

ISO 9000 & 14000



DEFINITION & OVERVIEW

- BENEFITS
- ELEMENTS
- STEPS FOR REGISTRATION

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WHAT IS ISO 9000?

- ISO 9000 is a series of international standards concerning quality management and assurance developed to help organizations establish and maintain an effective quality management system (QMS). The standards can help business entities fulfill regulatory requirements, improve continuously, and ensure customer satisfaction.
- ISO 9000 helps a company to satisfy its customers, meet regulatory requirements, and achieve constant improvement.

BENEFITS

- ISO certification helps in gaining customer trust.
- The series of standards encourages preventive thinking, which enables businesses to address issues before they arise and impact customers.
- It minimizes the errors in recurring processes.
- The standards help businesses save time through the efficient management of resources.
- The cumulative effects of implementing these standards can result in increased market share and profit potential.
- The set standards reduce manual work through process automation and process integration.
- Employees have a clear idea regarding their roles and responsibilities. This improves job satisfaction.
- It recognizes the weaknesses of an organization and recommends corrective measures.
- It sets the basic framework for developing an optimal process and total quality management (TQM)

ELEMENTS OF ISO 9000

- Inspection and testing
- Design control
- Management responsibility
- Internal quality audits
- Servicing
- Training
- Contract review
- Process control

- Product identification and tracking
- Corrective and Preventive Actions (CAPAs)
- Quality system
- Control of Non-confirming product
- Statistical techniques
- Purchasing
- Document and data control

Inspection and Testing

Management Responsibility

Design Controls

All incoming parts and materials must be inspected prior to use. In-process and final inspections should also occur before the finished product is shipped. Records of all inspections should be maintained. An organization's management team should develop a quality policy and manual. The quality policy outlines the organization's strategic goals and mission, whereas the quality manual documents the scope of the QMS. Product teams should develop a comprehensive plan for designing and developing the product. Design changes should be thoroughly documented and reviewed by key stakeholders throughout the new product development process.

Additionally, verification and validation testing are necessary to ensure that the finished product meets user requirements and performs as intended.

Internal Audits

Training Management

Servicing

Organizations should perform routine internal audits to ensure that their QMS meets the requirements of applicable regulations and standards. Results of the audit are subsequently communicated to the management team, and any deficiencies are addressed. Organizations must develop, maintain, and track training records to ensure that employees remain proficient on all current company policies, processes, and procedures Servicing of products should follow formal written procedures and meet customer expectations.

Contract Review

Process Control

Purchasing

Product and service contracts should be reviewed to ensure that they align with customer needs and expectations. The development of procedures such as work instructions and assembly instructions is necessary to ensure that products are produced consistently, efficiently, and with fewer errors. Procurement teams should document and implement procedures for evaluating vendors and suppliers and establish guidelines for sourcing parts and materials.

Document Control

Product Identification and Tracking

Corrective and Preventive Actions (CAPAs)

A robust system must be in place to ensure that all product documentation is created, distributed, reviewed, revised, stored, and disposed of in a controlled manner. Proper labeling is necessary to ensure that products are easily identifiable and traceable throughout the lifecycle.

Teams must conduct investigations to identify the root cause of product nonconformities. In turn, countermeasures should be put in place to correct and prevent issues from reoccurring.

Quality system

Control of Non-confirming products

Statistical techniques

 This system comprises of quality manual in which supporting procedures are created and maintained.

- Materials or products that do not comply with the specifications are rejected and separated from normal production. The concerned authorities can decide whether the rejected materials will be used, reworked or returned to the supplier.
- Control graphs, graphs and other analysis methods determine the working a process and facilitate its continuous improvement.



STEPS FOR ISO CERTIFICATION

Pre-Requisite to ISO Certification process

Choosing the type of ISO Certification: Various types of ISO certification available such as

- 1. ISO 9001 2008– Quality Management
- 2. ISO 14001-- Environmental Management
- 3. ISO 27001 -- Information security Management
- 4. ISO 22008 Food Safety Management and so on.

Choosing an ISO Certification Body: It is very important to choose recognized and credible certification body.

When choosing the ISO registrar, should follow following points

- 1. Evaluate several ISO certification service providers.
- 2. Check if they are following the CASCO standards.(CASCO is the ISO committee)
- 3. Check weather it is accredited or not.



STEPS FOR ISO CERTIFICATION

Create an application/ contract:

The applicant and the registrar should agree on a contract. This contract usually defines rights and obligations of both parties and includes liability issues, confidentiality, and access rights.

Quality Documents Review:

The ISO auditor will view all the quality manuals and documents related to various policies and procedures being followed in the organization. ISO auditor to identify the possible gaps against the requirements stipulated in the ISO standards.

Make an action Plan:

After the ISO auditor communicates the existing gaps in the organization, then the organization should prepare an action plan to eliminate these gaps.



STEPS FOR ISO CERTIFICATION

Initial Certification Audit:

The initial certification audit is divided in to Two categories

Stage-1: The ISO auditor will audit the changes made by the organization. Then they will try to identify the possible non-conformities in the systems and procedures to the desired quality management system.

Stage 2 After all the required changes are done in the organization, the ISO auditor does the final auditing. The auditor will check whether all the non-conformities have been eliminated or not as per ISO quality standards, if the ISO auditor is satisfied, they will prepare the final ISO audit report and forward it to registrar.

Completing the ISO Certification:

After all non-conformities are addressed and all the findings are put in the ISO audit report, the registrar will grant you the ISO certification.

Surveillance Audits:

Surveillance audit is basically conducted to ensure that ISO quality standards are being maintained by the organization It is conducted from time to time.

WHAT IS ISO 14000?

ISO 14000 is a set of standards created to help companies around the world reduce their adverse impact on the environment. It's a framework for improved and more environmentally-conscious quality management systems by organizations large and small. ISO 14000 is meant to be a step-by-step guide for establishing and then achieving environmentally-friendly objectives for business practices and products. The purpose is to help companies manage processes efficiently while minimizing environmental effects.

BENEFITS

- Companies and customers may also pay more for products that are considered environmentally friendly.
- On the cost side, meeting the ISO 14000 standards can help reduce costs, as it stresses the efficient use of resources, limiting waste, recycling, and even finding new uses for previously disposed of byproducts.
- It is sign of a commitment to the environment, which can be used as a marketing tool for companies.
- It also help companies meet certain environmental regulations.
- To sell products to companies that use ISO 14000- certified suppliers.
- Satisfies investor criteria.
- Improve industry- government relations.

ISO 14000 STANDARDS

The ISO 14000 family of standards is developed by ISO Technical Committee ISO/TC207 and its various subcommittees.

ISO 14000: standards and practices can be applied to any organization, regardless of size or industry.
ISO 14001: 2015 Environmental management systems - Requirements with guidance for use.
ISO 14004: 2016 Environmental management systems - General guidelines on implementation.
ISO 14005: Environmental management systems - Guidelines for a flexible approach to phased implementation.
ISO 14006: 2011 Environmental management systems - Guidelines for incorporating eco-design.
ISO 14015: 2001 Environmental management - Environmental assessment of sites and organizations (EASO)

ISO 14000 STANDARDS

- ISO 14020:2000 to 14025: 2000 Environmental labels and declarations- General Principles
- ISO/NP 14030: Green bonds -- Environmental performance of nominated projects and assets; discusses postproduction environmental assessment
- ISO 14031: 2013: Environmental management Environmental performance evaluation Guidelines
- ISO 14040: 2006 to 14049: 2006: Environmental management Life cycle assessment discusses pre-productive planning and environment goal setting
- ISO 14050: 2009: Environmental management Vocabulary; terms and definitions
- ISO/TR 14062: Environmental management Integrating environmental aspects into product design and development
- ISO 14063: 2006: Environmental management Environmental communication Guidelines and examples
- ISO 14064: 2006: Greenhouse gases; measuring, quantifying, and reducing green house gas emissions.
- ISO 14090: 2019: Adaptation to climate change Principles, requirements and guidelines

ELEMENTS OF ISO 14000

- Environmental policy: Develop a statement of organization's commitment to the environment. Use this policy as a framework for planning and action.
- * Environmental aspects: Identify environmental attributes of the products, activities and services.
- * Legal and other requirements: Identify and ensure access to relevant laws and regulations.
- Objectives and Targets: Establish environmental goals for the organization, in line with the policy, environmental impacts, views of interested parties and other factors.
- * Environmental management program: Plan actions to achieve objectives and targets.
- * Structure and responsibility: Establish roles and responsibilities and provide resources.
- Training, awareness and competence: Ensure that the employees of the organization are trained and capable of carrying out their environmental responsibilities.
- * Communication: Establish processes for internal and external communications on environmental management issues.
- * **EMS documentation:** Maintain information on your EMS and related documents.
- **Document control:** Ensure effective management to procedures and other system

REGISTRATION AND THE AUDIT PROCESS

Two levels of certification

- 1. Self Declaration
- 2. Certification / Registration

Eight steps of registration process

- Decision
- Internal preparation
- Internal Determination
- Accredited ISO 14000 Registrar
- Preliminary assessment
- Document review
- Formal EMS audit
- Certification assessment
- Elimination of Nonconformance
- Registration Awarded

Step 1: Secure Commitment From the Top

- The need for resources (money, employee, time) that only top management can authorize.
- Inevitably there will be individual who prefer the status. When they hold senior position in the organization, it takes intervention by top management to overcome their resistance.
- The most importance aspect of leader is setting a positive example for employees to follow.

Step 2: Decision to Proceed

- Develop a rough draft of the costs for external services and time for internal tasks.
- An estimate of risk should be included in the decision-making process.
- Management should publicizing the ISO 14000 effort to all level of employees.

Step 3 Form a Steering Committee

- The steering committee provides leadership in establishing and implementing the EMS and in monitoring its performances.
- The steering committees role is to determine what is needed, secure the resources to satisfy those needs, and manage the activities of those given assignments.

Step 4 Steering Committee Training

- The steering committee members also must understand the rationale for undertaking the project, that the work does not end with registration, and that ISO 14000 will be a normal part of doing business forever.
- A team-building seminar should be included in the Steering Committees training since members will have to work effectively as a team.

Step 5 Train Internal Auditors

- The number of internal auditors needed will depend on the size and complexity of the organization.
- To ensure effectiveness, the internal auditors should complete an environmental course.

Step 6 Asses Current Conformance

- Usually observe by internal auditors (steering committee)
- The goal is to determine what needs to be done to satisfy the requirement of ISO 14000 and applicable laws and regulations.

Step 7 Plan Preparation Project

- Using the results of the initial assessment, develop a list of task that must be performed to bring the organization into conformance.
- The timeline and timeline chart also necessary for the steering committee to done some tasks or plan a schedule for the registration.

Step 8 Select Project Teams

- Once the plan has been develop, the steering committee then determines the composition of the team that will be assigned specific tasks.
- Ensure that the team is cross-functional. It will need someone with unbiased views (an outsider)

Step 9 Train Project Teams

- Once the members of project teams has been selected, they will be trained in some essential subjects.
- The trainer usually the trains internal auditors and senior manager.

Step 10 Activated Project Teams

- Project team activation should be a formal, structured and interactive process.
- The team activation
 - given overview of the project
 - set the schedule of meeting
 - proposed schedule for individual task and overall project

Step 11 Project Feedback and Monitoring

• The steering committee will receive feedback from all teams. The steering committee uses this information to monitor progress and to provide new instruction for the team as appropriate.

Step 12 Select a Registrar

- Companies typically select their registrar 6 to 18 months prior to the target date for the registration audit.
- Aspect of registrar
- background information on potential registrar
- solicit references on registrar from other companies
- question potential registrar directly
- make sure the potential registrar can accommodate your schedule for registration

Step 13 Preliminary Assessment Audit and Document Review

• The preliminary assessment audit is conducted to ISO 14000. The review usually conducted at the registrars facility

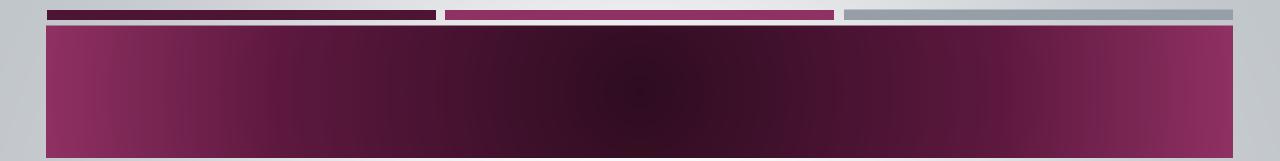
Step 14 Final Pre-audit Touch-Up

Before registration audit, the final preaudit touch-up must be free from any major or minor conformance.

Step 15 Registration Audit

• If no major non-conformance are found and the auditors are satisfied that the implementation of the EMS is sound, the lead auditor will recommend the registrar grant registration.

ISO 9000 Standards	ISO 14000 Standards
ISO 9000 is devoted to quality management. It is designed to help companies and other organizations ensure that the products and services they create and the processes they use to create them meet a high standard of quality and integrity.	ISO 14000 is a set of standards for companies and other organizations that want the processes they use and the products they create to have a minimal adverse impact on the environment.
ISO 9001:2015: Quality Management Systems - Requirements	ISO 14001 and ISO 14002: Specification of Environmental Management Systems
ISO 9000:2015: Quality Management Systems - Fundamentals and Vocabulary (definitions)	ISO 14004: Guideline Standard
ISO 9004:2018: Quality Management - Quality of an Organization - Guidance to Achieve Sustained Success (continuous improvement)	ISO 14015, ISO 14016, and ISO 14017: Environmental Auditing and Related Activities
ISO 19011:2018: Guidelines for Auditing Management Systems	ISO 14020, ISO 14021, and ISO 14024: Eco labelling
	ISO 14030 and ISO 14031: Environmental Performance Evaluation
	ISO 14040 – ISO 14043: Life Cycle Assessment



THANK YOU!!!

SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES, COIMBATORE.