

## **ISO 9000 Quality Management System**

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

## **What is a “Quality Management System”**

**The organizational structure, procedures, and resources that manufacturers and suppliers use to control the variables involved in the production of a product of consistent quality which meets defined specifications is called a quality system.**

## **What is a “Quality Management System”**

**The standards that are being adopted globally for quality systems compose the ISO 9000**

## **What is the “ISO”**

**International Organization for Standardization (ISO)**

**Founded in 1946**

## **International Organization for Standardization (IOS)**

**The central office of the ISO is in Geneva, Switzerland and the operations are managed by a Secretary-General that is a permanent appointment.**

**The Secretary-General reports to the President of ISO**

## **What is the “ISO”**

### **Goal**

**To promote the development of international standards and related activities, including conformity assessment,**

**to facilitate the exchange of goods and services worldwide.**

## **What is the "ISO"**

### **Organization**

***The organization is composed of member bodies from over 140 countries.***

***The U.S. member body being the American National Standards Institute (ANSI).***

## **What is the "ISO"**

### **Organization**

***Creates, through international consensus, a variety of standards on products, processes and information technology.***

## **What is the "ISO"**

### **Organization**

***The results of ISO's technical work are published as International Standards or Guides.***

***The ISO is not an enforcement agency – adherence to the standards is "voluntary"***

## **What is the "ISO"**

### **ISO 9000**

***Standards for quality systems are issued by the ISO***

***Primarily concerned with quality "management"***

## **What is the "ISO"**

### **ISO 9000**

***The standards were developed with international participation of more than 50 countries.***

## **What is the "ISO"**

### **ISO 9000**

***Organizations with implemented ISO 9000 quality systems can obtain certification – also called registration – of their quality system through a third party "Registrar."***

## **What is the "ISO"**

### **ISO 9000**

**The certification confirms that the organization's quality system meets the requirements of ISO 9000. Any organization, large, medium size or small, can implement an ISO 9000 quality system and obtain certification.**

## **What is the "ISO"**

### **ISO 9000**

**Primary driver for compliance was the European Community of 1992**

**Today – primary driver is "customer" requirement**

**Some EU market directives require registration to gain access to the EU**

## **What is the "ISO"**

### **ISO 9000**

**Personal contention – few pursue it "voluntarily"**

## **ISO 9000 Standards Change Over Time**

### **ISO Review Procedures**

**According to ISO procedures, all ISO standards, including ISO 9000, must be reviewed and revised or reaffirmed at least every five years.**

## **ISO 9000 is a "Series (family) of standards"**

**Three different quality system "models" of varying stringency for use in different applications**

**ISO 9001**

**ISO 9002**

**ISO 9003**

## **ISO 9000 is a "Series (family) of standards"**

### **Common elements in ISO 9001, 9002, and 9003**

**An effective quality system**

**Measurements are valid**

**Measuring and testing equipment is calibrated regularly**

**Appropriate statistical techniques**

**A product identification and traceability system**

## **ISO 9000 is a "Series (family) of standards"**

**Common elements in ISO 9001, 9002, 9003 (cont.)**

**Adequate record keeping system**  
**Adequate product handling, storage, packaging and delivery system**  
**Adequate inspection and testing system**  
**Process for dealing with nonconforming items**  
**Adequate personnel training and experience**

## **ISO 9001**

**Model for quality assurance in design, development, production, installation and servicing**

## **ISO 9002**

**Model for quality assurance in production, installation and servicing**

**appropriate for organization that are not involved with design and development**

**otherwise, identical to ISO 9001**

## **ISO 9003**

**Model for quality assurance in final inspection and testing**

## **Definition of a product**

**The result of activities or processes**

**A product may include service, hardware, processes, materials, software or a combination.**

**"Product" applies to the intended product offering only and not to unintended "by-products" affecting the environment**

## **Twenty Quality System Requirements**

- 1. Management Responsibility**
- 2. Quality System**
- 3. Contract Review**
- 4. Design Control**
- 5. Document and Data Control**
- 6. Purchasing**
- 7. Control of Customer-Supplied Product**
- 8. Product Identification and Traceability**
- 9. Process Control**
- 10. Inspection and Testing**

## ***Twenty Quality System Requirements (cont.)***

- 11. Control of Inspection, Measuring and Test Equipment***
- 12. Inspection and Test Status***
- 13. Control of Nonconforming Product***
- 14. Corrective and Preventive Action***
- 15. Handling, Storage, Packaging, Preservation, Delivery***
- 16. Control of Quality Records***
- 17. Internal Quality Audits***
- 18. Training***
- 19. Servicing***
- 20. Statistical Techniques***