Current Quality

Culture

Mini Paper

IE 361
ISO 9001

I. Introduction

The International Organization for Standardization (ISO) was established in 1946 to “promote the development of standardization and related world activities to facilitate the international exchange of goods and services, and to develop cooperation in intellectual, scientific, technological and economic activity.” (www.asq.org/stancert/iso.htm) The organization is based in Geneva, Switzerland and is comprised of 180 technical committees with approximately 130 member countries. The U.S representative to ISO is the American National Standard Institute (ANSI).

ISO 9000 is not a product standard but a quality system standard which applies to the process that creates the goods and services. ISO 9000 consists of three quality assurance models and a quality management model; ISO 9001, ISO 9002, ISO 9003, and ISO 9004.

- ISO 9001 is a model for quality assurance in design, development, production, installation, and servicing.
- ISO 9002 is a model for quality assurance in production, installation, and servicing.
- ISO 9003 is a model for quality assurance in final inspection and testing.
- ISO 9004 is a quality management model that contains guidelines for services, processing materials, and quality improvement.

Organizations are generally registered to one of the quality standards models to achieve standards of quality that are recognized throughout the world. Companies use ISO 9000 to control the quality of their products or services because they feel it will reduce costs that are incurred by poor quality. Since ISO 9001, "prepared in 1987 by Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC2, Quality systems", is the most comprehensive conformance model in the ISO 9000 series and includes all standards contained in ISO 9002 and ISO 9003, it will be the focus of this paper.

II. Certification & Registration

To become ISO certified an organization must develop a quality system, implement the quality system, perform an internal audit to verify that quality policies are being met, then have...
an accredited external auditor assess the quality system. A quality system is an "organizational structure of procedures, processes and resources needed to implement quality management" (ISO 8402, 1994, Clause 3.6). Within the above procedures there are a number of steps that need to be followed and thoroughly documented. (www.connect.ab.ca/~Praxiom/9001.htm)

In order to develop a quality system for an organization much of the responsibility falls on management. Management must first decide on a quality policy that will be used to clarify quality within the organization. Next, quality system responsibilities should be established and the resources needed to perform the responsibilities provided to employees whom authority will be given to perform the responsibilities. The quality system developed must then be well documented in a quality system manual. Within the quality system manual quality plans should describe a detailed method to fulfill the quality system requirements for products, processes, projects, and customer relations of the organization. Upon the completion of a well-documented quality system manual, standards of the quality policies should be established by the organization through requirements. Contract review requirements are used to review sales orders and customer contracts. Product design requirements are developed "to control the product design and developmental process." (Johnson 45) Guidelines for documentation and data control procedures should be made for reviewing, approving and managing the quality control system. The quality testing machines must also be well calibrated for accuracy and precision on a regular basis to maintain quality assurance standards.

In order to establish ISO 9001 registration an internal audit must first be performed to determine the credibility of the quality system. Once an organization determines the quality system implemented meets their standards of ISO 9001 through an internal audit, an application to an accredited registrar needs to be made. It is important to seriously consider the accredited registrar. The organization should obtain a listing of potential registrars, identify key questions to ask potential registrars, determine the accreditation status of the registrar, and "make sure that the registrar's scope of operations covers the business to be registered". (Peach 159) The registrar will perform a document review of the organizations documented quality system, make a facility preassessment, then a full assessment of the facility is performed after the registrar determines that the organization's "documented quality system conforms to the requirements of the selected management system quality standard". (Peach 163) The organization can expect to be registered if it has implemented all of the elements of ISO 9001, with only minor deficiencies detected.
during assessment, on a conditional or provisional basis. The conditional approval requires the organization to correct any deficiencies noted by the registrar.

III. Process Auditing

According to Peach, an audit is the process of comparing actions or results against defined criteria (Peach 192). Auditing, by its nature, looks for areas of noncompliance, and it is important for the auditor to try to provide a balanced report that identifies the positive as well as the negative aspects of an organization's quality system. An organization's quality system is maintained regularly by internal auditing and is ISO registered through an independent accredited registrar.

The role of an auditor is to determine whether or not a department is meeting the requirements of an established quality assurance standard by collecting objective evidence. Auditors obtain information from a variety of different people and interpret the data to make an informed judgment about the effectiveness of the quality system. Upon assessment, the audit team should meet to evaluate the information they found during the audit, ensure the validity of nonconformities, and report to quality assurance managers. The audit system is a critical part of ISO 9001 because it is designed to improve the process through verification of the effectiveness of the organization's quality system.

IV. The Future of ISO 9001

ISO 9001 has been reviewed, revised, and corrected by many over the years; with the 2000 drafts offering a complete restructuring. Development and changes will be continued for years to come. The ISO Technical Committee 176 is in the process of revising the standard to make it friendlier. This total renovation, which includes the merging of ISO 9002 and 9003 into ISO 9001, is to be finalized in November 2000 (http://www.iso-9000.co.uk/).

The focus of the 2000 drafts is to make ISO 9001 user-friendlier, focused on continuous improvement, and less confusing (Johnson 27). The 2000 draft is also designed to be more general, follow a process-based structure, has eight quality management principles, and is better suited with the ISO 1400 series of environmental management systems standards. The new formation will give ISO 9001 a completely different appearance. The 20 elements that ISO 9001
The five clauses of ISO 9001:2000 are:

- Quality Management System (2 elements)
  It states general requirements, including documentation for procedures and work instructions.

- Management Responsibility (6 elements)
  It states management’s responsibility to determine a system that meets customer needs and expectations, including quality objectives for each managerial level.

- Resource Management (4 elements)
  It determines necessary resources, such as human resources, facilities and new elements of work environment.

- Product Realization (6 elements)
  It is responsible for the processes of customer satisfaction, design, purchasing, production, and service operations

- Measurement Analysis and Improvement (5 elements)
  It is where the results are measured, analyzed, and improved through internal audits and continual improvement.

Though the 2000 revisions primarily contain the same elements as in ISO 9001:1994, they are organized differently and expanded in some cases. There are also some additional requirements, such as Customer Focus, Internal Communication, Assignment of Personnel, Facilities, Work Environment, Identification of Customer Requirements and Measurement, and Monitoring.

Throughout this paper, it is clear that ISO 9001 is more than just a standard in quality assurance in design, development, production, installation, and servicing. It is becoming the major part in most of the companies today. It reflects a well-organized operation with motivated people, and with the ISO 9001:2000 coming up, it is no wonder that ISO 9001 will become more and more important in today's world of commerce. In addition, conformance to the standard demonstrates a minimum level of acceptable performance that is universally recognized and accepted.
REFERENCES


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