U.S. Army Center for Health Promotion and Preventive Medicine

Just the Facts

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ISO 9000 STANDARDS

- **Quality Management Systems**
- **Document Procedures**
- **Quality System Compliance**

What is ISO 9000? International Organization for Standardization (ISO) 9000 are a set of internationally accepted standards on quality systems for organizations with design, manufacturing, and service capabilities. It is the beginning of a broader view on quality processes and systems. These ISO 9000 standards provide a model for documenting an organization's quality system and registering it to the international standards. The ISO 9000 series is a set of five individual, but related, international standards on quality management and assurance. As part of the registration process, an organization implements a quality system by following one of the three ISO 9000 models:

- ISO 9001 - Quality Systems Model for Quality Assurance in Design/Development: a model for quality assurance in design, development, production, installation, and servicing; it is the most comprehensive.

- ISO 9002 - Quality Systems Model for Quality Assurance in Production and Installation: a model for quality assurance in production, installation, and servicing.

- ISO 9003 - Quality Systems Model for Quality Assurance in Final Inspection and Tests: a model for quality assurance in final inspection and test; it is the least comprehensive.

ISO 9000 and ISO 9004 are standards to use as guidelines:

- ISO 9000 - Quality Systems Model for Quality Assurance Standards Guidelines for Selection and Use: a guideline that details the system; it is used as a guide to choose the right standards for an organization.

- ISO 9004 - Guidelines to Aid in the Development and Implementation of Internal Quality Management Element and Activities: a guideline to ensure an organization's ability to fulfill the requirements of ISO 9001 through ISO 9003 registration.

Objectives. The ISO 9000 standard objectives provide guidelines for an organization's management to develop a quality system. USACHPPM has chosen to follow the ISO 9001 quality-model based system. ISO 9001 quality system contains 20 elements:

- Management responsibility
- Quality System
- Contract review
- Control of nonconforming product
- Purchasing
- Inspection, measurement, and test equipment
- Handling, storage, packaging, and delivery
- Product identification and traceability
- Process control
- Training
- Corrective action
- Inspection and test status
- Design control
- Document control
- Internal quality audits
- Purchaser-supplied product
- Quality records
- Inspection and testing
- Statistical techniques
- Servicing

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Management Responsibility. Management will define and document the Center's quality objectives and will provide the resources necessary to implement these objectives. Examples of resources may be personnel, training, equipment, software, etc. Management must take an active role in building quality within the Center for the successful registration of our quality system.

Quality System. A quality system documents a system of procedures and instructions and how to implement them. An organization *does things right the first time* and continues doing them *the same way every time.* Whenever problems arise, an organization has documented procedures for handling and correcting them. The Quality Manual is the main document to ensure these procedures. It documents policies, work practices, Standing Operating Procedures, etc. that guide the system. The manual must have an established method for changing and updating material.

Auditing Procedures. An organization trying to receive ISO 9000 registration should use both self-audits and third-party audits. The Center's Quality Systems and Training Management Office will conduct in-house audits to assess our progress over a given time period. This is also a check for quality improvement. An organization should also hire a U.S.-accredited or internationally accredited registration company known as a "registrar." These registrars employ highly trained auditors to examine an organization's quality system to determine if it meets the guidelines of the organization's chosen ISO 9000 model standard. The auditors will:

- Talk to a large number of employees, from senior management to on-line employees.
- Review an organization's procedures to ensure all employees are following the written documentation.
- Ensure that all employees understand their job functions and how these jobs relate to the quality system.

Auditors will document if there are any areas of noncompliance. If there are serious problems, the organization will be able to correct these problems; the auditor will then return to review the changes.

ISO Registration. Registration indicates official third-party declaration that our quality system complies with the ISO 9000 standards. An organization *documents what it does, does what it documents, and then proves it.* To become ISO 9000 registered, an organization must:

- Implement a quality system that meets the requirements of one of the three ISO 9000 models (9001, 9002, or 9003).
- Document the quality system and put it into effect.
- Submit to a third-party audit by an accredited registrar who reviews the operation and the quality system that has been implemented; the registrar checks that all employees involved follow the appropriate procedures.

If an organization's quality system complies with the appropriate ISO 9000 model chosen, the organization will receive a certificate of approval.

Benefits. While ISO 9000 standards are voluntary, they are not a goal; they are the first step in achieving the Total Quality Concept. Some benefits of ISO 9000 Registration are:

- Better operation's control
- Cost savings due to improved productivity
- Improved customer relations - fewer complaints
- Improved domestic marketing
- Reduced scrap and rework
- Improved employee morale
- Improved access to foreign markets
- Improved products and services

By implementing a formal quality management system, USACHPPM ensures its customers that we are continually working to meet our customers' needs by improving our production and processes.

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