UNIT V QUALITY SYSTEMS 9

Need for ISO 9000- ISO 9000-2000 Quality System – Elements, Documentation, Quality auditing- QS 9000 – ISO 14000 – Concepts, Requirements and Benefits – Case studies of TQM implementation in manufacturing and service sectors including IT.

Evolution of of IS 9000 series of standards

The International Organization of Standardization (ISO) was founded in 1946 in Geneva, Switzerland. The development of International Standards is to facilitate the exchange of goods and services worldwide. ISO consists of more than 90 country members.

The ISO Technical Committee (TC) developed a series of International Standards for Quality Systems, which were first published in 1987. The standards (**ISO 9000,9001, and 9004**) were intended to be advisory and developed for use in **two-party contractual situations** and **internal auditing**.

These standards were adoted by European Community and have been accepted worldwide with emphasis on quality and economic competetiveness.

The fourth edition of ISO 9001 was released in the year 2008 and it replaces the third edition (ISO9001 : 2000), which have been amended to clarify the points in the text and also to enhance the compatibility with ISO 14001 : 2004.

Most countries have adopted ISO 9000 series as their national standards.

scope and purpose of ISO 9000 Series standards

The ISO 9000 series Stadnards is generic in scope. By design, the series can be tailored to fit any organization ‘s needs. Whether it is large or small, a manufaturerer or a service organization. It can be applied to construction, engineering, health care, legal, and other professional services as well as the manufacturing of anything from nuts and bolts to spacecraft. Its purpose is to unify quality terms and defi nitions used by industrialized nations and use those terms to demonstrate the supplier’s capability of controlling the processes.

In very simplified terms , the standards require an organization to say what it is doing to ensure quality, then do what it says,and, finally document or prove that it has done what it said.

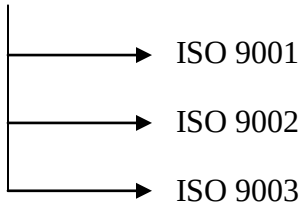
ISO 9000 Series of Standards.

ISO 9000: 2005 - Quality Management Systems (QMS) – Fundamentals and Vocabulary discusses the fundamental concepts related to QMS and provides the terminology used in the other two standards.

ISO 9001 : **2008 – Quality Management Systems (QMS) –** Requirements is the standards used registration by demonstrating conformity of the QMS to customers, regulatory and organization's own requirements.

ISO 9004 : 2000- Quality Management Systems (qms) – *GUIDELINES FOR PERFORMANCE IMPROVEMENT* provides guidelines that an organization can use to establish a QMS focused on improving performance.

ISO 9000



ISO 9001

Design, Development, Production, Installation & Servicing

ISO 9002

Production, Installation & Servicing

ISO 9003

Inspection & Testing

ISO 9004

Provides guidelines on the technical, administrative and human factors affecting the product or services.

BENEFITS OF ISO 9000 STANDARDS :

- Achievement of international standard of quality.
- Value for money.
- Customer satisfaction.
- Higher productivity.
- Increased profitability
- Improved corporate image
- Access to global market
- Growth of the organization
- Higher morale of employees

CLAUSES (ELEMENTS) OF ISO 9000 (During the year 1987)

4.1 Management Responsibility
- Adequate resources for the verification activities
- Need for trained personnel
- Work and verification activities including audits
- A Management Representative to be identified
- Review the Quality System performance and customer complaints periodically

4.2 Quality System
4.3 Contract review
4.4 Design Control
4.5 Documents Control
4.6 Purchasing
4.7 Purchaser – Supplied Product
4.8 Product Identification and Traceability
4.9 Process Control
4.10 Inspection and Testing
4.11 Inspection Measuring and Test Equipment
4.12 Inspection and Test Status
4.13 Control of Non – Conforming Product
4.14 Corrective Action
4.15 Handling, Storage, Packaging and Delivery
4.16 Quality Records
4.17 Internal Quality Audits
4.18 Training
4.19 Servicing
4.20 Statistical Techniques

CLAUSES (ELEMENTS) OF ISO 9000 (During the year 2000)

1. Scope
2. Normative Reference
3. Terms and Definitions
4. Quality Management System (QMS)
   - 4.1 General Requirements
   - 4.2 Documentation
5. Management Responsibility
   - 5.1 Management Commitment
   - 5.2 Customer Focus
   - 5.3 Quality Policy
   - 5.4 Planning
   - 5.5 Responsibility, Authority and Communication
   - 5.6 Management Review
6. Resource Management

6.1 Provision of Resources
6.2 Human Resources
6.3 Infrastructure
6.4 Work Environment

7. Product Realization
   7.1 Planning of Product Realization
   7.2 Customer related processes
   7.3 Design and Development
   7.4 Purchasing
   7.5 Production and Service Provision
   7.6 Control of Monitoring and Measuring devices
8. Monitoring and Measurement
   8.1 General
   8.2 Monitoring and Measurement
   8.3 Control of Non-Conforming Product
   8.4 Analysis of Data
   8.5 Improvement

(1) Discuss in detail the steps that are necessary to implement a Quality Management System.

IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEM :

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

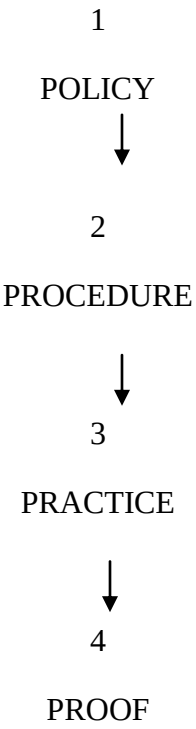
PITFALLS OF SUCCESSFUL IMPLEMENTATION :

1. Using a generic documentation program or another organization's documentation program
2. Over-documentation or documentation that is too complex
3. Using External Consultants without involvement
4. Neglecting to obtain top management's involvement

5. Developing a system that does not represent what actually occurs

DOCUMENTATION

In every organization, the quality system must be documented properly. The documentation of the system can be seen as a hierarchical format as shown.



Quality Audit

Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

Types of audit

- 3 types
  - **Process audits**
  - **Product audits**
  - **System audits**

Process audits

- Evaluation of the content and effectiveness of specific processes and work activities

- To confirm the process parameters and improve capability of the process
- To ensure the realization of process quality characteristics
- To ensure improvement of process control during service provision
- Product audits

-To identify opportunities for improvement to establish the quality level of units before final inspection and testing

-To establish the capability of the inspection function

-To determine the usefulness of inspection/tests

- Audits are distinguished by the party requesting:
- 1st party audit (internal audits) – the auditee audits its own quality system according to a quality standard.
- 2nd part audits (supplier audits) – the customer audits the supplier's quality system
- 3rd party audits – these are external certification audits by an independent institution in order to certify the quality system

Products audits

Investigation of products conformance to specified characteristics

-To obtain additional neutral assessment of product's level of quality

-To obtain additional assurance that specified quality requirements are met

System audits

- Evaluation all the elements of the quaity system in order to:-
- Verify usefulness, suitability and effectiveness
- Verify adequate documentation
- Verify compliance with requirements
- Determine weak points

Purpose of audits

- Registration / certification audit

- Verify that the organization's QMS meet the requirements of ISO 9001 : 2000

Internal audit

- Identify opportunities for improvement
- Maintain ISO 9001 certification

(2) What are the objevtives of Internal audit?

Objectives of the Internal audit

- To verify conformance to applicable standards
- To verify conformance to documented procedures
- To verify effectiveness of the processes in the system
- To identify opportunities to improve the system
- Creating and environment for successful audits (1)

QUALITY AUDITING

The term Audit refers to a regular examination and checking of accounts or financial records, settlement or adjustment of accounts.

It also refers to checking, inspection and examination of Production Processes.

PURPOSE OF QUALITY AUDIT :

- To establish the adequacy of the system.
- To determine the effectiveness of the system.
- To afford opportunities for system analysis.
- To help in problem solving.
- To make decision making easier etc.

TYPES OF QUALITY AUDIT :

1. First – Party Audit.
2. Second – Party Audit.
3. Third – Party Audit.

Quality audit can also be classified on the basis of the area taken into account for the audit such as

- System Audit.

- Process Audit.
- Product Audit.
- Adequacy Audit.
- Compliance Audit.

ISO 14000 – ENVIRONMENTAL MANAGEMENT SYSTEM (EMS)

The overall aim of the Environmental Management systems is **to provide protection to the environment** and **to prevent pollution.**

- The success of ISO 9000 along with increased emphasis on Environmental issues were instrumental in ISO's decision to develop Environmental Management Standards.

- In 1991, ISO formed the Strategic Advisory Group on the Environment (SAGE) which led to the formation of Technical Committee (TC) 207 in 1992.

- Mission of TC207 is to develop standards for an Environmental Management System (EMS) which was identified as ISO 14000.

- TC 207 has Established six sub-committees
    1. Environmental Management System (EMS)
    2. Environmental Auditing (EA)
    3. Environmental labeling (EL)
    4. Environmental Performance Evaluation (EPE)
    5. Life-Cycle Assessment (LCA)
    6. Terms & Definitions

Environmental Management System (EMS) :

EMS has two Evaluation Standards. They are

1. Organization Evaluation Standards 2. Product Evaluation Standards

REQUIREMENT OF ISO 14001

There are six elements

1. GENERAL REQUIREMENTS

- EMS should include policy, planning implementation & operation, checking & corrective action, management review.

2. ENVIRONMENTAL POLICY (Should be based on mission)

- The policy must be relevant to the organization's nature.
- Management's Commitment (for continual improvement & preventing pollution).
- Should be a framework (for Environmental objectives & Targets).
- Must be Documented, Implemented, & Maintained.

3. PLANNING

- Environmental Aspects
- Legal & other Requirements
- Objectives & Targets
- Environmental Management Programs

4. IMPLEMENTATION & OPERATION

- Structure & Responsibility
- Training, Awareness & Competency
- Communication
- EMS Documentation
- Document Control
- Operational Control
- Emergency Preparedness & Response

5. CHECKING & CORRECTIVE ACTION

- Monitoring & Measuring
- Nonconformance & Corrective & Preventive action
- Records
- EMS Audit

6. MANAGENMENT REVIEW

- Review of objectives & targets
- Review of Environmental performance against legal & other requirement
- Effectiveness of EMS elements
- Evaluation of the continuation of the policy

ISO 14000: Environmental Standards

ISO 14000

The International Organization for Standards published its Quality Management System (ISO9000) in 1987. ISO9000 became an instant world wide success.

In 1991, ISO formed **Strategic Advisory Group** on the **Environment (SAGE)**. The purpose of formation of this group was world wide increase in emphasis of management of environmental issues a part of quality management systems. This group proposed the formation of Technical Committee to develop standards that deal with environmental management system. This technical committee, TC 207 developed the standards called ISO14000.

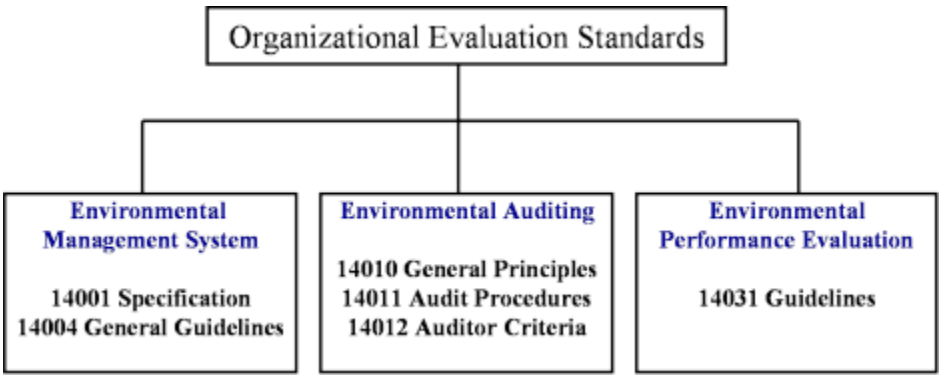
The EMS is part of a comprehensive management system that addresses with the overall business activities, including its products and services, affect the environment.

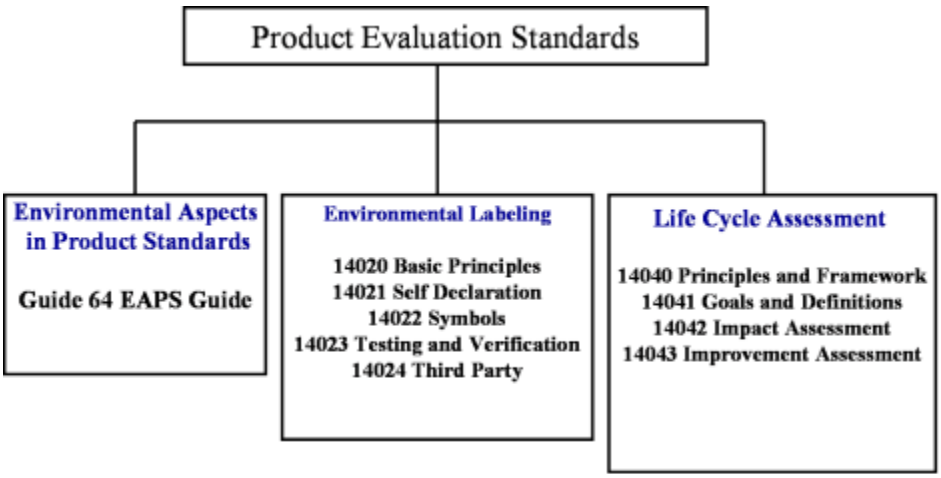
ISO14000 Series Standards

ISO14000 is a generic standard. When we state the term generic, we mean that- like ISO9000-it is not an industry specific standard.

The series is divided into two separate areas-the organization evaluation standards and the product evaluation standards. The first deals with Environmental Management System (EMS), Environmental Auditing (EA), and Environmental Performance Evaluation (EPE), whereas later deals with Environmental Aspects in Product Standards (EAPS), Environmental Labeling (EL), and Life-Cycle Assessment (LCA).

See following figures to understand the division of standards as mentioned above:



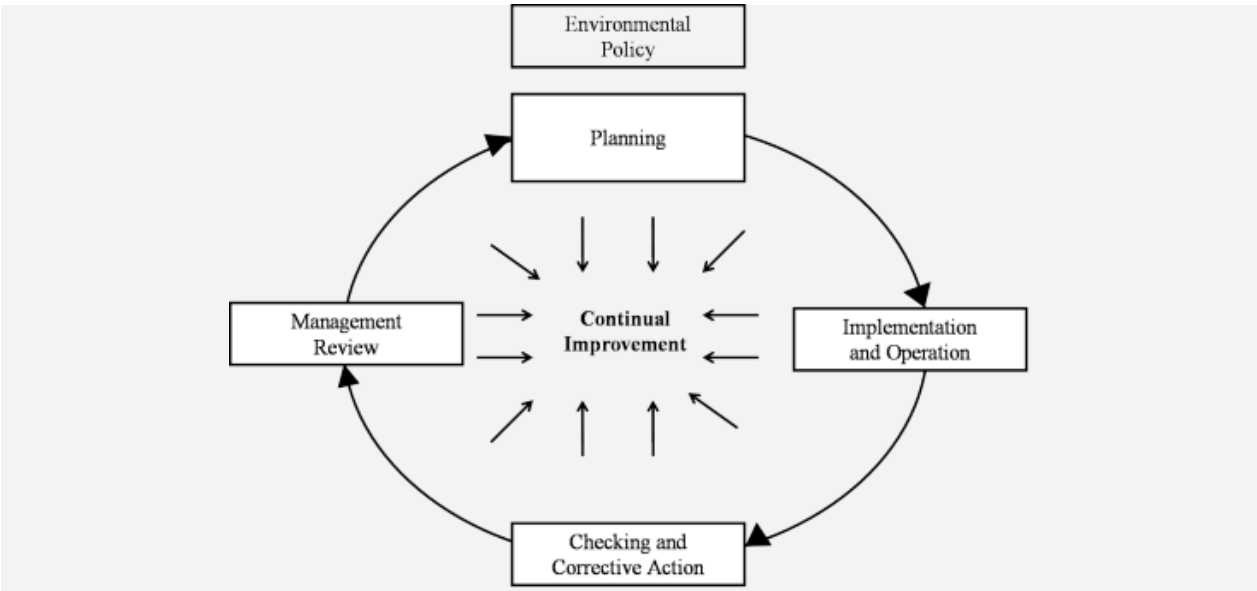


Concepts of ISO 14001:2004 Standards

In this post we will particularly discuss ISO 14001:2004 because this standards is the heart of all the environmental standards. This standard provides organizations with the elements of for an environmental systems, which can be integrated into other management systems to help achieve environmental and economic goals.

This standard provide guidelines for registration and/or self-declaration of the organization's environmental management systems. This standard is written in a manner that it can be applicable to all types and sizes of organizations. This standard is also capable to accommodate diverse geographical, cultural, and social conditions.

The demonstration of successful implementation of the system can be used to assure other parties that an appropriate EMS is in place. The basic approach to Environmental System can be understood with the help of following diagram:



Environmental Management System Model

ISO 14001:2004 works as follows:

- As stated earlier in this post that ISO14000 is generic in nature. It does not intend to specify the level of environmental performance of an organization. If that had been the case, ISO would have written it according to the specific activity of each business.
- However, ISO has developed many other environmental standards that deal with specific environmental standards. These standards are beyond the scope of ISO14001:2004 standards at the moment.
- ISO14001:2004 provide a framework to the organizations so that they could communicate about EMS matters with the other stakeholders including customers, environmental regulators, the public and so forth.
- It also provides framework to the organizations-irrespective of their current level of environmental maturity-to remain committed for environmental management and its continual improvement as well.

BENEFITS OF ENVIRONMENTAL MANAGEMENT SYSTEM :

GLOBAL BENEFITS

- Facilitate trade & remove trade barrier
- Improve environmental performance of planet earth
- Build consensus that there is a need for environmental management and a common terminology for EMS

ORGANIZATIONAL BENEFITS

- Assuring customers of a commitment to environmental management
- Meeting customer requirement
- Improve public relation
- Increase investor satisfaction
- Market share increase

- Conserving input material & energy
- Better industry/government relation
- Low cost insurance, easy attainment of permits & authorization