Unit V

INTRODUCTION TO IS/ISO 9004:2000

International standardization began in the electro technical field: the international electro Commission (IEC) was established in 1906. ISO (International Organization for Standardization) is a network of the national standards institutes of 156 countries, on the basis of one member per country, with a central secretariat in Geneva, Switzerland, that coordinates the system.

The objective of ISO is to promote the development of standardization and related activities in the world with a view to facilitating international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity. The results of ISO technical work are published as International Standards. Bureau of Indian Standards (BIS) is the Indian representative of ISO.

ISO is the world"s largest developer of standards that makes a positive difference, not just to engineers and manufacturers for whom they solve basic problems in production and distribution, but to society as a whole.

ISO provide governments with a technical base for health, safety and environmental legislation.

ISO 9000 STANDARDS

ISO 9000 series has five international standards on quality management.

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

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.

1
POLICY
2
PROCEDURE
3
PRACTICE
4
PROOF

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

1. System Audit.
2. Process Audit.
3. Product Audit.
4. Adequacy Audit.
5. Compliance Audit.

ISO 14000 – ENVIRONMENTAL MANAGEMENT SYSTEM

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

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