

## **ISO 9000 Quality Management System**

### **Lecture XI (b)** *[Chapter 2 in textbook]*

## **Quality System**

### **General**

***Establish documentation and maintain a quality system as a means of ensuring that product conforms to specified requirements***

***Prepare a quality manual covering the requirement of ISO 9000***

***Effectively implement the quality system and its documented procedures***

## **Design Control Elements**

- 1. General***
- 2. Design and development planning***
- 3. Organizational and technical interfaces***
- 4. Design input***
- 5. Design output***
- 6. Design review***
- 7. Design verification***
- 8. Design validation***
- 9. Design changes***

## **Design Control**

### **General**

***Establish and maintain documents and procedures to control and verify the design***

## **Design Control**

### ***Design and Development Planning***

***Prepare plans for each design and development activity***

***Define responsibilities for implementation***

***Assign activities to qualified personnel with adequate resources***

## **Design Control**

### ***Organizational and Technical Interfaces***

***Define interfaces between different groups that provide input into the design***

## **Design Control**

### **Design Input**

**Requirements (specifications) shall be identified, documented and reviewed**

## **Design Control**

### **Design Output**

**Output documented and expressed in terms that can be verified and validated against design review requirements**

**Meet design input requirements**

**Contain or make reference to acceptance criteria identify characteristics that are crucial to the safe and proper functioning of the product**

## **Design Control**

### **Design Review**

**Formal documented reviews of the design results shall be planned and conducted at appropriate stages of design**

**Participants shall include representatives of all functions concerned with the design stage being reviewed**

## **Design Control**

### **Design Verification**

**At appropriate stages of design, design verification shall be performed to ensure that the design stage output meets the design stage input requirements**

## **Design Control**

### **Design Validation**

**Performed to ensure that product conforms to defined user needs**

**Follows successful design verification**

**Normally performed under defined operating conditions**

**Multiple validation may be performed if there are different intended uses**

## **Design Control**

### **Design Changes**

**All design changes and modifications shall be identified, documented, reviewed and approved by authorized personnel**

## **Document and Data Control**

### **General**

**Establish and maintain documented procedures to control all documents and data that relate to the requirements of the standard**

**This may include documents of external origin such as standards and customer drawings**

## **Document and Data Control**

### **Document and Data Approval**

**Documents and data shall be reviewed and approved by authorized personnel prior to issue**  
**A master list identifying current revision status of documents shall be established and readily available**

**Pertinent issues of appropriate documents shall be available where operations essential to the effective functioning of the quality system are performed**

## **Quality System Registering Under ISO 9000**

**Quality system registration or approval (sometimes misnamed "quality system certification")**

**involves the assessment and periodic audit of the adequacy of a supplier's quality system by a third party, known as a quality system registrar**

## **Quality System Registering Under ISO 9000**

**Things to consider when selecting a registrar**

**Your system is for the benefit of your organization and describes the way that you do things**

**Registrars have no formal relationship to the International Organization for Standardization (however they are accredited by various National Standards Organizations)**

**Some registrar's certificates may not be recognized in other countries**

## **Quality System Registering Under ISO 9000**

**When a system conforms to the registrar's interpretation of an ISO 9000 standard, the registrar issues the supplier a**

**"Certificates of Registration"**

## **Quality System Registering Under ISO 9000**

**Interpretations of an ISO 9000 standard may not be consistent from one registrar to another.**

**The quality system is registered, not an individual product.**

**Consequently, quality system registration does not imply product conformity to any given set of requirements.**

## Quality System Registering Under ISO 9000

**Registration programs can be conducted in conjunctions with or independently from a product certification program.**

**Registrars may or may not concurrently operate a product certification program.**

## Evaluation of Registrars

**In 1989, the Registrar Accreditation Board (RAB) was established as an affiliate of the American Society of Quality Control (ASQC) to develop a program to evaluate the quality of services offered by registrars.**

**The RAB and ANSI agreed to form a joint U.S. program in December 1991.**

**In February 1992, RAB announced the establishment of an ISO 9000 auditor certification program.**

## ISO 9000:2000

### New Emphasis

**The new standard is more customer-oriented than the old standard. Although the old standard addressed meeting customer requirements and achieving customer satisfaction, the new standard addresses this in much greater detail. In addition, it expects you to communicate with customers and to measure and monitor customer satisfaction.**

## ISO 9000:2000

### Changes

**The new ISO 9001:2000 standard introduces some new requirements and modifies some old ones**

**[For the following list, the associated ISO 9001:2000 clauses are in brackets]**

## ISO 9000:2000

### Changes (cont.)

**Communicate with customers (7.2.3)**

**Identify customer requirements (5.2, 7.2.1)**

**Meet customer requirements (5.2)**

**Monitor and measure customer satisfaction (8.2.1)**

**Meet regulatory requirements (5.1)**

**Meet statutory requirements (5.1)**

**Support internal communication (5.5.3)**

**Provide quality infrastructure (6.3)**

**Provide a quality work environment (6.4)**

## ISO 9000:2000

### Changes (cont.)

**Evaluate the effectiveness of training (6.2.2)**

**Monitor and measure processes (8.2.3)**

**Evaluate the suitability of quality management system (8.4)**

**Evaluate the effectiveness of quality management system (8.4)**

**Identify quality management system improvements (5.1, 8.4)**

**Improve quality management system (5.1, 8.5)**

## **ISO 9000:2000**

### ***New emphasis***

***The new standard also emphasizes the need to make improvements. Although the old standard implicitly expects organizations to make improvements, the new standard makes this explicit.***

## ***From the International Organization for Standardization***

***The standards, guidelines and technical reports which make up the ISO 9000 family and which are listed below are available separately, or as collections. The ISO 9000 Compendium presents the ISO 9000 family in hard copy form.***

***[see ISO Document.doc]***