BP606T. Pharmaceutical Quality Assurance.

Unit-One

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PART-IV HOURS:02
ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for

ISO 9000 and ISO 14000

The International Organization of Standardization (ISO) is a worldwide federation consisting of member bodies from 91 countries, which promotes the development of international manufacturing, trade and communication standards.

ISO 9000 refers to a generic series of standards published by the ISO that provide quality assurance requirements and quality management guidance. ISO 9000 is a quality system standard, not a technical product standard. The ISO 9000 series currently contains four standards - ISO 9001, ISO 9002, ISO 9003 and ISO 9004. Firms select the standard that is most relevant to their business activities. However, these four standards will be revised in late 2000. More information is provided later in this paper under ISO 9000:2000.

ISO 14000 refers to a series of standards on environmental management tools and systems. ISO 14000 deals with a company's system for managing its day-to-day operations and how they impact the environment. The Environmental Management System and Environmental Auditing address a wide range of issues to include the following:

1. Top management commitment to continuous improvement, compliance, and pollution prevention.

2. Creating and implementing environmental policies, including setting and meeting appropriate targets.

3. Integrating environmental considerations in operating procedures.

4. Training employees in regard to their environmental obligations.

5. Conducting audits of the environmental management system.

ISO 9000 and ISO 14000 are tools to assist business and government to insure the quality of their products and services, and to manage the impact of their activities on the environment. Like all ISO standards, their use is voluntary unless a business sector makes them a market requirement or a government issues regulations making their use obligatory. Organizations that implement ISO 9000 and ISO 14000 voluntarily do so to improve operations and provide real benefits.

Why Consider ISO 9000 Registration

There are several benefits to implementing this series in your company. There is also a strong belief that having a documented quality procedure gives a firm a strong advantage over its competitors. For example, it will guide you to build quality into your product or service and avoid costly after-the-fact inspections, warranty costs, and rework.

Most importantly, more contractors are working with ISO certified customers every year as the certifications are more widely used and accepted in the United States.

Becoming ISO Certified or Registered

In order to become certified or registered (either term may be used) for three years, companies must be audited by a third-party registrar to make sure they comply with all of the elements of the standard. A registrar is a third-party company that is contracted to evaluate an organization's quality management system to the requirements of the ISO 9000/14000 Standards. For a list of accredited registrars contact:

Registrar Accreditation Board (RAB)
Phone: (888) 722-2440 or (414) 272-3937
Fax: (414) 765-8661, or
Email: **www.rabnet.com**

Typically, contracting firms apply for registration under 9001 if a contractor performs design work or 9002 if they just install work. In the case of the 9001 Standard, there are 20 elements covering such items as management responsibility, quality system, contract review, design control, document and data control and purchasing.

The auditing process takes an average of 12-24 months if the firm currently uses a quality system. Consultants can be hired to assist a firm in preparing for the audit. Using a consultant to help a firm prepare for registration is not required; however, research on certification shows an initial ISO 9000 series failure rate of 60% for companies that try to prepare without outside consulting help.

The cost of certification varies depending on the size and sophistication of a company. Some rough estimates are:

Certification Consulting $25,000 - $80,000
Certification Registrar $10,000 - $30, 000

Registrars typically perform an initial visit, two-three day preliminary audit and then a four-day final audit. Once a firm is registered, there are also some costs involved for surveillance audits,

which occur every six months and the re-audit process every three years. Additionally, each firm must have an internal audit team for continuous improvement and auditing.

Though the investment of time, money and staff resources are considerable in the ISO 9000/14000 certification process, most certified firms report returns on their investment through monetary savings, marketing advantages and better procedures and information to help them to continue to reduce costs and waste in their firms.

Approval

When a firm is approved, they receive a certificate of registration for the facility registered and ISO standard used. They can then use the certificate number and symbol on advertising and correspondence. The registrar lists them in its directory identifying facility locations, ISO standard used and certificate number. For continued certification, they should expect registrar surveillance audits about every six months and a re-audit every three years.

Changes Planned to ISO 9000 in 2000

The International Standards Organization (ISO) periodically reviews the ISO 9000 Standards to ensure they are current and relative to the needs of industry. As a result from feedback of the 1994 version of the standard, a new draft standard called ISO 9000:2000 is currently under review and is expected to be released in the last 3 months of 2000.

Key needs addressed in the new standard include:

1. A process or whole system approach
2. Compatibility with other management systems likes ISO 14000
3. Continuous improvement
4. Stakeholder needs
5. User friendly language

The following items are most likely to change when the ISO 9000 is finalized.

1. The current series has 20 published standards. The proposed new model will have a mere four, which are:

a. ISO 9000 - Concepts and Terminology

b. ISO 9001 - Model for Quality Assurance

c. ISO 9004 - Model for Quality Management

d. ISO 10011 - Guidelines for Auditing Quality Systems

2. Many elements of the 20 standards will be folded into the core set. Additionally, once ISO 9001:2000 Standard, the standard that applies to contracting firms is finalized, it will replace the need/use of ISO 9002 and ISO 9003 in this standard. This new standard will be flexible enough to incorporate all three previous standards into one.

3. The biggest change in the ISO 9001:2000 will be a new emphasis on the closed loop process. The revised standard is designed to place more emphasis upon "the processes" of a business, rather than being "system" based. This means emphasis is placed on the *plan, do, check-act model* already incorporated in ISO14001, the environmental standard.

ISO 9000 series of Standards

ISO 9000 is defined as a set of international standards on quality management and quality assurance developed to help companies effectively document the quality system elements needed to maintain an efficient quality system. They are not specific to any one industry and can be applied to organizations of any size.

ISO 9000 can help a company satisfy its customers, meet regulatory requirements, and achieve continual improvement. It should be considered to be a first step or the base level of a quality system.

ISO 9000 series of Standards

The ISO 9000 family contains these standards:

- ISO 9001:2015: Quality management system- Requirements
- ISO 9000:2015: Quality management system- Fundamentals and Vocabulary
- ISO 9004:2018: Quality management – Quality of an Organization
- ISO 19011:2018: Guidelines for Auditing management system

ISO 9000 history and revisions: ISO 9000:2000, 2008, and 2015

ISO 9000 was first published in 1987 by the International Organization for Standardization (ISO), a specialized international agency for standardization composed of the national standards bodies of more than 160 countries. The standards underwent major revisions in 2000 and 2008.

The most recent versions of the standard, ISO 9000:2015 and ISO 9001:2015, were published in September 2015.

ASQ administers the U.S. Technical Advisory Groups and subcommittees that are responsible for developing the ISO 9000 family of standards. In its standards development work, ASQ is accredited by ANSI.

ISO 9000:2000

ISO 9000:2000 refers to the ISO 9000 update released in the year 2000.

The ISO 9000:2000 revision had five goals:

1. Meet stakeholder needs
2. Be usable by all sizes of organizations
3. Be usable by all sectors
4. Be simple and clearly understood
5. Connect quality management system to business processes

ISO 9000:2000 was again updated in 2008 and 2015. ISO 9000:2015 is the most current version.

ISO 9000:2015 principles of Quality Management

The ISO 9000:2015 and ISO 9001:2015 standards are based on seven quality management principles that senior management can apply to promote organizational improvement.

ISO 9000 Quality Management Principles

1. Customer focus
   - Understand the needs of existing and future customers
   - Align organizational objectives with customer needs and expectations
   - Meet customer requirements
   - Measure customer satisfaction
   - Manage customer relationships
   - Aim to exceed customer expectations
   - Learn more about the customer experience and customer satisfaction
2. Leadership
   - Establish a vision and direction for the organization
   - Set challenging goals
   - Model organizational values
   - Establish trust
   - Equip and empower employees
   - Recognize employee contributions
   - Learn more about leadership
3. Engagement of people
   - Ensure that people's abilities are used and valued
   - Make people accountable
   - Enable participation in continual improvement

- Evaluate individual performance
- Enable learning and knowledge sharing
- Enable open discussion of problems and constraints
- Learn more about employee involvement

4. Process approach
   - Manage activities as processes
   - Measure the capability of activities
   - Identify linkages between activities
   - Prioritize improvement opportunities
   - Deploy resources effectively
   - Learn more about a process view of work and see process analysis tools
5. Improvement
   - Improve organizational performance and capabilities
   - Align improvement activities
   - Empower people to make improvements
   - Measure improvement consistently
   - Celebrate improvements
   - Learn more about approaches to continual improvement
6. Evidence-based decision making
   - Ensure the accessibility of accurate and reliable data
   - Use appropriate methods to analyze data
   - Make decisions based on analysis
   - Balance data analysis with practical experience
   - See tools for decision making
7. Relationship management
   - Identify and select suppliers to manage costs, optimize resources, and create value
   - Establish relationships considering both the short and long term
   - Share expertise, resources, information, and plans with partners
   - Collaborate on improvement and development activities
   - Recognize supplier successes
   - Learn more about supplier quality and see resources related to managing the supply chainPDF e-standard

30 YEARS OF ISO 9000

The ISO 9000 series of standards celebrated its 30th anniversary in 2017

First published in March 1987, ISO 9001: Quality management systems - Requirements has become the most successful standard in the history of the International Organization for Standardization.

The popularity of the ISO 9000 series paved the way for other management system standards, including:

ISO 14000: Environmental management system

ISO 26000: Guidance on social responsibility

ISO 31000: Risk management Principles and Guidelines

ISO 9001 certification

ISO 9001 is the only standard within the ISO 9000 family to which organizations can certify. Learn more about ISO 9000 training and certifications with ASQ's ISO 9000 courses and learning materials.

Get started with ISO 9000

ASQ is the only place to get ANSI/ISO/ASQ Q9001-2015, the American National Standard version of ISO 9001:2015.

Available formats include:

- Published hard copy
- E-standard for immediate download and viewing (Please note, e-standards cannot be printed.)
- Spanish edition
- Site license for posting an electronic version to your Local Area Network or Intranet.

RESOURCES FOR ISO 9000 AND OTHER STANDARDS

You can also search articles, case studies, and publications for ISO 9000 resources.

Certifying the Certifier (PDF) Over a three-year period, Quality Management Company (QMC) improved itself from the inside out—and became ISO certified in the process. ISO 9001 provided QMC with a logical framework for developing a quality management system.

Prescription for Community-Based Healthcare Includes ISO 9001 (PDF) The Community Anticoagulation Therapy Clinic demonstrates how ISO 9001 principles can provide a framework for a community model of care delivery and patient safety. Customer and provider surveys demonstrate 100% satisfaction with the clinic, which uses a controlled document system based on ISO 9001, internal and external auditing, and preventive and corrective action plans.

Agricultural Firms Gain Competitive Edge With USDA's ISO 9001-Based Verification Program (PDF) The U.S. Department of Agriculture's Process Verified Program uses the ISO 9001:2000 standard to evaluate the quality management systems of agricultural businesses.

U.S. Air Force Earns High-Flying Results with Quality Management Specifications for Suppliers (PDF) Adopting ISO 9001 compliance as a sourcing criterion in its supplier selection process and requiring suppliers' quality management representatives to become ASQ Certified Quality Auditors have saved the Air Force millions of dollars and nearly eliminated critical defects in supplier products and services.

Continuous Improvement in Public Schools Through ISO 9001:2000 (PDF) Since Racine Unified School District achieved ISO 9001:2000 certification, the district has made notable progress in closing the achievement gap between demographic groups in reading and math, decreasing truancy and suspensions and increasing parent satisfaction.

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ISO 14000 is part of a series of standards that address certain aspects of environmental regulations. It's meant to be a step-by-step format for setting and then achieving environmentally-friendly objectives for business practices or products. The purpose is to help companies manage processes while minimizing environmental effects, whereas the ISO 9000 standards from 1987 were focused on the best management practices for quality assurance. The two can be implemented concurrently.

ISO 14000 includes several standards that cover aspects of the managing practices inside facilities, the immediate environment around the facilities, and the life cycle of the actual product. This includes understanding the impact of the raw materials used within the product, as well as the impact of product disposal.

The most notable standard is ISO 14001, which lays out the guidelines for putting an environmental management system (EMS) in place. Then there's ISO 14004, which offers additional insight and specialized standards for implementing an EMS.

Here are the key standards included in ISO 14000:

- ISO 14001: Specification of Environmental Management Systems
- ISO 14004: Guideline Standard
- ISO 14010 – ISO 14015: Environmental Auditing and Related Activities
- ISO 14020 – ISO 14024: Environmental Labeling
- ISO 14031 and ISO 14032: Environmental Performance Evaluation
- ISO 14040 – ISO 14043: Life Cycle Assessment

- ISO 14050: Terms and Definitions