Background and historical significance of ISO 9000

The **"ISO,"** was taken from the Greek word *isos*, meaning equal. This name was selected by the organization because its mission is to create equal or uniform standards. The International Organization for Standardization (ISO) is a non–governmental organization located in Geneva, Switzerland. It was formed in 1947 with the mission of developing a common set of manufacturing, trade and communication standards to facilitate international trade. Countries are represented at IS0 by the national standards organizations (Table 1).

Table 1. Examples of standards organizations that belong to ISO

Canada Standards Council of Canada
France Association franqaise de normalisation
Germany Deutsches Institut fur Nomung
Mexico Direccion General de Normas
United Kingdom British Standards Institute
United States American National Standards Institute

Building a consensus over drafting and publishing of standards

A consensus process is used to develop the standards. Consensus is achieved through the voluntary involvement of all interested parties in the industrial sector in which the standard is being developed. Typically, manufacturers, suppliers, users, consumer groups, governmental agencies, and professional and research organizations are represented during the standards development process.

This process begins when countries negotiate the detailed specifications of the standard. The draft international standard (DTS) is generated and published when two-thirds of the IS0 members who have actively participated in the standard development process approve the DTS.

The International Standard is generated and published when 75% of member nations of IS0 cast a positive vote for the DTS. Voting on the standards is done by the standards organizations that are members of ISO. Each nation is allowed only one vote during the approval phase of a standard.

Evolution of ISO standards

The first version of the IS0 9000 standards was published in 1987. Just after publication of the 1987 version of the IS0 9000 series of standards, technical committee (TC) started to work to

revise the standards. The second version was published in 1994. The third revision was published on December 15, 2000 after significant changes were made in the process management structure.

IS0 9000:1987 – emphasis tended to be placed on conformance with procedures rather than the overall process of management.

ISO 9000:1994 – emphasized quality assurance via preventive actions, instead of just checking final product, and continued to require evidence of compliance with documented procedures.

ISO 9000:2000 – Deals with description approach to fundamentals of quality management system and revised vocabulary.

ISO 9001:2000 – replaced all the former standards i.e. ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994. The 2000 version sought (looked for) to make a radical change in thinking by actually placing the concept of process management. Expectations of continual process improvement and tracking customer satisfaction were made explicit (precisely and clearly expressed).

ISO 9004:2000 – Guidelines for continual improvement in quality management system.

ISO 9001:2008 – a quality management system being upgraded.

Now in order to stay in the world market, companies throughout the world, particularly US, Europe and Japan are rushing to embrace ISO 9000 quality standards. Figure 1 shows the trend of certification across the world.

PS 3000 -- Pakistani Equivalent of ISO 9000

PS 3000 is the Pakistan Standard equivalent for the ISO 9000 quality assurance standards.

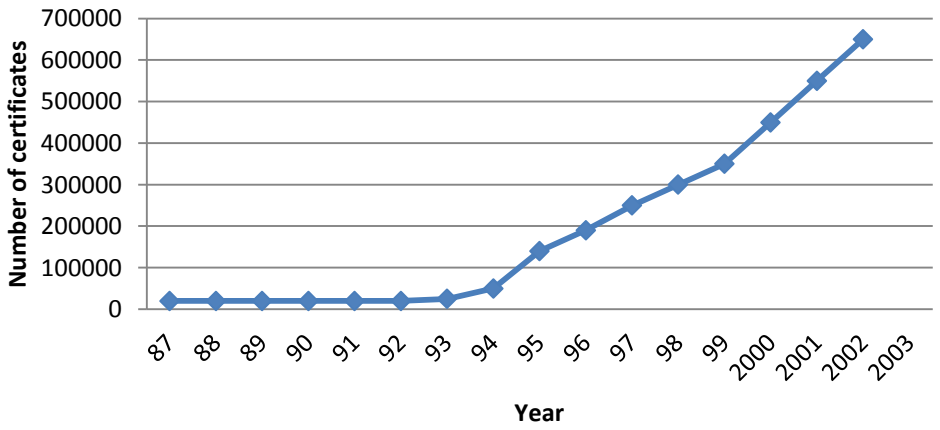

Figure 1: World–wide implementation of ISO 9000 until 2002.

Principles of ISO 9000

IS0 9004 is a guidance standard that describes the quality principles that must be addressed to increase the organization's effectiveness in meeting business goals.

These standards are based on the following principles:

1. Customer focus
2. Leadership
3. Involvement of people
4. Process approach
5. Systems approach to management
6. Continual improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relations

1. Customer Focus

A company's survival depends on its customers. Therefore, it is imperative that the company understands the customer's current and future needs. This critical information must be used to develop products and services that will not only meet the customers' needs but strive to exceed the customers' expectations. The standard requires that companies measure customer satisfaction and dissatisfaction.

2. Leadership

The IS0 9001 recognizes that executive management is responsible for establishing and maintaining the overall quality management system for a company. Leaders should create an environment that encourages people to achieve the organization's objectives.

3. Involvement of People

The company must motivate and enable all of its employees so they can reach their full potential, thus enabling the company to achieve its goals.

4. Process Approach

A process is defined as a "set of interrelated activities that transform inputs into outputs." A process model is used to define the relation of the various elements of a quality management system (Fig. 2).

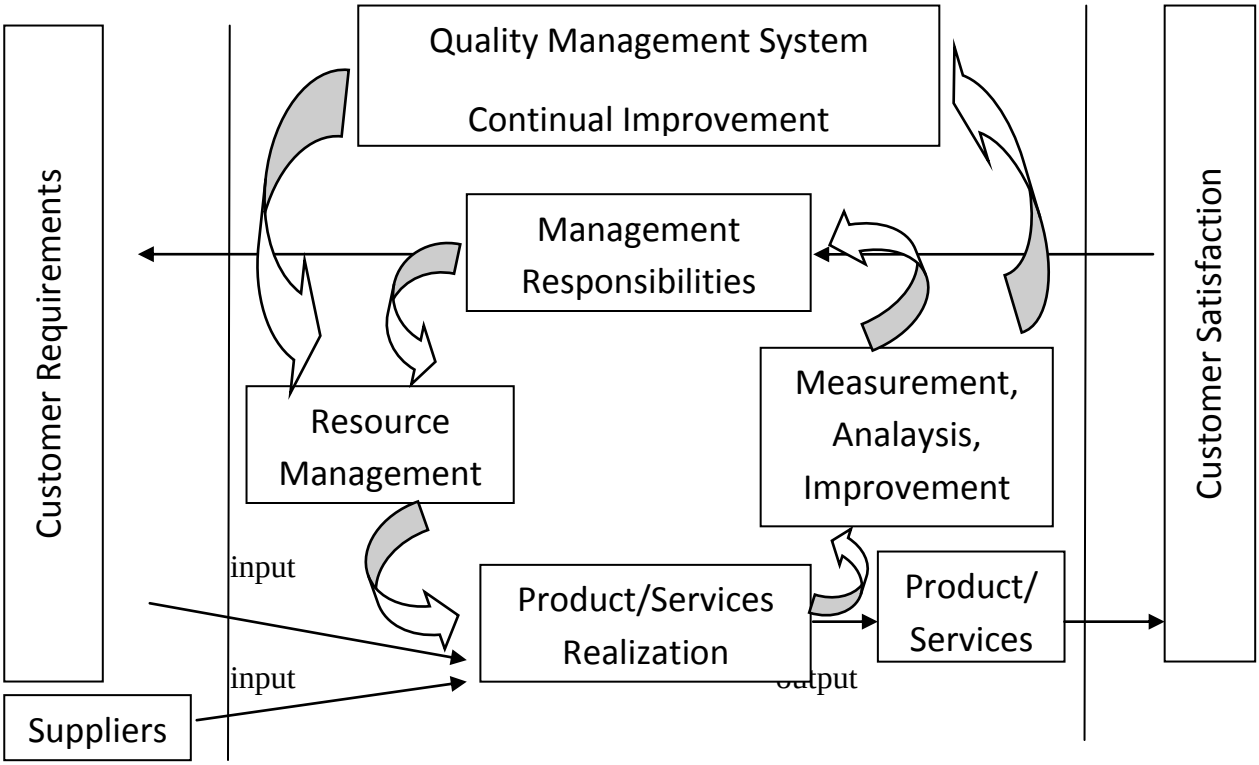

Fig. 2. Process model for various elements of a quality management system.

Various elements of a quality management system constitute structure of ISO which have been explained later after the principles of standards. The process model is also used to further define the relationship between inputs, value-added activities, information flow, procedures, measurements and outputs (Fig. 3). The inputs include materials (ingredients or components), machines, time and finances and information flow from customers. Monitoring and measurement opportunities are used to provide feedback and feed-forward information on the process and product quality.

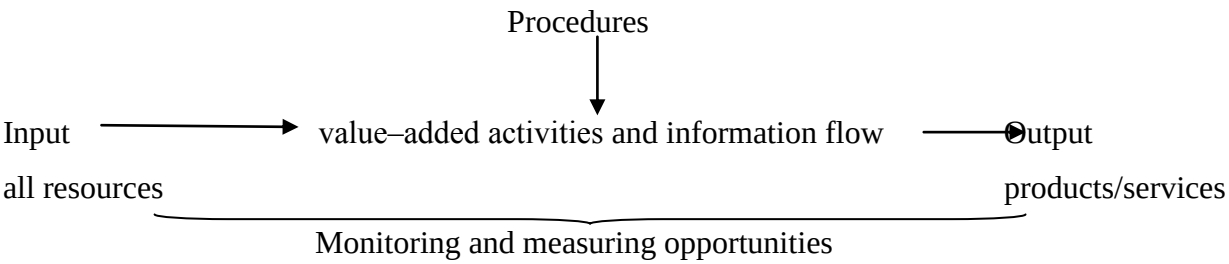

Fig. 3. Process model for the relationship between inputs, value-added activities, information flow, procedures, measurements and outputs.

5. Systems Approach for Management

The standard recognizes that processes do not operate in isolation. The output of one process usually becomes an input into another process (Fig. 4). These processes link together to form a system. Therefore, if a company is to be effective and efficient in meeting its goals, the company must manage all of the processes as a system rather than trying to manage each process individually.

Fig. 4. Processes from input to output to make a system.

6. Continual Improvement

To compete in the global marketplace companies must improve the overall efficiency and effectiveness of operations. Continual improvement is the tool that allows this to take place. It has the following forms:

- Technological breakthroughs
- Incremental improvements (improvements over time)

The word continual improvement was preferred by W. Edwards Deming and refers to interval of interruption (discontinuous). Companies should incorporate a plan-do-check-act cycle (PDCA or PDSA cycle) into management of the continual improvement process. In continual improvement, organization goes through process improvements in stages and these stages are separated by a period of time. This period of time may be necessary to understand if the improvement did actually happen or not.

Incremental improvements, also known as continuous improvement, include corrective and preventive actions. In this way, continuous improvement is a subset of continual improvement. It refers to duration without interruption. It involves a focus on linear or incremental improvement within existing processes.

Corrective actions provide a tool to assist a company in correcting known or identified problems. An effective corrective action program is designed not only to contain the existing problem but also to determine the root cause of the problem so that appropriate action can be taken to prevent reoccurrence.

Preventive actions are to be taken when the company identifies potential problems. Sources of information that can help the preventive action process include:

- customer response information including, complaints
- market analysis
- analysis of process and operational data and
- audit results

Statistical techniques can help the company evaluate these data.

7. Factual Approach to Decision Making

Facts rather than assumptions are used as the basis for making decisions. This requires the monitoring and measurement process. The objective is to use data to generate information and knowledge to make appropriate decisions. To properly control processes, companies must identify the following:

- key product or process characteristics
- sampling plans (which include targets, specifications, frequency of sampling)
- measurement methods
- analysis plan and
- action plan

The measurement process is not just limited to manufacturing. The company must measure other parameters such as customer satisfaction and effectiveness and efficiency of critical processes.

8. Mutually Beneficial Supplier Relations

Companies within the supply chain are interdependent and should actively work together to meet customer needs and ultimately exceed customer expectations.

Elements of a quality management system (or process management structure of ISO)

Following are the elements of a quality management system or process management structure of ISO:

1. Scope
2. Normative Reference
3. Terms and Conditions
4. Quality Management System
5. Management Responsibility
6. Resource Management

7. Product Realization
8. Measurement, Analysis and Improvement

1. Scope

1.1. General

This International Standard specifies requirements for a quality management system where an organisation aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements (legal requirements).

1.2. Application

All requirement of this international Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

2. Normative references

The previous documents are indispensable (essential or obligatory) for the application of the current document.

3. Terms and definitions

For the purpose of the current document, the terms and definitions given in ISO 9000:1994 (or any previous standard) are applied.

4. Quality management system

4.1. General requirements

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

4.2. Documentation requirements

4.2.1. General

The extent of the quality management system documentation can differ from one organization to another due to:

a) the size of organization and type of activities,
b) the complexity of processes and their interactions, and

4.2.2. Quality Manual

The organization shall establish and maintain a quality manual that includes

a) the documented procedures established for the quality management system, or reference to them and

b) a description of the interaction between the processes of the quality management system.

4.2.3. Control of documents

Documents required by the quality management system shall be controlled. A documented procedure shall be established

a) to ensure that relevant versions of applicable documents are available at points of use,

b) to ensure that documents remain legible (capable to read) and readily identifiable

4.2.4. Control of records

Records established to provide evidence of conformity to requirements shall remain legible, readily identifiable and retrievable (to bring back again, to regain or save).

5. Management responsibility

5.1. Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) establishing the quality policy,

b) ensuring that quality objectives are established and c) ensuring the availability of resources

5.2. Customer focus

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

5.3. Quality policy

Top management shall ensure that the quality policy provides a framework for establishing and reviewing quality objectives.

5.4. Planning

5.4.1. Quality objectives

Top management shall ensure that quality objectives, including those needed to meet the requirements for product are established.

5.4.2. Quality management system planning

Top management shall ensure that the planning of the quality management system is carried out in order to meet the requirements.

5.5. Responsibility, authority and communication

5.5.1. Responsibility and authority

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

5.5.2. Internal communication

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

5.6. Management review

5.6.1. General

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

5.6.2. Review input

The input to management review shall include information on:

a) results of audits (inspection of the audit procedures and records by a trained accountant),

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow-up actions from previous management reviews,

f) recommendations for improvement

5.6.3. Review output

The output from the management review shall include any decisions and actions related to:

a) improvement of the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements

6. Resource management

6.1. Provision of resources

The organization shall determine and provide the resources needed to enhance customer satisfaction by meeting customer requirements.

6.2. Human resources

6.2.1. General

Personnel shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2. Competence, training and awareness

Ensure that its personnel are aware of the relevance and importance of their activities and competent and trained to contribute to the achievement of the quality objectives.

6.3. Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

a) buildings, workspace and associated utilities,

b) processing equipments and

c) supporting services (such as transport, communication or information systems).

6.4. Work environment

The organization shall determine and manage the work environment (such as noise, temperature, humidity, lighting or weather) needed to achieve conformity to product requirements.

7. Product realization

7.1. Planning of product realization

The organization shall plan and develop the processes needed for product realization.

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes and documents, and to provide resources specific to the product;

c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements.

7.2. Customer - related processes

7.2.1. Determination of requirements related to the product

The organization shall determine:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities and

b) statutory and regulatory requirements applicable to the product

7.2.2. Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer.

7.2.3. Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,

b) customer feedback, including customer complaints.

7.3. Design and development

7.3.1. Design and development planning

The organization shall plan the design and development of product.

7.3.2. Design and development inputs

These inputs shall include

a) functional and performance requirements,

b) applicable statutory and regulatory requirements and

c) information derived from previous similar designs

7.3.3. Design and development outputs

Design and development outputs shall meet the input requirements for design and development ,

7.3.4. Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions

7.3.5. Design and development verification

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

7.3.6. Design and development validation

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

7.3.7. Control of design and development changes

Design and development changes shall be identified and records maintained.

7.4. Purchasing

7.4.1. Purchasing process

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

7.4.2. Purchasing information

Purchasing information shall describe the product to be purchased.

7.4.3. Verification of purchased product

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

7.5. Production and service provision

7.5.1. Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions.

7.5.2. Validation of processes for production and service provision

Validation shall demonstrate the ability of these processes to achieve planned results.

7.5.3. Identification and traceability

The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records.

7.5.4. Customer property

The organization shall exercise care with customer property (include intellectual property and personal data of a customer), provided for use or incorporation into the product. The organization shall identify, verify, protect and safeguard. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records.

7.5.5. Preservation of product

The organization shall preserve the product during internal processing.

7.6. Control of monitoring and measuring equipment

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified, or both, at specified intervals, or prior to use.

b) be adjusted or re-adjusted as necessary

c) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to confirm to requirements. Records of the results of calibration and verification shall be maintained.

8. Measurement, analysis and improvement (for product conformity and improvement)

8.1. General

The organization shall plan and implement the monitoring, analysis and improvement processes needed

8.2. Monitoring and measurement

8.2.1. Customer satisfaction

The organization shall monitor information relating to customer perception which may include obtaining input from sources such as customer satisfaction surveys, user opinion surveys, lost business analysis, warranty claims and dealer reports.

8.2.2. Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system is effectively implemented and maintained or not.

An audit is a documented procedure for establishing records and reporting results.

8.2.3. Monitoring and measurement of processes

Monitoring and measurement of processes shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

8.2.4. Monitoring and measurement of product

The release of product and delivery of service to the customer shall not proceed until the organization monitored and measured the characteristics of the product to verify that product requirements have been met.

8.3. Control of non-conforming product

The organization shall deal with nonconforming product by taking action to eliminate the detected nonconformity. Records of the nature of the nonconformities and any subsequent actions taken, shall be maintained.

8.4. Analysis of data

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made.

8.5. Improvement

8.5.1. Continual improvement

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

8.5.2. Corrective action

The organization shall take action (e.g. procedures or methods) to eliminate the causes of nonconformities in order to prevent recurrence.

8.5.3. Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.

Documentation

Documentation is a two-edged sword. It can benefit a company that has a well–designed, properly functioning quality management system. The 2000 version of IS0 9001 has a decreased emphasis on documentation as a means to achieve the quality requirements.

The standard only requires the following six documented procedures:

- Control of documents
- Internal audit
- Control of nonconforming product
- Corrective action
- Preventive action
- Control of records

In addition, there are requirements that ensure that all records be controlled and retained for a specified amount of time. To achieve the requirements of the standard, most companies use a three-tier system to document the processes. This system is supported by a fourth layer that consists of various quality records (Fig. 5). The whole system is based on sales, design, purchasing, manufacturing, accounts, personnel and after sale.

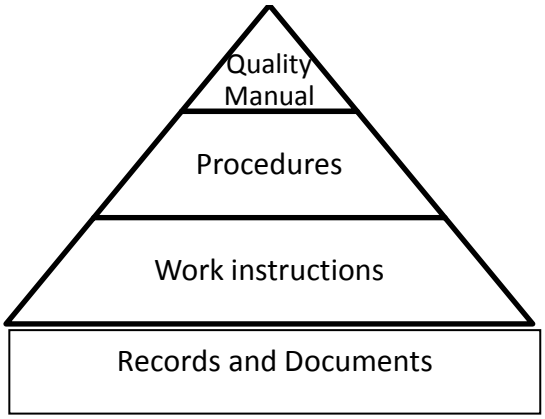

Fig. 5. Three-tier system, along with fourth layer consisting of various quality records, to document the processes.

The first tier is the quality manual. All organizations have in mind some principles, beliefs which are their broad guides to managerial conduct. The quality manual serves as a master document and defines the company's philosophy to achieve stated customer requirements. It also defines how the company will achieve the elements of IS0 9001. An international standard (IS0 10013-1995) provides guidelines for developing quality manuals (Table 2). The next level of

documentation is the procedures. Procedures provide a means to control critical activities for an individual department or for inter–departmental activities.

Table 2. Suggested Organization of a Quality Manual as Defined by IS0 10013-1995

Title, scope, field or application
Table of contents
Introduction about manual and organization
Quality policy and objectives of the organization
Description of the elements of the quality system-References to documented procedures
Optional Sections
Definitions
Guide to quality manual-Tells what is where in the manual
Appendix of supportive material

The third tier of the documentation system is the work instructions to control tasks. Work instructions provide the step-by-step activities that must be carried out so an individual can perform a specific job. The entire documentation system is supported by quality records and other documents. Examples of these documents that must be controlled include production records, specifications, drawings, recipes, formulas, regulations and standards. These documents are subject to periodic revision and employees must be able to reference the latest edition.

Implementing the Quality Management System

Typically, senior management will appoint an implementation team to manage the project on a day-to-day basis. This team must develop an understanding of the standard and the basic principles of quality management. Once the training is completed, the team should develop a systematic understanding of the company's existing manufacturing practices and control procedures. This can be done by flow diagramming the processes from purchasing through sales and servicing and then documenting those processes. Once the quality management system has been completely documented and implemented, the company can then allocate resources to fine-tune the system and to eliminate the root causes of the problems.

Certification, Registration and Accreditation

Obtaining IS0 9001 certification is a voluntary process. There is some confusion over these three terms as they are used as part of the IS0 9001 registration process. Part of the confusion stems from how various countries interpret the terms certification and registration.

Before starting to explain the certification to ISO 9000 standards, one should understand the differences between 'first party assessment', second party assessment' and ' third party assessment are as follows :

- First party assessment (also called self-assessment) is performed by an organization to evaluate the adequacy of its own quality system and compliance with a standard such as ISO 9001.
- Second party assessment is performed by customers to examine the quality system of their suppliers.

However, second party assessment is expensive and time consuming for both parties (customers and suppliers), and this is why third party assessment and certification systems have been developed in order to reduce the need for multiple assessments and to provide impartial expertise as and when needed.

- Third party assessment is conducted by a body which is not party to any contractual (legal agreement) relationships between customers and suppliers.

Certification bodies of quality systems provide confirmation that a supplier's quality system satisfies ISO 9000 applicable standard, or equivalent. The purpose of such certification is to give assurance that the supplier is capable of supplying products or services against appropriate standards.

Internationally, certification is a process of awarding a document that states that an organization has met certain requirements. For example, if a registrar determines that a company's quality management system meets or exceeds the requirements of IS0 9001, the registrar will issue a certificate that testifies to this fact.

Internationally, registration is the process of listing the certified company in a public registry. For example, after a company has been certified to either IS0 9001, the registrar will then list the company in a public registry with the scope of the certification, address and contact person.

Accreditation is a process by which an authoritative body gives formal recognition that an organization can perform certain tasks. For example, the Registration Accreditation Board

(RAB), in the U.S. gives formal recognition that a registrar has met certain minimal requirements. There are numerous authoritative bodies around the world with respect to IS0 9001 certification. These include Dutch Council for Accreditation or *(Ruud **WOY** Accreditiutie,* RvA) in The Netherlands and the United Kingdom Accreditation Systems (UKAS) in Great Britain.

ISO certification process

The certification process involves a complete review and evaluation of the supplier's (manufacturers) quality system. The process includes an initial visit (also called pre- assessment visit) made by the certification body to learn about the supplier's operations. Supplier's documentation is reviewed for compliance with the applicable requirements of the ISO 9000 standard. Deviations from the standard (Called nonconformance) must be corrected by the supplier before the formal assessment is scheduled. The third party auditors verify by objective evidence that the supplier implements his own procedures, and that the procedures conform to the intent of the requirements of ISO 9000 standards. If the results of the assessment are satisfactory, the supplier will be granted the certificate. The certificate is usually valid for three years.

Companies whose quality systems are certified to ISO 9000 standard will be subjected to periodic follow up audits by the third party (called surveillance visits) to ensure that their quality system is continuing to function effectively. Surveillance visits are usually conducted every six months.

Whom to approach for certification in Pakistan?

Pakistan Standards Institute (PSI), which is Principal Body for Maintaining ISO Standards in Pakistan, is under the administrative control of Ministry of Science and Technology, and is entrusted with the responsibility of procuring and selling those standards of ISO. In the absence of any registrar accredited to our own national standards body (PSI), Pakistani companies are left with no choice and are forced to approach foreign accredited registrars for their certification or only to those in-country "pre-assessment auditors" who are accredited to those foreign registrars. In addition there are only a few auditors in Pakistan who could even help companies "self-certify" themselves.

Controlling and regulation of ISO 9000 activities in Pakistan

It is the main responsibility of the PSI to come up with a concrete solution to help save those Pakistan companies who cannot afford costly third party foreign-accredited certifications but still want to compete with ISO 9000 certified companies.

Role for the Pakistan Engineering Council (PEC)

The PEC can also generate their own programs to help in:

1. Promoting the concept of self certification.

2. Helping smaller companies develop quality systems for certification.

3. Funding the training sessions for independent auditors who can self certify small companies at nominal charges.

4. Approach PSI to enact and accept self certification of companies, at least for in-country trade practices.

Benefits of Implementing IS0 9001

Many companies have listed a number of benefits from IS0 9001 registration, which include:

- Staying in business
- Expanding into new markets such as international markets
- Using a recognized quality logo as a marketing tool
- Increasing customer satisfaction
- Improving production
- Increasing quality to customers

In addition, several surveys have indicated that most companies save money by implementing a quality management system.

Benefits of HACCP

- Pro-active system for assuring safe production of foods
- Emphasizes prevention rather than inspection
- Addresses all types of Hazards-Microbiological, Physical and Chemical
- Reduces contamination
- Reduces recall/product destruction

IS0 9001 and HACCP

It is recommended that food processors do not combine their IS0 9001 quality management system with their HACCP system. These two systems have two different objectives. HACCP is a food safety management system that is designed to ensure the safe production of food. The IS0 9001 quality system is designed to meet customer requirements. Both systems may have some shared components.