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ISO 9001:2000 QUALITY SYSTEM DEVELOPMENT

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ISO 9001:2000, now adopted by more than 150 countries, establishes a common language for quality systems around the world. The standard specifies quality system requirements for an organization to demonstrate its ability to produce product that meets customer requirements or to enhance customer satisfaction through effective implementation and continual improvement.

The standard is generic and applicable to all organizations regardless of type, size or product. In the United States, the requirements for ISO 9000 are documented in ANSI/ISO/ASQ Q9001-2000.

ISO 9001:2000 is a process approach to a quality system. An organization of any size or nature is built on a process of using management and resources to deliver a product or service that meets customer requirements. An organization that adopts ISO 9001:2000 makes a strategic decision to improve processes, enhance customer satisfaction, meet market requirements and/or improve product quality.

The model for ISO 9001:2000 shown below illustrates the process links between the five main components of the standard – quality management system, management responsibility, resource management, product realization and measurement, analysis and improvement. It also illustrates the emphasis placed on the customer, understanding requirements and customer satisfaction.
About this session
The purpose of this exercise is to illustrate the development of an ISO 9001:2000 quality system for either a feed mill or an ethanol plant. Participants will work in teams to develop aspects of the quality system in each of the four key elements of the standard, along with the guiding element of the quality management system. A brief review of each of the five items, as illustrated in the diagram, follows.

Quality management system
In order to meet the requirements of the ISO 9001:2000 standard, an organization should establish, document and continually improve a quality management system. The four main areas of compliance are management responsibility, resource management, product realization, and measurement, analysis and improvement. Documentation and control requirements specify a quality manual, documents (such as procedures and work instructions) and records. These are proof of compliance.

Management responsibility
This section spells out the ISO 9001:2000 tasks and responsibilities for management. Top management is to provide evidence of a commitment to developing, implementing and improving the effectiveness of a quality management system. The commitment is shown through these six tasks.

- Internal communication: Communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.
- Customer focus: Ensure that customer requirements are determined and customer satisfaction is enhanced.
- Quality policy: Establish a quality policy and communicate it to the organization.
• Planning: Establish quality objectives that are measurable and consistent with the quality policy. In addition, management must ensure the requirements of the quality system are carried out to meet the requirements of ISO 9001:2000.
• Responsibility, authority and communication: Management must appoint a person to serve as management representative. This person needs to have the authority and responsibility to establish, maintain and improve the quality system. Management must ensure that responsibility and authority of the organization is established and communicated within the organization.
• Management review: Management is required to review the quality management system at prescribed intervals to ensure the quality management system continues to be adequate and appropriate for the organization.

Resource management
This section focuses on people, buildings and equipment, services and work environment of an organization. Management is to determine the competency required for people, then to provide the training needed to ensure people have the skills and knowledge needed for work that effects quality. In order for people to develop products or services to meet customer requirements, management must provide and maintain the necessary buildings, equipment, workspace and services. Also included is the proper work environment to meet product requirements.

Product realization
This section deals with the functional aspect of the business. Requirements for customer interactions, product design, purchasing, production control and control of measurement devices are defined.
• Customer: The company is required to review customer orders to ensure the company is capable of meeting customer demand; to implement effective customer communication strategies; and to determine all product requirements.
• Product design and development: The engineering team is required to follow the seven-step process of design planning, design input realization, design output verification, design review, design verification and validation, and design changes.
• Purchasing: The purchasing department is required to make sure the purchased product conforms to requirements. This may be accomplished through receiving inspection, supplier selection and monitoring, providing appropriate purchasing information to suppliers and arranging for audits of quality systems at suppliers, as needed.
• Production and service provision: Included is planning and control of production by providing information, equipment, work instructions and inspection and test activities. For agriculture applications, a key provision is identification and traceability, where required. Also included is the issue of customer supplied property and handling, storage, packaging and delivery.
• Monitoring and measurement devices: This section describes activities related to the inspection and test activities. It includes deciding what measurements and monitoring to do, selecting and calibrating the necessary equipment and controlling the equipment.
Measurement, analysis and improvement

The focus of this section is the planning and implementation of monitoring and measurement activities to show that the quality system and product conform to requirements and to improve the effectiveness of the quality management system. The following activities are included:

- Monitoring and measurement: This describes the measurement of customer satisfaction, planning and conduct of internal audits of the company quality system, monitoring and measurement of processes and inspection and test of products.
- Control of nonconforming product: The requirement pertains to product that does not meet customer or company requirements and the handling and control of the product to prevent unintended use or delivery.
- Analysis of data: A company will collect data from the quality system related to customer satisfaction, product quality, supplier performance and processes. This data should be analyzed to determine opportunities for improvement.
- Improvement: ISO 9001:2000 provides opportunity for continual improvement through corrective and preventative action processes.

Reference