ISO 9000 2000

Dr. Steve Vardeman

Prepared by:
Ashu Malviya
Darren Brackin
David Gustafson
Lee Nian Joe
Shierly Natalia
9-28-2001
What is ISO?

ISO stands for International Organization for Standardization, based in Geneva, Switzerland. The organization is a consortium of virtually all of the world’s industrialized nations- from Albania to Zimbabwe (Johnson 6). The consortium’s members come from over 140 national standards bodies.

Founded in 1946, the International Organization for Standardization developed industrial standards that would facilitate international trade. According to some ISO officials, the organization borrowed the acronym “ISO” from the Greek Word “isos,” meaning, “equal.” Its selection is based on the conceptual path that leads from “equal” to “uniform” to “standard.”

What is ISO 9000? What is ISO 9000 2000?

ISO 9000 is a series of quality assurance standards that were created by the International Organization for Standardization (Johnson 6). In 1979, the ISO Technical Committee 176 (ISO/TC176) was formed and developed the ISO 9000 series standards to harmonize the increasing international activity in quality management and quality assurance standards. Subcommittee 1 was established to determine common terminology. It developed ISO 8402: Quality-Vocabulary, which was published in 1986. Subcommittee 2 was established to develop quality systems standards – the result being the ISO 9000 series, published in 1987. This was revised in 1994 and then recently, in 2000.


ISO 9000 2000 standards apply to all types of organizations. It doesn't matter what size they are or what they do. It can help both product and service oriented organizations achieve standards of quality that are recognized and respected throughout the world.


The following shows the standards and guidelines versus the purpose of each guideline:
ISO 9000:2000, Quality management systems - Fundamentals and vocabulary
Establishes an understanding for the standards and define the fundamental terms and definitions used in the ISO 9000 family.

ISO 9001:2000, Quality management systems - Requirements
This is the requirement standard used to assess your ability to meet customer and applicable regulatory requirements and thereby address customer satisfaction. It is now the only standard in the ISO 9000 family against which third-party certification can be made.

ISO 9004:2000, Quality management systems - Guidelines for performance improvements
This guideline standard provides guidance for continual improvement of your quality management system to benefit all parties through sustained customer satisfaction. (ISO)

ISO 9002 and ISO 9003 have been dropped in ISO 9000 2000. When determining which standard to adopt, the primary factor to consider is the expectations of the organization’s customers. If the customers of your organization would not benefit from a specific adoption of one of the ISO derivative standards, then ISO 9001: 2000 is most appropriate (Iso9).

How ISO 9000 (ISO 9000 2000) is applied and implemented?
(Adapted from Johnson, ISO)
There are two ways to apply the ISO 9000 quality system standard.
1. To implement for quality management purposes and obtain its benefits.
2. To obtain certification, and registration to the ISO 9000-quality system standard.

Obtaining certification will assure that the benefits of quality management are obtained; another significant strategic advantage is reducing the number of supplier quality assurance audits (SQA) companies/ suppliers must undergo. The company’s product would be a “regulated product” as defined by the product directive of the European Community, which comprises of some 370 million consumers in 19 nations. Companies not producing “regulated products” are not allowed to sell their products in the European Community without certification of quality.

How to implement ISO 9000 2000 quality management system in an organization? The following are the general guidelines to implement ISO 9000 2000.
1. Identify the goals the organization wants to achieve.
2. Identify what others expect of the organization.
These are the expectations of interested parties (stakeholders) such as: Customers, Employees and Suppliers.


4. Apply the ISO 9000 2000 family of standards in the organization’s management system.
   Decide if the organization is seeking certification that the quality management system is in conformance with ISO 9001:2000 or if the organization is preparing to apply for a national quality award.
   - Use ISO 9001:2000 as the basis for certification.
   - Use ISO 9004:2000 in conjunction with your national quality award criteria to prepare for a national quality award.

5. Obtain guidance on specific topics within the quality management system

6. Establish the organization current status; determine the gaps between your quality management system and the requirements of ISO 9001:2000.

7. Determine the processes that are needed to supply products to the customers.

8. Develop a plan to close the gaps in step 6 and to develop the processes in step 7.
   Identify actions needed to close the gaps, allocate resources to perform these actions, assign responsibilities and establish a schedule to complete the needed actions.

9. Carry out the plan.
   Proceed to implement the identified actions and track progress to the schedule.

10. Undergo periodic internal assessment.

After reviewing documentation and conducting on-site assessments to confirm that a company’s quality system conforms to the ISO 9000 2000 standards, an accredited third-party can award the company registration to the ISO 9000 2000. This registration is renewable and enforced by a semiannual surveillance visits by the registration body. Registration is easy for companies that already have significant quality systems in place, and is also relatively easy to keep. It is not impossible to fake conformance to ISO 9000 2000. However, because customers will expect a certain standard of quality products from organization’s that are in conformance with ISO 9000 2000, an organization’s non-conformance can be easily discovered. It would be foolish to fake it as the standard focuses on performance, documentation, and objective evidence.

The benefits of registration can be substantial. It affords access to markets, and enhanced quality image, and significant competitive advantages. All the benefits notwithstanding, most American firms are after ISO 9000 2000 registration because of international considerations.
Benefits of ISO 9000 (ISO 9000 2000)

By implementing ISO 9000, the organization can expect to see significant internal and external benefits. A good quality system provides the following. (Quest)

Internal Benefits
1) Greater awareness and perception of quality
2) Positive cultural change
3) Increased efficiency of operational production
4) Effective control on the process and systems
5) Effective control in the product development and design changes

External Benefits
1) Perception of high quality standards, industry-wide
2) Improved customer satisfaction
3) Competitive edge
4) Reduced customer quality audits
5) Increased market share
6) Reduction in supplier base and assists in selecting suppliers
7) Facilitates Just-in-Time delivery

Conclusion

ISO 9000 (ISO 9000 2000) is a worldwide standard. The European Economic Area (EEA), which consists of the EU and EFTA, comprising of 19 countries and some 380 million consumers utilizes ISO 9000 standards widely. As of January 1, 1993, the adoption of the Single European Act has unified member nations into a single marketplace where goods, services, people and capital can move freely as within one country. The EU has begun requiring product certification for regulated products. Only approved products are allowed to be sold across European countries. There is also a standard called EN 29000, which is the equivalent of ISO 9000.

As organizations bearing ISO 9000 certification are perceived to offer better quality, registration to the ISO 9000 is fast rising around the world. Many U.S. government agencies, including the Department of Defense, the FAA and FDA, are in the process of harmonizing their quality requirements with the ISO 9000 standard. The recent unveiling of the QS 9000 by the automotive industry is also based on the ISO 9000 quality concept.

ISO 9000 is the recognized, accepted and mandated quality system for Europe and around the world and the time where ISO 9000 will be the rules by which the quality game is
played in the world is fast approaching. Business managers around the world need to understand the ISO 9000, except of course, those who do not care about survival.

References


(ISO), International Organization for Standardization

