KENNETH L. ARNOLD

THE MANAGER'S GUIDE TO ISO 9000

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THE MANAGER'S GUIDE TO **ISO 9000**

I would like to dedicate this effort to my parents, the Rev. Forest L. Arnold MEd. and the Rev. Virginia L. Arnold MA. They have provided me with physical, emotional, and financial support during this and many other projects. Beyond this support, they have given me love without bounds, without reservations, and without expectations of anything in return. This unconditional love and support have set the example for my life.

To all who know you, your lives are living examples of what it means to be a man and woman of God. While you are my parents by heredity, you are my best friends by choice. For that, I love you both very much.

FOREWORD

This book was written as a road map to guide the reader past all the pitfalls, U-turns, road hazards, and dead ends that were experienced by one company in its quest for certification to the ISO-9001 standard. As the terrain is constantly changing and viewed differently by each traveler undertaking the journey, it is impossible to anticipate every obstacle. This book attempts to provide enough information so that the reader will be able to cope effectively with situations as they arise.

The beauty of the ISO 9000 series standard is that it is conceptual—it allows the reader to determine the most effective way in which to implement the stated requirements. The downside, however, is that this conceptualist approach leaves the standard open for potential abuse.

The ISO 9000 series standards received thorough analysis by the International Organization for Standardization in Europe prior to being released. But the same sort of analysis and organization has not existed in the United States with regard to certification activities. The European Community exhibited far more forethought and concern in establishing registration boards to verify the qualification of agencies performing certification activities to the stan-

dard. The United States is only now coming up to speed in controlling, verifying, and promoting consistency among certification agencies. For this reason, many companies in the United States have opted to collaborate with European organizations to provide them with certification.

The basic intent and requirement of the standard have been coordinated within the European Community. Certification agencies use a similar base for analysis ensuring that verification activities will not vary substantially from one agency to another. No amount of coordination and control will ensure that each certification audit will proceed exactly as any other performed. However, enough attention has been concentrated in this area in the European Community to minimize the likelihood of certification agencies performing audits with radically different perceptions of the standard due to their own personal bias.

Unfortunately, this assurance does not exist with American certification agencies. American history is long and steadfast in the implementation of military and industry standards which focus solely on the product produced while allowing the process to run uncontrolled. It is deplorable that many American agencies will audit a company and audit to the ISO 9000 series standard with the same mentality used to evaluate a product-only oriented standard. Additionally, an excessive amount of money is wasted each day in the United States on consultants with the same product-oriented mentality and military standard bias. These exercises serve only to try to force an existing MIL-STD, product-oriented program into compliance with an International Standard that requires nothing at all of this nature. In light of this, companies pursuing certification should thoroughly investigate the certification agency they intend to use.

If an organization's intent is only to force its existing product-oriented program into compliance with and certification to the ISO 9000 series standard, the certification agency chosen should exhibit the same philosophy. The importance of the certification must also be determined. Currently, reciprocity agreements exist between many countries in the European Community regarding certification by specific agencies. If international recognition of the certification is a factor, it is imperative that the certifying agency

have credibility in the market where the company participates. What good is certification if it will not be accepted by the potential customer because of the certifying agency? In this case, it would be wise to verify that the potential marketplace will accept certification by a local agency promoting certification to ISO 9000. Additionally, if an agency is not certified by a recognized registration body, the focus, understanding, and basis on which the audit is performed may or may not be in line with the orginal intent of the standard and focus of this text.

Americans are experienced in determining percentages and creating paperwork to outweigh the product as a means of verifying the system. This mind-set must be broken if effective implemetation of the ISO 9000 Series Standard and execution of good business sense are ever again to be achieved in the United States.

To support the American approach, the standard was not adopted in the United States as issued. Time, money, and effort were wasted to "republish" the standard in an American form. Even now, at the writing of this Foreword, efforts are still being wasted in an attempt to prove that the ISO 9000 Series is not a unique document but bears its formation in a previously issued American military standard. And for what purpose is all of this activity being conducted? The European approach, as fortified by the standard, is "If it's good, accept it. Don't waste the effort to reinvent the wheel." In all fairness, America cannot claim sole rights to the nationalization of the ISO standard. The Germans, Japanese, and British all rejected adoption of ISO 9000 in favor of creating their own national standards which bear their identification systems but with verbiage directly from ISO 9000.

This book's approach may well be criticized for its "European" mentality. And justly, why not? It is a European Standard whether one calls it ISO 9000, BS 5750, or Q90. But far more than that, it is a good standard. It breaks the rules of focusing solely on the product and, if properly implemented, establishes a program to provide product acceptablity with process control.

Linda I. Laird

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I would like to express my deepest appreciation to Linda I. Laird CQE, CQA for the technical edit of this book. Linda was involved in developing the quality systems in the companies from which the implementation strategies detailed in the text were taken. Because of her input, through her technical competence and unique insight to the standard, the qualtiy of this product is greatly improved.

I would also like to express my sincere thanks to Susan Adamski for her help in proofreading and correcting the manuscript. Her many hours of work have helped make this book possible.

Finally, I extend my appreciation to the American National Standards Institute for allowing me to reprint portions of ISO 9001 and ISO 9004 1987 version and the ISO/DIS 9000 series draft standard.

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WHAT IS ISO 9000, AND WHERE DID IT COME FROM?

ISO 9000 is one of the more misunderstood series of standards in common use today. After leading a manufacturing facility into compliance with and certification to ISO 9001 and providing direction and resources to bring a chemical manufacturing facility into compliance with ISO 9002, I can say without hesitation that the ISO 9000 series of standards is *not* solely a quality control standard.

But if ISO 9000 is not a quality control standard, what is it? The standard is a guideline for the design, manufacture, sale, and servicing of a product. For the purpose of this book, a product can be defined as either hard (for example, a car, computer, or sheet of paper) or soft (such as the service provided by a bank, information provided by a computer, or a design file or specification). To implement this standard successfully, the team working to establish the system must view the ISO 9000 series as a complete design, manufacturing, sales, and servicing standard. The system developed must concentrate on consistency of purpose and focus on the requirements of doing business well. In summary, ISO 9000 is nothing more than a checklist for doing business on a world-class level.

The ISO 9000 standard is a unique document. It was written in such a way that it can be successfully implemented in almost any type of business without modification or change. It has been implemented in health care institutions, banks, chemical manufacturing companies, heavy blacksmith-type manufacturing shops, pharmaceutical manufacturers, and food processing plants. The ISO 9000 standard is different from many of the existing quality standards in that it does not require specific actions to be carried out. Many standards state in exacting detail the amount of NDE required, the amount and type of incoming inspection required, how to document in-process or final inspection, or what is required in an inspection and test plan. ISO 9000 does not take this approach.

For this reason, ISO 9000 encourages each company to determine how best to meet the intent and requirement of the standard. This allows for flexibility and individualization of a company's method of operation. The underlying philosophy suggests that each business must address specific elements (design control, purchasing, product qualification, and so forth) in order to be successful. The authors of this standard have effectively defined the areas of business that must be properly addressed for a company to produce a consistent product. The list of these areas was compiled into a group of documents called ISO 9000, 9001, 9002, 9003, and 9004. These documents define the requirements within each area that must be satisfied before a program can be certified.

A Word of Warning

It is only fair that I explain my viewpoint of ISO 9000 very early in this text. While working on this project I received two criticisms from a national quality society. The first was that I have taken a very "European" view of the standard. To this criticism, I plead guilty. I have been involved in directing the efforts of a manufacturing facility making oil-field stimulation equipment certified to the European standards BS 5750: Part 1, ISO 9001, EN 29001; 1987. I have also helped a chemical manufacturing plant develop a quality system certified to BS 5750: Part 2, ISO 9002, EN 29002; 1987. The certification body in each activity was the Norwegian firm Det Norske Veritas Quality Assurance LTD, and the audit

team did its work within the guidelines of the British scheme. I have developed this view as the certification program was initiated to allow both companies to compete better in Europe. As a result, I do have a European view of this standard.

I feel the approach outlined by ISO 9001 (be it European or American) is one that allows a company to use the standard as an improvement tool. The standard can be used as the structure through which to implement a Total Quality Management (TQM) program. The standard will allow a company to truly have a quality program that will pay for itself instead of being a drain.

If this is a European view, so be it. It is about time someone determined that quality programs must be custom fit to a company instead of the one-size-fits-all approach that many of the existing standards try to take.

This leads us to the second criticism made by the quality society, which was that this book was not written to describe in detail exactly how a program must be implemented to pass the certification audit. In other words I have not tried to develop a generic program that, if followed, might result in a certification. To this criticism, I also plead guilty. This book does not detail a program down to the percentage of parts that have to be inspected using military standard 105D, nor does it define who is required on a material review board, or how many copies of a form must be made. After having spent three years dissecting the ISO 9000 series standard, I can say without reservation that this series is one of the most forward-thinking approaches that has ever been taken for a quality system document. This series of standards has not taken a cookie-cutter approach to implementation, where everyone must do the same things and have the same programs. It provides overall direction while allowing the creativity generated from within each company to determine how best to implement the standard.

The International Organization for Standardization has taken the innovative approach that ISO 9001, 9002, and 9003 are minimum guidelines that should be followed for a company to do business well. This group of professionals understood that to dictate the detail of implementation would in itself doom this standard to a state of obsolescence before the ink dried on the paper. Why should anyone override this effort by publishing a work that tries

to push a personal view of how a quality program should function? The standard allows for innovation and improvement; a generic program can be neither cost-effective nor certifiable in all industries. The lack of specific program structure is the strong point of this standard.

What this book will do is look at each element of the standard, outline the intent, list the requirements, and give an example of an implementation strategy that has worked. I stress that the implementation strategy is an *example* of how the standard was implemented in a certified program, not a mandate for how it must be implemented. Find out what works well for your company and decide if what you are doing meets the intent of the standard, fulfills the requirement, and makes sense. If you can answer yes to each area, the program will probably pass a certification audit.

What About the 1994 Version?

This text was written in relation to the 1987 version of the ISO 9000 series standard. In March 1993, the first recommended revisions to the European series standard were presented to the member countries for possible ratification. The draft standard was referred to as ISO/DIS 9000 through ISO/DIS 9004. The member countries evaluated the standard and in September 1993 voted to accept the content of the modifications to the ISO 9000 standard. The modified standard will be issued in the spring of 1994 with the U.S. version being issued through the American National Standards Institute in late spring of 1994.

The American National Standards Institute has given us permission to reprint the 1987 version of ISO 9001 and 9004 along with reprinting any portions of the ISO/DIS 9000 series that we felt necessary to adequately present this topic. The verbiage of ISO 9001 and 9004 as cited in this book will be that of the 1987 versions as the revisions incorporated by the 1994 version have not altered the intent or basic requirements of the standard. The major revisions have provided further clarification of the 1987 standard or added requirements exceeding those originally issued.

Throughout the text, the additional requirements of the 1994 version will be identified and discussed. The terminology and re-

quirements that will be discussed in this text will be taken directly from the ISO/DIS 9001 standard. Although some minor editorial changes are expected to occur between the ISO/DIS and the formal issue of the ISO 9000 1994 series standard, no major content changes or additional requirements are expected.

In theory, the standard has been modified to stress even further the purpose of customer satisfaction. The introduction in ISO 9001 has been modified to state "for the purpose of a supplier demonstrating its capability, and for the assessment of such supplier capability by external parties." Where the 1987 version stated that the scope was ". . . aimed primarily at preventing nonconformances at all stages . . . ," the 1994 version states ". . . aimed primarily at achieving customer satisfaction by preventing nonconformity at all stages. . . .

There has also been expansion in the introduction to further define the purpose of this standard. This definition includes that the ISO 9000 series standards are to ". . . specify requirements which determine what elements quality systems have to encompass but it is not the purpose to enforce uniformity of quality systems." The standards are designed as ". . . generic, independent of any specific industry or economic sector." The introduction stresses that each organization must develop its quality system in regard to its specific needs, objectives, products, and services.

Where Did ISO 9000 Come From?

During World War II many countries (including the United States, Great Britain, and France) came together to stop the march of Germany, Italy, and Japan. The problem was that as the soldiers of countries fought side by side, major differences existed. Not only did the Allied countries have different languages, customs, and religious beliefs with which to contend, they also had differing munitions, vehicles, and units of measure. These differences prevented supplies (such as bullets) from being shared by forces fighting on the same side.

To keep this incompatibility of components from becoming a future issue, the first military standards were developed. Industry soon realized the merit of standardization and followed the lead

of the military; unfortunately, industries in each different country developed their own standards. The following is a list of a few of the standards that were developed over the years.

Year	*Standard*	*Source*
1963	MIL-Q-9858A	U.S. military
1969	AQAP	NATO
1971	ASME Boiler Code	American Society of Mechanical Engineers
1973	Defstan 05	U.K.
1973	API 14A	American Petroleum Institute
1975	CSA Z299	Canadian Standard
1975	AS 1821/22/23	Australian Standard
1979	BS 5750	British Standard
1985	API Q1	American Petroleum Institute

Many of the standards that are used today are direct descendants of these early standards. One element that was common among many of the military, petroleum, and government standards was heavy inspection focused solely on the end product, rather than the processes used to create it. The standards tried to fit everyone into the same mold, with armies of inspectors looking over people's work.

During the 1970s and 1980s the science of quality control evolved from reactive (inspection-dominant) to proactive (system-oriented) organizations. The focus changed from the end result (the product) and centered on the process by which it was produced. The theory behind this change was that if the process used to produce the product was developed and maintained properly, the product would be consistent and the quality could be improved. This theory was set forth by such leaders in quality as Juran, Deming, Crosby, and Feigenbaum, and it was the manufacturing approach taken by Japan in its efforts to become an industrial power.