

UNIT-5

QUALITY SYSTEMS

5.1 ELEMENTS OR CLAUSES OF ISO 9000

Quality system requirements:

There are twenty elements of a quality system

1. management responsibility
2. quality system
3. Contrast review
4. design control
5. document control
6. Purchasing
7. Purchaser supplied product (control of customer -supplied 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-conforming products.
14. Corrective and preventive action
15. handling, storage, packaging , preservation and delivery.
16. control of quality records.
17. Internal quality audit
18. Training
19. servicing
20. statistical techniques

Implementation of quality system(steps to registration)

ISO 9000 quality management system generally require the following steps

1. Top Management Commitment
2. Appoint the Management Representative
3. Awareness
4. Appoint an Implementation Team
5. Training
6. Time Schedule
7. Select Element Owners
8. Review the Present System
9. Write the Documents
10. Install the New System
11. Internal Audit
12. Management Review
13. Pre-assessment

- 14. Registration
- 15. Award of ISO 9000 certificate

5.2 DOCUMENTATION OF QUALITY SYSTEM:

The documentation serves as reference for the management, the staffs and other agencies whose involvement is essential for implementation of the quality system.

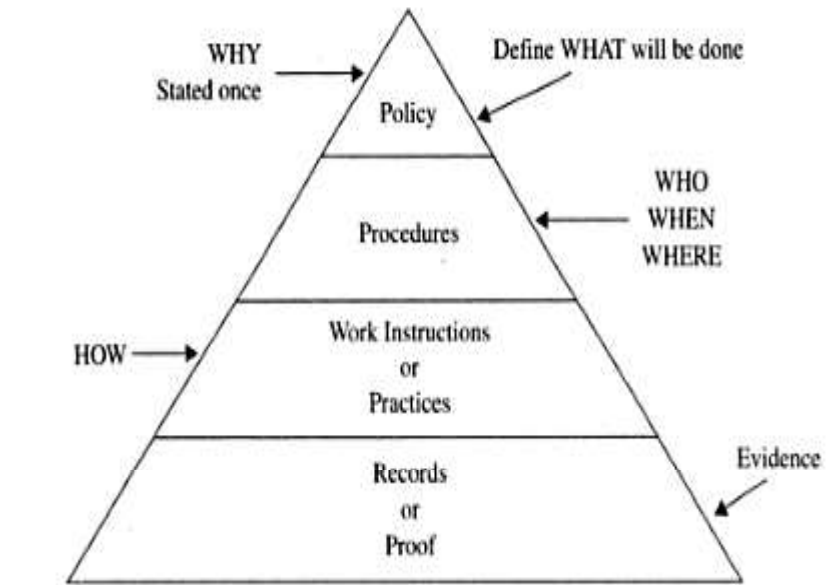


Figure : The documentation pyramid

Advantages:

- 1. Serves as a reference
- 2. Brings about clarity of objectives and targets.
- 3. provides standardization in work procedure.
- 4. Brings out consistency in operations.
- 5. Develops confidence amongst employees
- 6. generate customer's confidence.
- 7. provides a basis for continuous improvement.

Documents to be prepared:

The documents required by most organizations are,

- 1. Quality policy manual
- 2. Quality system procedures
- 3. Work instructions
- 4. Records/ Formats /forms.

Benefits of documentation:

- Documentation regularizes the method of performing the day-to-day activities.
- It provides formats for standardizing practices.
- It provides reference for assessing degree of enforcement in practice.
- It facilitates trouble shooting for tracking back on the process.
- It demonstrates the ISO quality system certification

5.3 QUALITY AUDITING:

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

Features of quality audit:

- The quality audits applies to quality systems .
- Quality audits are carried by staff who are not directly responsible in the areas being audited.
- Quality audit is an information gathering activity.
- Quality audits may be conducted for internal or external purposes.

Types of audits:

There are three types of audit

- 1.First party audit (or internal audit)
- 2.second party audit
- 3.Third party audit

Objectives or need for quality audit:

- 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
- To meet regulatory requirements.
- To permit the listing of the audited organizations quality system in a register.
- To evaluate an organizations own quality system against a quality system standard.

Stages of an audit:

1.audit planning

The key elements of audit planning are,

- Audit schedules
- Audit personal
- Notification to the audited

- Preparation of checklist.

2. Audit performance

The key elements of audit performance are,

- Opening/ entry meeting
- Audit process
- Audit deficiencies

3. Audit reporting:

Audit reporting may contain,

- Identification of the reference documents against which audit is conducted.
- Observations of non-conformities
- Corrective action requests.

4. audit follow –up

- The auditor is responsible only for identifying the non- conformity.
- Corrective action and subsequent follow-up should be completed with in a time period.

5.4 QS 9000 – AUTOMOTIVE QUALITY MANAGEMENT SYSTEMS:

Qs 9000 is a set of quality system requirements recently adopted by members of the automotive industry.

The objective of a QS 9000 is to develop fundamental quality systems based on continuous improvement, direct prevention, reduction of variation and waste elimination in the automobile supply chain.

1. QS 9000 can be applied to all internal and external suppliers of
2. Production materials
3. Production or service parts.
4. Heat treating, painting, plating services.

Structure of QS 9000

QS 9000 standards can be divided in to 3 sections.

Section 1: ISO based requirements

It includes the exact test of ISO-9001 with the addition of automotive / heavy trucking requirements.

Section 2: Automotive sector specific requirements

1. Production
2. Continuous improvement
3. Manufacturing capabilities

Section 3:Customer specific requirements

Each customer over and above the requirements specified in section 2.

Documents required for QS9000 program

- The QS 9000 quality system requirements
- Advanced product quality planning & control plan
- Failure mode & effects analysis
- Fundamental statistical process control
- Production part approval process manual
- Quality system assessment manual.

5.5 ISO 14000: ENVIRONMENTAL MANAGEMENT SYSTEM STANDARDS

The ISO 14000 standards are a set of norms for Environmental management System(EMS) either at organization and process level. The series of ISO 14000 standards are designed to cover ,

- 1.environmental management systems
2. Environmental auditing
3. Environmental performance evaluation
4. Life-cycle assessment
5. Environmental aspects in product standards.
6. Terms & Definitions

ISO 14000 series of standards

The entire ISO 14000 series can be divided into two areas they are,

- 1.Organisation evaluation standards
- 2.Product evaluation standards

1.Organisation evaluation standards:

Those standards consists of the following three categories,

- 1.environmental management system
- 2.Environmental Auditing(EA)
3. environmental performance evaluation

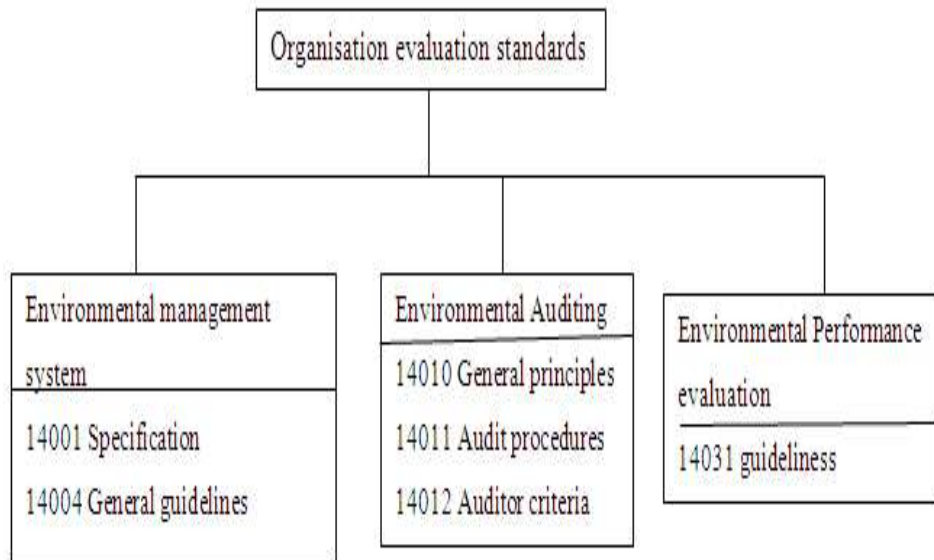


Figure: Organizational evaluation standards

2. Product Evaluation standards

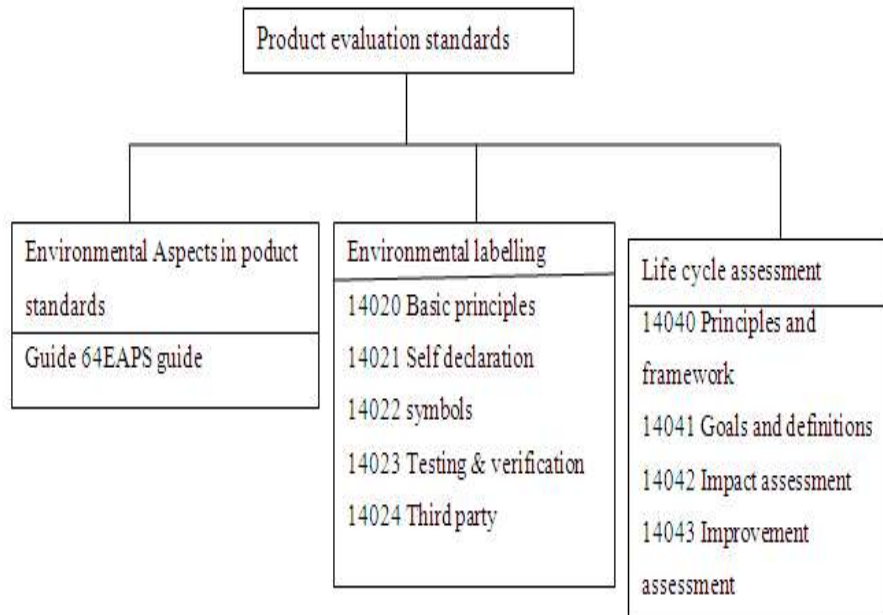


Figure:The product evaluation standards

The product evaluation standards consists of 3 categories,

- 1.environmental aspects in product standards
2. Environmental Labels and declarations
3. Life cycle assessment

Terminologies used in ISO 14000 standards

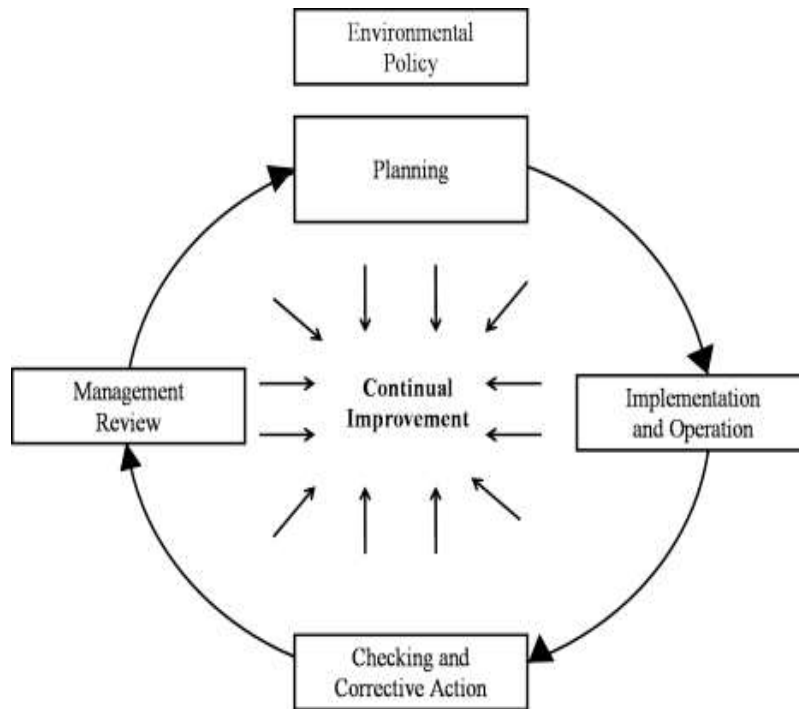
The concept and requirements of ISO 14000 have the following terms,

- 1.Environment
2. Environmental aspects
3. Environmental impact
4. environmental objective
5. Environmental target

5.6 CONCEPT OF ISO 14000(EMS MODEL)

The EMS model consists of 5 stages. They are

1. Environmental policy
2. Planning
3. Implementation and operation
4. Checking and corrective action
5. Management review



5.7 REQUIREMENTS OF ISO 14000(Major elements of EMS)

The major elements are:

1. General requirements
2. Environmental policy
3. Planning
4. Implementation and operation
5. Checking and corrective action
6. Management review

1. General requirements

- General requirements state the general requirements of ISO 14000 to the organization.
- It requires that an organization should establish and maintain an EMS.
- The EMS include policy, planning, implementation operation, checking correction

2. Environmental policy

- Environmental policy explains the contents that are to be included in the environmental policy
- Hence the following issue are stated in the environmental policy
 1. Management commitment to continuous improvement
 2. Prevention of pollution
 3. Creating a frame work for setting objectives
 4. Education and training for environment

3. Planning

i. Environmental aspect

- Environmental aspect explains about the environmental aspect and its relation with the environmental impart any environmental aspect is identify using FMEA analysis.

ii. Legal aspects

- Legal aspects explain about the organization to have a procedure to identify and have a procedure to identify and have access to all legal requirement.
- Legal requirements include the industry code of practice contracts, agreement with public authority and other regulatory action.

iii. Objectives and target

- This element describes the organization to establish and maintain the objective and target at each level.
- The procedure should also prevent such accident and emergency situation.

iv. Environmental management programs

4. Implementation and operation

- i. Resources, Roles, Responsibility and authority
- ii. Training, awareness, and competency
- iii. Communication
- iv. Environmental management system documentation
- v. Document control
- vi. Operational control
- vii. Emergency preparedness and response

5. Checking and corrective action

i. Monitoring and measuring

Establish and maintain procedures to regularly monitor, and measure key characteristics of operations and activities

ii. Non conformance corrective and preventive action

This element describes the procedure to define responsibility and authority for handling and investigating non conformance.

iii. Records

Establish and maintain procedures for identifying, maintaining and disposing environmental records.

iv. EMS audit

Establish and maintain procedures for periodic EMS audits to ensure

- Conformance to EMS standards
- Proper implementation and maintenance
- Proper availability of audit results to management.

6. Management review

- The organizations top management shall periodically overview the EMS ensure its suitability and effectiveness.
- The review shall address the need for changes in policies, objectives and so on.

5.8 BENEFITS OF ISO 14000 (EMS)

- The benefit by adopting EMS can be put under two categories namely
 - a) Global benefit
 - b) Organizational benefit

a. Global

- 1. Facilitate trade and remove trade barriers
- 2. Improve environmental performance of planet earth

3. Build consensus that there is a need for environment management and a common terminology for EMS.

b. Organizational

1. Assuring customers of a commitment to environmental management
2. Meeting customer requirements
3. Maintaining a good public / community relations image
4. Satisfying investor criteria and improving access to capital
5. Obtaining insurance at reasonable cost
6. Increasing market share that results from a competitive advantage
7. Reducing incidents that result in liability
8. Improving defense posture in litigation
9. Conserving input materials and energy
10. Facilitating the attainment of permits and authorization
11. Improving industry/government relations

2MARK QUESTION ANSWERS

1. Give the ISO 9000 Series of Standards?

1. ISO 9000, "Quality Management and Quality Assurance Standards Guidelines for Selection and Use".
2. ISO 9001, "Quality Systems – Model for Quality Assurance in Design, Development, Production, Installation & Servicing".
3. ISO 9002, "Quality Systems – "Model for Quality Assurance in Production, Installation & Servicing".
4. ISO 9003, "Quality Systems – "Model for Quality Assurance in Final Inspection and Test".
5. ISO 9004-1, "Quality Management and Quality System Elements – Guidelines".

2. What is the need for ISO 9000?

ISO 9000 is needed to unify the quality terms and definitions used by industrialized nations and use terms to demonstrate a supplier's capability of controlling its processes.

3. Give some other quality systems?

- i. QS-9000
- ii. TE-9000
- iii. AS9000

4. What are the three sections of QS-9000?

- i. Common requirements, which include the exact text of ISO 9001 and the addition of automotive/heavy trucking requirements.
- ii. Additional requirements covering production part approval process, continuous improvement and manufacturing capabilities.