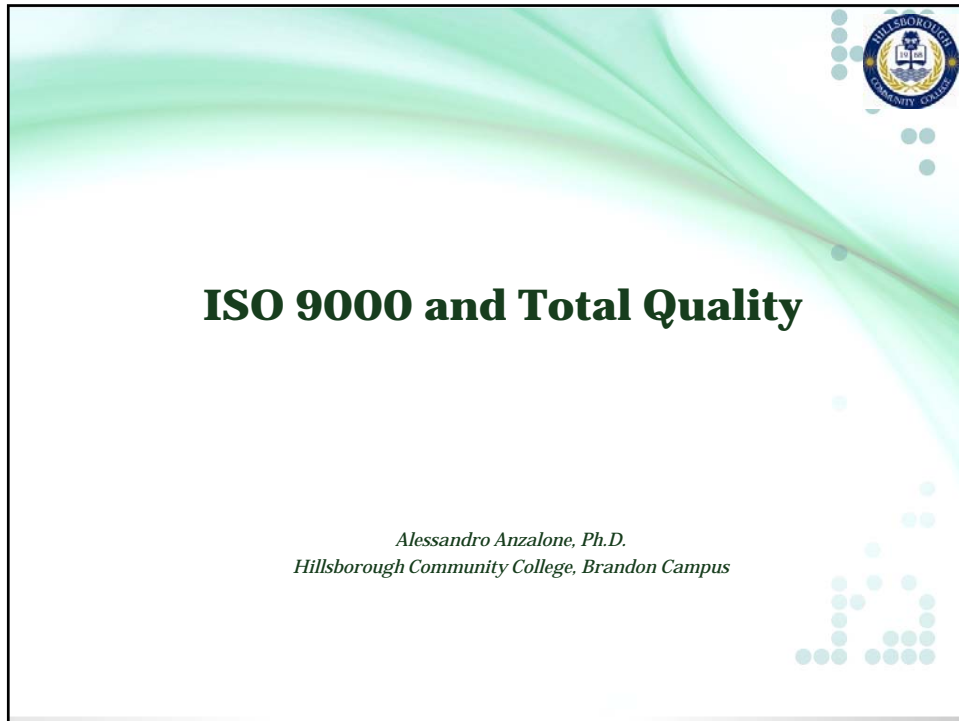


ISO 9000 and Total Quality

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Agenda

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ISO 9000: The International Standard for Quality Management Systems



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. The thrust of ISO 9000 is for organizations to implement a QMS conforming to the standard's requirements and, through the consistent, rigorous employment of the QMS, 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.

http://www.iso.org/iso/iso_9000_essentials

ISO 9000: The International Standard for Quality Management Systems



The ISO 9000 family is made up of three documents:

- ✓ ISO 9000:2000 is a guidance document that describes the fundamentals and the vocabulary of the quality management system.
- ✓ ISO 9001 specifies the requirements for the QMS. It is the standard's only document to which organizations may be certified/registered.
- ✓ ISO 9004 is a guidance document for continual improvement of organizational performance, systems, processes, and products/services as measured through the satisfaction of customers and other interested parties.

ISO 9000: The International Standard for Quality Management Systems



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. ISO 9000 is about standardizing the approach organizations everywhere use to manage and improve the processes that ultimately result in their products and services. ISO 9000 is applicable to any organization, whether in the private or the public sector, whether large or small, and applies to those components of the organization that can have an impact on product or service quality. These typically include the departments responsible for engineering/ design, purchasing, manufacturing, quality assurance, and delivery of the organization's products and services.

ISO 9000: The International Standard for Quality Management Systems



When an organization demonstrates conformity to ISO 9001 to an independent (3rd party) registrar firm, the registrar can certify (or register) the organization. Registration provides assurance to customers worldwide that products or services from the organization can be expected to consistently meet customer requirements. To maintain its registration, the organization must constantly strive to ensure that the QMS continues to function effectively and that it is continually improved. That is done through consistent and rigorous application of the QMS and a system of formal, documented internal audits in interaction with the organization's top management, interspersed with periodic independent audits by the registrar firm. *Registration may be lost if the registrar's audits determine that the organization is not conforming to the requirements of its registered QMS.*

ISO 9000: The International Standard for Quality Management Systems



The Eight Principles: ISO 9000's Basis

The ISO 9000 QMS is based on eight principles from total quality management (TQM):

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.

ISO 9000: The International Standard for Quality Management Systems



The Eight Principles: ISO 9000's Basis

The ISO 9000 QMS is based on eight principles from total quality management (TQM):

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 the other's resources and knowledge results in value for all.

ISO 9000: The International Standard for Quality Management Systems



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

Dr. W. Edwards Deming introduced the Plan—Do—Check—Act (PDCA) cycle to the Japanese in 1950, and it became one of the seeds of Japan's quality revolution that gave us TQM. PDCA has made its way to ISO 9000 and is said to be the operating principle of ISO's management system standards.' Its function is to operate in a never-ending loop, resulting in continual improvement for products/services, processes and systems of processes.

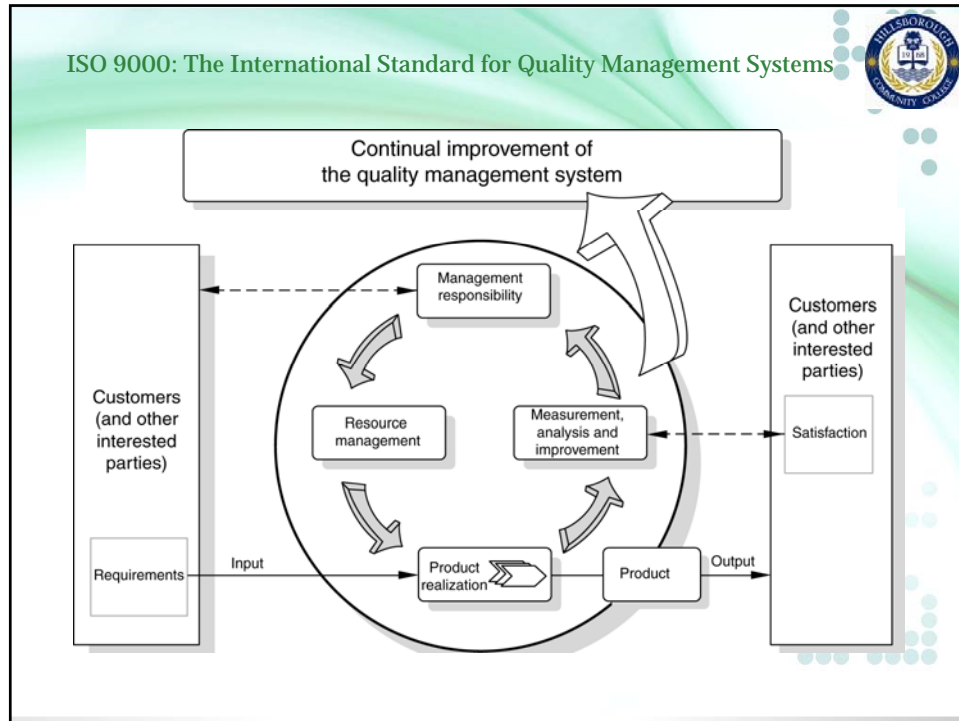
ISO 9000: The International Standard for Quality Management Systems



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

1. **Plan.** Establish objectives and develop the plans to achieve them.
2. **Do.** Put the plans into action.
3. **Check.** Measure the results of the action; that is, is the planned action working, or were the objectives met?
4. **Act (or Adjust).** Learn from the results of the Check step, make any necessary changes to the plans, and repeat the cycle.





ISO 9000's Objective

Aims of ISO 9000

The original aim of ISO 9000 was to ensure that the products or services provided by registered organizations were consistently fit for their intended purpose. ISO 9000 raised the standard's aim to a new level. Customer focus and continual improvement, along with the other six quality management principles that have been incorporated into the standard, are intended to *make registered organizations more competitive*. This is essentially the same objective as that of total quality management.

How ISO 9000 Is Applied to Organizations



No organization is required by any government to use ISO 9000. Some government and corporate customers may well require their suppliers to be ISO 9000 registered (or at least conforming), but 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. 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 9001:2000.

How ISO 9000 Is Applied to Organizations



- The organization, once registered, must
- ✓ Apply its QMS to its operations according to the standard and exactly as the QMS states
 - ✓ Continually assess the effectiveness of the QMS and make changes to improve it
 - ✓ Conduct periodic internal QMS audits
 - ✓ Submit to external (third-party) surveillance audits at least annually by its registrar
 - ✓ Submit to a new registration audit every third year by a registrar

The ISO 9000 Quality Management System: A Definition



To secure registration, organizations must develop and use quality management systems conforming to the requirements of ISO 9001. The first question asked by someone unfamiliar with ISO 9000 is “What is a quality management system?” As stated in ISO 9000, a QMS is a management system to direct and control an organization with regard to quality.

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

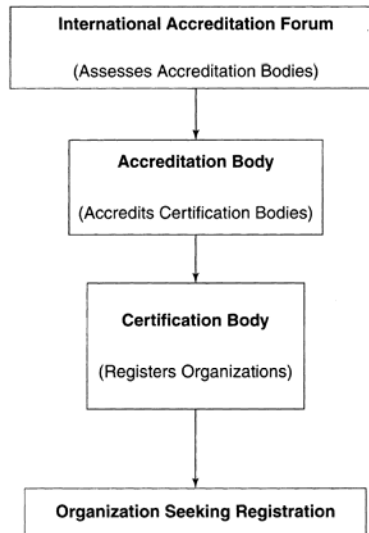


Figure 14-2
Authority Flow for ISO 9001:2000
Registration

ISO 9000 Registration Statistics



Table 14-1
ISO 9000 Registrations Worldwide

Registrations	2002	2003	2004	2005	2006	2008
World Total	167,124	497,919	660,132	776,608	897,866	1,016,558
Growth	122,736	330,795	162,213	116,476	121,258	118,692
Number of Countries	133	149	154	161	170	179

1. China	180,107
2. Italy	117,437
3. Japan	89,375
4. Spain	63,883
5. Germany	51,568
6. United States	49,820
7. India	45,473
8. United Kingdom	45,409
9. France	23,697
10. Netherlands	21,003

Organizational Registration to ISO 9001



The organization that wants a conforming ISO 9000 QMS must go through a process that includes the following steps (steps 5 and 7 are omitted for nonregistering organizations):

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 so forth 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.
4. The organization's top management must ensure that customer requirements are determined and met.

Organizational Registration to ISO 9001



The organization that wants a conforming ISO 9000 QMS must go through a process that includes the following steps (steps 5 and 7 are omitted for nonregistering organizations):

5. If registering, the organization must hire an accredited registrar company to examine its systems, processes, procedures, quality manual, records, and related items. If everything is in order and if the registrar is satisfied that the organization is effectively using the QMS, registration will be granted. Otherwise, the registrar will inform the organization of the areas requiring work (but will not tell the company specifically what must be done), and another audit will be scheduled.
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.

The Benefits of ISO 9000



Organizational Benefits

The ISO 9000 quality management system is designed to “provide the framework for continual improvement to increase the probability of enhancing customer satisfaction and the satisfaction of other interested parties. It provides confidence to the organization and its customers that it is able to provide products that consistently fulfill requirements.” ISO claims that beyond customer satisfaction, cost and risk-management benefits will also accrue to the organization. These benefits translate to improved competitiveness—the same as TQM’s objective. The ISO claims these benefits result from emphasizing the eight quality management principles on which the standard is based.

The Benefits of ISO 9000



Customer Benefits

Customers want products or services that meet their requirements, and they want them at a competitive price. Like TQM, ISO 9001 can help the organization in both areas. 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. Customers have increased confidence in the products and services of ISO 9000—registered organizations because they know that appropriate quality management processes are employed and that an independent registrar ensures that this continues to occur.

The Origin of ISO 9000



ISO 9000 and total quality management originated independently of each other, for different reasons, in different parts of the world, and at different times. The ISO 9000 series of standards was originally developed in response to the need to harmonize dozens of national and international quality standards then existing throughout the world. To that end, the ISO, a worldwide federation of national standards organizations from more than 158 nations, formed Technical Committee I 76 to develop ISO 9000.

ISO 9000 was developed by this international team that includes the American National Standards Institute (ANSI), the U.S. member of ISO. ANSI was represented by the American Society for Quality (ASQ). The first version of ISO 9000 was released in 1987. By that time, the total quality management movement was more than 35 years old. As a result of this standard, suppliers of products and services are able to develop and employ a quality management system that is recognized by all their customers regardless of where on the planet those customers might be.

Comparative Scope of ISO 9000 and Total Quality Management



The two principal quality initiatives at work in the world today are ISO 9000 and total quality management. Consequently, it is helpful to explain the relationship between the two. The following statements outline the relationship. Each statement is explained in the sections that follow in this chapter.

- ✓ ISO 9000 and TQM are not interchangeable.
- ✓ ISO 9000 is compatible with, and can be viewed as a subset of, TQM.
- ✓ ISO 9000 is frequently implemented in a non-TQM environment.
- ✓ ISO 9000 can improve operations in a traditional environment.
- ✓ ISO 9000 may be redundant in a mature TQM environment.
- ✓ ISO 9000 and TQM are not in competition.

Comparative Scope of ISO 9000 and Total Quality Management



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	✓

Figure 14-3
Total Quality Management Characteristics Compared with Those of ISO 9000

Management Motivation for Registration to ISO 9001



Appropriate motives for adopting ISO 9000 include the following:

- ✓ To improve operations by implementing a quality management system that satisfies the ISO 9000 requirements for management responsibility; resource management; product realization; and measurement, analysis, and continual improvement
- ✓ To create or improve a quality management system that will be recognized by customers worldwide
- ✓ To improve product or service quality or the consistency of quality
- ✓ To improve customer satisfaction
- ✓ To improve competitive posture
- ✓ To conform to the requirements of one or more major customers (although adoption would be better motivated by internal considerations, such as the preceding five)

ISO 9000 and Total Quality Management Working Together



ISO 9001 :2000 registration can be a good first step into TQM. In a paper published by the European Union titled “ Working Document on a European Quality Promotion Policy, or the European Way Toward Excellence,” the authors had this to say:

“ISO 9000 registration often is the most practical route to demonstrate compliance for European regulations with a quality system element. In parallel, the use of ISO 9000 by companies can be regarded as a first step toward a more global management of companies, similar to the one arising from the European model of total quality management.”

We are not sure how the “ European model” of total quality management differs from that of the rest of the world, but the point is that, regardless of geographic location, people who understand both ISO 9000 and total quality have concluded that the two are compatible and that ISO is properly seen as a subset of total quality.

The Future of ISO 9000



Credibility of the Standard

Consider for a moment the importance of credibility as related to ISO 9000 registrations. ISO 9000 is viable as a standard only as long as its registrations are honestly and competently issued. If that cannot be assured, then ISO 9000 will die. Many, including the authors, believe that the credibility of ISO certification has become diluted because there has been insufficient oversight of the registrars. Some are excellent, but others have been less than stellar in their assessments and awarding of certificates. To correct this problem, ISO, together with the International Electrotechnical Commission, has issued a new standard ISO/IEC I 702 I :2006, which is designed to restore the confidence in management system registration. It places rigorous requirements for competence and impartiality on the certifying bodies; the deadline for conforming was September 15 2008 Registrar conformity will be verified by the accrediting bodies, both by reviewing the registrar's organization, personnel, and procedures and by observing actual audits performed by the registrar.

The Future of ISO 9000



Updating ISO 9000

ISO 9000 has been revised three times since its original release. The 2000 version, incorporated major changes in the standard as it was being developed and improved through the incorporation of features from total quality management. The 2008 version has few significant changes.

References

Quality Management for Organizational Excellence: Introduction to Total Quality, 6th Edition, David Goetsch and Stanley Davis, copyright 2010, Pearson, ISBN: 978-0-13-501967-2.

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