

ISO 9000 and total quality: The Relationship

Lecture 6

ISO 9000:

The international standard for QMS

- The ISO 9000 is a family of standards and guidelines related to the quality management system (QMS). It sets the requirements for the assurance of quality and for management's involvement. To
 - Improve customer satisfaction by fulfilling customer requirements;
 - Achieve continual improvement of organizational performance and competitiveness;
 - Continually improve its processes, products, and services; and
 - Comply with regulatory requirements.
- It is important to note that ISO 9000 does not specify a level of quality or performance for any product or service provided by an organization. That is left to the organization to determine with its customers.

The Eight Principles: ISO 9000's Basis

- 1. Customer Focus.** Understand the customer's needs, meet the customer's requirements, and strive to exceed the customer's expectations.
- 2. Leadership.** Establish unity of purpose and organizational direction and provide an environment that promotes employee involvement and achievement of objectives.
- 3. Involvement of People.** Take advantage of fully involved employees, using all their abilities for the benefit of the organization.
- 4. Process Approach.** Recognize that things accomplished are the results of processes and that processes along with related activities and resources must be managed.

The Eight Principles: ISO 9000's Basis

- 5. System Approach to Management.** The multiple interrelated processes that contribute to the organization's effectiveness are a system and should be managed as a system.
- 6. Continual Improvement.** Continual improvement should be a permanent objective applied to the organization and to its people, processes, systems, and products.
- 7. Factual Approach to Decision Making.** Decisions must be based on the analysis of accurate, relevant, and reliable data and information.
- 8. Mutually Beneficial Supplier Relationships.** Both the organization and the supplier benefiting from one another's resources and knowledge results in value for all.

Plan–Do–Check–Act: ISO 9000's Operating Principle

- Plan–Do–Check–Act is now the *operating principle* of ISO's management system standards. Its function is to operate in a never-ending loop, as described in the following steps resulting in continual Improvement for products/services, processes, and systems of processes.
- **Plan.** Establish objectives and develop the plans to achieve them.
- **Do.** Put the plans into action.
- **Check.** Measure the results of the action; that is, is the planned action working, or were the objectives met?
- **Act (or Adjust).** Learn from the results of the third (Check) step, make any necessary changes to the plans, and repeat the cycle.

How ISO 9000 is applied to organizations

- No organization is required by any government to use ISO 9000. Usually whether to adopt the ISO 9000 QMS is strictly up to the organization's management. Once management decides to go with ISO 9000, then it is faced with the task of developing its QMS to conform to the requirements of ISO 9001.
- The ISO 9001 lays down the requirements for *what* an organization's QMS must do but does not dictate *how the* QMS should do it in any particular organization. The organization determines that for itself and, if seeking registration, employs an accredited registrar firm to verify its conformance to ISO 9001.

The ISO 9000 QMS: a definition

What is a quality management system?

The quality management system is composed of all the organization's policies, procedures, plans, resources, processes, and delineation of responsibility and authority, all deliberately **aimed at** achieving product or service quality levels consistent with customer satisfaction and the organization's objectives. When these policies, procedures, plans, and so forth are taken together, they define how the organization works and how quality is managed.

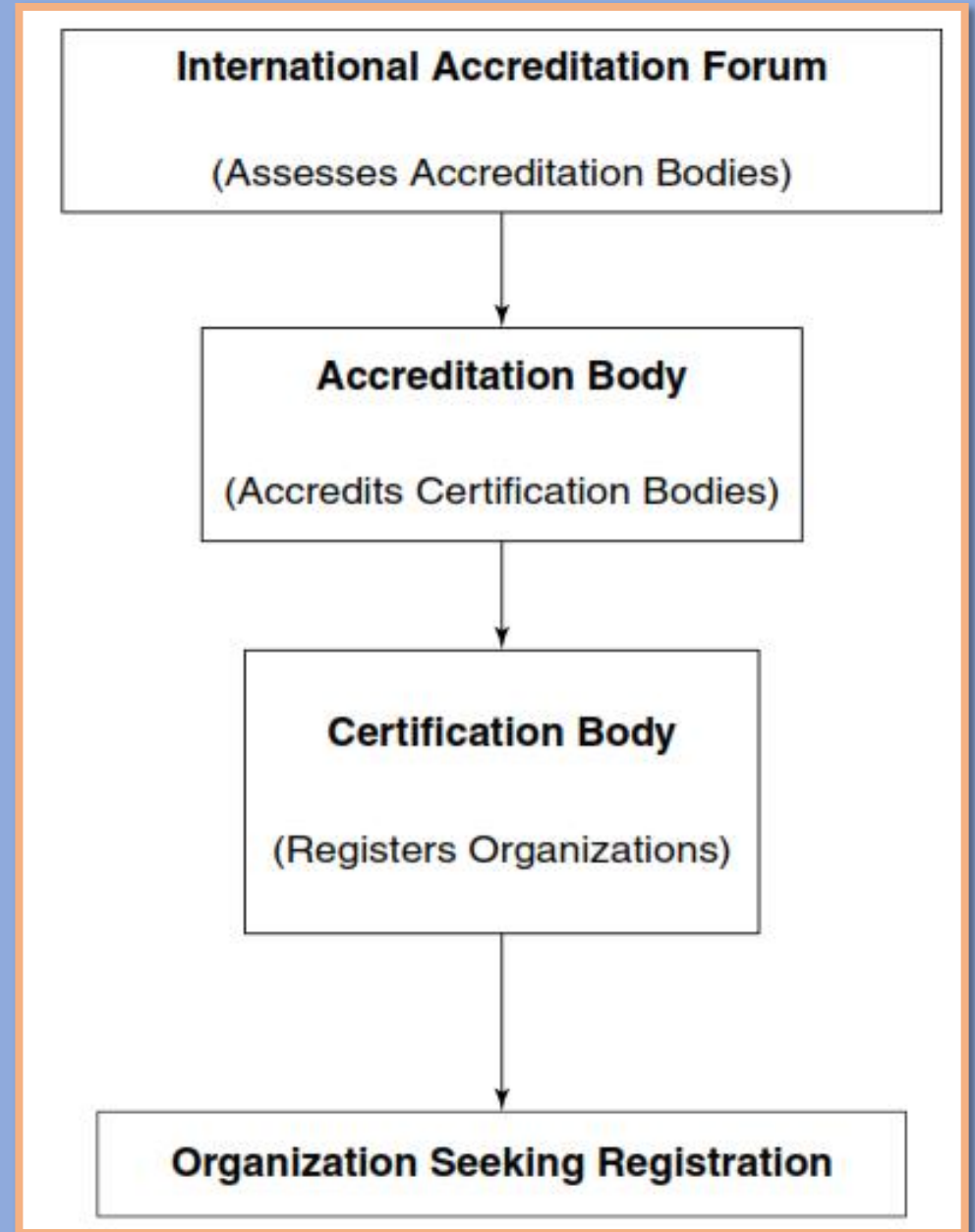
Authority for certification/registration

- When an organization says it is certified or registered to ISO 9001, one may ask, “By what authority?” You understand by now that registration or certification, with registration more commonly used in the United States is awarded by a registrar firm. These firms, sometimes referred to as certification bodies, are almost always private companies that have auditing expertise.
- Well, then, Who gives them the authority to grant ISO 9000 registration certificates? How do we know that they are competent to determine which organizations get registered and which Do not? The answer is that all certification bodies for ISO 9000 must themselves be accredited by a higher level group called an accreditation body.

ISO 9001 and industry specific applications

The ISO 9001 standard is intentionally generic so that it can be applied to any given organization, public or private. However, selected industries have found it helpful to tailor the ISO 9001 standard specifically for their use. The benefits of developing industry-specific versions of the ISO 9001 standard are that it encourages:

- (1) the training and deployment of auditors with industry-specific knowledge rather than ISO 9000 generalists and
- (2) A more accurate Interpretation of the standard for a given industry.



Organizational registration to ISO 9001

- The organization that is registered by a recognized CB will have more credibility in the world's marketplace, something that may be crucially important. In addition, the registered organization must conform to ISO 9001 and have an independent third party (the registrar) continually observe its conformance in order to maintain its ISO 9001 cert
- ISO 9001 can help the organization. Customer requirements will be met if the organization listens to customers and designs and manufactures its products accordingly. Prices can be more competitive because waste is minimized as improved processes become more efficient, benefiting both the organization and its customers.

Steps to be ISO 9000 QMS registered

1. Develop (or upgrade) a **quality manual** that describes how the organization will assure the quality of its products or services.
2. **Document procedures** (or upgrade existing documentation) that describe how the various processes for design, production, continual improvement, and soon, will be operated. This must include procedures for management reviews and audits.
3. The organization must secure (and provide evidence of, if registering) top management's commitment to the QMS and continual improvement.

Organizational registration to ISO 9001

4. The organization's top management must ensure that customer requirements are determined and met.
5. If registering, the organization must hire an accredited registrar company to examine its systems, processes, procedures, quality manual, records, and related items.
6. Whether registered or not, the organization must conduct its own **internal audits** to ensure that the systems, processes, and procedures are working effectively.
7. Once registered, the outside registrar will make **periodic audits** for the same purpose. These audits must be passed to retain registration.

Comparative scope of ISO 9000 and TQM

Characteristics	ISO 9000	TQM
Customer focus (internal and external)	✓	✓
Obsession with quality		✓
Scientific approach to problem solving	✓	✓
Long-term commitment	partial	✓
Teamwork		✓
Continual process and product improvement	✓	✓
Education and training intensive	✓	✓
Freedom through control		✓
Unity of purpose	✓	✓
Employee involvement and empowerment	partial	✓