

Mark Kaganov

# The Perfect Manual

**A Guide to Lean  
Management Systems**

ISO 9001:2008  
ISO 13485:2003  
ISO 14001:2004  
BS OHSAS 18001:2007  
and other standards

**Seventh edition**

QW Enterprises, LLP, a fictional company referenced in this book,  
does not have any association with any other company  
that may carry the same name.

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# **1 Chapter 1**

# **Foreword**

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## 1.2 Introduction

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Through my work as an auditor and a consultant with dozens of companies in the United States, Great Britain, Mexico, Japan, Russia and Southeast Asia, I have witnessed the implementation of numerous quality management systems (QMS) and environmental management systems (EMS). Assessing various systems, I realized that what seemed to be a simple task of creating a quality or environmental management system manual and documenting a company's commitment to a particular standard can create significant difficulties for businesses of various sizes, in diverse industries, in different countries. Simply speaking, during my career in the registration and consulting businesses, I have not yet seen a manual during an initial review that addressed all the requirements of applicable standards.

I wrote this book for two reasons. First, I wanted to help companies overcome the tedious and time-consuming task of developing a quality or environmental manual by showing an example of a manual for ISO 9001 2008 (ISO 9001) [2] standard. Second, and more important, the purpose of this book is to show a method for creating a quality, environmental or any other manual, so that in the future, you can develop a manual for any standard or regulation, whether it is ISO 13485, AS9100, FDA's 21 CFR 820, European Council Directive 93/42/EEC or any other.

This book describes a model of a quality manual and several key processes to support the initial release of the manual.

The documents and approaches described in this book have been successfully implemented and used by dozens of companies around the World. This book will help both beginners and experienced professionals develop clear and concise manuals and efficient documentation structures for their management systems.

## 1.3 About the Author

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Mark Kaganov was born and raised in Moscow, Russia. He graduated from Moscow University of Radio-electronics and Automation, where he earned his Bachelor's and Master's degrees in design and technology of electro-mechanical equipment. While attending the university, he worked for the Institute of Plastics, the former USSR's leading organization in the research and development of plastic materials. Mr. Kaganov designed manufacturing processes, and developed test equipment and processing methods for materials used in electronics, automotive, aerospace, agricultural, consumer and other industries. In the late 1970's, Mark Kaganov was an active member of the group representing the USSR on the ISO Technical Committee (TC) 61 that worked on the development of test methods for plastic materials for ISO standards.

In 1981, Mr. Kaganov immigrated to the United States and continued his professional career in Quality Management and Research & Development in the plastics, electronics, and medical device manufacturing industries. He has worked for major US corporations such as Capitol Records, RCA, COBE Laboratories and Medtronic.

Since 1990, Mark Kaganov is a Director of Operation and a Lead Consultant at Quality Works. The company specializes in assisting businesses with development, implementation, consulting, training and auditing of management systems compliant with ISO 9001, ISO 13485, ISO 14001, AS9100, BS OHSAS 18001 and FDA 21 CFR 820.

Since 1996, Mark Kaganov worked for a number of world's leading registrars and notified bodies as an Account Manager and a Lead Auditor. His qualifications include ISO 9001, ISO 14001, ISO 13485, Medical Device Directive 93/42/EEC and Canadian Medical Device Regulations. In early 1998, Mark Kaganov led the first registration assessment in North America to the ISO 13485 standard for medical device manufacturers. His industrial experience covers plastics, electronics, optics, aerospace, automotive, defense, medical equipment manufacturing and others.

Working in the registration business, Mark Kaganov has assisted dozens of companies around the world in certifying their ISO 9001, ISO 13485 and ISO 14001 management systems. For a number of years, Mark Kaganov has been certified as a QMS Lead Auditor with the International Register of Certificated Auditors (IRCA), England and an EMS Lead Auditor with the Registrar Accreditation Board (RAB) in the US.

During his professional career, Mark Kaganov has published several books and technical papers in the areas of research of plastic materials, the economics of manufacturing, the technology of ion-selective electrodes, QMS, EMS and Internet business. His first book, "ISO 9001 - A Practical Guide to the Development and Implementation of a Quality Manual," was translated into Russian. Shortly after Standards and Quality Press released the book in Moscow in 1999, it became an instant success. Mark Kaganov has also authored five international patents. For more details on the author's background and qualifications, visit Quality Works Website at [www.quality-works.com/Mark-Kaganov.htm](http://www.quality-works.com/Mark-Kaganov.htm)

## 1.4 ISO – Brief Overview

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ISO is a non-governmental organization established in 1947 in Geneva, Switzerland. Today, ISO has more than one hundred member countries. The mission of ISO is to promote the development of standardization and related activities in the global marketplace, to simplify the international exchange of goods and services, and to develop cooperation in the spheres of intellectual, scientific, technological and economic activities.

The term "ISO" refers to the International Organization for Standardization. You may be curious about the difference between the names of the organization: International Organization for Standardization (<http://www.iso.ch/infoe/intro.htm>), and the initials, ISO. If it were an acronym, you'd think it would be IOS. But the truth is, it's not an acronym.

ISO is derived from the Greek word *isos*, which means "equal". The prefix -iso occurs in many words, such as isometric, meaning equal measure or dimensions, isonomy, meaning equality of laws or people before the law, and others. From equal to "standard," the choice of ISO as the name of the organization is easy to follow. The name also has the advantage of being the same in each of the organization's three official languages - English, French and Russian. Therefore, the confusion that would arise through the use of an acronym is avoided. In other words, IOS would not correspond to the official title of the organization in French -

Organization Internationale de Normalisation or in Russian – Международная Организация по Стандартизации.

What does this worldwide standardization mean to you and me? Well, thanks to ISO, for example, we can get cash from an automated teller machine (ATM) in New York City, Hong Kong, Buenos Aires or Moscow. The format of the credit cards, phone cards and smart cards is based on a series of ISO standards. The use of these standards, which outlines features such as the size and thickness of the card as well as the location and data format on the magnetic strip, means that all ATMs, telephones and other card machines throughout the world can read the cards. Since its establishment, ISO has focused primarily on the development of product-specific standards. However, in the mid 1980s, ISO started its work on systems-related standards. This direction eventually resulted in the well-known ISO 9000 series of standards, ISO 13485 for medical device manufacturing, ISO 14001 environmental management systems and others.

## 1.5 The History of Quality

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The history of requirements for quality systems, or at least some elements of quality systems, goes back to pre-historic times. Almost 4,000 years ago, in the 18th century B.C., Hammurabi, the king of Babylonia, developed the first recorded code of law. The Hammurabi's Code is a collection of laws and edicts, and is considered the earliest comprehensive legal standard. The code was engraved on a block of black diorite nearly 2.4 meters, or 8 feet high. A team of French archaeologists unearthed this block in Susa, Iraq, formerly ancient Elam during the winter of 1901-1902. The block, broken into three pieces, has been restored and now rests in the Louvre Museum in Paris. Hammurabi's Code, translated by L. W. King [2], presents a few articles that appear to relate to a quality system:

*Article 122. "If any one give another silver, gold or anything else to keep, he shall show everything to some witness, draw up a contract and then hand it over for safe keeping."*

*Article 229. "If a builder builds a house for someone, and does not construct it properly, and the house which he built fall in and kill its owner, then that builder shall be put to death."*

While article 122 implies the need for a contract, required by element 7.4.2 of the ISO 9001 standard, article 229 appears

to refer, quite extremely one might say, to a corrective action, required by element 8.5.2 of the standard. Centuries later, on January 11, 1723, Peter the Great issued a decree, also, as a corrective action I presume, to whip the owner of the Tulsk's Armory Plant for supplying defective ammunition to the Czar's army.

The history of standards for contemporary quality systems traces back to 1959. Then, the U.S. Department of Defense released a quality management program under the designation MIL-Q-9858. For nearly three decades, this standard was primarily used in the U.S. defense and aerospace industries. In the mid 1960s, the former Soviet Union introduced a national standard (KC YKP) in an attempt to manage quality across the country.

In 1979, the British Standards Institution (BSI) developed the first commercial standard for quality systems that became known as BS 5750. That same year, BSI issued its first certificate to a small cement plant in England for compliance with BS 5750. It took almost another decade for the international community to recognize the benefits of standards for quality systems.

In 1987, ISO completed and released its 9000 series of standards, incorporating most of the elements of BS 5750 into its ISO 9001 standard. The ISO 9000 series of standards first gained popularity in Europe, when the European Union (EU), under the title EN 29000, adopted ISO 9000. By the late 1980's, BS 5750 and ISO 9000 standards had reached the U.S. market.

ISO 9001 standard is not product specific and can be used by a wide range of manufacturing and service companies. Long time ago, I saw a flag-size poster on a theater in Singapore bragging about its registration to the ISO 9001 standard. One of my European colleagues recently mentioned that he received an application to register a church choir.

The ISO 9001 standard requires that a company develops and implements a basic quality management system, using the

specific elements to ensure the company is capable of maintaining uniformity of its processes and, as a result, provides its customers with a consistent quality of products and services. ISO 9001 group comprises a series of standards outlining the requirements and guidelines for quality management systems. There are three core standards in this group:

ISO 9000:2005 - Vocabulary [3]

ISO 9001:2008 - Requirements

ISO 9004:2000 - Guide for performance improvement [4]

## 1.6 Why We Need ISO 9001

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Businesses worldwide have to confront the challenges of an ever progressively intricate, competitive and challenging business environment. Numerous aspects are involved in the process from winning bids with the right margins, producing goods or services per agreed upon requirements, managing resources and costs, and others. If effective planning and execution are not present, negative financial consequences are inevitable. As a result, companies develop systems and processes to reduce or eliminate potential pitfalls, streamline operations, ensure cohesive relationships between functions. ISO 9001 standard provides well-tested and recognized foundation for such an environment.

An ISO 9001 compliant quality management system provides strong assurance that company's processes are in compliance with documented requirements to fulfill contractual obligations and customer needs. ISO 9001 QMS promotes a systematic approach to effectively manage business operations by providing a structure for processes, focusing on continual improvement and reducing errors and waste.

Most companies that have implemented ISO 9001 or similar systems report significant improvements in productivity due to an increase in customer satisfaction and reduction in customer returns and internal failures. Effectively implemented quality systems help to define processes and develop discipline, which in turn, helps to "do things right the first time." A published survey showed that companies that implemented a quality

system for QS 9001 reduced failure rates by 40 percent and customer returns by 54 percent, reducing total cost of nonconformance by 53 percent. [5]

Most companies that undertake the effort to implement ISO 9001 quality management systems are better prepared to satisfy their interested parties, including their customers. Some of the advantages of an effective quality system include:

- Formalized systems ensure consistent quality and punctual delivery of products to the customers;
- Fewer rejects result in less repeated work and warranty costs;
- Errors are detected at the earliest stages and not repeated;
- A simplified environment for managing periods of change or growth;
- An improved awareness of company objectives;
- Responsibilities and authorities clearly defined;
- Improved utilization of time and materials;
- Improved relationships with customers and suppliers;
- The benefits of use of a Registrar's logo on marketing materials;
- An improved corporate quality image;
- A reduced number of customer audits;
- An improved record management system in case of litigation, and others.

## 1.7 How to Work With This Electronic Book

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When you purchase this publication we will e-mail you a .zip file with template documents in Microsoft® Word and Microsoft® Excel formats listed in the Documents Chapter.

It is a good idea to organize your QMS documents in some sort of a system on your computer's hard drive or better yet on your server. For example, you may create the following folder structure:

- (E:)**
  - Management system**
    - Archive documents**
    - Current documents**
      - [Documentation Master List 01](#)
      - [Document Template Procedure 01](#)
      - [...and so on...](#)
  - External documents**
    - [ISO 9000:2005 Standard](#)
    - [ISO 9001:2008 Standard](#)
    - [ISO 9004:2000 Standard](#)

- Records**
  - DCRs
    - [DCR 1001](#)
    - [DCR 1002](#)
  - Management Reviews
    - [Management review 080721](#)
    - [... and so on...](#)
  
- Redline documents**
  - [Documentation Master List D2](#)
  - [Document Template Procedure D2](#)
  - [Documentation Management Procedure D2](#)
  - [Organizational Chart D2](#)
  - [DCR Form D2](#)
  - [DCR Log D2](#)
  - [Records Procedure D2](#)
  - [Quality Manual D2](#)
  - [Quality Policy D2](#)
  - [Quality Manual Review Checklist 9001:2008 D2](#)
  
- References** (Entire folder - read only)
  - [Documentation Master List D1](#)
  - [Document Template Procedure D1](#)
  - [... \(All original documents you ordered\)](#)

The first thing we need to do is to copy all your new document templates into your References folder. Make sure that all these files are read only and cannot be accidentally changed. All these files are identified as revision D1, meaning that they are in a draft stage and this is the first draft revision.

To start working with your files, we need to move them into your Redline documents folder. After you copy the files, you may start modifying the contents of the files to reflect the conventions of your documentation system and practices of your company. To differentiate your revisions from the original drafts, I suggest you identify them as revision D2 or second draft. To work effectively with these files, you need to be familiar with Microsoft® Word formatting features. While modifying the documents, make sure that you do not delete section breaks. This formatting feature is widely used

throughout the documents. If deleted, they will affect the appearance of pages and the contents of the footers and headers.

Visit our Website to learn about electronic documentation systems at [www.quality-works.com/dms](http://www.quality-works.com/dms)

# <sup>2</sup> Chapter 2 Quality Manual 101

## 2.1 What is a Quality Manual?

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A quality manual is the main, top-level document of a quality management system. It is similar to a constitution of a country or a manifesto of a party. This type of document establishes the policy level position of a government, party or in the case of a quality manual, a company's QMS. There are two published definitions of what a quality manual for an ISO 9001 system should be:

ISO 10013, Guidelines for Developing Quality Manuals [6], element 4.2, gives detailed suggestions for creating a quality manual. It defines a quality manual, among other requirements, as a document that should "...consist of, or refer to, the documented quality system procedures intended for ... planning and administration of activities which impact on quality..."

ISO 9001:2008, element 4.2.2 describes a quality manual as a document containing:

" ...

- a) The scope of the quality management system, including details of and justification for any exclusions;
- b) The documented procedures or reference to them;

- c) A description and interaction between the processes of the QMS.”

If we follow the requirement 4.2.2 of ISO 9001:2008 Standard, our quality manual simply need to contain:

- The scope of the organization’s activities,
- Identification and justifications for any exclusions,
- A description of the QMS processes,
- References to documented QMS procedures, and
- Interaction between the processes of the QMS

After we defined our scope and formulated exclusions, we have to describe applicable QMS processes per ISO 9001 Standard. This task is quite simple. We just need to transform the standard from a set of requirements into your company’s commitment to satisfy those requirements with the appropriate level of details. You also may consider including into your quality manual:

- A table of contents,
- Company information,
- Procedure index,
- Manual-to-standard correspondence table, if your manual numbering differs from the standard, and
- Standard-to-manual correspondence table, if you develop an integrated manual.

These features will help you easier navigate the manual. Another important function of a quality manual, very often overlooked, is as a marketing tool. Well written and professionally published, a quality manual may become a powerful marketing instrument. It can communicate to your potential customers, suppliers and subcontractors that your company is not only a quality-conscious organization, but that it also knows how to document and communicate its commitment to quality. I always wonder what companies achieve by stamping their quality manuals with “CONFIDENTIAL” red stamp in bold capitol letters. As far as

I'm concerned, a quality manual is a company's resume for quality, and if you hide your resume, there is a very good chance you will never get a job! All Quality Works customers are encouraged to make their quality manuals public. You may easily see how many companies followed this philosophy and put their quality manuals on their Websites: just type "quality manual" in your browser!

Once I browsed a trade show in Hong Kong. One of the displays attracted my attention with impeccable composition and very professional color coordination. As I approached the booth, I saw a Chinese woman talking to a group of visitors. While enjoying the artistic displays, I noticed a thin book on the counter. The cover contained a few artistically arranged Chinese characters and the logo of one of the World's largest registrars. I leafed through the book wondering what business this company was in – lighting fixtures as it appeared from the displays, or perhaps publishing books in Chinese for the registrar.

Meanwhile, the woman finished the conversation with her visitors and approached me. We introduced ourselves and she enthusiastically started to tell me about her company. When I asked her what her company had to do with publishing, referring to the booklet, she replied with a proud smile: "This is our quality manual!" She said the company put a lot of effort into it. But, she continued, "It's paid for itself many times over by generating business for us." Someday I'd like to frame that manual and put it on the wall – it's a beautiful piece of art!

## 2.2 Quality Manual – Two Philosophies

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There are two schools of thought concerning the origin of manuals and other management system documents. One categorically declares that a template-based quality manual will not work and that each company should develop its own. This conviction stems from the belief that if documents are not written within the company, its personnel will not have accountability for them and will not follow them.

If one were to carry this thought to the next level, one might find it necessary to reject such common tools as Newton's laws, multiplication tables, Microsoft® Word and others not written by end users. It is often helpful to use a sample to achieve a desired outcome. It isn't always necessary or practical to reinvent the wheel. Writing your own documents does not necessarily mean that your personnel will follow them. I have worked with companies that wrote their own manuals and procedures and still did not use them, not having a clue as to what was written in them!

Another point of view, to which I adhere based on years on experience, is that a quality manual is a generic document. Virtually any company can use a model of a quality manual to develop its own "from scratch," or to enhance an existing one. I have seen proof of this in a number of companies of various

sizes in different parts of the world. Based on the thousands of template procedures that are being sold, there are also very strong indications that many second-level processes are generic enough to use a model for their construction.

One of my clients recently demonstrated the benefits of this approach. The company purchased templates for the top-level documentation. Key personnel had experience and were quite familiar with the QMS concepts. The company was a small start-up of approximately 30 people. It took them only three months to implement a functional system and achieve ISO 13485 certification.

If you adhere to the first school of thought and believe that a company should develop its own quality manual “from scratch,” you may not need this book. However, you still may want to use it later to check how well you have done the job. You may create your own manual by toiling through numerous, difficult-to-read and understand standards, figuring out various cross-elemental specifics and implied references, finding interpretations and learning through your own experience.

There is nothing wrong with this approach. As a matter of fact, I went the same route when I was learning the trade. I have studied the standards for years, interpreted them by communicating with experts in the field, reviewed dozens of manuals and assessed dozens of companies. As with anything else, you can rely on the experience of experts, or make a significant investment in becoming an expert yourself. It is you choose...

To assess the cost of developing a quality manual for ISO 9001 standard, I surveyed about three dozen of my customers to estimate the time they spent preparing their quality manuals. All surveyed personnel reported average to high levels of expertise in quality management systems. Responses indicated that the time span was between two and four weeks, with an average of three weeks.

Based on a U.S. salary survey data, [7] a quality manager, on the average, made approximately \$86,000 a year. This translates, for three weeks, into about \$6,000 for direct time only. Add to this number approximately 100 percent overhead, which is typical for a medium- to large-size company, and you may easily end up paying about \$12,000 for a document that contains some 30 – 40 pages. For this price, it'd better be good! If you agree this cost is too high, let's talk about how this book can help you develop your quality manual for a small fraction of that cost.

## 2.3 Quality Manual – The Ten Commandments

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- 1 Thou Shalt Not shy away from purchasing and using Quality Works' models of quality manuals and documentation to save Thou's time and money.
- 2 Thou Shalt create a quality manual as company's QMS resume and a marketing tool for the benefit of all interested parties.
- 3 Thou Shalt ensure that thy quality manual covers all the requirements of applicable standards.
- 4 Thou Shalt Not go crazy referencing the same standards and regulations in the quality manual over and over again
- 5 Thou Shalt include in thy quality manual a table of contents and the scope.
- 6 Thou Shalt reference thy quality policy in thy quality manual.
- 7 Thou Shalt Not put technical or proprietary information into Thou's quality manual.
- 8 Thou Shalt create a cross reference matrix between corresponding standards and Thou's quality manual
- 9 Thou Shalt Not create duplicate systems to deal with identical or similar processes.
- 10 Thou Shalt Not ignore sub-elements and details of the standards in Thou's quality manual.

## 2.4 Quality Manual Model

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Now let's get serious... Since you have read this far, I take it you are not sitting in a library or at your computer loaded with CDs reading standards. So let's talk about our model of a quality manual and see how it can save you time and a significant amount of money in getting your company started in the creation of a quality management system that meets the requirements of the ISO 9001:2008 standard and also makes good business sense.

Our model of a quality manual follows a straightforward approach. It establishes the commitment of a company to the particular standard in a short and concise form. If the element 5.6.1, for example, states that the "Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness," our manual will state:

*"QW Enterprises, LLP's top management reviews the quality management system at least quarterly to ensure its continuing suitability, adequacy and effectiveness per the [Management Review Procedure](#)."*

Following this approach in documenting commitments to specified requirements, we will end up with a quality manual that addresses all applicable requirements of the standard and provides references to supporting documents. I know you are

eager to start working on your quality manual right away, but there is more preparation to be done. A quality manual is not a stand-alone document. Being only a part of a quality management system, our quality manual requires a few supporting processes.

# **3 Chapter 3 Getting Started**

## 3.1 Documentation Structure

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ISO 10013, Guidelines for Developing Quality Manuals, gives an example of a documentation structure for ISO 9001 quality systems. While this document suggests using a three-level structure, most companies implement four-level documentation structures to include records, as required by element 4.2.4 Control of quality records, of the ISO 9001:2008 Standard. A typical four-level documentation structure includes: Quality Manual, Procedures, Instructions and Records.

Actually, the documentation structure starts from the policy. The policy defines, among others, commitments to what standard a company intends to comply with. If you choose to use this approach, your quality management system documentation will have five levels, similar to the structure below:

Quality policy	- level 1
Quality Manual	- level 2
Procedures	- level 3
Instructions	- level 4
Records	- level 5

## 3.2 Naming Your Documents

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As you may have noticed, the titles of the documents in the structures above are quite short. Various companies use different conventions for their document titles, very often excessively wordy. For example, one of my customers titled their quality manual “Quality Management System Quality Manual.” In my opinion, these tongue-twisting explicit titles are waste of time and money: somebody has to type them and everybody has to refer to them all the time.

It is a very typical convention in the medical device manufacturing and other regulated industries to call the second-level documentation “Standard Operating Procedures”, known as SOPs. Unless one has a level called “Non-standard Operating Procedures,” I really do not see a practical or economical reason for long titles like these. As long as the short name conveys the idea and leads us to the right place, let’s use it. I will promote this optimization and reduction of waste approach throughout this book. Let’s not make things more complicated than they practically need to be.

## 3.3 Numbering Your Documents

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It is not a specific requirement of the ISO 9001 or any other standard to identify a part or a document by its number. It is perhaps a common-sense measure and a worldwide practice in any documentation system, to give a document or a component a number, a title and to identify its revision level. As with documentation titles, document numbering is also an area for creativity and an opportunity for optimization.

I once worked with a company of less than 100 people, manufacturing fairly simple devices. Their documentation system consisted of a few numeration systems depending on the type of document. One of the procedures had a number 0000057-001, which they simply called "fifty seven." Drawings though had numbers similar to 327-856-99-17.

Is it acceptable to have long and difficult-to-read and remember numbers? Yes, of course! Is it practical? I do not believe so! In the example above, the procedure number, without the tab, contained seven digits. This meant that the system was prepared to handle almost 10 million document or part numbers (PN). The company had approximately 250 documents and probably would never go beyond 300. If nothing else, just reading these numbers with five sequential zeros may give one a headache. Those folks figured it out too - that is why they called that document 0000057-001 just

“fifty seven.” Surprisingly, this is not the worst case I have experienced! The company that won my “The Worst Part Number” Grand Prize used 12 (!) alphanumeric characters to identify their part numbers.

If you are designing and building a Trident-class submarine, a MIG-27 jet fighter or an international space station, you most likely will need millions of parts, so a long part number format would be justifiable and will make sense. Otherwise, save yourself the trouble of reading all those zeros and make your numbering system practical. If your operation is small, use a four-digit part number format that allows for 9,999 parts, which is probably enough for majority of companies. Ten thousand parts is too much? Drop it to three digits – you may always change it later if you need to. One of my customers, who won my “The Best Part Number” Grand Prize, numbered their documents as 101, 102, 103, and so on. Short and sweet!

Another issue with the part-numbering format is part number designation. Some systems associate a part number with a particular part type. For example, 10xxx indicates a procedure, 20xxx indicates a drawing, PLxxx indicates a policy-level document, and so on. My experience with a number of medical device manufacturers has convinced me in the benefits of a “no designation” system. Three systems that used designation formats I worked with have failed. Just recently, one of my customers reported that they ran out of range in their part-numbering format. The system allowed for identification of material type through a two-digit designator within the part number. When the system was designed a few years ago, needing more than 99 materials was not considered possible. Unfortunately, things changed, and just a few years later, the company needed more than 99 materials causing the existing part number format to fail.

Despite these limitations, many companies still use designation-based document or part-numbering systems. A Design Management Procedure, for example, may be numbered as SOP 4.4-1. With ISO 9001:1994, it meant that

this document related to element 4.4, design management. Well, it does not mean the same in the new ISO 9001:2008 revision, simply because design management clause now addressed in the clause 7.3.

What is the solution and how to resolve such issues now? The part-numbering format either becomes designation-free and those 4.4, 4.5 and others do not mean anything anymore or somebody needs to change the numbers of all quality system documents within the company, with no practical benefits to the company for this Herculean task! Customers and shareholders definitely will not see any rewards for this initiative. An alternative approach to designation-based part numbering is a designation-free system. In such systems parts are given sequential unique numbers within a specified format, regardless of their type, material, application or other attributes.

Going further with this optimization initiative, one may ask why we need part numbers at all. Isn't the part title the best designator? Isn't "Records Procedure 01" a unique set of characters? Why then do we need to add to it QSP-07 or something like this? Through my auditing and consulting career I met just very few companies that used these number-free systems. Less to write, less to remember, less chances to make mistakes – life is good! Our approach to development of documentation system also suggests using only part title and its revision level to identify a document or a part. For example: Records Procedure 01.

## 3.4 Forms: To Control or Not to Control

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One of the controversial issues with interpretation of ISO 9001:2008 Standard and others is control of forms. Many companies, by some reason, treat forms differently than documents, leaving them not controlled. I believe the Standard clearly defines requirements for control of documents in element 4.2.3:

*“Documents required by the quality management system shall be controlled.”*

Forms and tables are frequently used within management systems. Often, it is not necessary to write a traditional instruction with the purpose, scope and details of a process if a simple table is sufficient to provide these instructions. One of the typical non-conformities that companies get during audits of their management systems is against forms that are not part of the documentation system. When questioning the validity of a form without a number, I often hear: *“This is just a form.”* It always escapes me, why should a form be different from any other instruction? How would we know that we need a form if it is not referenced in our documentation system? After all, if you are not managing forms and decide to modify them, how can you be sure that the latest revision is being used? At best it would be difficult. In practice it would be

impossible. Well, exactly what is a form? A quick quiz will help answer this question. What would you call the list in Figure 1?

**Figure 1**

- 1 Use the form below

Your company name	Your company URL

- 2 Enter your company's name into the first column;
- 3 Enter your company's URL into the second column

I bet that most of you would call this three-line direction an instruction or a procedure. If we follow this instruction, we most likely will end up with a figure like this:

**Figure 2**

Your company name	Your company URL
My Company, Inc.	www.mycompnay.com

Now, imagine that we were given the same blank table without written instructions. Wouldn't we do exactly the same as following Figure 1 instructions? Are we going to end up with the same Figure 2 when we are done? To make long story short, if we agree that our first three-line instruction in English was a "real" instruction, that justifiably needs to be controlled, the second, blank form, resulting in the same output as a written instruction, must also be a controlled document!

I think that the confusion regarding forms is based on the fact that forms serve two purposes. Blank forms are concise

instructions written in tabular language. After a form is filled out, it becomes a record. Unlike instructions, records are not expected to have a part number or a revision level. Records are managed in a different manner. Let's remember this and treat our blank forms as instructions letting the documentation management process govern them. There are a couple of simple tests you may take when you are tempted to use a form that has not been assigned a part number or otherwise identified:

- If you created a form and found it had been changed, would you like to know who did it and why?
- If you changed your form, would you like personnel to use the most recent revision?
- If you were on vacation, would you like folks to be able to locate your form just by finding a reference to it in your documentation system?

If you answered, "yes" at least once, your form is a definite candidate for being a controlled document, and falls under the scope of your documentation management process.

# **4 Chapter 4**

# **Key**

# **Processes**

## 4.1 Documentation Master List

---

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Even though ISO 9001 does not require a Documentation Master List, it still may be a good idea to have one. A master list is an index of all documents used in a company, referencing their titles and revision levels. A master list may be seen as a map to your documentation system with key information regarding documents, such as status, issuing Documentation Change number and date and obsolete Documentation Change number and date. We will start creating our documentation system from this map. Apparently, the master list is a good candidate for a tabular format. Since we agreed that these documents should be controlled, let's title this document Documentation Master List and assign its current revision D1. A copy of this document is shown in the Documents Chapter.

Obviously, Documentation Master List is practical only for paper-based systems. If your organization uses an electronic system, the list of current documents may serve as Documentation Master List.

# The Perfect Manual

<b>QW</b>		<b>Documentation Master List</b>						
		Revision D1						
Line number	Document title	Documentation level	Revision level	Status	Issue date	Issue DCR	Obsolete date	Obsolete DCR
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
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## 4.2 Change Record

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It is practical to keep records of documentation changes. As a matter of fact, in some regulated industries it is a requirement. These records contain such information as the purpose of change, effectivity dates for new documents, evidence of review and approval, and others.

There are numerous ways companies achieve this. The most popular approach is to have a Documentation Change Record as a stand-alone document with the corresponding sections. We will use this approach and will discuss this document later in this publication.

Another frequently used approach is to document change information within the document itself. While I have seen a number of management systems utilizing this method, I do not believe it is practical. Eventually, after numerous changes, the document grows due to change information pages which are not essential for most users.

Regardless of the method you choose, it is helpful to have a summary of change. For example, correction of errors, improvement, modification due to process changes, etc. These short descriptions will allow you to trend reasons for change and therefore assess effectiveness of your documentation management system. This summary of change is included in our Documentation Master List as shown below:

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<b>QW</b>		<b>Documentation Master List</b> Revision D1
Line number	Document title	Change: brief description
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
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## 4.3 Document Distribution Matrix

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A document distribution matrix is a mechanism for recording the location of hard copy documents. Element 4.2.3 of the ISO 9001 standard requires to "...ensure that ... documents are available at points of use." There are a couple of approaches that businesses use to keep track of document locations. One is to have a distribution matrix on the document itself. The benefits of this approach, while quite frequently used, are not clear. What if we need to add a department or a person to this list? I suppose we will need to revise the document only for the purpose of adding a line to the distribution table. It does not appear to be practical or economical.

Another method is to create a distribution matrix. This matrix may be a part of our Documentation Master List and may look like this:

# The Perfect Manual

---

Document title	Distribution Matrix				
	COO	QA	R&D	Fin	...
Documentation Master List	---	1	---	---	
Template Procedure	---	1	---	---	
Documentation Management Procedure	---	1	---	---	
Organizational Chart	1	1	1	1	
...					

This matrix shows that the QA department has 1 copy of all documents. It also indicates that one copy of the Organizational Chart is distributed to each department. This system is successfully used by a number of businesses which utilize hard copy based systems. Distribution Matrix section of our Documentation Master List is shown below:

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<b>QW</b>		<b>Documentation Master List</b> Revision D1									
Line number	Document title	Distribution									
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
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## 4.4 Documents of External Origin

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Element 4.2.3 of ISO 9001 standard requires us to manage documents of external origin. It is expected that the revisions of such documents as national and international standards and regulations, customers' drawings and suppliers' specifications be monitored to ensure that only the latest or specified revisions of these documents are used. There are a number of approaches to keep track of the revisions of external documents. The three most common are:

- (1) Subscribe to a service that provides information related to revision changes to the external documents. While this approach appears to be the most convenient, consider the costs associated with this approach. Depending on how many standards and documents you need to track, your cost may be significant. For example, one of my customers is tracking some 50 standards, for which they are paying about \$7,000 per year. These services will track national and international standards, but doubtfully will engage in tracking your customers' drawings and suppliers' specifications.
- (2) "Do-it-yourself" - if we employ this approach, we will need to periodically contact the issuer of the standard, drawing or other document to verify its current revision. If we choose to track our external documents by

ourselves, we may create an external document list with the document name, current revision level, company's phone or URL and who verified it and when. To document this process we may use our existing Documentation Master List as shown in the Documentation Chapter.

- (3) Assign responsibility - if we employ this approach, we may simply place a label on each standard saying, for example, "It is the responsibility of the user to verify that this is the most recent revision of this document prior to use." This will establish a method of control.

A comparison of these methods shows that the least expensive, but also least reliable, is the third method, while the most reliable and expensive is the first. Make a choice depending on your budget and needs.

Since our quality management system is intended to comply with ISO 9001 Standard, we need to add at least this standard as an external document to our Documentation Master List.

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<b>QW</b>		<b>Documentation Master List</b> Revision D1	
Line number	Document title	External Document Verification record	
		Issuer or re-seller	Verification record
1			
2			
3			
4			
5			
6			
7			
8			
9			
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## 4.5 Document Reference Matrix

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If you use a paper or manual system, a document reference system may serve as a “where used” list for a product structure, similar to a Bill of Materials (BOM). Let’s say that you referenced several instructions in one of your documents. After a while, one of these instructions becomes obsolete. How do we know where references to this obsolete document are located, so we can update them? There are a few approaches to this.

Some companies, using their Material Requirement Planning (MRP) systems, create a BOM for each document specifying what documents are referenced within. When a document becomes obsolete, you simply run your “where used” report to know where it was referenced. If you do not use such a system, a reference matrix may be a part of your Documentation Master List. An example of this matrix may look like this:

Document title	Reference Matrix				
	Documentation Master List	Template Procedure	Documentation Management Procedure	Organizational Chart	...
Documentation Master List	N/A	---	---	---	
Template Procedure	Yes	N/A	Yes	---	
Documentation Management Procedure	Yes	---	N/A	---	
Organizational Chart	Yes	---	---	N/A	
...					

This matrix shows that our master list references all documents in it and the Documentation Management Procedure, for example, references the Document Template Procedure. So, if we decide to obsolete the Document Template Procedure, this matrix will allow us to know that it is referenced in the Documentation Management Procedure. Therefore, the Documentation Management Procedure also needs to be updated to reflect this change.

Another approach to the reference matrix may be computerized hyper linking. If your documents are located on your computer system or within an electronic Documentation Management System (DMS) with hyperlink management capabilities, references simply may be established through the use of hyperlinks. If a document becomes obsolete, verification of its hyperlinks will provide a list of the documents where the obsolete document was referenced or your DMS will remind you to update the link. More information on on-line documentation management systems can be found at <http://www.quality-works.com/dms.htm>

# The Perfect Manual

<b>QW</b>		<b>Documentation Master List</b> Revision D1											
Line number	Document title	Referenced in:											
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
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## 4.6 Document Template Procedure

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None of the standards require specific formats for documents used within a management system. Particular requirements may apply if you choose to follow particular national or international standards and reference them in your quality system as external documents. For example, a format for drawings becomes a requirement, if we choose to comply with ASME-Y14.100, Engineering Drawing Practices.

It is a good practice to provide guidelines on how to format a quality manual, a procedure or a document of any level. This will help to create documents with a consistent format and professional appearance. Consistent appearance of documents is especially critical for documents with external distribution, as the format becomes a corporate identity issue. It is not that uncommon for large, well established corporations with a strong corporate image to have 2-3 inch thick Corporate Identity Manual. To specify a format for our quality manual, procedures and instructions let's issue a document called Document Template Procedure shown in Documentation Chapter. Let's add it to our Documentation Master list with the D1 revision.

Similar to the Document Template Procedure, you may consider creating similar templates for forms in portrait and landscape formats. These templates will not only help you with



## 4.7 Documentation Management Procedure

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Element 4.2.3, Control of documents, of the ISO 9001 standard requires the establishment of a documented procedure for this area. A quality manual is a document and therefore is subject to element 4.2.3 requirements. So, before we start working on the quality manual, we have to develop a procedure to define methods for the creation, maintenance and obsolescence of the quality manual and other documents of our system.

The standard, as well as many companies around the world, call this function "documentation control." Born in the Soviet Union under what was undoubtedly one of the most totalitarian regimes in the world, I am averse to the word "control." There are also indications that this word started to be considered misleading in the Western world as well. Quality Control discipline, for example, was transformed into Quality Assurance, emphasizing prevention rather than the detection of problems. The American Society for Quality Control (ASQC) renamed itself in 1997 to the American Society for Quality (ASQ). So let's also switch from control to management to demonstrate our awareness of contemporary thinking, and manage our documentation system with a Documentation Management Procedure.

**QW**      **Documentation Management Procedure**  
Revision D3  
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<b>3. General.....</b>	<b>2</b>
<b>4. Documentation types and formats.....</b>	<b>2</b>
<b>5. Document identification .....</b>	<b>3</b>
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<b>7. Document changes .....</b>	<b>4</b>
<b>8. Documentation change process .....</b>	<b>5</b>
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The Documentation Management Procedure you use will depend on the type of the media for your documentation system. Traditional paper systems, where documents are produced, approved and maintained on paper, are still perhaps the most frequently used approach. However, an

increasing number of companies are switching from paper to electronic, computer-based documentation systems.

Documentation Management Procedures for these two systems differ for a number of reasons. An electronic media system won't require, for example, a master list as a separate document – an active document directory on your computer or a network will serve this function. The Documentation Change Record Log may not be needed, as your software may be programmed to generate a change number. Our Documentation Management Procedure covers both, paper and electronic systems. Let's title this procedure Documentation Management Procedure, assign it revision D1 and add it to our Documentation Master List.

## 4.8 Organizational chart

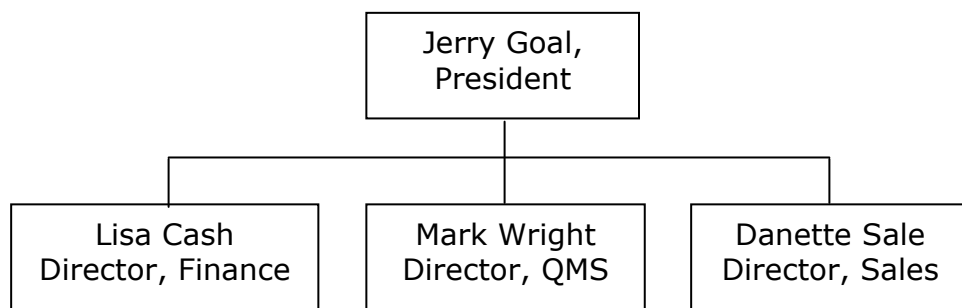
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An organizational chart lists all the functions within a company and establishes relationships between these functions. Use of an organizational chart addresses the requirement of the element 5.5.1 of ISO 9001 standard, Responsibility and authority. This element requires an organization to define "...responsibilities and authorities ..." within the organization. There are a number of formats used for this purpose.

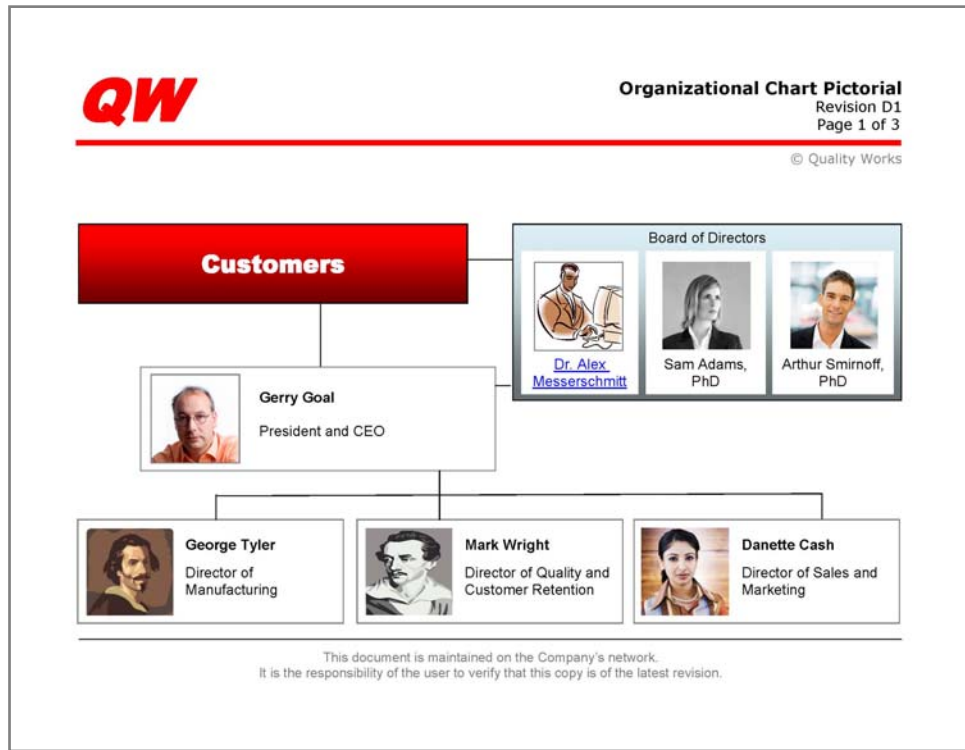
One of the most typical formats for an organizational chart is a block diagram. The blocks are arranged in the hierarchical structure showing reporting relationships of company's functions and personnel. A typical organizational chart in this format is shown below:

### Block Diagram Organizational Chart



## Pictorial Organizational Chart

One of the most visual formats is a pictorial organizational chart. If you have access to a digital camera and color printers, this may be the way to go. These charts are very easy to remember and use. A sample of this type of organizational chart is shown below.



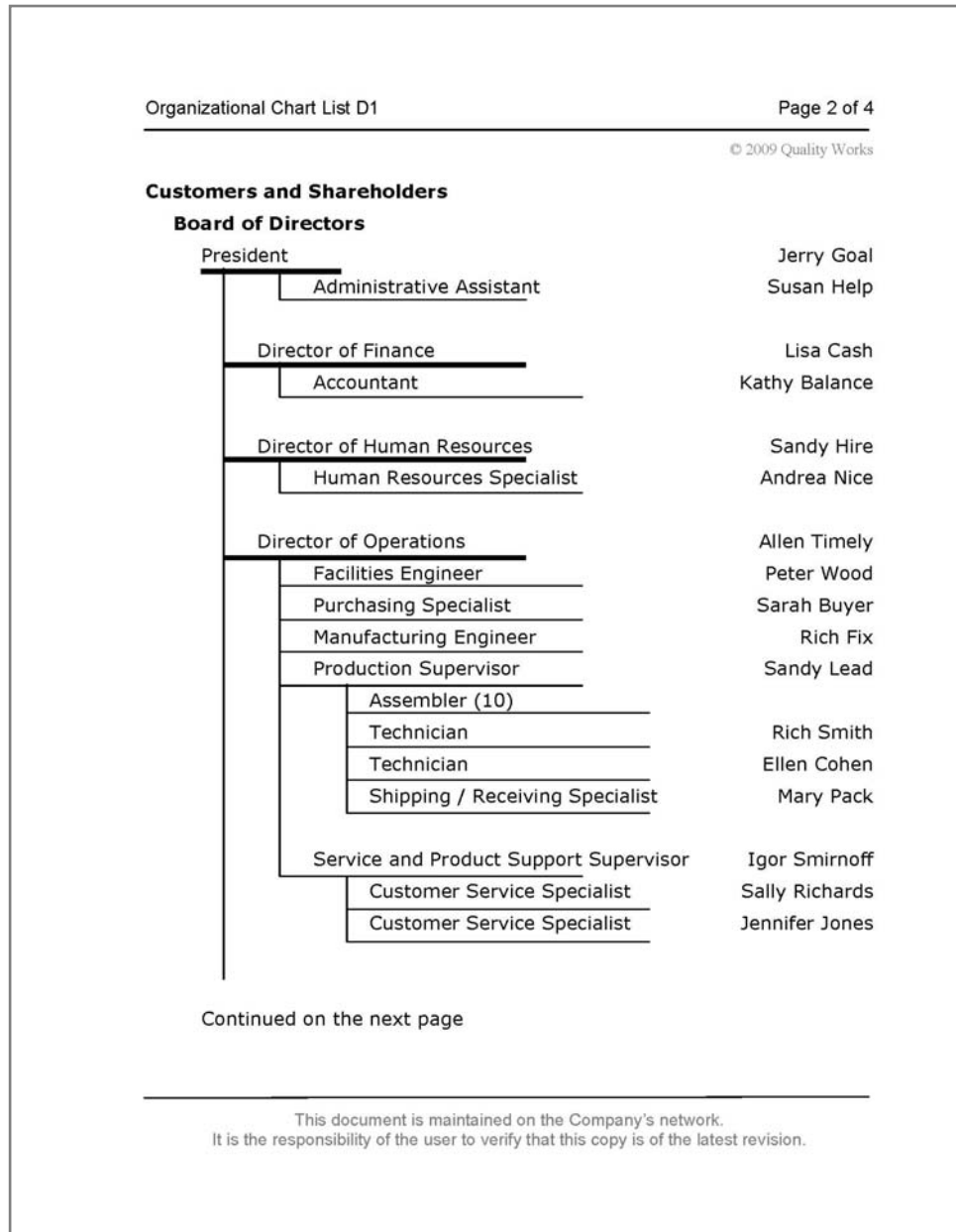
## List Organizational Chart

Another format of an organizational chart may be as simple as a list similar to your hard drive directory structure. The benefit of using this format is its simplicity. A simple text format without time-consuming photos or block diagrams may work well in the beginning.

Our Documentation Chapter includes both templates: Pictorial and a list Organizational Chart. These two templates are

# The Perfect Manual

included in our Documentation Master List. Let's add these documents to our master list with their revisions D1.



## 4.9 Records Procedure

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Element 4.2.4 of ISO 9001 Standard, Control of records, requires a system for management of records. As soon as we approve and release our first DCR, this DCR becomes our first record. What do we do with it? Element 4.2.4 requires a system to ensure that records are:

- Identified,
- Appropriately stored,
- Retrievable,
- Retained for a defined period of time, and
- Appropriately dispositioned.

The standard requires establishing periods for retention of records. Knowledge preservation, legal and customer requirements may affect the retention times. It is not uncommon to see numerous retention times for records. Some companies choose to simplify this process by limiting retention times to one or two periods. In practice, especially small businesses, maintain their records for the life of the business regardless of their nature. If you choose to establish one common retention period, the Records Matrix may be simplified by eliminating the Period column. The retention period may simply be documented within the text of the procedure. Our Records Procedure is shown in the Documents Chapter. Let's add it to our Documentation Master List with its initial draft revision D1.



**Records Procedure**

Revision D1

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**1 Purpose**

This procedure defines methods and assigns responsibilities for generation, collection, retention, maintenance and disposal of records.

**2 Scope**

This procedure applies to all departments that establish and maintain records related to the Company's Management System. Where specified by the contract, additional documents and technical instructions may be classified as records.

**3 General**

Records are generated and maintained to provide evidence that Company's Management System complies with the requirements of applicable standards and regulations and contract requirements. Records are also maintained for preservation of knowledge and legal purposes.

**4 Generation of records**

Due to the nature of the Company's business, the Company generates and maintains records on two media: hard copy and electronic. All employees and departments responsible for generation of records are encouraged, when possible, to scan their records and store them electronically.

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## 4.11 Quality Policy

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Element 5.3 of ISO 9001 Standard requires “The management...” of an organization to establish a quality policy and ensure that the policy:

- Is appropriate to the purpose of the organization;
- Includes a commitment to comply with requirements;
- Includes a commitment to continual improvement of the effectiveness of the QMS;
- Provides a framework for establishing and reviewing quality objectives;
- Is communicated and understood within the organization;
- Is reviewed for continuing suitability

When developing your quality policy, consider your organization's vision and mission statements. Taking them into account will help you set a framework as to how your quality policy can ensure conformance with the companies' long term plans and continual improvement. Also, make sure that all the requirements for a quality policy listed in the standards are addressed.

Surprisingly, very few companies we worked with achieved this objective. By some reason, often companies formulate their quality policies as a mission statement. For example:

*"All [Company name] employees are committed to enhancing human health by providing high quality, safe and effective [type] products and services which meet our customers' needs, focusing on continuous improvement."*

In the statement above, the company probably meant "continual improvement", not "continuous" improvement, which is hard, if not impossible, to achieve. Also, this sample does not appear to address compliance with requirements, framework for review of quality objectives and communication of the quality policy.

One of the companies I had "pleasure" of working with, took this "short quality policy" approach to the extreme. Their quality policy read::

*"I improve the Quality of Patient Care and all things [Company name]"*

You are probably scratching your head and wondering if I forgot a line or two or just simply joking. No, I am not joking and I did not misspelled or took a single word out of this sorry example, except for the company name!

This practice of presenting a mission or a vision statement as a quality policy is quite common. If you really have to use your mission statement as or within your quality policy, I suggest considering the following approach, using the example above:

*"All My Company, Inc. employees are committed to enhancing human health by providing high quality, safe and effective products and services that meet our customers' needs with focus on continual improvement by:*

- *Maintaining a Quality Management System to meet requirements of the ISO 9001:2008 standard;*

- *Complying with all applicable regulatory requirements,*
- *Continually improving the effectiveness of our Management System,*
- *Periodically reviewing the performance of the Management System and our quality objectives.*
- *Communicating this quality policy to our employees, and*
- *Reviewing the quality policy for its continuing suitability.”*

This example uses your mission statement which is supported by specific commitments to address requirements of the standard. Using this approach or a sample of Quality Policy from our documentation set, will provide your organization with a quality policy that reflects its vision and at the same time meets requirements of the standard.



When you formulate your Quality policy, avoid including any specific targets or goals - these may change more frequently than you will want to update your policy, Also stay away from declaring that your company is or planning to be a world or industry leader - auditors may ask you to prove it. I did worked though with a couple of customers who did these declarations and in fact were industry leaders, but it cost them thousands of dollars a year to demonstrate this fact through independent complex competitive customer surveys.

As a rule, companies want their quality policies be visible, so they display them in the lobbies, offices' walls, communication boards, etc. These displays intend to remind everyone of the company's quality policy. It has been my experience that these displays are usually not under revision control. Most companies I worked with simply retyped their quality policies from their quality manuals to frame them to show to the public. Sounds simple and easy, but there is a problem with this approach - retyped policies are not controlled.

Surprisingly, only two or three of our customers controlled their quality policy displays and tracked their distribution. I believe it is more practical to have just one quality policy. Our quality manual references such a policy that can be used for display. Our Master List contains a document titled Quality Policy Display. The Documentation Master List Distribution Matrix will assure that all hard copies of this document are tracked. If we change our quality policy, we will be able to locate all its copies and replace them with the new revision.

Let's title our quality policy the Quality Policy Display and add it to our Documentation Master List. To see an example of a quality policy that meets requirements of ISO 9001:2008 Standard, visit our Website at <http://www.quality-works.com/Quality-policy.htm>.

Perhaps you noticed that the two last statements in the policy regarding happy employees and financial performance are not required by the standard. This is just an example of how you can customize your quality policy. From my perspective,

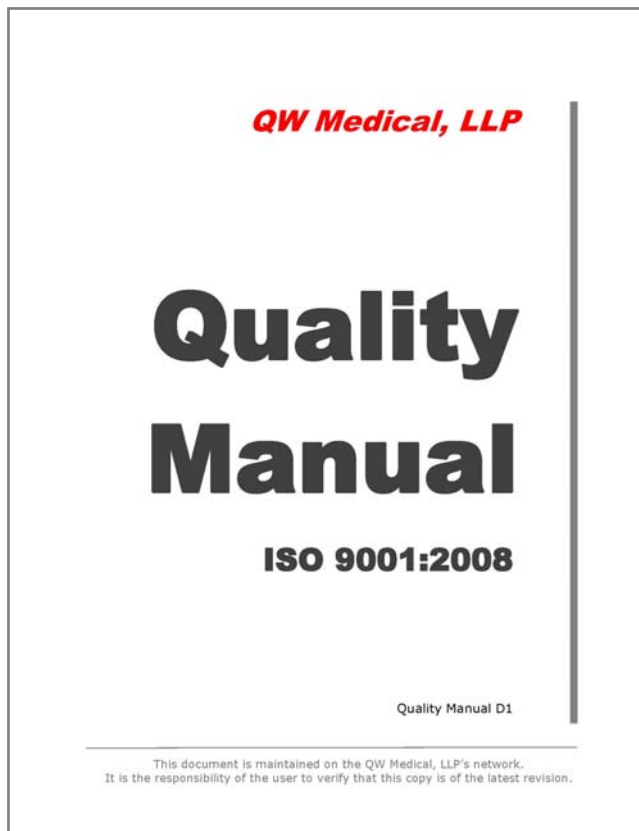
happy employees make better products and profitability assures that financial resources are available for an effective management system.

## 4.12 Quality Manual

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The Documents Chapter contains a template of ISO 9001:2008 quality manual. Details on how to customize your manual are shown in the following chapters. Let's name this document Quality Manual, assign it revision D1 and add it to our Documentation Master List.



## 4.13 Quality Manual Review Checklist

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Regardless of whether you use this book to create your quality manual from scratch, or use our model to tune-up your existing manual, it is a good to verify our new manual before its release. Remember that we started from the objective to create a manual that covers all requirements of the ISO 9001:2008 Standard. To make sure that we've accomplished this goal and did not overlook anything, let's use the ISO 9001:2008 Quality Manual Review Checklist, shown in the Documents Chapter.

This checklist is simply a map of the standard with a list of elements, sub-elements, details and notes. As a rule, registrars use similar checklists to review quality manuals for compliance with applicable standards. For more details on how to develop and use various checklists, check out my article at <http://www.quality-works.com/learn-manual-checklist-9001.htm>

Our ISO 9001:2008 Quality Manual Review Checklist is shown in the Documentation Chapter. Let's name it as such and add it to our Documentation Master List with the revision D1.



## 4.14 Documentation Change Record (DCR)

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To release a document, it is a good idea to create a record to specify the nature of the change and to provide evidence of review and approval as required by element 4.2.3 of ISO 9001:2008 Standard. The following information will be needed on this form:

- DCR number;
- Change type: permanent or temporary;
- Originator name;
- Change description;
- Reason for change: Improvement, Correction of previous releases or others;
- List of other documents affected by the change;
- Disposition of existing stock of physical inventory;
- Validation record;
- Review and approval records, including regulatory approval, if applicable;

This form is shown in the Documentation Chapter and is titled Documentation Change Record. Let's assign it revision D1 and add it to our Documentation Master List.

<b>QW</b>	<b>Documentation Change Record</b>	
	Revision D1	
<b>General</b>		
	Date	
	Documentation Change Record No.	
	Change type	
	Urgency of change	
	Originator	
	Effectivity Date from	
	Effectivity Date to (if temporary)	
	Preliminary approval	
	Change description	
<i>Change description, if "Change is described below" is selected above</i>		
<b>Reason for change</b>		
<i>Reason for change if "Other: describe below" is selected above</i>		

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## 4.16 Summary

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In summary, to release our Quality manual, we need to develop and release the following core documents:

1. Documentation Master List,
2. Document Template Procedure,
3. Form Template Portrait,
4. Form Template Landscape,
5. Documentation Management Procedure,
6. Documentation Change Record,
7. Documentation Change Record Log,
8. Organization Chart,
9. Records Procedure,
10. Records Matrix,
11. Quality Policy,
12. ISO 9001:2008 Quality Manual Review Checklist,
13. Quality Manual,
14. ISO 9001:2008 Standard, as an external document

Which one of these documents comes first? Well, there is no “first” document in this list. By releasing the Documentation Master List first, we will not have a mechanism for recording the change. Releasing the Documentation Change Record first, we will not know how to identify it. Releasing the change log, we will not know what format to use, etc. this list is a bit like the chicken and the egg. To get a documentation system started, at a minimum, we need to develop and release all the documents listed above simultaneously.

## 4.17 The First DCR

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An example of a completed DCR, which will be used to release the first revision of our Quality Manual as well as other key documents, is shown in the Documents Chapter. To complete your own DCR simply follow the instructions in the DCR Form. When you are ready to submit your first DCR for review and approval, include copies of all documents that you propose to release along with it. It is also a good idea to include a CD or a memory stick containing the files of the documents you want to release or change, unless you are processing your changes electronically.

As you may have noticed, our first DCR has a “Temporary” status, which is not by accident. It was released as “temporary” to validate the new procedures that we developed. You may be surprised how many trials it takes to polish a procedure! Some time ago, we worked with a company on the documentation for a new product line. The process was under Validation Protocol, so we kept track of how many revisions were made to our manufacturing procedures. If you guessed around 5, you were very close to our experience! We released approximately 15 procedures with an average number of modifications of 4.

<b>QW</b>	<b>Documentation Change Record</b>	
	Revision D1	
<b>General</b>		
Date	July 10, 2009	
Documentation Change Record No.	1001	
Change type	Temporary	
Urgency of change	Normal	
Originator	Mark Wright	
Effectivity Date from	July 12, 2009	
Effectivity Date to (if temporary)	September 12, 2009	
Preliminary approval	Sarah Allison	
Change description	Change from current to attached	
<i>Release of the key documents for ISO 9001 2008 Quality Management System</i>		
<b>Reason for change</b>	Improvement	
<i>initial release of the key ISO 9001 2008 QMS processes for validation purposes</i>		

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# **5 Chapter 5 Customizing your Quality Manual**

## 5.1 Navigation

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Whether you are creating your quality manual from scratch or tuning-up an existing manual, it is a good idea to keep the numbers of the elements of your manual referenced to the standard. A simple table, similar to the one below will serve as a good map.

The manual		ISO 9001:2008
Sec	Process / Clause	Clause
1	Table of contents	---
2	Company information	---
3	Definitions	---
4	Scope	---
5	Quality management system	4
5.1	General requirements	4.1
5.2	Documentation requirements	4.2
6	Management responsibility	5
6.1	Management commitment	5.1
6.2	Customer focus	5.2
6.3	Quality policy	5.3
6.4	Planning	5.4
6.5	Responsibility, authority and communication	5.5.
6.6	Management review	5.6
	...	

If your manual includes additional sections not required by the standard or you use an integrated manual for more than one standard, you should consider including standard-to-manual reference table to simplify navigation for yourself and your

## The Perfect Manual

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auditors. For example, an integrated system manual for ISO 9001:2008 and ISO 14001:2004 may look like this:

9001	14001	Manual	
		Process / Clause	Sec
---	---	Table of contents	1
---	---	Company information	2
---	---	Definitions	3
---	---	Scope	4
4	4	Management system	5
4.1	4.1	General requirements	5.1
4.2	4.4.4	Documentation requirements	5.2
5	---	Management responsibility	6
---	4.2	Environmental policy	6.3
5.1	4.2	Management commitment	6.1
5.2	---	Customer focus	6.2
5.3	---	Quality policy	6.3
5.4	4.3	Planning	6.4
5.5	4.4.1	Responsibility, authority and communication	6.5
5.6	4.6	Management review	6.6
		...	

## 5.2 Corporate Manual

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### **Introduction**

While numerous successful models of ISO 9001, ISO 13484, ISO 14001 and other management systems have been developed and are being used in various industries, approaches to documenting management system structures for multi-site enterprises are limited at best. This section discusses a method for establishing a top-level documentation structure that allows a business with multiple facilities to use common management system policy and manual. This significantly improves consistency of the corporate message regarding quality, environmental, health & safety and other policies, while reducing the number of documents within the organization's management system

### **Current practices create inconsistencies**

Through my work as a Lead Auditor with major registrars, I observed dozens of large multi-location companies struggling with connecting their corporate policies and manuals with the supporting, location-specific documents. To develop a manual for a company with numerous facilities, organizations take two routes. Some companies create site-specific manuals as copies of the corporate manual; others produce site-specific manuals that are totally independent from the corporate manual.

In the first case when a site-specific manual is a copy of the corporate manual with modifications specific to a given site,

mechanisms to keep the manual coordinated with the corporate manual are rarely defined. Difficulties of keeping these documents in sync are due to the fact that corporate manuals are controlled by the home office, while local manuals are responsibility of site's documentation control departments.

The second technique, when manuals are completely independent, very often leads to major disconnect of the corporate and local policies and manuals. From the corporate identity and simply business consistency points of view, an organization should not find itself in a position of having different or conflicting commitments of its facilities to quality, environmental issues, customer satisfaction, safety hazards and other requirements of applicable standards. One of our large customers demonstrated this point well. The corporate quality policy and manual addressed majority of the requirements of applicable standards and referenced appropriate regulations. At the same time, Mexico facility did not reference required ISO 13485 standard, Costa Rica missed a commitment to compliance with regulatory requirements, yet another US location failed to document their quality policy all together!

As we can see, both discussed approaches to creation of location's manuals as copies of the corporate manuals or independent manuals do not appear to be practical. Besides, if a company has already spent time on developing a manual, why should another employee in the same organization spent more time to create a similar or duplicate document?

### **Corporate manuals can be used by all locations**

To solve this problem, let's review, as an example, ISO 9001 quality manual model, specifically supporting document reference method. As a common practice, a manual references supporting documents within the text of the manual. For example, clause 5.5.1 of the manual, Responsibility and authority, may read:

QW Enterprises, LLP's Management Team ensures that the responsibilities and authorities are defined and

communicated within the organization per the [Resource Management Procedure](#) and the [Organizational Chart](#).

This approach works well for a single location company. It also will work for a multi-site organization for common documents that are used at all locations. For example, such processes as Management Review, NC-CAPA Procedure, Documentation Management Procedure, Audit Procedure, and others may be the same for all locations and therefore be referenced in the quality manual as shown above. However, what if our locations need to use different organizational charts, product realization procedures, and other site-specific documents? If we choose to maintain a common manual using reference method above, clauses of the manual should list corresponding documents for all locations which may not be practical. Below we will explore how a corporate manual can practically reference location-specific documents to support commitments of the company's common manual.

The same reference structure as for a single-location company can be used if the number of locations is small, let's say two or three. In this case, clause 5.5.1 of our corporate manual may state:

QW Enterprises, LLP's Management Team ensures that the responsibilities and authorities are defined and communicated within the organization per the [Resource Management Procedure](#), [Organizational Chart HO](#) and [Organizational Chart Ontario](#).

This example shows references to the common Resource Management Procedure and site-specific organizational charts for the Home Office (HO) and the Ontario locations. While this model works well for a limited number of facilities, it becomes impractical when the number of locations is significant.

### **Manual Reference Matrix**

For companies with large number of locations, where we need to reference in the manual numerous documents including those controlled by satellite locations, we have another option.

We can establish a document to connect corporate manual commitments with the site-specific supporting documents. Let's name this document a Manual Reference Matrix and consider the following document reference structure.

Manual's clause

Manual Reference Matrix Table of Contents (ToC)  
Site-specific Manual Reference Matrix  
Corresponding site-specific document

Our Manual Reference Matrix ToC is simply a list of all company's locations and their Manual Reference Matrixes. This list may look this:

Manual Reference Matrix Table of Contents

[Home Office \(Denver, Colorado, USA\)](#)

[Ontario \(Canada\)](#)

[St. Petersburg \(Russia\)](#)

[Guanajuato \(Mexico\)](#)

[Port Williams \(Chile\)](#)

[... etc,](#)

To illustrate this model, let's document the same clause 5.5.1 of our corporate manual with references to site-specific organizational charts:

QW Enterprises, LLP's Management Team ensures that the responsibilities and authorities are defined and communicated within the organization per the [Resource Management Procedure](#) and site-specific Organizational Charts per the [Manual Reference Matrix ToC](#).

This clause tells us that to support commitments above the company uses common Resource Management Procedure and site-specific organizational charts. To locate a site-specific organizational chart, we need to refer to the Manual Reference Matrix Table of Contents. Following the hyperlink "Ontario (Canada)" we will find the site-specific Manual Reference Matrix Ontario. Locating element 5.5.1 in the Ontario Manual Reference Matrix, we will find that Ontario location uses for

this clause of the manual a document titled [Organizational Chart Ontario](#).

A Manual Reference Matrix may be formatted as a three-column form as shown below:

### Quality Manual Reference Matrix

Corporate Quality Manual		Site: Ontario
Sec	Process / Clause	
	...	
5.5.1	Responsibility and authority <a href="#">Resource Management Procedure</a>  <a href="#">Organizational Chart HO</a>	<a href="#">Resource Management Procedure</a> <a href="#">Organizational Chart Ontario</a>
	...	

### Scopes and exclusions

Now, when we successfully resolved the issue with references to site-specific documents, let's see how we can address different scopes, exclusions and other similar elements. Let's say that our corporate office maintains an integrated quality and environmental management system compliant with ISO 9001:2008 and ISO 14001:2004 standards. The corporate office management system satisfies all requirements of ISO 9001 standard and therefore does not declare any exclusions.


At the same time, our Ontario facility is certified to ISO 9001:2008 only and does not perform design function, therefore excluding design from its scope of certification. These differences can be documented within the same Manual Reference Matrix. Section 1.1, Purpose and scope of the matrix references ISO 9001:2008 and ISO 14001:2004 standards for the corporate office, while Ontario facility references only ISO 9001:2008. Similarly, element 1.2 of the matrix, Application, states for the corporate office:

“Application, QW Enterprises LLP’s Management System satisfies the full range of requirements of ISO 9001:2008 Standard.”, while for the Ontario facility this element reads: “QW Enterprises LLP’s Ontario facility does not perform design function, therefore, design is excluded from the scope for this facility.” As shown in the illustration below:

**Quality Manual Reference Matrix**

<b>Corporate Quality Manual</b>		<b>Site: Ontario</b>
<b>Sec</b>	<b>Process / Clause</b>	
1	Table of contents	Title
1.1	Purpose and scope <a href="#">ISO 9001:2008</a> <a href="#">ISO 14001:2004</a>	<a href="#">ISO 9001:2008</a>
1.2	Application QW Enterprises LLP’s Management System satisfies the full range of requirements of ISO 9001:2008 Standard.	QW Enterprises LLP’s Ontario location does not perform design function, therefore, design is excluded for this facility
2	Company information	Corporate
	...	

After completion of the template matrix for a given location, this document, as any other, will be given a document title, a document number, if required, and be released through the local documentation change process. This approach will ensure consistency of the quality manual across all locations of the company.



**Quality Manual Reference Matrix**  
Revision D1  
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Corporate Quality Manual		QW Enterprises, LLC - Denver facility
Sec	Process	
<b>1</b>	<b>General</b>	
1.1	Purpose and scope	
	<a href="#">Applicable standards and regulations</a>	Same as corporate
1.2	Application	
	QW Enterprises LLP's QMS satisfies the full range of requirements of ISO 9001:2000 Standard.	Denver facility does not design product, therefore design and development requirement is excluded from its scope of activities
1.3	Applicable standards and regulations	
	<a href="#">ISO 9001:2008, Quality management systems - Requirements</a>	Same as corporate
2	Company information	
	123 Innovation Drive, Sun City, AS, 123456, USA. Phone: (123) 123-4567 Web site: <a href="http://www.qwmedical.com">www.qwmedical.com</a>	One QW Circle, Denver, CO 23457, CO, USA. Phone: (234) 777-9900 Web site: <a href="http://www.qwmedical.com/co">www.qwmedical.com/co</a>
3	Definitions and conventions	
	Per Quality Manual	Same as corporate

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## Controlling Manual Reference Matrix

It is a good idea to make your Manual Reference Matrix ToC a part of your Corporate Manual. It is also beneficial to control your Manual Reference Matrix Template through the corporate documentation management system to ensure consistency of the matrix format used by different locations. Each of your facilities will use this template matrix to document their site-specific references addressing requirements of the corporate manual.

After completion of the Manual Reference Matrix by a given location, this document, as any other, will be given a document title, a document number, if required, and be released through the local documentation change process. Any changes to the corporate manual should trigger review and, if necessary, changes to the Manual Reference Matrix Template and Manual Reference Matrixes of all locations.

# **6 Chapter 6 Documents**

## 6.1 Documents - Table of Contents

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The full version of this book includes an ISO 9001:2008 compliant Quality Manual and key procedures per the list below:

- Documentation Master List,
- Document Template Procedure,
- Form Template Portrait,
- Form Template Landscape,
- Documentation Management Procedure,
- Documentation Change Record,
- Documentation Change Record Log,
- Organization Chart,
- Records Procedure,
- Records Matrix,
- Quality Policy,
- ISO 9001 Quality Manual Review Checklist, and
- ISO 9001 Quality Manual.

# **7 Chapter 7 Afterword**

## 7.1 Afterward

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If you followed advices of this book and, using the referenced documents, created and released your first DCR, you have definitely saved yourself a lot of time and money, as I promised in the beginning. However, just having manual and key procedures will not bring a company an effective quality management system. An effective management system is one that practically represents your organization's processes and is understood and used by the organization. Make sure that everyone knows and understands your quality manual and policy. Make sure that procedures and instructions are used by the functions for which they were written.

So what's the next step? Continue developing, validating and implementing other procedures and instructions to cover all elements of the standard as well as your specific processes. Encourage everyone to provide input to relative documents. While developing second-level procedures, do not forget that their intent is not only to define your processes, but also to support particular elements of your quality manual. Before release, make sure that your second-level procedures address all elements of the manual where they are referenced. To locate all occurrences of a title of a procedure in the manual, you may use the Find function in your word processor or the Procedure index in our Quality Manual.

I hope this book helped you to get started. Good luck with your efforts in creating a quality management system that meets the requirements of all applicable standards and regulations. I wrote this book for you, gentle reader, and

would like to continue to improve upon it. Any feedback on this publication that you may provide will help me to enhance future editions. Please drop me a line and let me know what you think. If you are still reading a preview version and need to get your quality manual released, get the full version of the book. Visit our site at [www.quality-works.com](http://www.quality-works.com) and order your copy today!

## 7.2 License Agreement

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## 7.3 References

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- [1] ISO 9001:2008 – Quality management systems – Requirements
- [2] Encyclopedia Britannica, The Eleventh Edition, 1910.
- [3] ISO 9000:2005 – Quality management systems – Fundamentals and vocabulary
- [4] ISO 9004:2000 – Quality management systems – Guidelines for performance improvement
- [5] “Big Three Are Serious About QS-9000 Certification”, Amy Zuckerman, Quality Progress, January 1998.
- [6] ISO 10013:2001 “Guidelines for developing quality manuals.”
- [7] <http://www.salaryexpert.com>