International Organization for Standardization

ISO 9000 Quality Management

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO 9000)

- ISO 9001 **is an international** quality management **standard. It** is **rapidly becoming the most popular quality standard in the** world**. Thousands of** organizations **in over** 100 countries **have adopted it, and many more are in the process of doing** so**. Why?**

  - **Because it controls** quality.
  - **It saves money.**
  - **Customers expect it and competitors use it.**

- ISO is not an acronym. It is derived from the Greek word **isos,** meaning equal.

- ISO is only responsible for creating and publishing international standards.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO 9000)

- The ISO 9000 series is a set of related international standards on **quality management and quality assurance.**
- They are **generic**, not specific to any particular products.

ISO 9000 Standards

- The term ISO 9000 unfortunately has two different meanings: it refers to a single standard (ISO 9000) and it refers to a set of three standards (ISO 9000, ISO 9001, and ISO 9004). All three are referred to as quality management system standards.

Standards in the ISO 9000 family include:

- **ISO 9000** - covers the definitions and terminology and is used to clarify the concepts.
- **ISO 9001** - sets out the requirements of a quality management system and is often used for certification purposes.
- **ISO 9004** –**set of guidelines** and is used to achieve sustained success. Focuses on how to make a quality management system more efficient and effective

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO 9000)

ISO is a network of the national standards institutes of 170 countries on the basis of one member per country, founded on 1947 with a Central Secretariat in Geneva, Switzerland, that coordinates the system.

ISO 9000 Quality Management Family

ISO 9000

Fundamentals and vocabulary for QMS

ISO 9004

Guidelines for QMS

ISO 9001

Requirements for establishing & maintaining QMS

"ISO 14000" Environmental management

"ISO 50001" Energy management

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO 9000) DEFINITIONS According to ISO 9000:2000

- **Quality** is "Degree to which a set of inherent (existing) characteristics fulfils requirements.“

- **Quality improvement** is "Part of quality management focused on increasing the ability to fulfill quality requirements.

- **Quality Planning** is "art of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfill quality objectives.“

- **Continual improvements** is a recurring activity to increase the ability to fulfill requirements. It is often described by a PLAN-DO-CHECK-ACT Cycle (PDCA)

- **Process approach**: A process is using resources to transform inputs into outputs. An organization can function more effectively if it identifies its processes and manages them accordingly.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO 9000) DEFINITIONS According to ISO 9000:2000

- **Supplier** is "a organization or person that provides a Product". Product can be a physical as well as a service. More and more businesses make use of outsourcing meaning that they make use of **suppliers** where they had previously provided the products internally. This is done in order to focus more on the core business processes.

- C**ustomer** is "an organization or person that receives a Product". Product can be a physical as well as a service. **Customers** are the source of incomer for any business. There demand has to be satisfied, so that they continue buying products from the company. **Customers** determine the Requirements. Because of their importance Customer focus is one of the Quality principles of ISO 9000:2000.
- ***Also called consumer, client, end-user, retailer, buyer, beneficiary, receiver or purchaser***

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO 9000)

Approach to ISO 9000

- ISO 9000 provides a starting place for quality efforts. The standards merely stipulate where organizations need documentation to validate processes and approaches but never dictate how much they require.

- ISO 9000 is **not a product registration standard;** it in *no way measures or recognizes the quality of a company's product, nor does it mean that two companies with ISO 9000 registrations are equivalent.*

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO 9000)

ISO 9000 requires:

1. Management that is committed, involved, focused and responsive.

2. People who are organized, responsible, authorized, competent, empowered and knowledgeable.

3. Processes those are visible, traceable, consistent, repeatable, measurable and documentable.

4. Documents those are appropriate, relevant, simple, understandable and consistent with processes in use.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO 9000)

The ISO 9000 standards basically have three requirements.

- First, the company must document the quality system and business process in detail.
- Second, the company must make sure each employee understands and follows the guidelines put forth by the documentation.
- Third, the documented quality system must be constantly monitored through internal and external audits, and changed or updated when necessary.

What Organizations can benefit from ISO 9000?

- The ISO 9000 2000 Standards apply to all kinds of organizations whether they are businesses, non-profit-organizations, educational or governmental organizations.

- These organizations can be active in all kinds of areas.

- Some of these areas include accounting, aerospace, agriculture, aviation, banking, biotechnology, catering , chemicals, coaching, communications, computing, construction, consulting, consumer products, design, drilling, education, electronics, energy, engineering, entertainment etc.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO 9000)

Quality Policy.

- This policy is meant to be an outward statement of its commitment to its customers and to the provision of quality products.
- The **Quality Policy** is a more abstract concept. It finds its practical and measurable expression in the Quality Objectives.
- The **Quality Policy** should be in line with the purpose and mission of the organization or company it is written for. It also should be understandable by all members of the organization, employees, managers as well as other stakeholders.
- For example, the quality policy statement of control Design Inc. is

CONTROL DESIGN, INC.

Quality Policy Statement

"Achieve customer satisfaction and meet requirements through continual improvements of the Quality Management System."

Bill Small	Dave Nemcsik	Rob Dominick
Bill Small	Dave Nemcsik	Rob Dominick
V.P. / General Manager	V.P. – Sales / Operations	Director of Quality & Safety

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO 9000)

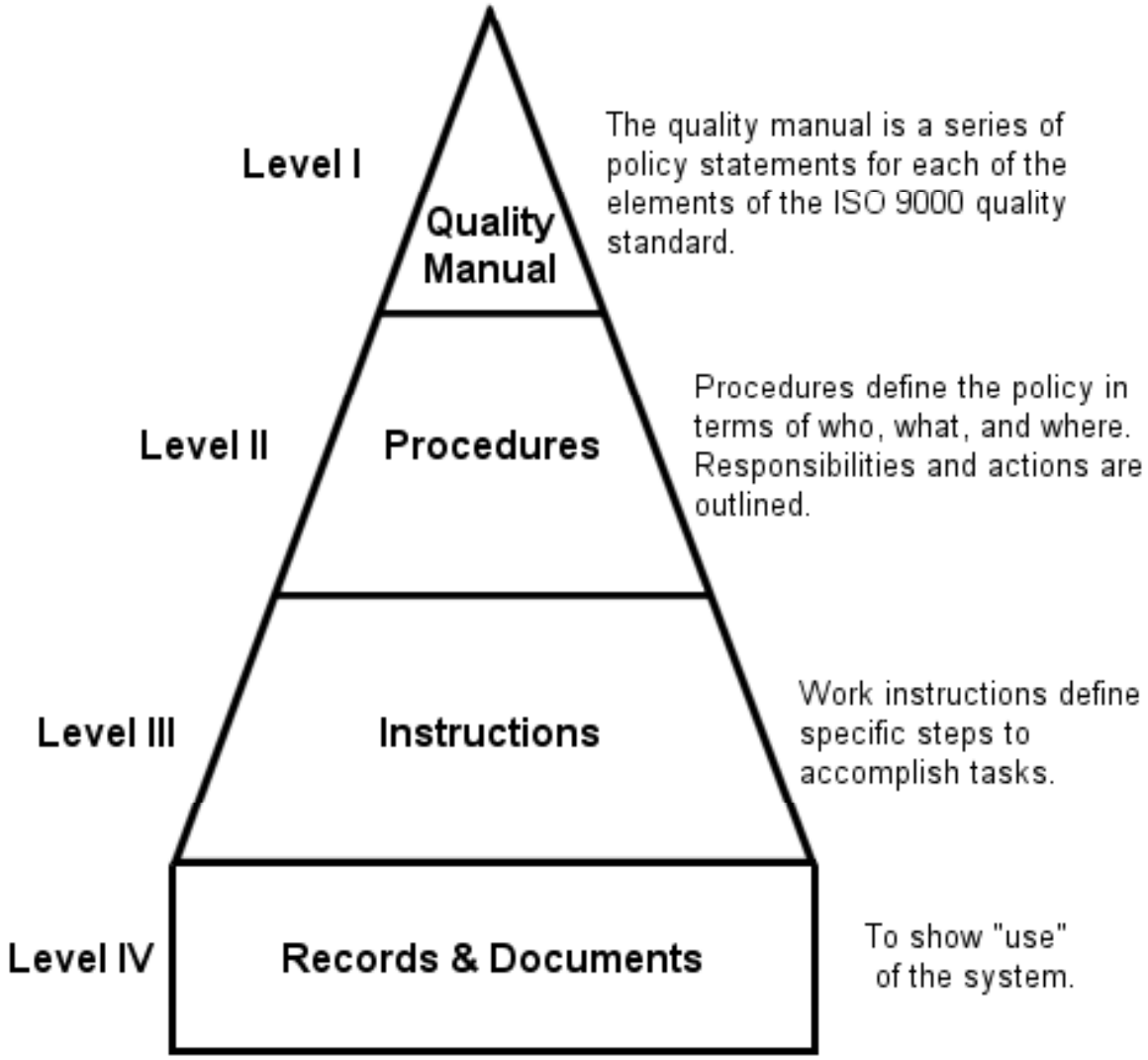
Quality Objectives

- The Quality Objectives are the practical outline of the Quality Policy. They are an expression to aim for meeting certain requirements like zero defects for a certain Product or a response time below a specified limit for a certain service. It is important that a Quality objective is measurable.

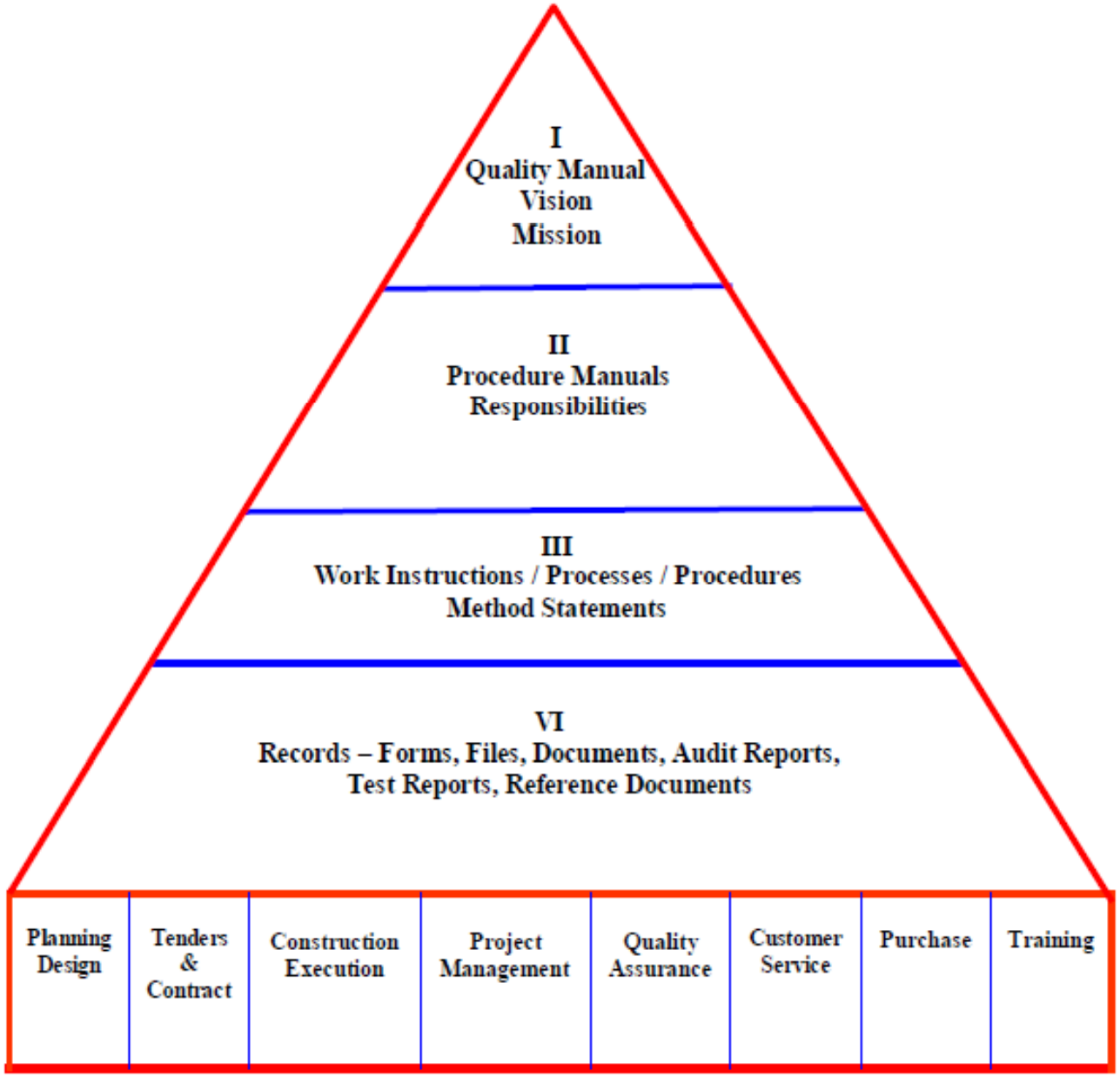
Quality Manual

- According to ISO 9000:2000 a Quality Manual is defined as a "Document specifying the quality management system of an organization."
- A Quality Manual includes descriptions of processes and procedures within the organization. Also Work Instructions and Flow Charts can be included. *A Process or Procedure can be described narrative or with the help of drawings, tables and charts. Forms for records and other documents can also be included.*

ISO 9000 documentation structure



ISO 9000 DOCUMENTATION STRUCTURE *FOR CONSTRUCTION*

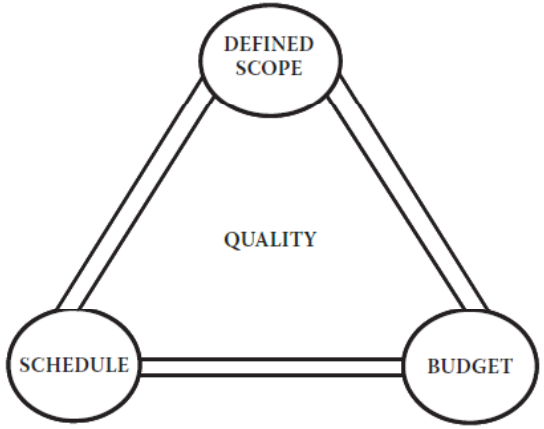


Quality in Construction

- "Quality of construction is even more difficult to define.
  - First of all, the product is usually not a repetitive unit but a unique piece of work with specific characteristics.
  - Secondly, the needs to be satisfied include not only those of the client but also the expectations of the community into which the completed building will integrate.

- The quality of construction projects can be defined as follows: **Construction project quality is the fulfillment of the owner's needs per defined scope of works within a budget and specified schedule to satisfy the owner's/user's requirements.** The phenomenon of these three components can be called the "construction project trilogy"

Construction project trilogy.



Special features in the construction industry that limit the implementation of the ISO 9000 standard

There are special features in the construction industry that limit the implementation of the ISO 9000 standard. The following are some of these features:

1. A construction project is usually a unique collection of people, equipment, and materials brought together at a unique location under unique weather conditions, while most manufacturing is a system of mass production wherein all of these factors are consistent with producing typical products over and over again.
2. Performance testing in construction is generally not feasible as a basis for acceptance.
3. It is common to have separate contracts for design and construction.
4. It is not feasible to reject the whole constructed project after completion while attached to the purchaser's land.

Special features in the construction industry that limit the implementation of the ISO 9000 standard

1. Decisions to reject a defective part of a constructed project need to be taken promptly before succeeding parts are constructed or installed.
2. The number of parties involved in the constructed project's procurement is more than those involved in manufacturing procurement. Achieving quality construction requires effort from all parties. This makes the interface and responsibilities of the various individuals and organizations more complicated than in manufacturing.
3. The organizational structure of a construction company varies depending on the nature of the project, while the same structure in a manufacturing company is almost unchanging. This affects the smoothness of communication and interface between the responsible individuals.
4. Turnover of manpower in construction is higher than in manufacturing, which affecting the precision of long-term plans.
5. Construction projects are very complicated and their execution may take years.

Advantages of implementing the ISO 9000 to a construction company

1. Optimizes resources usage in the organization.
2. Improves awareness of company's objectives and policies.
3. Improves communication between various departments in the same organization.
4. Improves tractability of quality problems.
5. Cuts down material wastage.
6. Formalized systems ensure consistent quality services.
7. Provides useful documented reference.
8. Improves work quality with fewer rejects and less repeated work.
9. Rectifies errors at early stage.
10. Improves relationship with the owner, subcontractors, engineer – architect and material suppliers.
11. Improves corporate quality image.
12. Introduces continuous improvement through a review of the quality system.
13. Improves records and makes retrieval of information easy in case of litigation.
14. Helps project to be completed within the time frame stipulated in the contract.

Difficulties and Obstacles in Introducing the ISO-9000 Standard in Construction

Difficulties and obstacles in introducing the ISO-9000 Standards to some developing countries are:

1. Customer practice of awarding contract to the lowest bidder.
2. Lack of skilful workmanship.
3. Outdated construction technology due to lack of funds for research and development.
4. Lack of continuous professional development.
5. Poor building materials which do not meet specifications.
6. Poor design by inexperienced architects and engineers.
7. Short construction period.
8. Conflict of interest among the contractual parties.

Implementing ISO 9000 Quality Management System

The 14 essential steps, briefly described below, are to be followed through in order to implement ISO 9000 quality management system successfully.

Step 1: Top management commitment

Step 2: Establish implementation team

Step 3. Start ISO 9000 awareness programs

Step 4: Provide Training

Step 5. Conduct initial status survey

Step 6: Create a documented implementation plan

Step 7. Develop quality management system documentation

Step 8: Document control

Step 9. Implementation

Step 10. Internal quality audit

Step 11. Management review

Step 12. Pre-assessment audit

Step 13. Certification and registration

Step 14: Continual Improvement

Implementing ISO 9000 Quality Management System

Step 1: Top Management Commitment

- The top management (managing director or chief executive) should demonstrate a commitment and a determination to implement an ISO 9000 quality management system in the organization.
- Without top management commitment, no quality initiative can succeed.

The top management should provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:

1. Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
2. Defining the organization's quality policy and make this known to every employee.
3. Ensuring that quality objectives are established at all levels and functions.
4. Ensuring the availability of resources required for the development and implementation of the quality management system,
5. Appointing a management representative to coordinate quality management system activities, and Conducting management review.

Implementing ISO 9000 Quality Management System

Step 2. Establish Implementation Team

➢Establish implementation team and appoint a Management Representative (MR) as its coordinator to plan and oversee implementation. Its members should include representatives of all functions of the organization -Marketing, Design and development, Planning, Production, Quality control, etc.

The MR should also act as the organization's "quality management system champion," and must be a person with:

1. Total backing from the CEO,
2. Genuine and passionate commitment to quality in general and the ISO 9000 quality management system in particular,
3. The dignity - resulting from rank, seniority, or both - to influence managers and others of all levels and functions,
4. Detailed knowledge of quality methods in general and ISO 9000 in particular.

The members of the implementation team should also be trained on ISO 9000 quality management systems by a professional training organization.

Implementing ISO 9000 Quality Management System

Step 3. Start ISO 9000 Awareness Programs

- ISO 9000 awareness programs should be conducted to communicate to the employees the aim of the ISO 9000 quality management system;
- The advantage it offers to employees, customers and the organization; how it will work; and their roles and responsibilities within the system.
- Suppliers of materials and components should also participate in these programs.
- The awareness program should emphasize the benefits that the organization expects to realize through its ISO 9000 quality management system.
- The program should also stress the higher levels of participation and self-direction that the quality management system renders to employees. Such a focus will go far to enlist employee support and commitment.
- The programs could be run either by the implementation team or by experts hired to talk to different levels of employees

Implementing ISO 9000 Quality Management System

Step 4. Provide Training

- Since the ISO 9000 quality management system affects all the areas and all personnel in the organization, training programs should be structured for different categories of employees - senior managers, middle-level managers, supervisors and workers. The ISO 9000 implementation plan should make provision for this training.

- The training should cover the basic concepts of quality management systems and the standard and their overall impact on the strategic goals of the organization, the changed processes, and the likely work culture implications of the system.

- Initial training may also be necessary on writing quality manuals, procedures and work instruction; auditing principles; techniques of laboratory management; calibration; testing procedures, etc.

- When in-house capacity to carry out such training is not available, it may be necessary to participate in external training courses run by professional training organizations. Alternatively, an external training institution could be invited to conduct in-house training courses.

Implementing ISO 9000 Quality Management System

Step 5. Conduct Initial Status Survey

- ISO 9000 **does not require duplication of effort or redundant system**. The goal of ISO 9000 is to create a quality management system that conforms to the standard.

- With the aid of the flow charts, a record of existing quality management system should be established.

- The basic approach is to determine and record how a process is currently carried out. In introducing a quality management system, the emphasis is on the **improvement of the existing processes** or the re-organization of processes.

- In general, the steps to follow are the following:
  1. Ascertain and establish the following: What is the present operation/process? What already exists?
  2. Analyze the relevant sections of the quality standard - ISO 9001:2000: What is actually required?
  3. If necessary, supplement and change operational arrangements in accordance with the standard, develop documents and records, and describe operations/ processes:
  4. What is the desired operation/process?

Implementing ISO 9000 Quality Management System

Step 6. Create a Documented Implementation Plan

- Once the organization has obtained a clear picture of how its quality management system compares with the ISO 9001:2000 standard, all non-conformances must be addressed with a documented implementation plan.

The implementation plan should be thorough and specific, detailing:

1. Quality documentation to be developed
2. Objective of the system
3. Pertinent ISO 9001:2000 section
4. Person or team responsible
5. Approval required
6. Training required
7. Resources required
8. Estimated completion date

- These elements should be organized into a detailed chart, to be reviewed and approved. The plan should define the **responsibilities of different departments** and personnel and **set target dates for the completion of activities**. Once approved, the Management Representative should control, review and update the plan as the implementation process proceeds.

Implementing ISO 9000 Quality Management System

Step 7. Develop Quality Management System Documentation

Documentation is the most common area of non-conformance among organizations wishing to implement ISO 9000 quality management systems.

Documentation of the quality management system should include:

1. Documented statements of a quality policy and quality objectives, A quality manual,
2. Documented procedures and records required by the standard ISO 9001:2000, and
3. Documents needed by the organization to ensure the effective planning, operation and control of its processes.

A list of the documents to be prepared should be drawn up and the responsibility for writing the documents should be assigned to the persons concerned in various functional departments. They should be advised to prepare the drafts within a specific time frame.

Implementing ISO 9000 Quality Management System

Step 8: Document Control

Once the necessary quality management system documentation has been generated, a **documented system must be created to control it.** Control is simply a means of managing the creation, approval, distribution, revision, storage, and disposal of the various types of documentation. Document control systems should be as simple and as easy to operate as possible -- sufficient to meet ISO 9001:2000 requirements.

Document control should include:

1. Approval for adequacy by authorized person (s) before issue,
2. Review, updating and re-approval of documents by authorized person (s),
3. Identification of changes and of the revision status of documents,
4. Availability of relevant versions of documents at points of use,
5. Identification and control of documents of external origin,
6. Assurance of legibility and identifability of documents, and
7. Prevention of unintended use of obsolete documents.

The principle of ISO 9000 document control is that employees should have access to the documentation and records needed to fulfill their responsibilities.

Implementing ISO 9000 Quality Management System

Step 9. Implementation

- It is good practice to implement the quality management system being documented as the documentation is developed, although this may be more effective in larger firms.

- In smaller companies, the quality management system is often implemented all at once throughout the organization.

- Where phased implementation takes place, the effectiveness of the system in selected areas can be evaluated.

- It would be a good idea initially to evaluate areas where the chances of a positive evaluation are high, to maintain the confidence of both management and staff in the merits of implementing the quality management system.

- The implementation progress should be monitored to ensure that the quality management system is effective and conforms to the standard. These activities include internal quality audit, formal corrective action and management review.

Implementing ISO 9000 Quality Management System

Step 10. Internal Quality Audit

- As the system is being installed, its effectiveness should be checked by regular internal quality audits.

- Internal quality audits are conducted to verify that the installed quality management system:
  - Conform to the planned arrangements, to the requirements of the standard (ISO 9001:2000) and to the quality management system requirements established by your organization, and
  - Is effectively implemented and maintained.

- Even after the system stabilizes and starts functioning, internal audits should be planned and performed as part of an ongoing strategy.

- A few staff members should be trained to carry out internal auditing.

- Use ISO 19011 for guidance in auditing, auditor qualification and programmes.

Implementing ISO 9000 Quality Management System

Step 11. Management Review

- When the installed quality management system has been operating for three to six months, an internal audit and management review should be conducted and corrective actions implemented.

- The input to management review should include information on:
  1. Results of audits,
  2. Customer feed back,
  3. Process performance and product conformity,
  4. Status of preventive and corrective actions,
  5. Follow-up actions from previous management reviews,
  6. Changes that could affect the quality management system, and
  7. Recommendations for improvements.

- Management reviews should also address the **pitfalls to effective implementation,** including lack of CEO commitment, failure to involve everyone in the process, and failure to monitor progress and enforce deadlines.

Implementing ISO 9000 Quality Management System

Step 12. Pre-assessment Audit

- When system deficiencies are no longer visible, it is normally time to apply for certification.
- However, before doing so, a pre-assessment audit should be arranged with an independent and qualified auditor.
- Sometimes certification bodies provide this service for a nominal charge.
- The pre-assessment audit would provide a degree of confidence for formally going ahead with an application for certification.

Step 13. Certification and Registration

- Once the quality management system has been in operation for a few months and has stabilized, a formal application for certification could be made to a selected certification agency.
- The certification agency first carries out an audit of the documents (referred to as an "adequacy audit"). If the documents conform to the requirements of the quality standard, then on-site audit is carried out.
- If the certification body finds the system to be working satisfactorily, it awards the organization a certificate, generally for a period of three years.
- During this three-year period, it will carry out periodic surveillance audits to ensure that the system is continuing to operate satisfactorily.

Implementing ISO 9000 Quality Management System

Step 14: Continual Improvement

- Certification to ISO 9000 should not be an end. You should continually seek to improve the effectiveness and suitability of the quality management system through the use of:
  1. Quality policy
  2. Quality objectives
  3. Audit results
  4. Analysis of data
  5. Corrective and preventive action
  6. Management review