UNIT-5 QUALITY SYSTEMS

ISO stands for International Organization for Standardization

ISO 9001 REQUIREMENTS

1. Scope

2. Normative References

3. Definitions

4. Quality Management Systems

- ✓ Documentation
  - Quality Manual
  - Control of documents
  - Control of records

5. Management Responsibility

- ✓ Management Commitment
- ✓ Customer Focus
- ✓ Quality policy
- ✓ Planning
- ✓ Responsibility, authority and communication
- ✓ Management review

6. Resource Management

- ✓ Human resources
- ✓ Infrastructure
- ✓ Work Environment

7. Product or service realization

- ✓ Planning of product realization
- ✓ Customer related processes
- ✓ Design and development

8. Measurement, Analysis and improvement

- ✓ Monitoring and measuring
- ✓ Analysis of data
- ✓ Improvement

ISO 9001 IMPLEMENTATION

Top Management Commitment:

- The chief executive officer (CEO) must be willing to commit the resources necessary to achieve the certification.
- Without the CEO's support the process may continuously run in to unnecessary road blocks or even be doomed to failure.

Appoint the Management Representative:

- The next step is to appoint the management representative.
- This person is responsible for coordinating the implementation and maintenance of quality system and he is the contact person for all parties involved in the process both internal and external.
- The representative can be a member of the top management group who is able to ensure that the quality system is effectively implemented, documented and maintained.

Awareness:

- An awareness program is required because the process is going to affect every member of the organization as well require their input, it stands to reason that everyone should understand the quality system.
- The employees should know how it will affect their day-to-day operations and the potential benefits.
- This information can be relayed through short, one hour awareness training sessions.

Appoint an implementation team:

- After every one has been informed of the organizations intentions to develop the quality system, an implementation team should be assembled.

- This team should be drawn from all levels and areas of the organization so that it is representative.
- It is important to keep the project visible for all employees.

Training:

- The implementation team, supervisor and internal audit team should be trained.
- This activity can be accomplished by sending team leaders for training and make them to train the rest of the members by one or two day seminar.

Time Schedule:

- A time schedule has to be framed for the implementation and registration of the system.
- This time frame will vary depending on the size and type of organization and the extent of its existing quality system.
- Most organizations can complete this entire process in less than 1.5 years.

Select Element Owners:

- The implementation team should select owners for each of the system elements.
- Many of these owners will be the members of the implementation team.
- Owners may be assigned more than one element.
- The more people involved, the more effective the system.

Review the present system:

- The present system has to be reviewed.
- Copies of all the quality manuals, procedures, work instructions and forms which are used presently are obtained.
- These documents are sorted in to system elements to determine what is available and what is needed to complete the system.
- This is called as gap analysis.

Write the document:

- Prepare written quality policy and procedure manuals, they can be combined in to one document.
- Write appropriate work instructions to maintain the quality of specific function.
- This process should involve every employee, because the best person to work with instruction is the one who performs the job on a regular basis.

Install the new system:

- Integrate the policies, procedures and work instructions in to the day today workings of the organization and document what is being done.
- Be sure all people are trained.

Internal Audit:

- Conduct an internal audit of the quality system.
- This step is necessary to ensure that the system is working effectively.
- Minor corrections to the system are made as they occur.
- A cross section of the trained people should be used for the audit team.

Management Review:

- A management review is conducted.
- The management review is used to determine the effectiveness in achieving the stated quality goals.

Pre assessment:

- This step is optional.
- If a good job has been done on the previous steps pre assessment is not necessary.

Registration:

- It has three parts
  - Choosing a registrar
  - Submitting an application
  - Conducting the registrar's system audit.

➢ A registrars audit usually lasts one to three days and will consist of an opening meeting , the process the auditors will follow, the audit itself and closing meeting to discuss the findings of the audit.

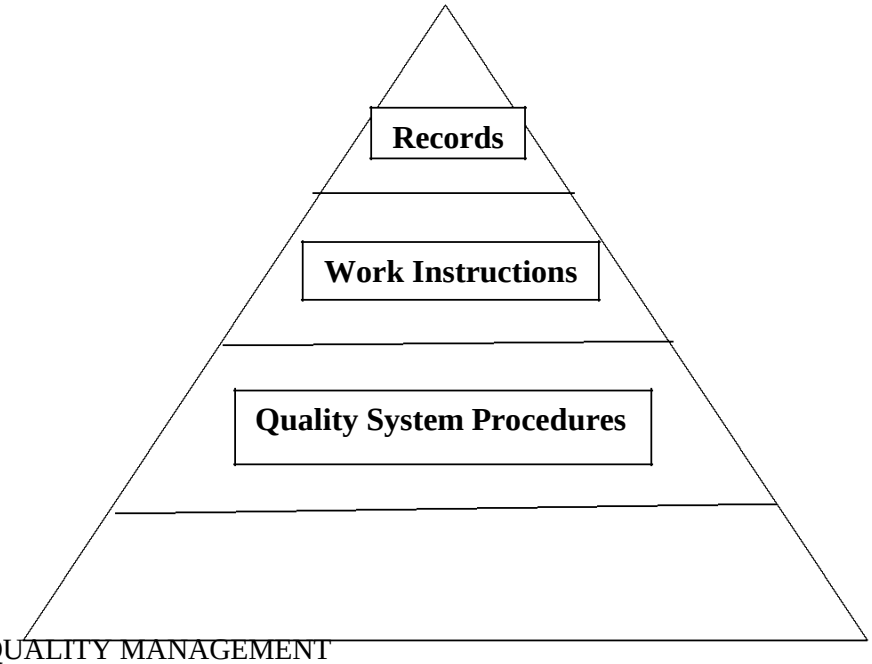
DOCUMENTATION OF QUALITY SYSTEM

- Proper documentation is the pre-requisite for implementing quality system.
- The documentation serves as a reference for the management, the staff and other agencies whose involvement is essential for implementation of the quality system.
- Advantages of having a documented quality system:
  - ✓ Serves as a reference
  - ✓ Brings about clarity of objectives and targets
  - ✓ Provides standardization in work procedures
  - ✓ Brings about consistency in operations
  - ✓ Develops confidence amongst employees
  - ✓ Generates customers confidence
  - ✓ Provides a basis for continuous improvement

Documents to be prepared:

- Quality Policy Manual
- Quality System Procedures
- Work Instructions
- Records/formats/forms

The documentation Pyramid:



Quality Policy Manual

1. Quality Policy Manual:

- ✓ Quality policy manual is the first level of documentation. This is the document that defines 'what will be done 'and 'why'.
- ✓ It should be short and simple definition of the organizations quality intentions.
- ✓ The remainder of the policy manual addresses what will be done to comply with the standard being used.
- ✓ The policy manual communicates the quality policy and objectives of an organization.
- ✓ This manual is a living document. Because it reflects the current system being followed in the organization.

2. Quality System Procedures:

- ✓ The second level of documentation is the quality procedures. These procedures describe the methods that will be used to implement and perform the stated policies**.**
- ✓ These procedures define who should perform specific tasks, when the task should be done and where the documentation will be made.
- ✓ These documents collectively define the organizations operations from receiving an enquiry to delivering a completed product or service.
- ✓ These procedures are confidential documents of the organization and therefore need not to be revealed to others.

3. Work Instructions:

- ✓ The third level of documentation is generally company specific. It gives details of how individual work processes (e.g.: welding, casting) are carried out with in a company.
- ✓ Work instructions should also specify how the work should be done, who should undertake the work and what records are to be maintained.
- ✓ The work instructions may be in the form of a detailed drawing, recipe, routing sheet, specific job function, photograph, video or simply a sample for comparison of conformity.
- ✓ The work instructions should be written by the employee who performs the task.

4. Records:

- ✓ These provide evidence of activity having been performed in compliance with quality system procedure.
- ✓ Records may be forms that are filled out, a stamp of approval on a product or a signature and date on some type of document.

QUALITY AUDITING

- ❖ Quality auditing should be carried out in order to verify whether a quality system is effective and suitable.

Definition:

A quality system audit is defined as "a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements, whether these arrangements are implemented effectively and whether these are suitable to achieve objectives"

Objectives of Quality Audits:

- ✓ To determine the conformity or non-conformity of the quality system elements with regard to specified requirements.
- ✓ To determine the effectiveness of the implemented quality system in meeting specified quality objectives.
- ✓ To meet regulatory requirements, if applicable.
- ✓ To permit the listing of the audited organizations quality system in a register for third party certification.
- ✓ To evaluate an organizations own quality system against a quality system standard.

Types of Audits:

- ❖ **First party audit (or internal audit):**
  This refers to an internal audit where the auditee is its own client, i.e. audit is done by an organization, working on itself.
- ❖ **Second party audit:**
  This refers to audit by one organization on another organization (auditee). This type of audit is normally done on a supplier by a customer.
- ❖ **Third party audit:**
  This refers to audit by an independent organization on a supplier , for accreditation assessment purposes.

Stages of an Audit:

There are four stages

1. Audit Planning

2. Audit Performance

3. Audit reporting

4. Audit follow-up

Stage 1: Audit Planning (It has 4 key elements)

i. **Audit schedules**: It is a matrix of the timings, which details when each audit element is to be checked throughout the year.
ii. **Audit personnel**: It refers to the appointment of an auditor.
iii. **Notification to the auditee**: This is the formal and timely request by audit to auditee for making available all quality system documents relevant to the audit.
iv. **Preparation of checklist:** This lists all specific questions to be asked during audit.

Stage 2: Audit Performance

i. **Opening/entry meetings:** Opening meeting is organized to initially brief the auditee about the scope of audit.
ii. **Audit process:** Audit is done according to the schedule and should cover entire scope, as planned. Regular liaison meetings should be held.
iii. **Audit deficiencies:** During auditing, clear and precise discrepancy reports are raised. All discrepancies should be based on sound and objective evidence.

Stage 3: Audit Reporting

i. Audit reporting deals with the recording of any non conformity and summarizing the audit findings.
ii. The audit report may contain:
    - Identification of the reference documents against which audit is conducted (ie quality system standard), company's quality manual.
    - Observation of non conformities
    - Corrective action requests

Stage 4: Audit Follow-up

i. The auditor is only responsible for identifying the non conformity. But the auditee is responsible for determining and initiating corrective action needed to correct a non conformity.
ii. Corrective action and subsequent follow up should be completed within a time period.

These 4 stages complete the ISO 9000 quality system audit

ISO 14001

What is ISO 14001?

- It is an Environmental Management System (EMS) that uses a continual improvement approach in achieving and demonstrating sound environmental performance.
- The goal is for organizations to control the impacts that their activities, products and services have on the environment.
- ISO 14000 is the standard, and ISO 14001 is the document containing the requirements.

Overview of the Requirements of the ISO 14001 Standard

- The organization must develop an effective system that meets the requirements of the Standard.
- Document, implement and maintain the system.
- The EMS documents need to be controlled.

Follow a Plan-Do-Check-Act approach.

– Plan - Establish the objectives and processes needed to deliver the results (in line with the EMS).
– Do - Implement the needed processes of the EMS.

– Check - Check the processes against the policy, objectives, targets, regulations, and report on the results. (Auditing)

– Act - Take actions that will continually improve the EMS.

Requirements (Plan): Management

- Top Management must be committed to and involved in the design and implementation of the EMS.
- They will write the Environmental Policy and be responsible for making sure it is communicated and implemented.
- Many specific responsibilities are assigned to Top Management to ensure their input and participation.
- After implementation Management will conduct management review to ensure continued effectiveness of the system.
- Requirements (Plan): Resources
- The EMS must clarify what resources, human and physical are required to create safe products and operations.
- During development of the system you will determine how to ensure competent personnel, identify training that is required, and identify the infrastructure and work environment required
- Requirements (Plan): Form EMS
- Your organization will need to plan all of the processes that go into making your product to ensure safe conditions.
- You will need to state of scope of the EMS and clearly identify the products and define the locations or sites that are part of the EMS.

Requirements (Do): Environmental Review

- An initial environmental review will be needed.
- An assessment of environmental aspects and their Impacts will have to be performed.
- Regulatory, legal and other requirements will need to be identified.
- Environmental programs with targets and objectives will need to be established, implemented and evaluated on an ongoing basis.
- Emergency preparedness procedures will be required to address potential accidents and emergencies.
- Measuring and monitoring of product and process characteristics that can have an impact on the environment will be required.

  - Measuring and monitoring equipment will need to be controlled and calibrated.

  - A process will be needed for the Environmental Safety Team to evaluate compliance to legal and other requirements.

Requirements (Check):Control Nonconformities

- Establish and document a system for controlling nonconformities.
  - – When specified product and process limits are exceeded potentially unsafe conditions must be identified, assessed, controlled and dispositioned appropriately.
  - – Identify corrections and corrective actions to mitigate environmental impacts and to eliminate the nonconformity and its cause.
- Establish the internal audit process.

  - Train auditors, and plan internal audits to establish an audit program that will determine if the EMS is effective and up to date.
- Control the records associated with the EMS.
- Conduct regular management reviews to ensure effectiveness of the EMS.

Requirements (Act): Improve your EMS

- Continually improve the EMS through the use of:
  - – Management reviews
  - – Internal audits
  - – Corrective actions
  - – Analysis of data / results
  - – Update the EMS

ISO 14001 IMPLEMENTATION STEPS

Implementation: Conduct the Environmental Gap Analysis

You must determine your position with regards to the environment:

- – Are there GAPS that need to be bridged?
- – What are they and where are they located?
- – How can they be improved?
- – Who will be taking corrective / preventive actions?

Your environmental position needs to be analyzed so that the GAPS can be bridged / closed.

Conduct the Environmental Gap Analysis

Conduct a Gap Analysis – Complete a series of assessments in the following order:

- – Perform Initial Environmental Review
- – Perform Environmental Assessment – Aspects/Impacts

– Identify Legal and Other Requirements
– Identify Environmental programs with objectives and targets

Based on the results of the assessments, implement Improvement actions.

- Implementation: Form a Team
- Appoint a Management Representative
  - This individual will be the ISO project manager.
- Assign a Environmental Safety Team
  – This team will be active in the design and development of the EMS and participate in the on going operation of the system.
- Assign a Management Team
  - This team will be providing the direction and guidance for the development and implementation of the EMS.
- The Management Team will act as a steering team for the project, assigning responsibilities, providing resources and coordinating the project.
  – The Management Team can assign task teams to work on specific processes that must be designed and documented for the EMS.
- Each task team will evaluate the current process that they are assigned to and the requirements of the standard.
  – A new or modified process will be developed, documented and submitted to the Management Team for review and approval.
- After the task teams have designed and documented a new or modified process, it must be implemented.
- Train all employees that are involved in the process
- When the required processes have been implemented, start your internal audit program and management review meetings.
- Use information / results from internal audits and management review to make improvements to the EMS.
- Run your system long enough to generate records for the Registrar to audit.
- Make sure all employees are trained on ISO 14001
- Have a Registrar conduct your Registration Audit.