

Documentation for ISO 9000

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The ISO 9000 series of Quality Standards redefines how business will be conducted into the next century. The series is designed to measure the effectiveness of the Quality System in place, thereby ensuring both customer and company needs are always satisfied. The foundation of a robust Quality System is its documentation: problems in this area represent the largest single cause of registration failures. Quality System documentation also forms the basis upon which the 3rd party registrar builds the audit plan for your company.

INTRODUCTION

The ISO 9000 series of Quality Standards was developed in response for the need to assess a supplier's capability in meeting product requirements. This was especially true for companies in the non-military marketplace. The growth of the global economy has placed added emphasis on this assessment of suppliers, many of whom may be on the opposite side of the globe. The adoption of a single standard of Quality Measurement has created a major upheaval in the way business is conducted today, especially in North America.

Successful implementation of these global standards is greatly enhanced by understanding the basis upon which they were built. Implementing ISO 9000 for the right reasons will ensure that the benefits realized are maximized. Basing ISO implementation on the wrong strategy will lead to major headaches and significant costs.

WHAT DOES ISO 9000 REQUIRE?

The ISO 9000 series of standards establishes the ground rules that companies around the world have accepted as necessary for the common assessment of Quality. Unlike many quality systems of the past, ISO 9000 is not concerned with the end product, but rather the processes by which that product evolves. The same standard is used whether you are producing stereos, aerospace electronic devices, hearing aids, or computer software.

The key to ISO 9000 is the documentation of the Quality System. As W. Edwards Demming so succinctly demonstrated, people want to perform well on the job but are often hampered by the lack of a clear

understanding of what is required. Clear, concise, and understandable process descriptions and job instructions are the foundation of a robust Quality System.

ISO 9000 has defined 20 key elements that comprise a Quality System and sets out how they are to be monitored and controlled. One of the most important elements is the process and procedural documentation. Each of the 20 elements must be clearly and completely documented, and this documentation must be maintained and controlled.

WHERE DO TECHNICAL WRITERS FIT?

Technical writers, as is usually the case, become involved far too late in the process in most cases. North American business has yet to fully appreciate the contributions made by qualified technical communicators. Involving the technical writer early in the implementation process will make the whole documentation process smoother and less problematic. Aside from the actual process and procedure documentation, communication experts can assist in areas such as internal promotion of the implementation effort and promotion amongst the company's customers and suppliers.

ISO 9000 DOCUMENTATION STRUCTURE

The documentation created for ISO 9000 registration is submitted to the company's 3rd-party registrar prior to them visiting the site to conduct the actual audit. In fact, one type of documentation is used by the registrar to develop the audit plan for your company.

Structuring your ISO 9000 documentation to facilitate the audit process only serves to enhance the potential for a successful audit. This structuring will also make it easy for you to plan and monitor your documentation efforts, both for the registration audit and all subsequent maintenance audits.

DOCUMENT CONTROL AND ISO 9000

Once the documentation structure has been defined and the documentation written, a strategy for controlling it must be put in place. ISO 9000 requires that documentation must be readily available to those who need it, be of current issue, and that all obsolete material be completely removed from the system. The control of documentation, from creation of new material through to the destruction of obsolete material, presents one of ISO 9000's biggest challenges. It is also one of the elements audited by your 3rd-party registrar.

DOCUMENTING ISO 9000

A thorough analysis of each element prior to writing ensures the resulting documentation will meet ISO 9000's criteria. Specific characteristics exist for robust Quality Systems, and these must be clearly established within the organization. Since ISO 9000 registration is not a one-time occurrence, clearly documented procedures for maintaining a compliant Quality System must be in place.

Historically, companies have produced policy and procedure manuals which, because they contained corporate policies, were often not made available to all employees. As a result, the procedures were also not readily available. ISO 9000's requirement that procedures be readily available to all persons performing the work usually necessitate the separation of these procedures from the policy manual.

Perhaps the biggest stumbling block for North American businesses is the requirement to clearly define and document the processes that it uses. Developing documentation that tells HOW we do something is not new to us, but accurately describing WHAT it is we do is far less common. Most of our existing documentation is product or department based. ISO looks only at the processes used to create products, and these generally run across many areas of an organization. We can no longer write documentation in isolation, the whole organization must be considered when writing ISO-compliant documentation.

WHEN IS ENOUGH, ENOUGH?

One of the complaints often heard about ISO 9000 refers to the large amount of documentation that is perceived to be required. While procedural documentation is important to the proper functioning of an effective Quality System, many companies tend to over document.

First and foremost, you must remember that it is *your* company and the documentation must fit the company, *not* the standard. The ISO 9000 series of Quality Standards does indicate key characteristics of a properly functioning Quality System, but how they are implemented is the responsibility of the organization. ISO documentation must reflect what the company does, not what it thinks the ISO auditor will want to hear.

In determining whether procedural documentation is required, look at the skill sets of the people performing the task as well as any unique requirements the company may have for completing the task. In many cases, documentation will not be required because there is no unique process and/or the person has been trained in how to complete the task. Would you write a procedure on how to answer a telephone when we all know how to use this device? Would you write a procedure on how to write procedures when your company uses professional technical writers?

SUMMARY

Documentation is the foundation of an ISO-compliant Quality System and technical writers possess the key skills required to developing this key component. Documenting ISO 9000 requires careful analysis of the requirements and the creation of usable process and procedure documentation.

Becoming involved with an ISO implementation project will enhance your profile as a professional technical writer and add new dimensions to your career.

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