ISO 9000 Quality Standard

Background Information

There is a worldwide trend towards more stringent customer expectations with regard to quality. Accompanying this trend has been a growing realization that continual improvements in quality are often necessary to achieve and sustain good economic performance.

ISO – The International Organization for Standardization (ISO) is the specialized international agency for standardization, at present comprising the national standards bodies of 91 countries. The American National Standards Institute (ANSI) is the member body representing the United States. ISO is made up of approximately 180 Technical Committees. Each Technical Committee is responsible for one of many areas of specialization. The object of ISO is to promote the development of standardization and related world activities with a view to facilitating international exchange of goods and services and to developing cooperation in the sphere of intellectual, scientific, technological and economic activity. The results of ISO technical work are published as international standards.

In 1987, ISO published the original set of quality assurance standards commonly known as ISO 9000. The ISO Quality Management and Quality Assurance System Standards provide a set of requirements for quality assurance systems. A quality assurance system includes a company’s organization, resources, policies and procedures for meeting customer requirements. Compliance with ISO 9000 standards indicates that a producer has a basic quality assurance system in place.

Increasingly, European customers expect US companies to have their quality systems registered (audited) to one of the standards of the series. This involves having an accredited independent third party conduct an on-site audit of the company’s operations against the requirements of the appropriate standard.

Quality Systems Implementation

Some of the obstacles that can interfere with successful implementation and that must be avoided can include, unrealistic time frames, resistance to change, lack of management commitment, insufficient training, or subjective interpretation of the standards.

The areas most frequently resulting in Non-Certification by companies to date have been in document control, design control, purchasing, inspection and testing, quality systems, process control and inspection, or measuring and test equipment. Although all areas of the company’s quality assurance program are required to be in compliance with the standard, management should perform extra reviews to ascertain compliance in these above areas.
The appropriate personnel under the direction of management should review the standards and develop, implement and maintain a minimum set of quality systems and procedures to satisfy the ISO 9000 standard.

Further, these personnel will provide confidence to management that the intended quality is being achieved and is:

- Documented
- Demonstrable
- Effective
- Maintained

**Level 1 – Quality Policies and Objectives**

The first level of documentation is often referred to as a "Quality Manual" and is separate and distinct from the procedures. The purpose of this level of documentation is to state in a concise and brief format, the policies and objectives of the company for achieving a desired level of quality for the organization or division.

At a minimum, the Quality Manual is required to address each one of the paragraphs of the applicable ISO Series that the company plans to become registered against.

Each area that is written should include three parts: Scope, Policy and Responsibilities.

The **Scope** portion should simply state the purpose of the covered area.

The **Policy** portion should state the company policy regarding the applicable ISO clause.

The **Responsibility** portion should state who, in generic titles or positions, is responsible for the policy.

Although there is no standard format or requirement for the Quality Manual, a sample manual is provided in this guide for you to use as a template to create your own Quality Manual.

**Level 2 – Quality Procedures**

The second level of documentation should be more detailed and address the procedure(s) of an activity for a department or function and the personnel (generic titles or positions) responsible for accomplishing the procedure(s). These procedures can be organized on a departmental basis.
Samples of Level 2 type departmental procedures and responsibilities documentation are provided in the ISO Policies and Procedures System. The ABR ISO9000:2000 Quality Procedures start with the designation "QP" and may be used as a template to create your own procedures. They are not the only format or method to accomplish the requirements.

The procedures in this manual provide format and verbiage to describe tasks and activities that are typical for organizations that meet ISO 9001:2000 requirements. They certainly are not the only format nor functional descriptions of these tasks and activities. They are intended to provide a foundation for you to develop the procedures that work for your company. As you rewrite the procedures for your application, be sure to verify your modifications against the requirements of the ISO standard to ensure all requirements are still addressed.

An example of where you may want to change the format is the Effectiveness Criteria section of certain procedures. Section 4.1 (c) of the ISO 9001:2000 standard requires that the criteria and methods to determine the operation and control of processes are effective to be determined. It does not require the methods and criteria to be defined in the procedures; other methods may be used.

The primary reason this section was included in the procedures was to encourage thought in this area. Often times, effectiveness of a process, task, or activity is assumed to be known. The assumptions may not be verbally expressed and frequently there is no agreement between departments or even between employees in the performing department. Defining these criteria and obtaining consensus among interested parties can result in significant improvement.

When determining these criteria, a holistic approach as to what is best for the company should be used. An obvious example involves Purchasing. In the past, Purchasing effectiveness was measured by the purchase price of materials. The obvious fallacy with this measure is that out of specification or marginal components result in increased costs downstream and may actually result in higher total costs.

**Level 3 – Quality Work Instructions**

This level of documentation should be very detailed on "how" to accomplish a specific job, task or assignment.

For example, a work procedure could be developed for assembling the final housing of a product with step-by-step instructions including such detail as the torque requirements of the fastening screws.

Individual work instructions are very specific to an industry or company. Supplemental documentation may be used including User’s Manuals,
Level 4 – Quality Forms and other Documents

The last level of documentation can include forms, records, checklists, surveys, and other documents used in the production or delivery of a product or service.

Samples of quality level 4 type Reports and Forms and other documents are provided in this manual and may be used as a template to create your own forms. The forms provided should be used as guides, not necessarily as final documents. Again, they are there to provide examples and foundations for you to work from.

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The following procedures are ISO 9000 procedures written to also include ISO 14001 requirements and are found at the end of the SOP Section of this manual. They are intended to be used as templates for companies interested in integrating their ISO 14001 and ISO 9000 systems. Only procedures where the requirements of ISO 14001 and ISO 9000 overlap are included.
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