4-07-20 Introduction to the ISO 9000 Quality Standard

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Payoff

Organizations developing software or contracting for its development may need to comply with ISO 9000, a quality standard published by the International Standards Organization in Geneva. This article is intended to familiarize the IS manager with the ISO 9000 standard, how it compares with the Malcolm Baldrige National Quality Award, and how an organization and its auditors prepare for certification. An overview of the software development standard is included.

Introduction

The International Standards Organization (ISO) is a worldwide federation of national standards bodies. The work of preparing international standards is carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. In liaison with International Standards Organization, international organizations (governmental and nongovernmental) also take part in the work.

The emphasis for international standards originated in the European Community's plan to become a single market with international standards becoming effective at the end of 1992. At that time, organizations wishing to do business in the common market were required to meet those standards, which are now accepted worldwide. There are five related quality management standards in what is referred to as the ISO 9000 series. Each of the five standards (numbered 9000 to 9004) addresses a different topical area.

For example, ISO 9000 affects the development and maintenance of software. In addition, the International Standards Organization 9000 standard provides some basic definitions and concepts. It summarizes the other standards in the series and explains how to select and use them. The International Standards Organization 9001, 9002, and 9003 standards ensure external quality in contractual situations. ISO 9004 contains guidance on the technical, administrative, and human factors affecting the quality of products and services.

External and Internal Quality

The International Standards Organization 9001 standard is directed at the development of a quality product or service. It is written to ensure conformance to specified requirements during design and development, production, installation, and servicing. Because software development is focused on the creation of a product, it is a part of ISO 9001. (See the Appendix for specific guidelines on the 9001 to software development and maintenance.)

ISO 9002 is used for production and installation. It is the standard that governs the manufacture of a product. It is designed to ensure conformance to production and installation methods.

ISO 9003 is the standard directed at the final test and inspection of products. The standard presumes an extensive quality control function and specifies what is needed for conformance to requirements.

ISO 9004 is for internal use only and lists the components that compose quality systems. In the US, the Malcolm Baldrige National Quality Award defines the model of a
quality system. International Standards Organization 9004 describes a slightly different quality system, but it, too, provides the detail of the quality system and the responsibilities of management. International Standards Organization 9004 as well as the Baldrige Award standard could be used to evaluate a company's quality management system to determine the degree of maturity of that system.

ISO 9000 Certification

The worldwide emphasis on quality has resulted in many organizations evaluating their suppliers' processes. These audits of supplier capabilities are sometimes a prerequisite to purchasing. Companies have learned that good processes produce good products.

One of W. Edwards Deming's 14 quality principles is to limit suppliers to those that demonstrate they can continually produce quality products. Organizations, such as Ford Motor Co., that have followed Deming's principles have reduced the number of suppliers dramatically. However, it takes a lot of time and effort for one company to certify the adequacy of the processes of another company.

The objective of the International Standards Organization 9000 series of standards is to certify that an organization has quality manufacturing processes. Thus, if a supplier wanted to demonstrate competence of products, it would make application to demonstrate that it meets the ISO 9000 standards.

Countries establish, or accredit, organizations to audit companies to determine whether they are in compliance with the ISO 9000 standards. This is an audit of the organization's processes. If the ISO 9000 auditors determine that the company's processes are in compliance with the standards, they issue a certificate good for three years, subject to annual validation that nothing has changed. Companies receiving the certificate can then advertise themselves as being in compliance with the ISO 9000 standards.

Documentation Requirements

The ISO 9000 audit is heavily focused on evaluation of documentation. Four tiers of quality system documentation are required:

- First tier—the quality manual.
- Second tier—quality management procedures (i.e., core procedures).
- Third tier—area work instructions (i.e., standard operating procedures, test methods, calibration methods).
- Fourth tier—forms, records, books, and files.

The Malcolm Baldrige National Quality Award assessment is focused primarily on results. The ISO 9000 assessment is based solely on documentation. Organizations can be certified under the ISO 9000 standards without demonstrating continuous improvement of quality products or demonstrating continuous improvement processes. Organizations may need several certifications, depending on the diversity of their products.

One organization that has obtained certification and has written about it is E. I. du Pont de Nemours & Co. (Quality Progress, November 1991). Du Pont had been subjected to customer audits for some time, in which the customers evaluated the organization's processes. However, in preparing for the International Standards Organization 9000 audit,
du Pont quickly realized that although it had extensive quality manuals (two at 500 pages each), most of these quality systems were not adequately defined, documented, or rigorously followed. Du Pont also realized that none of the customer audits had been conducted with the degree of competence and thoroughness that the ISO 9000 assessment requires.

**The ISO 9000 Audit**

The International Standards Organization 9000 audit is the basis for becoming certified. It is performed by auditors trained in conducting those audits and thoroughly knowledgeable about the standards. The audits are extensive and can last several days or weeks, depending on the size of the organization.

The audit follows the general pattern of an operational audit. It is much more typical of the audit performed by an internal audit group than that performed by an external auditor.

**Step 1: Preliminary Walkthrough.**
The auditor must gain an understanding of the area or department under review. This includes determining what the organization does, getting copies of and understanding the organizational chart, understanding the products produced, and arriving at an overview of the processes that produce those products or services. At the end of this step, the auditor should have a general understanding of the business of the organization under review.

**Step 2: Process Control Review.**
During this step, the auditor attempts to understand the process and whether that process is in place and working. During this review, the auditor asks questions and reviews documentation and other evidential matter. The step involves extensive questioning of the people doing the work. For example, if the auditor saw instructions next to a piece of data entry equipment, the auditor might ask: If the procedure is changed, who changes the sheet of paper next to the data entry equipment? The auditor might also ask such questions as How do employees determine which tasks they should work on first thing in the morning? How do employees determine the priority for changes made to the software?

**Step 3: Testing.**
The auditor must validate that the quality process is in place and working. These tests are usually selected at random. Some auditors use judgment sampling, whereas others use statistical sampling. What is important is that the auditor is convinced that the quality process as it exists in the manuals is operational within the organization.

**Step 4: Making a Certification Decision.**
At the end of step 3, the auditor must make a decision about whether the organization warrants ISO 9000 certification. There are general guidelines for this, although those guidelines are not well publicized. However, assuming that the ISO 9000 audit is similar in scope to that performed by the Software Engineering Institute, if an organization meets 80% of the standards of ISO 9000, it would be certified. In other words, if 80% of the items within the standard are in place and working, the organization would warrant certification. This is not a hard-and-fast rule, but it is a guideline for estimating whether an organization would meet the ISO 9000 certification standard.
Preaudit Activities

Many organizations take one to two years to prepare for the International Standards Organization 9000 audit. During that time, their processes are defined in greater detail, documented, and placed into practice.

Usually, an organization will undertake a concentrated effort to reach a status of quality that warrants ISO 9000 certification before requesting the certification audit. These preassessment and preaudit activities involve four basic steps.

Step 1: Understanding the Applicable ISO 9000 Standard.
The organization must know precisely which standard it must meet. This can involve taking an ISO 9000 course, inviting ISO 9000 experts in-house to explain the standard, or conducting extensive self-study based on available ISO 9000 literature.

Step 2: Conducting a Preassessment.
The existing quality system should be measured against the standard. This would be similar to the certification audit but not performed for certification. The purpose of the preassessment is to identify the gap between the current quality system and that system that would be needed to gain accreditation.

Step 3: Developing a Plan of Action for Quality Improvement.
A plan of action should be developed to move the organization from the current quality level to the ISO 9000 certification level. This plan should indicate what should be done, the amount of resources required, and the sequencing of implementation of the actions.

Step 4: Implementing Improvements and Reassessing.
Management must approve the action plan, allocate the resources, and oversee the implementation of the action plan. Once the necessary actions have been implemented, the quality system should be preassessed again. If the preassessment does not show the organization to have reached the ISO 9000 certification level, steps 3 and 4 are repeated as frequently as necessary to reach the appropriate level.

Guidelines for Reaching ISO 9000 Certification

Organizations that follow certain practices or guidelines appear to be much more successful in obtaining certification. The recommended guidelines for moving to International Standards Organization 9000 certification are:

- Finding a champion in senior management to drive the process for reaching certification.

- Ensuring that all involved parties to the certification programs are adequately trained in the ISO 9000 standard and the organization's objectives for obtaining certification.

- Obtaining expertise from an organization knowledgeable in ISO 9000 to act as a consultant during a process. It is generally helpful to have this consultant perform the preassessment audits.
Developing the quality manual and all quality procedures using the internal staff that will be responsible for implementing those procedures. Generally, buy-in to quality procedures is achieved only when the workers themselves develop those procedures.

- Providing incentives and recognition programs for the staff involved in ISO 9000 to be awarded once certification has been achieved.

- Communicating progress toward ISO 9000 certification on a regular basis to all employees affected by the ISO 9000 program.

- In preparing for ISO 9000 certification, performing only those activities that are necessary for improving the quality of the organization’s products and services. Generally, if high-quality products are the objective, the work procedures and standards to achieve that high quality will satisfy the certification requirements—in other words, certification is a by-product of the quality management system.

- Not expecting ISO 9000 certification to solve all the company's quality problems. It is merely a step on the path to continued high quality.

**Listing of ISO 9000 Standards**

The American National Standards Institute (ANSI, 11 West 42nd Street, New York NY 10036) is the major distributor for International Standards Organization 9000 standards in the US. In other countries, companies should contact their government's standard-setting organization.

- The five standards in the ISO 9000 series are:

  
  - ISO 9000. Quality systems—model for quality assurance in design, development, production, installation, and servicing.
  
  
  
  - ISO 9004-1. Quality management and quality system elements—Part 1: guidelines. The quality management and quality assurance standards are:

    
    - ISO 9000-3, Part 3: guidelines for the application of ISO 9001 to the development, supply, and maintenance of software (see the Appendix at the end of this article).
    
    - ISO 9000-4, Part 4: application for dependability management. The quality management and quality system elements are:
The guidelines for auditing quality systems are:


Conclusion

ISO 9000 is an important international standard that affects the way organizations do business, especially in Europe. Individuals in any profession, including IS, should be knowledgeable about the impact of this standard on business.

The standard includes an audit to be performed before certification can be awarded. This article describes how an organization's auditors can assist in performing preassessment audits and help the organization prepare for International Standards Organization 9000 certification. Organizations can take three specific actions to understand and prepare for International Standards Organization certification.

Awareness Training

Both the internal auditors and organizational management need training in the standard, why it is important, and how organizations prepare and become certified. The company's auditors can participate in this training, arrange for the training, or recommend to management that the training be obtained.

Obtaining Guidance in Writing Control Manuals

Auditors are viewed as experts in control and should be able to provide guidance in writing control manuals. The auditors can work as a team developing formats and manuals that define the control procedures for the organization. The ISO 9000 is heavily a documentation audit, and thus well-prepared documentation is important not only in performing control procedures but in evaluating the adequacy of control procedures.

Performing an ISO 9000 Preassessment

Auditors can obtain training in conducting ISO 9000 audits and use those skills to perform the preassessment audit for their own organizations. In instances in which the auditors may not feel adequate to perform the audit, they may assist the audit team. In this way, they can both improve their own skills and potentially reduce the cost of having an outside group perform the ISO 9000 preassessment.

Author Biographies

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