ISO 900O

“QUALITY MANAGEMENT SYSTEM”

The ISO 9000, a well-known and widely accepted **Quality Management System**, is a series of **standards** developed by the **International Organization for Standardization (ISO)** in Geneva, Switzerland**.**

There are **five standards** in the **ISO 9000** Series, such as ----

(i) **ISO 9000 :** It is the contour map furnishing the guidelines for selection and use of ISO series standards.

(ii) **ISO 9001 :** Model for quality assurance in design/development, production, installation and servicing.

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(iii) **ISO 9002 :** Model for quality assurance in production and installation.

(iv) **ISO 9003 :** Model for quality assurance in final inspection and test.

(v) **ISO 9004 :** Quality management and quality system elements – Guidelines.

NEED FOR ISO 9000 CERTIFICATION :

(I) **Customers,** all over the world, like to have confidence in manufacturer's capability to design, develop, produce and service. **Competition** is forcing industries to get **ISO 9000 certification**.

(II) It is the only credibility passport which certifies that a company meets international standards in designing, developing, producing, installing and servicing the products it supplies.

(III) The time has already come, when an industry will not be able to export to World markets without **ISO 9000 certification**.

(IV) **ISO 9000** is based on the philosophy that an integrated, systematic and planned approach only can ensure quality.

BENEFITS OF ISO 9000 CERTIFICATION:

There are manifolds benefits, direct as well as indirect, resulting from **ISO 9000 Quality System Standards**. Some of them are given below.

(1) It provides a competitive edge in the domestic and global markets.

(2) It provides a climate for consistent improvement in quality.

(3) **ISO 9000** reduces wastes and repairs – enhancing profits in turn.

(4) It maintains streamlined records.

(5) It maintains streamlined material handling and storage.

(6) It changes the attitude of workforce, the result is – improved house keeping, work atmosphere and quality awareness.

(7) Process of quality improvement is maintained.

(8) Products right in the first instance, no rework and nothing for recertification.

(9) **ISO 9000** gives international recognition of ability, credibility and expertise, thereby increasing the number of customers.

(10) Supplier without ISO certification can face higher insurance rates, or, be denied insurance in some markets.

LIMITATIONS OF ISO 9000 :

(1) Implementation of this system is very demanding of resources.

(2) Assessment and registration are expensive.

(3) Work-Culture need to be changed or improved.

(4) Upgrading of manufacturing and test facilities is essential.

(5) Unless carefully planned, the system can become non cost effective.

(6) Dedication, will to improve and constant improvement are must for success.

THE QALITY NOTION (AN IDEA OR UNDERSTANDING):

Quality is the conformance to requirement or specification. It is the fitness for the purpose. In other words if a product serves your purpose well, it can be called of good quality. Quality is what the customer wants. According to ISO 8402 (1986), Quality is defined as the totality of features and characteristics of product or service, in conformance with customer's stated or implied needs. Needs may include safety, reliability, maintainability, economics etc. The quality should not be confined to product quality alone, rather quality should mean – to be quality of the system. Quality cannot be inspected into a product, it has to be manufactured along it. The concept of quality as an inspection function is obsolete now, it is perceived to be a process control function.

QUALITY CONTROL :

The operational techniques and activities that are used to fulfill requirements for quality is **Quality Control**. It aimed both at monitoring a process and at eliminating causes of unsatisfactory performance at relevant stages of the quality loop (Quality spiral) in order to result in economic effectiveness.

There are two main aspects of Quality control :

(i) Make things right first time. In other words, production should be defect free.

(ii) Work for continual improvement in quality.

QUALITY POLICY :

The overall quality intentions and direction of an organization as regards quality, as formally expressed by top management. Quality policy shall be consistent with Company's policy and top-management must ensure that its corporate quality-policy is clearly understood, implemented and maintained. This will ensure the degree of commitment of top-management to quality.

QUALITY MANAGEMENT :

It is the aspect of the overall management function that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources and other systemic activities for quality, such as quality planning, operations and evaluations.

QUALITY SYSTEM :

Quality system is defined as the organizational structure, responsibilities, procedures, processes and resources for implementing quality management. It is the system which is needed to meet the quality objectives of the organization.

BENEFITS OF QUALITY SYSTEM :

(1) Quality performance is institutionalized.

(2) Efficient tool to achieve and ensure consistent quality improvement.

(3) Reduces wastes and time consuming reworks and repairs – increasing profits in turn.

(4) Saves money as quality system ensures efficient and sound procedures.

(5) Provides a competitive edge in domestic as well as global market.

(6) Brings confidence to the consumer.

QUALITY OBJECTIVE :

(1) The organization should achieve and sustain the quality of the product so as to meet continually the purchaser's stated or implied needs.

(2) The organization should provide confidence to its own management that the intended quality is being achieved and sustained.

(3) The organization should provide confidence to the purchaser that the intended quality is being, or will be, achieved in the delivered product or service or service provided. When contractually required, this provision of confidence may involve agreed demonstration requirements.

TOTAL QUALITY ELEMENTS OR INGREDIENTS :

There are **four** basic elements of total quality operation :

a) Quality awareness.

b) Management Attitude.

c) Tools and Techniques of Process Management.

d) Quality System Standards.

ELEMENTS OF QUALITY SYSTEMS :

In the operation of Quality System, the following elements have essentially to be taken care of :

1. Management Responsibility.

2. Quality System.

3. Contract Review.

4. Design Control.

5. Document Control.

6. Purchasing.

7. Purchase – Supplier Product.

8. Product Identification and Traceability

9. Process Control.

10. Inspection and Testing.

11. Inspection, Measuring and Test Equipment.

12. Inspection and Test Status.

13. Control of Non – Conformity Product.

14. Corrective Action.

15. Handling, Storage, Packing and Delivery.

16. Quality Records.

17. Internal Quality Audits.

18. Training.

19. Servicing.

20. Statistical Techniques.

CHARATERISTICS OF ISO 9000 :

(i) **ISO 9000** can be implemented in any type and size organization.

(ii) It is independent of the product, size and country.

(iii) It has international acceptance and recognition.

(iv) It ensures consistent improvement in quality.

EQUIVALENT OF ISO 9000 SERIES TO CORRESPONDING IS STANDARDS :

Sl. No.	International Standard	Corresponding Indian Standard
01	**ISO 8402 : 1986** Quality - Vocabulary	**IS 13999 : 1988** Quality Systems – Vocabulary (identical)
02	**ISO 9000 : 1987** Quality management and quality assurance standards – Guidelines for selection and use.	**ISO 14000 : 1988** Quality systems – Guide lines for selection and use of standards on quality systems (identical).
03	**ISO 9001 : 1987** Quality	**IS 14001 : 1988** Quality systems – Model

	systems – Model for quality assurance in design/development, production, installation and servicing.	for quality assurance in design/development, production, installation and servicing (identical).
04	**ISO 9002 : 1987** Quality systems – Model for quality assurance in production and installation.	**IS 14002 : 1988** Quality systems – Model for quality assurance in design/development, production, installation and servicing (identical(.
05	**ISO 9003 : 1987** Quality systems – Model for quality assurance in final inspection and test.	**ISO 14003 : 1988** Quality systems – Model for quality assurance in final inspection and test (identical).
06	**ISO 9004 : 1987** Quality management and quality system elements – Guide lines.	**ISO 14004 : 1989** Quality systems – Guide lines on elements of quality management system (second revision) (Technically equivalent).

PREREQUISITES FOR IMPLEMENTING ISO 9000 QUALITY SYSTEM :

For effectively implementing ISO 9000 Quality systems, any organization must the following requirements :

1. Development of Quality Awareness.

2. Imparting Education and Training to Employees.

The education and training program for employees should be structured for three levels on the lines of **ISO 9004**, as given bolow:

(a) Training for executives and managerial personnel.
(b) Training for technical personnel.
(c) Training to work – force (shop floor) and production supervisors.

3. Introduction of Motivation and Incentive Programs.

4. Development of Measuring Equipments Laboratory.

5. Development of Planning Scheme for Implementation.

6. Above all, to have firm commitment of top management to fully support the Quality system with a strong will a strong will and faith to make it success.

CORRECTIVE ACTION : (As per ISO 9000 and ISO 9004)

The implementation of corrective action begins with the detection of a quality problem (e.g. materials, components or products non-conforming to quality standards) and involves taking measures to eliminate or minimize the recurrence of such a problem.

The supplier shall establish, document and maintain procedures for ---

a) Investigating the cause of non conforming product and the corrective action needed to prevent recurrence.

b) Analyzing all processes, work operations, quality records, service reports and customer complaints to detect and eliminate potential causes of non-conforming product.

c) Initiating preventive actions to deal with problems to a level corresponding to the risks encountered.

d) Applying controls to ensure that corrective actions are taken and they are effective.

e) Implementing and recording changes in procedures resulting from corrective action.

QUALITY PLANNING (ISO 90030& 9004) :

It is a written document which must be read and understood by every body from top to bottom in the organization before implementing quality systems. It is consistent with all other requirements of a company's quality management system.

Quality Plan should Define:

- The quality objectives to be attained.
- The specific allocation of responsibilities.
- The specific procedures, methods and work instructions to be applied.
- Suitable testing, inspection, examination and audit programmes at appropriate stages (for example, design, development)
- A method for changes and modification in a quality plan as projects proceed.
- Other measures necessary to meet objectives.

PROCEDURE FOR CORRECTIVE ACTION:

(1) The responsibility and authority for instituting corrective action should be defined as part of the quality system.

(2) The significance of a problem affecting quality should be evaluated in terms of its potential impact on production costs, quality costs, safety, reliability etc.

(3) Investigation of possible causes (cause and effect relationship) resulting in non-conforming products should be carried out.

(4) Analysis of problem to determine root cause should be done before planning preventive measures.

(5) In order to prevent a future recurrence of a non conformity, it may be necessary to change a manufacturing process, packaging, storage process, product specification etc.

(6) When the preventive measures are implemented, their effect should be monitored in order to ensure that desired goals are met.

(7) For work-in-process, remedial action should be instituted as soon as practicable in order to limit the cost of repair, reworking or scrapping. Recall finished goods not conforming to quality standards.

(8) Permanent changes resulting from corrective action should be recorded in work instructions, product specifications or the quality system.

INSTALLATION PROCEDURE OF ISO 9000 QUALITY SYSTEM :

ISO 9000 Quality system is just a model that stipulates certain time honoured quality management practices as guide lines and minimum requirements. Therefore every organization, today, is bent upon installing ISO 9000 Quality system. This system can be installed in several stages, that have to be sequentially undertaken. The time involved in installation depends upon the size and complexity of the organization.

The basic steps to be followed for **ISO 9000 certification** are given below:

(1) Quality Awareness training.

(2) Form task force.

- ***Strategic :*** Management – Quality Policy/Quality Manual.
- **Tactic :** Departmental Heads – Quality Procedures.
- **Operational :** Supervisors – Work Instructions/Drawings.

(3) Analyze existing practices and corrective action.

(4) Design and develop standards procedures.

(5) Prepare Documentation.

- **Quality Manual.**
- **Quality Procedures.**
- **Work Instructions.**

(6) Implement the Quality System

(7) Quality Auditing.

(8) Preliminary Audit by Third Party.

(9) Apply for Accreditation.

(10) Maintain the System.

QUALITY MANUAL :

Quality Manual is the typical form of the main document used in drawing up and implementing a quality system. The primary purpose of a Quality Manual is to provide an adequate description of the quality management system while serving as a permanent reference for implementation and maintenance of that system. Procedures should be laid down for making changes, modifications, revisions or additions to the contents of a quality manual. In large companies, the documentation relating to the quality management system may take various forms, such as:

a) Corporate Quality Manual.

b) Divisional Quality Manuals, and

c) Specialised quality manuals (for example, design, procurement, project, work instructions).

In brief, a **Quality Manual** includes the following:-

- The Quality Policy of the company;
- Organizational structure of the quality assurance department;
- Job description of the quality assurance personnels;
- Relationship of the quality control department with other departments;
- Quality control/inspection procedures and documentation (with a copy of every form in use).

QUALITY PROCEDURES:

It instructs the workforce how the quality objectives mentioned in the quality manual can be obtained. Procedures document inter-documental activities, detailing the working and interaction of different sections of the company, for fulfilling the requirements of quality.

The procedures specify what has to be done, by whom, when, where and how will it be done. A common format and a suitable numbering system has to be devised for all procedures. This enables easy identification of individual sections and individual procedures in each section.

WORK INSTRUCTIONS:

Work instructions deal with a lower level of activities than the **quality procedures**. While procedures describe who does what, work instructions give specific information about the standards of quality to be achieved. The instructions include what has to be done, the proper sequence of work stages, the materials and equipments to be used, the environmental conditions to be maintained, reference/standards to be adhered to and instructions for special processes, if any, like welding, annealing, soldering etc. the instructions also include the recordings, product/process affected, issue and control and authorization of the concerned signatories.

QUALITY AUDITING (ISO 9004 : 1987) :

It is independent and objective evaluation of the out going product level, as it would be measured and judged from the view point of the customer, whether that customer be the ultimate user, a dealer, the next department or another plant.

Quality Audits may be of the following types :

(1) Internal Audits.

(2) Customer audits.

(3) Independent third party audits.

An appropriate audit plan should be formulated and established to achieve the stated quality objectives. **Audit Plan format** should cover the following:

a) Specific activities and areas to be audited.

b) Suitability of personnel carrying out audits.

c) The basis for carrying out audits (for example, organizational changes, reported deficiencies, routine checks and surveys).

THIRD PARTY AUDIT:

A third/external party assessment is carried out by an independent body to establish the extent to which an organization meets the requirements of an applicable standards or set of regulations.

Third party can assess an organization against any quality standard but the concentration here is given on ISO 9000 : 1987 against which assessment can be made. It is an independent audit body which would normally issue a ***certificate of registration***, indicating acceptance of the organization as ***A Company of Assessed Capability*** i.e., witness to the world that this assessed organization complies with all the requirements of ISO quality standards.

ACCREDITATION :

The next step for the organization is to apply for accreditation.

- The **National Accreditation Council for Certification Bodies (NACCB)** funded by **Department of Trade and Industry (DTI)** is responsible for the accreditation and supervision of ***Certification Bodies*** in U.K. an accredited certification body issues the ***Crown and Tick logo*** only after certification within its accredited scope. Some bodies have accreditation in a wide range of activities and they assess organizations to ISO standards.

- After, an assessment by an independent audit body is successfully concluded, the ***certification body*** will issue a certificate, attached to which is a definition of the scope of activities which have been assessed.

- A few ***Accredited Certification Bodies*** are as follows:-

  (a) ASTA Certification Services, Prudential Chambers, 23/24 Market Place, Rugby CV 21 3 DT.

  (b) Lloyd's Register Quality Assurance Limited, Norfolk house, Wellesley Road, Croydom CR 9 2 DT.

  (c) Bureau Veritas Quality International Limited, 3rd floor, 70 Borough High Street, London SE1 1XF.

- Certification bodies carry out assessment in accordance with documented procedures. Most of the certification bodies are always prepared to issue copies carrying informations regarding registration.

MAINTAIN THE SYSTEM :

- ✓ The Quality system is to be reviewed periodically by the ***management***, by performing ***internal audits*** and taking corrective actions where necessary based on audit reports, thus streamlining the system.

- ✓ The ***Certification body*** also maintains some system of monitoring to ensure continued compliance with the standard.

Monitoring the quality system needs to have a system of regular, unannounced audits, reassessment at regular intervals, etc.

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