

“Speaking Out”

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Francis has worked extensively in the medical products industry and has a great working knowledge of the FDA's CGMP. He also specializes in the implementation and internal auditing of the various Quality Management System standards including, ISO 13485, AS9100, and ISO 9001.

QUALITY MANAGEMENT SYSTEMS

ISO 9004: The Other Half of the Consistent Pair

By Francis Lamm

When the International Organization of Standardization released the ISO 9000 family of Standards in the early 1990's, it was recommended that organizations planning to become registered to ISO 9001 also obtain copies of ISO 9000 and ISO 9004 as reference guidelines. By definition:

- ISO 9000 describes the fundamentals of quality management systems and specifies the terminology for quality management systems.
- ISO 9001 specifies the requirements for a quality management system where organizations need to demonstrate their ability to provide products and services that fulfill customer and applicable regulatory requirements that result in continuous improvement and customer satisfaction.
- ISO 9004 provides guidelines that consider both the effectiveness and efficiency of the quality management system. The purpose of this reference standard is to promote performance improvement of an organization and continuing satisfaction of customers and other interested parties. Since other ISO standards for automotive, aerospace, and medical organizations were derived from ISO 9001, ISO 9004 could also be utilized as a complementary reference with those standards.

Most companies concentrate on learning and implementing ISO 9001 and ignore ISO 9004. Current releases of ISO 9001 and ISO 9004 form a consistent pair of standards on quality management to facilitate mutual understanding in national and international trade across all types of products and services.

Unlike the ISO 9001 standard, ISO 9004 is not another document to which companies get registered. It was created to assist organizations in further understanding performance improvement and what ISO 9001 is looking for by providing more detailed references, definitions, suggestions and clarification in direct reference to each section of ISO 9001. It is a useful reference guide to help organizations understand the requirements of ISO 9001 during the pre-registration process and as a reference after certification.

After ISO 9001 registration is achieved, some organizations periodically use the self-assessment section of ISO 9004 to determine where their



organization is in relation to the suggested guidelines. Depending on the assessment results, companies can use parts of ISO 9004 to initiate and make improvements based on where deficiencies and opportunities for improvement are found. A periodic self-assessment can be utilized by itself or in conjunction with the management review process to help insure each area of the company is meeting requirements.

ISO 9004 takes each clause of ISO 9001 and expands the details to provide suggestions and examples of how elements in ISO 9001 can be applied to an organization. Once a company is registered and certified, ISO 9004 uses a common sense approach to help improve the business. Most consultants agree that ISO 9004 breaks down the ISO 9001 requirements in an easy to read and user-friendly manner. For example, ISO 9001 states ‘an organization must provide a work environment that achieves conformity to product requirements’. ISO 9004 goes further and states the elements that could affect the work environment such as safety rules, training, ergonomics, workspace and social interaction.

One of the most difficult aspects of ISO 9001 is defining exactly what the term “continuous improvement” means in everyday language. ISO 9004 provides general suggestions, examples, and sources of information to research when considering potential areas for practical continuous improvement programs.

The current ISO 9001 standard places more emphasis on management responsibility than earlier releases. Here again, ISO 9004 helps clarify some practical aspects management can utilize to satisfy the requirements for management review. For example, ISO 9001 states management must periodically review the QMS. ISO 9004 provides specific areas that management may consider as part of the review requirement, including internal audit results, supplier performance, customer satisfaction, opportunities for improvement, etc..

In spite of the potential advantages, ISO 9004 has not gotten the attention and use to complement ISO 9001 it deserves. I usually encourage clients to obtain and utilize ISO 9004 prior to and after registration as a reference aid and clarification of the clauses in ISO 9001. Few have seen the value, particularly if they initially utilized outside consultants to assist their organizations in developing and implementing an ISO 9001 QMS. Usually, they are looking for a guidance standard that applies directly to their specific organization and their copy of ISO 9004 sits on the shelf gathering dust.

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