - Requirements. As stated in the title, its objective is to present the requirements for a quality management system. It does not say how these requirements should be approached or implemented. It's up to each company to decide the best way of fulfilling the requirements. There are certain things that standard does not require (see the section **What ISO 9001:2000 Doesn't Require**).

The standard is organized into major sections, as follow:

Section 1 - Scope

Section 2 - References

Section 3 - Terms and definitions

Section 4 - Quality Management System

Section 5 - Management Responsibility

Section 6 - Resource Management

Section 7 - Product Realization

Section 8 - Monitoring and Measurement

First three sections deals with the scope of the standard (for companies that wants to prove to their customers the capability of supplying products which meet customer requirements and to increase customer satisfaction by applying the system in an effective manner, when is needed to apply exclusions from standard requirements - only within section 7), what references are used (ISO 9000:2000) and definitions of terms supplier, organization and client.

Important clauses of the standard are 4, 5, 6, 7 and 8, which will be detailed below. For an overview of basic requirements see the next chapter of this document.

Section 4 - Quality Management System

- 4.1 General requirements
- 4.2 Documentation requirements
 - o 4.2.1 General
 - o 4.2.2 Quality manual
 - o 4.2.3 Control of documents
 - o 4.2.4 Control of records
- Section 5 - Management responsibility
- 5.1 Management commitment
- 5.2 Customer focus
- 5.3 Quality policy
- 5.4 Planning
 - o 5.4.1 Quality objectives
 - o 5.4.2 Quality management system planning

- 5.5 Responsibility, authority & communication
 - o 5.5.1 Responsibility & authority
 - o 5.5.2 Management representative
 - o 5.5.3 Internal communication
- 5.6 Management review
 - o 5.6.1 General
 - o 5.6.2 Review input
 - o 5.6.3 Review output
- Section 6 - Resource management
- 6.1 Provision of resources
- 6.2 Human resources
 - o 6.2.1 General
 - o 6.2.2 Competence, awareness & training
- 6.3 Infrastructure
- 6.4 Work environment
- Section 7 - Product realization
- 7.1 Planning of product realization
- 7.2 Customer-related processes
 - o 7.2.1 Determination of requirements related to the product
 - o 7.2.2 Review of requirements related to the product
 - o 7.2.3 Customer communication
- 7.3 Design & development
 - o 7.3.1 Planning of design and development
 - o 7.3.2 Inputs for of design and development
 - o 7.3.3 Outputs from of design and development
 - o 7.3.4 Review of design and development
 - o 7.3.5 Verification of design and development
 - o 7.3.6 Validation of design and development
 - o 7.3.7 Changes to design and development
- 7.4 Purchasing
 - o 7.4.1 Purchasing control
 - o 7.4.2 Purchasing information
 - o 7.4.3 Verification of purchased product
- 7.5 Production and service provision
 - o 7.5.1 Control of production & service provision

- 7.5.2 Validation of processes for production & service provision
- 7.5.3 Identification and traceability
- 7.5.4 Customer property
- 7.5.5 Preservation of product
- 7.6 Control of monitoring and measuring devices
- Section 8 - Measurement, analysis and improvement
- 8.1 General
- 8.2 Monitoring and measurement
 - 8.2.1 Customer satisfaction
 - 8.2.2 Internal audit
 - 8.2.3 Measuring & monitoring of processes
 - 8.2.4 Measurement & monitoring of product

- 8.3 Control of nonconformity
- 8.4 Analysis of data
- 8.5 Improvement
 - 8.5.1 Continual improvement
 - 8.5.2 Corrective action
 - 8.5.3 Preventive action

Remember that according to section 1.2 Application, the only possible exclusions to standard requirements can be made within clause 7. No exclusion is possible under sections 4, 5, 6, and 8. Exclusions decided for section 7 has to be very well sustained.

Summary of ISO 9001:2000 requirements

Many thanks to Dr. Terry Russell from Centre for ISO 9000 for his generous contribution to this section...

4. Quality Management System

4.1 General Requirements

You must have a documented quality system which is kept up to date and continually improved.

Comments: Documentation can be in any kind of format, like paper or electronic.

There is a requirement for:

- identify involved processes;
- determine the sequence of involved processes;
- determine methods by which you can be sure that identified processes are working correctly;
- make sure that you provide needed resources for operating identified processes and you monitor them;
- monitor and improve of your system.

4.2.2 Quality Manual

The standard requires a Quality Manual which has to be up to date.

If there is any exclusion from standard requirements, they have to be mentioned in the manual, along with good explanatory reasons for which those requirements are not applied.

Comment: Most of the time is useless to put the entire documentation in a single book. Try to separate them as suits your needs better.

The manual has to reference or contain the procedures required by the standard; there are six areas that needs documented procedures.

Interaction and succession of the processes should be included into manual. There can exist flow chart diagrams.

4.2.3 Control of Documents

You must ensure that correct version of documents is available for use. They must be reviewed and approved prior to use.

You should know what documents exist and which version is the correct one.

You must make sure that the documents are kept in good order, so that they can be easily read.

If you need external documents in order to produce your products or services, you must describe how you control them (what happens when new ones are received or when existing ones become obsolete or no longer required, etc).

If you keep old versions for reference purposes, you must describe how you stop them from being used by accident.

Comments: There must exist a procedure, which must describe how is addressed each requirement of this clause. Pay attention that because of this clause, you may end up in a severe bureaucracy!

4.2.4 Control of Records

You must make sure that you keep sufficient records to prove that you are operating your quality management system correctly.

You must keep them for a defined minimum period, at your choice.

You must keep them in good condition, in such a way that they can be easily found.

This clause requires that you have a procedure which ensures that quality records are suitably controlled with regard to:

- defining what records are required;
- how and where they are stored;
- ensuring that they can be retrieved;
- describing their retention time and subsequent disposal;
- you should also describe who is responsible for these activities.

Comments: There must exist a procedure, which must describe how is addressed each requirement of this clause. Pay attention what records are useful and which are not. At least the records required by the standard must exist.

5. Management Responsibility

5.1 Management Commitment

Top management commitment to development and improvement of the system must be defined.

A quality policy must exist and also quality objectives must exist.

Management reviews must be conducted at regular time intervals.

Top management must ensure that sufficient resources are provided.

5.2 Customer Focus

Commitment of top management regarding determining, meeting and enhancing customer satisfaction must be defined.

Comments: A good solution would be to define a person or a group of persons responsible for determining customer requirements and expectations.

5.3 Quality Policy

The company has to have a relevant policy for products or services provided to clients.

- Quality Policy is one of the most important facets of your quality system. It is the top-level document of the system;
- It should include a commitment to meet requirements (customer and legal, etc.), and to continually improve the effectiveness of the quality management system;
- Quality policy must ensure that there exist a system for establishing and reviewing quality objectives;
- Quality policy must ensure that staff are aware of quality policy and what it means to them, and how they contribute to achieving the objective of having your Quality Policy;

Quality policy must be periodically reviewed.

Comments: A good solution for establishing quality policy and its review would be management review meetings.

5.4.1 Quality Objectives

Top management must make sure that adequate resources has been provided to achieve the required level of quality. Here, objectives for quality must be established by top management, using measurable terms.

Comments: Pay attention that quality objectives must be measurable. It's useless to set an objective and after that, not to be able to say if it was achieved or nor, or in what extent. Even if there is no specific requirement to record quality objectives, they should be included in quality manual or elsewhere.

5.4.2 Quality Management System Planning

Top management must ensure that needed resources are provided, in order to ensure that objectives for quality are planned and identified.

When changes are made to system, top management must ensure that the integrity of the system is maintained. Those changes must be made in a controlled way so that the system continues to meet the requirements of ISO 9001:2000.

5.5.1 Responsibility, Authority and Communication

Top management must be sure that responsibilities and authorities are defined and communicated throughout entire organization.

Comments: Identified responsibilities should be documented, for a better understanding and communication. People should be aware of who they report to and who reports to them (if relevant). They have to be aware of the general structure of the organization, or at least have access to that information, when they need it.

5.5.2 Management Representative

Top management has to appoint a person from management level who will be the "Management Representative". Responsibilities of Management Representative include:

- ensuring that the quality management processes are operating correctly;
- reporting the performance of the system to the top management;
- promoting awareness of customer requirements in the company.

Comments: Even if there is no particular requirement of the standard, there should exist a record for who is Management Representative. There is no suggestion on how to choose the proper person. However, that person has to come from management level and must have sufficient authority to carry out specified duties.

5.5.3 Internal Communication

Top management must ensure that there is adequate communication between the various levels of staff and between different departments, etc. and this communication is referring to effectiveness of quality management system.

5.6 Management Review

5.6.1 General

Top management must review the operation of the quality system, so as to ensure that it is up to date and effective. Top management must also consider how to improve the system and what changes are needed for it.

Comments: Records of these analyzes must be maintained.

5.6.2 Review Input

Inputs for review must be defined (e.g. inspection results, customer surveys, internal audit reports, etc). The standard lists some specific topics which must be addressed:

- results of audits;
- customer feedback;
- process conformity;
- product (service) conformity;
- status of corrective and preventive actions;
- follow-up actions from previous reviews;
- changes that could affect the system;
- recommendations for improvement.

Comments: Mentioned topics are minimum requirements. There should be more topics for management reviews, since these reviews are used especially for determining how the system works and what need to be improved, for a better performance and increased customer satisfaction.

5.6.3 Review Output

Standard requires that output of the management review to be defined. There are certain things that must result as output of the management review, required by the standard:

- improvements to the effectiveness of the management system;
- improvement of the product/services supplied by the company;
- resources needs (i.e. what resources are needed to achieve these improvements).

Comments: Mentioned topics are minimum requirements. There should be more topics for management reviews output, since these reviews are used especially for determining how system works and what need to be improved, for a better performance and increased customer satisfaction.

6. Resource Management

6.1 Provision of Resources

Organization must ensure that are provided adequate resources to enhance customer satisfaction and to implement the required processes and to improve them.

6.2 Human Resource

6.2.1 General

Organization must ensure that adequately trained and experienced personnel is undertaking appropriate jobs.

Comments: This requirement may be translated as follows: "proper person to proper place".

6.2.2 Competence, Awareness and Training

Competence of personnel must be determined. Organization has to provide needed training, to fulfill the requirements set in 6.2.1. Effectiveness of training must be evaluated. Employees must be aware of the importance of tasks they are undertaking. Adequate records must be kept for education, training, experience and abilities.

Comments: Competence is the combination of experience, abilities, training and education.

7. Product Realization

7.1 Planning of Product Realization

Organization must:

- determine the quality objectives and requirements for your products;
- ensure that exist adequately plan for all of the processes and sub-processes needed for products/services;
- plan the required inspection/testing activities;
- identify what records must be kept, to prove that the product has been properly produced;

If each item produced or service supplied is different, the company will need to produce a plan for each one.

Comments: If the company produces each time a different product or service, recorded plan for each of them must be kept, in accordance with requirements set in 4.2.4.

7.2 Customer Related Processes

7.2.1 Determination of Requirements Related to the Product

The company must find out what customer requires, with regard to the actual supplied product or service and also any obligations that arise from it (such as legal requirements, warranties and support, etc.).

Comments: One important thing that the company has to determine is what are the unspecified requirements, but needed for intended use of the product or service. This may be tricky most of the time, because plenty of things can be taken in consideration.

7.2.2 Review of Requirements Related to the Product

The company must ensure that customer requirements are defined.

If they are not defined in writing, the company must identify how to confirm what it is that you thought the customer wanted.

The company must ensure have the resources to supply what has been ordered before acceptance of the order.

Organization must define how changes in requirements are recorded, how information is circulated around to relevant sections of organization.

Comments: There is a mandatory requirement in the standard about keeping records for the review, also for action arising from it.

7.2.3 Customer Communication

The company must identify how the customer contacts the organization, especially for product information, feedback including complaints, enquiries and orders, including amendments, etc.

7.3 Design and Development

7.3.1 Planning of Design and Development

The company must ensure that are identified various design & development processes and the related review stages. Also has to identify all relevant responsibilities.

7.3.2 Inputs for Design and Development

The company must identify what the design inputs are (i.e. what information is needed in order to design or develop the product or service).

Inputs should include any relevant functional requirements, standards, legal requirements (e.g. mandatory safety requirements, packaging disposal/recycling requirements, CE marking requirements, etc). Where it is relevant, it should consider similar previous designs and learnings from them.

Adequate records must be kept for this activity.

7.3.3 Outputs for Design and Development

The company must specify the design outputs (e.g. plans, drawings, schematics, etc.) in such a way that they can be checked to ensure that they meet the design requirements.

They must be suitable for use by the organization that receives them. For example, the manufacturing department may require a Bill Of Materials, a "gold" sample, and a full set of engineering drawings, etc. Design plans should state what is required, after the organization have discussed and agreed this with the recipient (whether an external customer or an internal department).

7.3.4 Review of Design and Development

The company must review the progress of the design activities at appropriate stages.

These can include theoretical calculation checks, beta testing, etc.

Organization must identify and record any problems and propose follow-up actions. The plans should identify what these stages are and when they occur.

Records must be kept for these reviews.

Comments: Adequate records must be kept for this activity. This is a very good moment for initiating preventive actions.

7.3.5 Verification of Design and Development

The company must verify designs to ensure that the design meets the design input requirements.

Plans should state how and when you plan to do this.

Comments: Adequate records must be kept for this activity.

7.3.6 Validation of Design and Development

The company must ensure that the product or service works correctly in practice.

In some cases, validation may include reviews of customer feedback after release of the product. This may lead to subsequent design changes, or changes in future products.

Plans should state how and when you plan to do this.

Comments: Adequate records must be kept for this activity.

7.3.7 Changes of Design and Development

The company must ensure that any changes are reviewed and recorded.

It must also consider the effect that the changes may have on any sections of the design work already completed or under way.

Comments: Adequate records must be kept for this activity.

7.4 Purchasing

7.4.1 Purchasing Control

The company must ensure that suitable suppliers are selected, and they are told clearly what the company wants from them, so that to receive wanted things.

Comments: Records are needed to be kept, regarding evaluation of suppliers.

7.4.2 Purchasing Information

Purchase orders (or letters of contract, etc.) must clearly state what it is wanted.

These must be reviewed for adequacy before they are sent to the vendor.

Comments: No records are required by the standard to be kept, but most of the time they are used in practice.

7.4.3 Verification of Purchased Product

There is a requirement for the company to determine if the supplier has supplied proper products. This is what is called "receiving inspection".

If the product was not inspected upon receiving, it has to be inspected some time (the "in-process inspection").

If the company decides to make needed inspections to supplier's premise, before the goods are released, this has to be mentioned in purchasing documents.

If the client decides to make the verification of product at supplier's premise, the company is still responsible for making a suitable product for client.

7.5 Product and Service Provision

7.5.1 Control of Production and Service Provision

The company has to take in consideration various things needed for product realization or supply of service. These have to be controlled. Items that need to be considered, specified by the standard are:

- information which specifies the characteristics of the product (so that inspections and functional tests can be properly conducted);
- provision of work instructions (or SOPs, Method Statements, etc.). This can be by written instructions, drawings, photographs, samples, etc.;
- provision of suitable equipment and appropriate maintenance of the equipment;
- availability and use of suitable monitoring and measuring devices;
- provision of procedures for release, delivery and (if applicable) post-delivery activities (e.g. installation, commissioning, servicing, etc.).

Comments: Where needed, work instructions must be prepared and made available for use.

7.5.2 Validation of Processes for Production and Service Provision

Companies that have processes which produce items that cannot be tested directly (e.g. welding operation), has to validate such processes.

A special process is that one in which deficiencies appear only after the release of the product or service to the client. In other words, when the results of internal testing is not possible (unless by destroying the product) or gives only subjective proves, validation of processes must be applied.

The company has to:

- review, approve and revalidate production and/or service processes;
- approve and revalidate equipment and personnel involved in these activities.

The company has to define also:

- which methods or procedures must be followed when producing or servicing the product/service;
- what qualifications/experience are required for people involved in the processes;
- what records must be kept.

Comments: If the company has to validate special processes, records regarding validation must be kept.

7.5.3 Identification and Traceability

Where appropriate and to the extent necessary, organization must ensure that materials and goods are identified, so as to prevent accidental mix-ups.

In some industries it may be necessary to trace exactly which materials from which supplier were used in which goods. This may also extend to knowing which operators were involved. The aerospace industry is a good example of this sort of level of traceability.

If there is a requirement for traceability (legal, customer, etc.), the company must define adequate methods for unique identifying of items, starting to client order, going through purchasing from suppliers, processes, and ending with delivery to client. Record must be kept to demonstrate traceability.

Comments: Labeling is a typical method. Other methods include signs on the wall with a picture of the items. Metal rods can have colored paint put the end. However, if the differences are immediately obvious, there may be no need to label goods.

7.5.4 Customer Property

This clause is applicable if the company receives items that will be incorporated into final product, which will be supplied back to client. It is applicable also when the company receives data from the client, e.g. drawings, plans. etc.

If any problems are discovered, or customer property is damaged or lost while under company's control, it must be reported back to the customer and records must be kept.

Comments: This clause is applicable only when goods or data are received from client to be incorporated into the final product, which is given back to the client.

7.5.5 Preservation of Product

The company must ensure that all materials, subassemblies and finished goods, etc. are stored and handled so as to prevent them from damage or deterioration.

However, this is not just limited to your stores or warehouse. It includes all areas where materials are handled, processed or moved.

Also included in this section are the steps that company must take to ensure that goods are not damaged following final inspection. If it is organization's responsibility to deliver goods to client (that is, they do not arrange for the collection of the goods), then company must also choose method of carriage appropriately. (If you use a carrier/courier, then they should be included in your supplier selection methods.

7.6 Control of Monitoring and Measuring Devices

The company must identify what measurements need to be made, and what equipment must be used.

Where measuring equipment is used to inspect or set up the goods that you manufacture, you must ensure that they are accurate enough for the purpose. You should have then regularly checks (calibration). You must be able to prove that the equipment is calibrated, so keep records of it

If you find that the equipment is faulty, you must consider the effect of that fault on the measurements taken using the equipment since the last time you knew it was OK. This may mean that you have to recall goods (e.g. if a braking system on a motor vehicle could have been adversely affected), or it may mean that no action is required (e.g. if the inaccuracy is not enough to cause any adverse consequences). Either way, you must formally consider the matter and record the consideration and the decision.

Comments: Records must be kept for calibration of devices. If calibration is not possible against national or international standards, the basis for verification must be recorded (e.g. anti viral software from a market leader). If an equipment is later found faulty, records must be kept regarding consideration of the effect of the problem.

8. Measurement, Analysis and Improvement

8.1 General

The company must identify and plan measurement and monitoring activities in order to ensure that product and/or service is suitable and to enable improvement to processes and product.

Organization must consider the need for statistical techniques.

Company has to consider the process by which is seeking continually improvement of the system.

Comments: The standard does not require the use of statistical techniques to be used; it just require the investigation of needed techniques. It's unlikely for a company not to use statistical techniques. After all, every one is analyzing the sales, by creating a simple chart... Continual improvement is one of the biggest issues of the standard, along with customer satisfaction.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

The company must monitor customer feedback regarding its satisfaction (how requirement were fulfilled by the company).

This feedback must be an input for management review meetings.

8.2.2 Internal Audit

The company must perform internal audits, to ensure that the system meets ISO 9001:2000 requirements, also determining the level of implementation.

A written procedure is required to address this clause.

Internal audits must be planned.

Planning has to consider the importance and status of processes, also the results of previous audits.

It must be defined the criteria, scope, frequency of the audit and audit methods.

Auditors must be independent and impartial.

Auditors should have needed competence to perform audits.

Those responsible for managing the nonconformances found must decide for the need of actions and must implement in a diligent manner those ones, if any.

Records must be kept for internal audits.

Comments: Internal auditing process is critical for quality management system. Suitable auditors should be used. If they are from inside the company, they have not to be afraid by their boss, nor to pursue hypothetical nonconformances, just because he or she had a dispute with someone else.

8.2.3 Measuring and Monitoring of Processes

Adequate methods must exist in order to prove that processes for production of good or supply of service are suitable and will continue to be suitable.

8.2.4 Measuring and Monitoring of Product

At appropriated stages in production process, the company must measure the product, in order to determine the conformity of product.

Records for tests and inspections must be kept.

Records must identify the person responsible for releasing the product to the next stage of production or to the client.

Releasing the product to the client must be made only when all planned inspections and tests were successful.

Comments: This clause is focusing on what is called "in-process inspection" and "final inspection".

8.3 Control of Nonconformity

Organization must ensure that nonconforming product is not used or supplied accidentally.

Nonconforming product must be identified.

Nonconforming product must be treated in a way, decided by a relevant authority.

Records regarding the nature of nonconformance and actions for treatment must be kept.

Reworked product must be verified (inspected) so that to ensure that it satisfy the requirements.

If a nonconforming product was released to the client, organization must take adequate measures, correlated to the effects (actual or potential) of the nonconformance.

Comments: A written procedure is required by this clause. Recording nonconformances is the first step towards continual improvement.

8.4 Analysis of Data

Organization has to collect, to process and analyze relevant data in order to prove the suitability of quality system.

Data must come from specific sources and the output of analyze must provide information related to customer satisfaction, product conformance with requirements, processes characteristic and tendencies, suppliers and opportunities for preventive actions. These items are required by the standard.

Comments: As a requirement, this analyze must lead the company to improvements, based on facts, not suppositions.

8.5 Improvement

8.5.1 Continual Improvement

This clause requires continual improvement of effectiveness of quality system which exists in organization. Basic motors for improvement are:

- quality policy;
- quality objectives;
- results of audits (either internal or external);
- analyze of data;
- corrective actions;
- preventive actions;
- management reviews.

Comments: The clause asks for continual improvement regarding the effectiveness of the system. This means that improvement is not strict related to the product or service supplied by organization. It can appear in processes, communication, human resource value, better evaluation systems, etc. In fact, any change made by organization, which lead to a better result than previous one is considered to be an improvement. Any other method that organization thinks it's suitable has to be used in order to achieve continual improvement.

8.5.2 Corrective Action

The company must act so that to eliminate the cause of nonconformances.

Corrective action (action taken to eliminate the cause) has to be in accordance with the effect of the problem.

What is mandatory for an organization to comply with is:

- analyze of nonconformances;
- determining of causes;
- identify if there is needed corrective action.

Only if the company decide a corrective action is needed, the standard requires the determination and implementation of it, also the analyze of corrective action result.

It's mandatory to maintain records regarding the results of implemented corrective actions.

Comments: A written procedure is required for addressing these requirements of the clause. Fighting against problem's cause, gives the company what is required by clause 8.5.1 (improvement). Failing in identifying primary cause of a problem will lead the organization to spend time and money in a wrong direction, which in many cases complicate things; initial problem will come over and over... Would be a good idea to link this clause to clause 8.3 Control of Nonconformity.

8.5.3 Preventive Action

The company must act so that to eliminate the cause of potential nonconformance.

Preventive action (action taken to eliminate the cause of a potential problem) has to be in accordance with the effect of the problem. What is mandatory for an organization to comply with is:

- identification of potential nonconformance;
- analyze of it;
- determining of causes;
- identify if there is needed preventive action.

Only if the company decides a preventive action is needed, the standard requires the determination and implementation of it, also analyze of preventive action result.

It's mandatory to maintain records regarding the results of implemented preventive actions.

Comments: A written procedure is required for addressing these requirements of the clause. Fighting against potential problem's cause, gives the company what a good chance to save money. That way, is prevented loose because of what is called poor quality.

ISO 9004:2000 Explained

Many companies may find that ISO 9004:2000 named Quality Management Systems - Guiding Lines for Improvement of Performances is an add-on to ISO 9001:2000 standard. The creators of 9004 standard intended that. 9004:2000 standard takes the requirements stated in ISO 9001:2000 standard, and then gives guidance on them. Most of the time, details included in the standard have a more general purpose, allowing for each company to pick up those one that suits better the existing needs.

The standard does not provide examples. Even if this may be judged in a wrong way, the reason for which no specific examples are mentioned is quite simple: let's assume that two companies that make the same product, have the same internal organize, same number of employees, and same machines decide to apply ISO 9001:2000 standard and because of their limited experience goes for guidance offered in 9004:2000. If this standard would provide specific examples, both companies would apply them as they are stated, resulting two companies which have a quality management system in place but that cannot be differentiated by the customers. There would be a meaningless competition between them! Returning to current situation, if these companies apply to ISO 9001:2000 standard, and read the general guidance set in ISO 9004:2000, they have a more degree of freedom in judging and selecting the items that would help them in the quest for a better performance and more satisfied clients.

ISO 9004:2000 standard contains a section dedicated for self evaluation of a company that has implemented a quality management system. Even if this is still just a guide, some companies may find that guide useful, especially when limited experience exists. The questions set in the guide have most of the time a general purpose, but may be detailed according to the specifics of the company.

In section A.2 named Maturity Levels of Performance, of that self evaluation guide is included a table referring the maturity levels which exist in a quality management system. Five levels of maturity are identified as follows:

Level 1 - No formal approach. Companies with quality management systems which have this level have unpredictable results, and are characterized also by lack of evidences regarding quality. They run a business in a very unpredictable way, rather than managing the business. All of

us have seen companies appearing and disappearing over night...

Level 2 - Reactive approach. Usually, companies that fall into this level have a system based on corrections for solving problems. From time to time, minimum data regarding the results of improvements are taken in consideration. For them, the rule "make and correct" is a usual lifestyle, neglecting the understanding of what they are doing or how capable they are. Production cost in such companies is big and also, in many situations there is no or poor vertical communication. Employees are seen as simple machines, and the superiority of managers over them is similar with human race over monkeys. Unless changes occur in such companies, in order to improve things, most of these companies will end up in closing their business.

Level 3 - Stable approach of a formal system. This level characterizes companies which have a systematical process approach. Also, there are visible signs of systematical improvement (continual improvements, most of the time, however simple or very simple). There is available data regarding the conformance with stated objectives. Managers of such companies take in consideration the trends of processes and have a suitable understanding of what their business means. However, elements of a level 2 maturity still exist, like reactive approach. Part of the middle management of these companies has or attends trainings regarding management abilities. Often, their achievements are not used within the company as it should be. These companies have lows and highs in their activity, and are not capable all the time to fully understand real causes of them. They will be happy for highs, will go upset for lows. Recovering from lows is a painful process, not all the time a successful one. Many of the world companies have systems which fall into this level.

Level 4 - Sustained continual improvement. This level characterizes companies that learned the useful lessons of their level 3 life. They understood that middle management has a key role in organization and employees are part of it. Employees are not simple machines, they have needs and expectations, which the company struggles to meet. A very good level of communication exists in these companies, no mater the direction. Plenty of data is recorded and analyzed and good decisions are made based on facts, not suppositions. Constant high quality of product is on focus in these companies and there exist signs that they are fighting also to exceed expectations, beyond fulfillment of requirements.

Such companies have visions for the future and their mission is most of the time adequate. Improvements exist most of the time; they can be small or large and the company finds needed resources for them. Planning is an important part of company's life.

Level 5 - Best performance in class. In this level, companies are doing detailed benchmarking to prove their competitiveness against competitors. Their processes are strongly integrated. The future of such companies is sure, the security of jobs is provided. Customers have a high degree of confidence in products or services made by the company. Every person in the company is involved in processes not because of constricts, but because of awareness. High level of training is provided to personnel, according to their specific needs. Fulfillment of customer requirements is like "another day at the office" and anticipation of customer expectation is on a constant focus. New products are made after extensive researches of that initial expectations of the clients, to become new requirements for the company. Companies having this level of maturity are the best examples of how to manage a business rather than running the business.

Please note that hints provided above are not stated into ISO 9004:200 standard, except the classification of levels... They are our observations after detailed studies on many companies. Hints provided reflect only the essence of our

studies, correlated to classification provided into ISO 9004:2000 standard.

What ISO 9000 does not require

Many thanks to Dr. Terry Russell from Centre for ISO 9000 for his generous contribution to this section...

During years and years of consultancy, we've seen many people believing that the standard requires much more than they are capable of, no matter which version of the standard was in discussion. This happens especially for beginners, but we noted that even experienced persons had misjudged the requirements of the standard. Below are some classical examples of what ISO 9001:2000 does not require.



You don't have to have leading edge machinery and technology!

Even if this would be a perfect situation, ISO 9001:2000 requires you to provide adequate equipment. Adequacy is strictly related to customer requirements. In other words, when a customer asks you to make a product for him, you will have to take in consideration what are those requirements, and perform an analyze to determine if you are capable of doing that. If the answer of analyze is yes, then is OK, with

the technology and machinery you have available. If not, inform the customer that you can't meet his requirements. Analyze has to take in consideration, among other things, if your machinery is capable of making that product or not. Conclusion: if you believe that your equipments are not suitable for an ISO 9001:2000 certification, just revise that idea...



ISO 9001:2000 is not telling you when the suitable moment for going for a certification is!

Many companies have in their mind to start applying ISO 9001:2000 standard. However, they believe that that moment has not come yet, because of changes in internal organizing, low qualification of employees, etc. This idea is completely wrong. The best way of managing changes in organization, improving the human resource level is to have a quality management system based on ISO 9001:2000 standard. For instance, the standard requires you to manage in a rational way any changes of the system; in other words, think of a

change, establish it, then put it into practice as an experiment, checking how suitable it is. If it's suitable, make that change permanent. If not, forget it. According to standard requirements, you'll have to maintain the integrity of the system (which is what you are doing day by day in the company) when changes occur. As for human resource issue, the standard requires for you to provide needed training, so that to reach "the proper employee at proper place".



ISO 9001:2000 is not asking you not to make mistakes!

One of the most bizarre ideas of ISO 9001:2000 standard is that you are not allowed to make mistakes. In other words, all the time you have to make a perfect product, without rejects. If you will achieve this level, your company is will be a perfect one! Perfection is in heaven, not on earth. Let's remember some of the basic requirements of the standard. One of them is continual improvement. If you reached the perfection, no continual improvement is possible any more,

this means that you are not complying with standard requirements. This would be a big problem... What you have to know is that ISO 9001:2000 requires from you to learn from your previous mistakes, as much as possible. The way of doing that is to analyze nonconformance, figure out what was the cause, then decide if there is needed any corrective action, and if the answer is yes, come up with one, if possible.



ISO 9001:2000 does not require tons and tons of documentation!

Some believes that every little thing that is done in the company has to have an associated documentation, which clearly describes that. This is completely wrong. Each company seeks to be more effective and efficient. Having large documentations may be useful, but not all the time. The standard simply says that the amount of documentation

has to be correlated with the complexity of processes and experience of employees. Bureaucracy is not an ISO 9001:2000 requirement at all! When high complexity of processes exist or when low qualification of working force exist, then documentation should be issued.



ISO 9001:2000 it doesn't require you to open the door for the customer!

Of course, this is just an example, related to polite human behavior, but is not a standard requirement. In other words, the standard does not tell you how to do things, but requires you to prove that you did them. It's entirely up to you to decide what you will do. In a simple way: the standard does not care how you do things! A recent example we faced: An

architectural company said to us: I believed that you, as consultants, will tell me how to draw!!! Totally wrong, since we are not architects. It's each company's freedom to decide how they will do things...



ISO 9000 and Quality Gurus

You may wonder what's behind ISO 9000? Who are those guys who established principles, incorporated in ISO 9000. First of all, let's see who are these guys who contributed to quality. They are: Walter Shewhart, Edwards Deming, Joseph Juran, Genichi Taguchi, Armand Feigenbaum, Kaoru Ishikawa, and Philip Crosby.



Walter A. Shewhart (1891 - 1967)

Born in Illinois, USA, Shewhart graduated University of Illinois and then he obtained the doctorate in physics at University of California in 1917. Working at Western Electric Company as an engineer, he was able to make a serious contribution to a major problem: reliability of the equipment buried underground. Control charts created by him were used to differentiate between assignable sources of variation and pure chances of variation. Shewhart studied randomness and recognized variability which exists in all manufacturing processes. In his opinion, reducing variability is equivalent to quality improvement. Later Shewhart worked for Bell Telephone Laboratories until his retirement in 1956. He wrote several articles and books, most representative being Economic Control of Quality of Manufactured Product in 1931, Statistical Method from the Viewpoint of Quality Control in 1939. On more things about Shewhart: he is considered to be the grandfather of quality control.



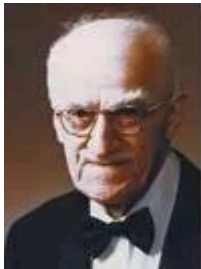
W. Edwards Deming (1900 - 1993)

Known as the father of quality, Deming was a statistics professor at New York University during the 40s. He studied for several years with Walter Shewhart; this was the base of his contribution to quality. After World War II, Deming was involved in assisting Japanese companies to reborn from their own ashes. His contribution was in improving quality, by setting a 14 points principles which should be the foundation for achieving quality improvements. Japanese companies applied extensively these principles; today's power of Japan and quality of their products has a strong root in this matter. Deming emphasized on the role of management in achieving quality. He noted that around 15% of poor quality was because of workers, and the rest of 85% was due to bad management, improper systems and processes. In his opinion, managers should involve employees in solving the problems, not simply to blame them for poor quality. Deming's 14 principles are:

- create constancy of purpose (short term reactions has to be replaced by long-term planning),
- adopt the new philosophy (management should adopt his philosophy, rather than to expect the employees to do that),
- cease dependence on inspection (it concerns to variation - in other words, if there is no variation, no inspection is needed because all products shows no defects),
- move towards a single supplier for any one item (working with several suppliers, automatically involves variation in raw materials),
- improve constantly and forever (it refers to decreasing variation, as a key to better quality),
- institute training on the job (another source of variation is the lack of training of workers; train them properly to do a certain job, and they will do it with far less variation),

- institute leadership (distinction between leadership and supervising),
- drive out fear (eliminate fear at worker's level to get their support for improvements. Fear is counter productive),
- break down barriers between departments (here comes the concept of "internal customer" which is found in TQM; a department is a supplier for next one. The second one is the client for the first one),
- eliminate slogans (usually, it's not the employee who did it wrong, but it's the system who allowed that. No need to create tension on worker, as long as the system fails to prevent problems),
- eliminate management by objectives (as long as workers had to achieve an established production level, quality will be a secondary target),
- remove barriers to pride of workmanship (bringing problems all the time to worker's ears, will create a discomfort for them. Lower satisfaction of workers equals a lower interest for doing good items),
- institute education and self - improvement (education is an asset. Everyone has to improve themselves),
- transformation is everyone's job (improvements exists at every level).

The most important book he wrote among other is Out of the Crisis in 1987. What is relevant to this book along these 14 principles is that he initiated the movement toward Total Quality Management, even he didn't used this expression. Nowadays, there exists Deming Prize, introduced by JUSE (Japanese Union of scientists Engineers); this prize is awarded annually for best proponent of TQM.



Joseph M. Juran (born in 1904)

Architect of Quality: The Autobiography of Joseph M. Juran (McGraw-Hill, 2003)... "Juran, now 99 years old, Juran begins his tale with his humble beginnings as a Romanian peasant and his family's immigration to the United States. He recounts how he overcame poverty, anti-Semitism, bitterness and despair... His is a tale of how education wins over ignorance, persistence prevails over complacency and, more than anything else, how faith--in God, in family, in humanity and in the American dream - is rewarded."

The pattern for Juran's life of hard work and dedication was set at an early age. "We grew up with no fear of long hours or hard work," he writes. "We learned to seek out opportunities and to use ingenuity to gain from them. We accepted the responsibility for building our own safety nets. By enduring the heat of the fiery furnace, we acquired a work ethic that served us the rest of our lives."

As a child, Juran endured the loss of his beloved mother, an indifferent father, bitter winters, the terror of anti-Semitism. Many residents of his native village in Romania perished in Nazi death camps - and grinding poverty. Consequently, he entered the working world bitter and socially inept, yet he was driven to succeed.

Juran's story parallels many of the great events of the 20th century. He landed his first job at Western Electric, which was the hot growth company of the 1920s. He weathered the Great Depression, he served his adopted country during World War II by working in the Lend-Lease Administration, he helped Japan rebuild its devastated economy and he showed U.S. manufacturers how to compete successfully in the world market...

Also remarkable is the success of Juran's siblings. They, too, overcame their humble beginnings and led successful lives. For example, his brother, Rudy, became a successful bond trader; his brother, Nat, had a successful career in Hollywood, earning an Academy Award; his sister, Minerva, earned a doctorate degree and became a college professor - no small feat for a female Romanian immigrant."

Quality Digest issued an article: "No one in the last hundred years has had more influence on the worldwide practice of quality in business than Dr. Joseph Juran... In Architect of Quality, Juran recounts his fascinating life story, revealing how he overcame dire poverty and childhood tragedy to make a profound impact on business and society. Juran retraces his inspiring life journey - from

an impoverished, tragic childhood in a tar-papered shack to his career as the revered man who helped invent and champion quality management systems, quality tools, and teams long before they became standard practice. Architect of Quality delves deep into Juran's motivations, sharing for the first time how the early hardships he faced and his relentless, aggressive spirit shaped his character and fueled his determination to succeed."

Juran is considered to be after Deming the most important contributor to quality management. He became well known after his book publishing Quality Control Handbook in 1951. In Japan, Juran worked with manufacturers and taught classes on quality. Even his philosophy is very similar to Deming's philosophy, there exists some differences: while Deming emphasized the need for organizational transformation, Juran believed that implementation of quality initiatives does not need dramatic changes. Juran is the author of definition for quality: fitness for use, rather than simply conformance to specifications. This way, Juran took into account the client, in terms of his needs. Quality trilogy "quality planning, quality control and quality improvement" represents another large contribution to quality. First part of trilogy is concerned with identification of customers, product requirements and override of business goals. The second part of trilogy implies the use of statistical control methods. As for the third part, Juran believes that improvement should be continual, as well as breakthrough.



Dr. Genichi Taguchi (born in 1924)

Raised in textile town of Takamachi, Japan, Taguchi studied textile engineering. WW II found him in Astronomical Department of navigation Institute. After several years in Ministry of Public Health and Welfare of Japan, where he met Matosaburo Masuyama, a statistician who supported him, he was hired at electrical Communication Laboratory, a rival of Bell Laboratories (see the story of Deming). Here, Taguchi worked to find ways of improving quality and reliability. Taguchi collaborated with Shewhart and Fisher.

Taguchi's contribution to quality consists in what is called Taguchi Loss Functions, also design of experiment to product design. His estimation was that 80% of all defective items are caused by poor design. Therefore, emphasis should be on design stage. Design of experiment is an engineering approach which is based on developing robust design; this is a design which results in a product which can perform over a wide range of conditions. In other words, it's easier to design a product which would operate under a large range of conditions, than to control these conditions so that the product to work as intended.

Loss function has implication to quality costs. Traditionally, if a product characteristic falls outside specification limits, it will increase the cost of poor quality. However, if that characteristic is closer to specifications and not to intended target, the quality of that product is poorer, even if it still satisfies the requirements. This may lead to lower customer satisfaction. Taguchi proposed that as conformance values moves away from the target, loss increases as a quadratic function. This means that smaller differences from the target result in smaller costs.



Armand V. Feigenbaum

Initiator of the concept of Total Quality Control, Feigenbaum published in 1961 one of his referencing book, named Total Quality Control. An interesting aspect regarding this book is that it was written when he was a doctoral student at MIT. The power of his ideas were discovered by Japanese in 1950s, about the same time Juran visited Japan. Quality principles set by Feigenbaum lay down on 40 keys. He promoted the concept of a working environment where quality developments cover entire organization; every single person in organization must have a truly commitment to improve the quality. Learning from other's success story is essential.

In his book Quality Control: Principles, Practices and Administration, Feigenbaum strove to move away from the then primary concern with technical methods of quality control, to quality control as a business method. Thus he emphasized the administrative

viewpoint and considered human relations as a basic issue in quality control activities. Individual methods, such as statistics or preventive maintenance, are seen as only segments of a comprehensive quality control program.

Quality control itself is defined as: "An effective system for coordinating the quality maintenance and quality improvement efforts of the various groups in an organization so as to enable production at the most economical levels which allow for full customer satisfaction". He stresses that quality does not mean "best" but "best for the customer use and selling price". The word "control" in quality control represents a management tool with 4 steps: Setting quality standards, Appraising conformance to these standards, Acting when standards are exceeded and Planning for improvements in the standards.

Quality control is seen as entering into all phases of the industrial production process, from customer specification and sale through design, engineering and assembly, and ending with shipment of product to a customer who is happy with it. Effective control over the factors affecting product quality is regarded as requiring controls at all important stages of the production process. These controls or jobs of quality control can be classified as:

- New-design control,
- Incoming material control,
- Product control,
- Special process studies.

Feigenbaum argues that statistical methods are used in an overall quality control program whenever and wherever they may be useful. However such methods are only part of the overall administrative quality control system, they are not the system itself. The statistical point of view, however, is seen as having a profound effect upon Modern Quality Control at the concept level. Particularly, there is the recognition that variation in product quality must be constantly studied within batches of product, on processing equipment and between different lots of the same article by monitoring and critical quality characteristics.

Modern Quality Control is seen by Feigenbaum as stimulating and building up operator responsibility and interest in quality. The need for quality-mindedness throughout all levels is emphasized, as is the need to "sell" the program to the entire plant organization and the need for the complete support of top management. Management must recognize that it is not a temporary quality cost-reduction activity. From the human relations point of view, the quality control organization is seen as both:

- A channel for communication for product-quality information,
- A means of participation in the overall plant quality program.

Finally, Feigenbaum argues that the program should be allowed to develop gradually within a given plant or company. Feigenbaum's preface to the third edition of Total Quality Control in 1983 emphasizes the increased importance of buyers' perceptions of variation in quality between companies and also the variation in effectiveness between the quality programs of companies. Quality is seen as having become the single most important force leading to organizational success and company growth in national and international markets. Further, it is argued that: "Quality is in its essence a way of managing the organization" and that, like finance and marketing, quality has now become an essential element of modern management.

Against this background, Total Quality Control is seen as providing the structure and tools for managing quality so that there is a continuous emphasis throughout the organization on quality leadership:

- genuine investment in, and implementation of, modern technology for quality throughout sales,
- engineering and production: and top-to-bottom human commitment to quality and productivity.

As Feigenbaum says: "In effect, quality and its costs are managed and engineered and motivated throughout the organization with the same thoroughness and depth with which successful products and services are themselves managed and engineered and produced and sold and serviced". Such Total Quality Control programs are highly cost-effective because of their results in improved levels of customer satisfaction, reduced operating costs, reduced operating losses and field service costs, and improved utilization of resources. By-products such as sounder setting of time standards for labor may also be most valuable. Thus a Total Quality System is defined as: "The agreed company-wide and plant wide operating work structure, documented in effective, integrated technical and managerial procedures, for guiding the coordinated actions of the people, the machines and the information of the company and plant in the best and most practical ways to assure customer quality satisfaction and economical costs of quality." Operating quality costs are divided into:

- Prevention costs including quality planning
- Appraisal costs including inspection
- Internal failure costs including scrap and rework
- External failure costs including warranty costs, complaints, etc.

Reductions in operating quality costs result from setting up a total quality system for two reasons:

- Lack of existing effective customer-orientated customer standards may mean current quality of products is not optimal given use,
- Expenditure on prevention costs can lead to a several fold reduction in internal and external failure costs.



Kaoru Ishikawa (1915 - 1989)

Ishikawa was a Japanese consultant, father of the scientific analysis of causes of problems in industrial processes. One of his greatest contributions to quality was the diagram which has his name "Ishikawa diagram" or Fishbone Diagram.

Professor Ishikawa was born in 1915 and graduated in 1939 from the Engineering Department of Tokyo University having majored in applied chemistry. In 1947 he was made an Assistant Professor at the University. He obtained his Doctorate of Engineering and was promoted to Professor in 1960.

He has been awarded the Deming Prize and the Nihon Keizai Press Prize, the Industrial Standardization Prize for his writings on Quality Control, and the Grant Award in 1971 from the American Society for Quality Control for his education program on Quality Control.

While, perhaps ironically, the early origins of the now famous Quality Circles can be traced to the United States in the 1950s, Professor Ishikawa is best known as a pioneer of the Quality Circle movement in Japan in the early 1960s, which has now been re-exported to the West. In a speech to mark the 1000th quality circle convention in Japan in 1981, he described how his work took him in this direction. "I first considered how best to get grassroots workers to understand and practice Quality Control. The idea was to educate all people working at factories throughout the country but this was asking too much. Therefore I thought of educating factory foremen or on-the-spot leaders in the first place." In 1968, in his role as Chairman of the Editorial Committee of Genba-To-QC (Quality Control for the Foreman) magazine, Dr Ishikawa built upon quality control articles and exercises written by the editorial committee for the magazine, to produce a "non-sophisticated" quality analysis textbook for quality circle members. The book Guide to Quality Control was subsequently translated into English in 1971, the most recent (2nd) edition being published by the Asian Productivity Organization in 1986. Amongst other books, he subsequently published What is Total Quality Control? The Japanese Way which was again translated into English (Prentice Hall, 1985).

As with the other Japanese quality gurus, such as Genichi Taguchi, Kaoru Ishikawa has paid particular attention to making technical statistical techniques used in quality attainment accessible to those in industry. At the simplest technical level, his work has emphasized good data collection and presentation, the use of Pareto Diagrams to prioritize quality improvements and Cause-and-Effect (or Ishikawa or Fishbone) Diagrams. Ishikawa sees the cause-and-effect diagram, like other tools, as a device to assist groups or quality circles in quality improvement. As such, he emphasizes open group communication as critical to the construction of the diagrams. Ishikawa diagrams are useful as systematic tools for finding, sorting out and documenting the causes of variation of quality in production and organizing mutual relationships between them. Other techniques Ishikawa has emphasized include control charts, scatter diagrams, Binomial probability paper and sampling inspection.

Turning to organizational, rather than technical contributions to quality, Ishikawa is associated with the Company-wide Quality Control movement that started in Japan in the years 1955-1960 following the visits of Deming and Juran. Under this, quality control in Japan is characterized by company-wide participation from top management to the lower-ranking employees. Further, all study statistical methods. As well as participation by the engineering, design, research and manufacturing departments, also sales, materials and clerical or management departments (such as planning, accounting, business and personnel) are involved. Quality

control concepts and methods are used for problem solving in the production process, for incoming material control and new product design control, and also for analysis to help top management decide policy, to verify policy is being carried out and for solving problems in sales, personnel, labor management and in clerical departments. Quality Control Audits, internal as well as external, form part of this activity.

To quote Ishikawa: "The results of these company-wide Quality Control activities are remarkable, not only in ensuring the quality of industrial products but also in their great contribution to the company's overall business." Thus Ishikawa sees the Company-wide Quality Control movement as implying that quality does not only mean the quality of product, but also of after sales service, quality of management, the company itself and the human being. This has the effect that:

- Product quality is improved and becomes uniform. Defects are reduced.
- Reliability of goods is improved.
- Cost is reduced.
- Quantity of production is increased, and it becomes possible to make rational production schedules.
- Wasteful work and rework are reduced.
- Technique is established and improved.
- Expenses for inspection and testing are reduced.
- Contracts between vendor and vendee are rationalized.
- The sales market is enlarged.
- Better relationships are established between departments.
- False data and reports are reduced.
- Discussions are carried out more freely and democratically.
- Meetings are operated more smoothly.
- Repairs and installation of equipment and facilities are done more rationally.
- Human relations are improved.

One major characteristic of Japanese Company-Wide Quality Control is the Quality Control Circle Movement started in 1962, with the first circle being registered with the Nippon Telegraph and Telephone Public Corporation. Starting in industry in Japan, these have now spread to banks and retailing, and been exported world-wide. Success in the West has not been so extensive as in Japan, however, although even there have been limitations too. The nature and role of quality circles varies between companies. In Japan a quality circle is a typically voluntary group of some 5-10 workers from the same workshop, who meet regularly and are led by a foreman, assistant foreman, work leader or one of the workers. The aims of the quality circle activities are:

- To contribute to the improvement and development of the enterprise,
- To respect human relations and build a happy workshop offering job satisfaction,
- To deploy human capabilities fully and draw out infinite potential.

These aims are broader than is consistent with a narrow definition of quality as often used in the West, and Circle activities reflect this. The members of the circle have mastered statistical quality control and related methods and all utilize them to achieve significant results in quality improvement, cost reduction, productivity and safety. The seven tools of quality control are taught to all employees:

- Pareto charts
- Cause and effects diagrams
- Stratification
- Check sheets
- Histograms

- Scatter diagrams
- Shewhart's control charts and graphs.

All members of the circle are continuously engaged in self-and-mutual development, control and improvement whenever possible, the circles implement solutions themselves, otherwise they put strong pressure on management to introduce them. Since management is already committed to the circles, it is ready to listen or act. Circle members receive no direct financial reward for their improvements.

The Japanese experience of quality circles itself provides an insight into the problems of implementation in the West. Strangely enough, however, many companies in the West have attempted to minimize or even cover up the Japanese origins, apparently to avoid cultural rejection on antagonism to "Japanese workaholics" grounds. Even in Japan many quality circles have collapsed, usually because of management's lack of interest or excessive intervention. However, many have worked. There are now more than 10 million circle members there. The benefits are typically seen as being minor from any one improvement introduced by a quality circle, but that added together they represent substantial improvements to the company.

Perhaps more importantly, greater worker involvement and motivation is created through:

- An atmosphere where employees are continuously looking to resolve problems,
- Greater commercial awareness
- A change of shop floor attitude in aiming for ever increasing goals.

Quality circles have been vigorously marketed in the West as a means of improving quality. There seems to be agreement, however, that they cannot be used naively, and take careful adoption for use in Western companies. Adoptions have been various and of varying effectiveness; in some companies circles have been successful, or regarded as such, in others they have failed. Many commentators, such as Philip Crosby, have warned against the fashion for quality circles as a cure-all for poor employee motivation or inadequate quality and productivity in either white-collar areas or on the shop floor. The senior American Quality Guru Joseph Juran, in particular, has gone further, in throwing doubts on their likely effectiveness in the West at all where few company hierarchies are permitted with executives trained in quality management.



Philip B. Crosby (1926 - 2001)

Philip Crosby is a particularly well-marketed and charismatic Quality Guru. An article in the Financial Times a few years ago described him thus: "Florida has provided him with a year-round tan. That, and his thinning golden hair and snappy dress give him the look of a sunbelt Senator rather than a man from the quality department. He does have a campaign button in his lapel. It says ZD, of course, for Zero Defects.' Financial Times 26 November 1986.

Crosby is a graduate of the Western Reserve University. After naval service in the Korean War, he held a variety of quality control jobs starting as line inspector. One early experience was as quality manager on the first Pershing missile program. He worked his way up within ITT and for fourteen years he was a Corporate Vice President and Director Quality of ITT, with world-wide responsibilities for quality.

In 1979 he published Quality is Free, which became a bestseller. In response to the interest shown in the book, he left ITT that year to set up Philip Crosby Associates Incorporated. At the Quality College established in Florida he started to teach organizations how to manage quality as advocated in his book. Crosby published his second bestseller, Quality Without Tears in 1984, and he is also the author of The Art of Getting Your Own Sweet Way. More recently he has published a group of three management books, Running Things, The Eternally Successful Organization and Leading: The Art of Becoming An Executive.

Crosby's name is perhaps best known in relation to the concepts of Do It Right First Time and Zero Defects. He considers traditional quality control, acceptable quality limits and waivers of sub-standard products to represent failure rather than assurance of success. Crosby therefore defines quality as conformance to the requirements which the company itself has established for its

products based directly on its customers' needs. He believes that since most companies have organizations and systems that allow (and even encourage) deviation from what is really required, manufacturing companies spend around 20% of revenues doing things wrong and doing them over again. According to Crosby this can be 35% of operating expenses for service companies. He does not believe that workers should take prime responsibility for poor quality; the reality, he says, is that you have to get management straight. In the Crosby scheme of things, management sets the tone on quality and workers follow their example; whilst employees are involved in operational difficulties and draw them to management's attention, the initiative comes from the top. What zero defect means is not that people never make mistakes, he says, but that the company does not start out expecting them to make mistakes.

As indicated earlier, not everyone agrees with this approach to quality. As Crosby himself said: "I never received any encouragement from the quality establishment. These are ideas whose time has come. This was an idea whose time had come, but it took 20 years before people realized it." In the Crosby approach the Quality Improvement message is spread by creating a core of quality specialists within the company. There is strong emphasis on the top-down approach, since he believes, without reservation, that senior management is entirely responsible for quality. His goal is to give all staff the training and the tools of quality improvement, to apply the basis precept of Prevention Management in every area. This is aided by viewing all work as a process or series of actions conducted to produce a desired result. A process model can be used to ensure clear requirements have been defined and understood by both the supplier and the customer. He also views quality improvement as an ongoing process since the word 'program' implies a temporary situation.

Crosby's Quality Improvement Process is based upon the Four Absolutes of Quality Management:

- Quality is defined as conformance to requirements, not as 'goodness' nor 'elegance'.
- The system for causing quality is prevention, not appraisal.
- The performance standard must be Zero Defects, not "that's close enough".
- The measurement of quality is the Price of Non-conformance, not indices.

The Fourteen Steps to Quality Improvement are the way that the Quality Improvement Process is implemented in an organization. They are a management tool which evolved out of a conviction that the Absolutes should be defined, understood, and communicated in a practical manner to every member of the organization:

- Make it clear that management is committed to quality.
- Form quality improvement teams with senior representatives from each department.
- Measure processes to determine where current and potential quality problems lie.
- Evaluate the cost of quality and explain its use as a management tool.
- Raise the quality awareness and personal concern of all employees.
- Take actions to correct problems identified through previous steps.
- Establish progress monitoring for the improvement process.
- Train supervisors to actively carry out their part of the quality improvement program.
- Hold a Zero Defects Day to let everyone realize that there has been a change and to reaffirm management commitment.
- Encourage individuals to establish improvement goals for themselves and their groups.
- Encourage employees to communicate to management the obstacles they face in attaining their improvement goals.
- Recognize and appreciate those who participate.
- Establish quality councils to communicate on a regular basis.
- Do it all over again to emphasize that the quality improvement program never ends.

In his book Quality is Free, Crosby identifies additional quality-building tools, including the Quality Management Maturity Grid which enables a company to measure its present quality position. In Quality Without Tears he develops the Quality Vaccine which comprises twenty one ingredients for Executives to use to support the implementation process. As his books on leadership reflected

his broadening approach to improvement, he defined five new characteristics essential to becoming an Eternally Successful Organization:

- People routinely do things right the first time.
- Change is anticipated and used to advantage.
- Growth is consistent and profitable.
- New products and services appear when needed.
- Everyone is happy to work there.

After reading relevant facts and theories of these gurus, let's try to understand how these theories mix up with ISO 9001:2000. An important observation is the following: the content of the table below is not exhaustive; there may be other concepts of these gurus not included below. However, this will not diminish the value of such concepts, nor will deny any link with ISO 9001 standard.

4.1 General requirements

DEMING: Divide every company activity into stages, identifying the customer of each stage as the next stage.

4.2.4 Control of records

JURAN: Prove that processes can produce the product under operating conditions.

5.1 Management commitment

DEMING: Major importance of top management regarding their commitment to quality.

CROSBY: Commitment of top management to quality.

5.2 Customer focus

DEMING: Concern regarding delighting the customer, rather than merely satisfying the customer.

CROSBY: Commitment of top management to quality.

5.3 Quality policy

DEMING: Create constancy of purpose (short-term reactions has to be replaced by long-term planning).

CROSBY: Commitment of top management to quality.

5.4.1 Quality objectives

DEMING: Create constancy of purpose (short-term reactions has to be replaced by long-term planning).

JURAN: Quality is not an accident, it must be planned. Establish optimal quality goals. Quality objectives are assigned to specific functions.

CROSBY: Commitment of top management to quality.

5.4.2 Quality management system planning

JURAN: Quality is not an accident, it must be planned.

5.5.2 Management representative

DEMING: Consumer is the most important part of the production line. Drive out fear so that all may work effectively for the organization.

CROSBY: Raise quality awareness and personal concerns of all employees.

5.5.3 Internal communication

CROSBY: Establish quality councils to communicate on a regular basis.

6.2 Human resources

FEIGENBAUM: Human resource is the basic issue in quality control activities.

6.2.2 Competence, awareness and training

DEMING: Institute training on the job (proper training means lower variation, meaning better products).

CROSBY: Train supervisors to actively carry out their part of the quality system improvement program.

7.2.1 Determination of requirements related to the product

JURAN: Identify customer needs.

7.3 Design and development

JURAN: Develop a product that can respond to customer needs.

TAGUCHI: Institute design of experiment, in order to produce a robust design. Design and development may reduce poor quality.

7.4.1 Purchasing control

DEMING: Move towards single suppliers (evaluate them and if they are capable, keep them).

JURAN: Create measuring systems for quality.

7.5.1 Control of production and service provision

JURAN: Develop and optimize production processes.

CROSBY: Do it right first time.

8.1 Measurement, analysis and improvement. General

FEIGENBAUM: Statistical methods are only part of the overall administrative quality control system.

8.2.3 Measuring and monitoring of processes

SHEWHART: Institute control charts.

JURAN: Create measuring systems for quality.

CROSBY: Measure processes to determine where current and potential quality problem lies.

8.2.4 Measuring and monitoring of product

SHEWHART: Institute control charts.

DEMING: Cease dependence on inspection (reduction of variation).

JURAN: Create measuring systems for quality.

ISHIKAWA: Fishbone diagrams.

CROSBY: Zero defects.

8.4 Analysis of data

SHEWHART: Institute control charts.

DEMING: Cease dependence on inspection (reduction of variation).

JURAN: Create measuring systems for quality.

CROSBY: Zero defects.

8.5.1 Continual improvement

JURAN: Continual improvement of methods should take place at each stage.

8.5.2 Corrective action

ISHIKAWA: Fishbone diagram for identifying causes of problems.

CROSBY: Take actions to correct problems.

8.5.3 Preventive action

ISHIKAWA: Fishbone diagram for identifying causes of problems.

CROSBY: Take actions to correct problems.