CHAPTER

4

Contents

Recommended QMS Documentation

4.1 Overview of Documentation Requirements

4.1.1 Introduction

In Part 1, our goal was to create an organizationwide, business-oriented QMS, in which the financial and quality objectives were transparent. The QMS was to be based on the canonical set of ISO 9000 texts (i.e., ISO 9000:2000, ISO 9001:2000 (the Standard), and ISO 9004:2000).

It is now necessary to establish the key components of an effective QMS in terms of the Standard's documentation requirements, both from a mandatory basis and an implied overall effective hierarchy of documentation. In this regard, all documentation requirements (SHALLS) are to be addressed. Of prime importance are the mandatory documentation requirements, summarized in Section 4.1. These requirements are explicitly required by the Standard and form the umbrella under which all the other documents are contained.

To accomplish this, it is necessary first to categorize the several sets of documentation needed to produce a fully compliant and effective QMS. The four key sets are as follows:

- The Standard's mandatory documentation;
- The Standard's implied documentation;
- The registrar's required documentation;
- Required regulatory (compliance) documentation.

Whereas the Standard's mandatory documentation is defined by the Standard's SHALLS, there is considerable disagreement over what constitutes the various other required documents.

4.1.2 Recommended Documentation Taxonomy

The so-called ISO 9000 tiers (hierarchal levels of information) originated out of industrial-military requirements and have become a de facto standard because of their usefulness. The most common set of tier documents observed consists of the quality manual as tier I, SOPs as tier II, work instructions as tier III, and records as tier IV.

This set of tiers used by many writers in ISO 9001:1994 documentation systems has caused some confusion because forms were normally either missed or mixed in with records, even though form is a valid taxonomy term. By contrast, records are filled-in forms and can exist at any level of the documentation system. In fact forms, as structure, represent the lowest level of information flow and should be placed at the lowest level in the hierarchy. In addition, SOPs and work instructions are classified as different levels of documentation even though they are both procedures.

To complicate the matter further, SOPs are actually written in the form of both policy and process rather than procedure, as a procedure tells an individual how to do a specific task and is not meant to define a complex flow of information between functions. Unfortunately, the term *procedure* is still used in the Standard to include the description of a process, and so the confusion continues. A dictionary on this subject will not help because terms such as process and procedure are thrown together in a hodge-podge of equivalency. Something much more useful must be done to define an effective documentation taxonomy.

For the sake of clarity—which may be ephemeral—a process, as defined by the Standard's vocabulary, is meant to describe how a set of inputs is transformed into a set of outputs. The process moves through various phases until the activity results in a specified output.

On the other hand, to clearly differentiate between the defined process terminology, it is necessary to place a more constrictive use on the term *procedure*. For our purposes, a procedure describes the manner in which specific input activity, transformation activity, or output activity is accomplished. It is a subset of the process and is taken in steps that result in the completion of a specific activity (e.g., the Internal Audit Procedure describes the steps taken to carry out an internal audit, the In-House Calibration Work Instruction describes the steps needed to calibrate micrometers using a secondary Standard such as a gage block set, and a Power Supply Test Plan describes the steps needed to test out a power supply unit under robust conditions).

By contrast, for example, the Audit Process includes the previously described Audit Procedure plus all of the supplemental audit activities. Such activities include audit responsibility and authority, audit plans, audit training, audit corrective action protocols, audits of suppliers, audits by the registrar or regulatory agencies (e.g., FDA, notified bodies), and audit reviews by top management.

4.2 The Four-Tier Pyramid Concept

Our first task, then, is to remove the previously stated ambiguities and describe clearly what constitutes the general set of QMS documents so that our model is directly applicable to an effective documentation structure. As a memory aid, we will use the tier concept (i.e., tiers I–IV), but with a more specific set of definitions.

A useful icon in this regard is to place the four tiers in the form of a documentation pyramid (see Figure 4.1) [1].

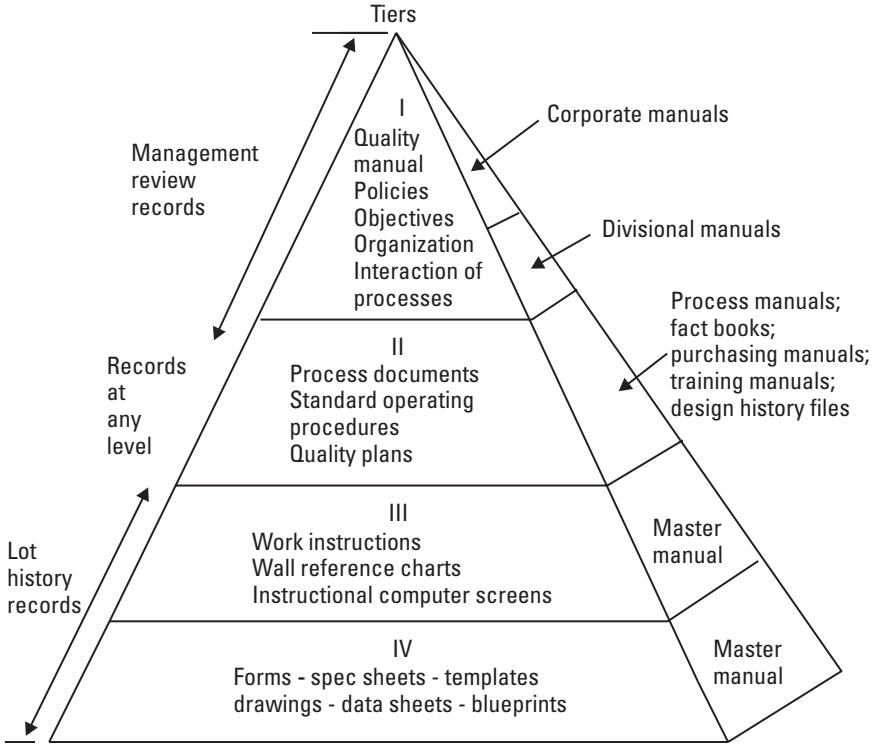


Figure 4.1 The four-tier operational pyramid concept—ISO 9001:2000 guidelines.

4.2.1 Matrix Format

The four tiers can also be described in the form of a table (e.g., see Table 4.1). The matrix form provides another class of information related to the specific content of a given tier [2].

4.2.2 Operational Tiers

We have specified in Table 4.1 that the documentation pyramid represents the operational flow of information (i.e., day-to-day processes carried out by use of dynamic and current documentation). That is why records are not included in tier IV. This is contrary to common usage, which we believe is incorrect from a taxonomy standpoint. We realize that this is a fine point, yet it causes considerable confusion among QMS designers.

Records should be listed as a distinct category of documentation within the QMS documentation umbrella. Although it is unnecessary to consider records in the form of a taxonomy, it is sometimes quite useful for organizational purposes. For example, the following records could be filed according to tiers:

- Management review minutes are records at the tier I level because they are part of the policy-making top-management control system.
- Corrective action reports are tier II records because they are directly associated with a SOP.
- A completed/filled-in tier III work instruction (e.g., verification test instruction), becomes a tier III record.

4.2.3 Guidelines

The proposed documentation taxonomy—policy, process, procedure, form—fits readily into this documentation pyramid. However, the tiers and various examples of documents are merely guidelines. It is the quality manual, quality objectives, identified processes and their controls, control plans where applicable, six specific procedures, supplemental documents if applicable, work instructions if applicable, and records that are clearly mandatory hierarchal documents in the Standard.

4.2.4 Four Tiers

The four-tier operational pyramid does emphasize the impact of the quality manual (manual) on the entire documentation structure, although—as noted—the pyramid is only meant to be a guideline because it does not

Table 4.1
The Four Suggested Operational Tiers of ISO 9001:2000 Documentation (Records Can Be Maintained at Any Tier)

Tier	ISO 9000 Category	Content Description	Deals with...
I	Quality manual Corporate Divisional Departmental	A time-independent document describing the organization's policies written in conformance with the Standard. Scope of QMS Details of exclusions Documentation of quality policy Documentation of quality objectives Description of organization Identification of processes Description of processes interactions Inclusion or reference of procedures	The organization's response to each SHALL The "rules of the house"—the methods used to ensure compliance Definition of responsibility
II	Process documents and high-level procedures SOPs Departmental operating procedures Business plans Quality plans	Time-dependent documents that describe either the overall processes of the organization or a combination of process and high-level procedures Enterprise processes Six mandatory procedures Documents needed to ensure the effective planning, operation, and control of the processes Employee handbook	Purpose—what, when, where, who, and why at a high level Flow of information from area to area, department to department, building to building
III	Lower-level procedural documents Wall reference charts Instructional computer screens Work instructions Directions	Time-dependent, detailed step-by-step work instructions on how to complete a task (e.g., at the operator or bench level)—sometimes integrated into tier II documents Purchasing work instructions Manufacturing work instructions Training syllabus	How one does the job—tells the reader in a step-by-step fashion Provision of the necessary data to perform the tasks
IV	Unfilled-in forms, graphics, or spec sheets Templates Blueprints Schematics Specifications Drawings	Generally time-independent documents that specify the data requirements called out in the various documents and/or specific data sources, or graphically indicate requirements or state specifications Many of the forms are used as records once they are filled in and filed, although specific records are required at all levels Complementary documents to support work instructions	The forms used to demonstrate that a procedure requiring either data taking or data input was done Drawings and/or specifications used in manufacturing or troubleshooting The templates required to measure and fabricate

replace the actual linkage that must be present from document to supplemental document.

4.2.5 Navigation Is Key

The four-tier structure readily provides levels for the type of documents that are usually encountered. However, some companies have as few as two defined levels and some as high as six defined levels. The number of levels is irrelevant. What is relevant is that they are presented in a way that aids the reader to easily navigate throughout the system.

4.2.6 Clearly Link Lower Tiers from the Manual

What is usually found is that the ISO management representative is cognizant of the total documentation structure but everyone else has great difficulty locating specific documents within the overall taxonomy. As a result, during an interview, when the auditee becomes confused over where to locate a document, I always suggest that they start with the manual and work down through the documented system. This usually helps, but only when the manual is clearly linked to the lower tier documents.

For online systems, this is readily accomplished with hyperlinks. However, it must be made relatively simple for the reader to quickly find the manual icon on the network, and with it the links.

4.2.7 Waterfall Effect

The use of a four-tier pyramidal structure for the QMS documentation is recommended to maximize communication to users. Once the four-tier hierarchy has been established, the total documentation system tends to behave with a waterfall effect (i.e., the number of process documents are less than the number of procedural documents, which in turn are less than the number of forms). We have illustrated this effect graphically in Figure 4.2.

In this figure, we have made the assumption that the quality manual is a stand-alone document (i.e., only contains quality policy statements and refers to lower tier documents). As demonstrated later, this is not the only possible configuration for the system, but it greatly helps to describe our concept.

The tendency for documentation growth must always be challenged. However, the use of the described techniques will tend to minimize this growth.

4.2.8 ISO 9000 Hierarchal Drivers

In Figure 4.3, we see that the four-tier concept is universal (i.e., the Standard defines the quality manual responses, the quality manual responses confine

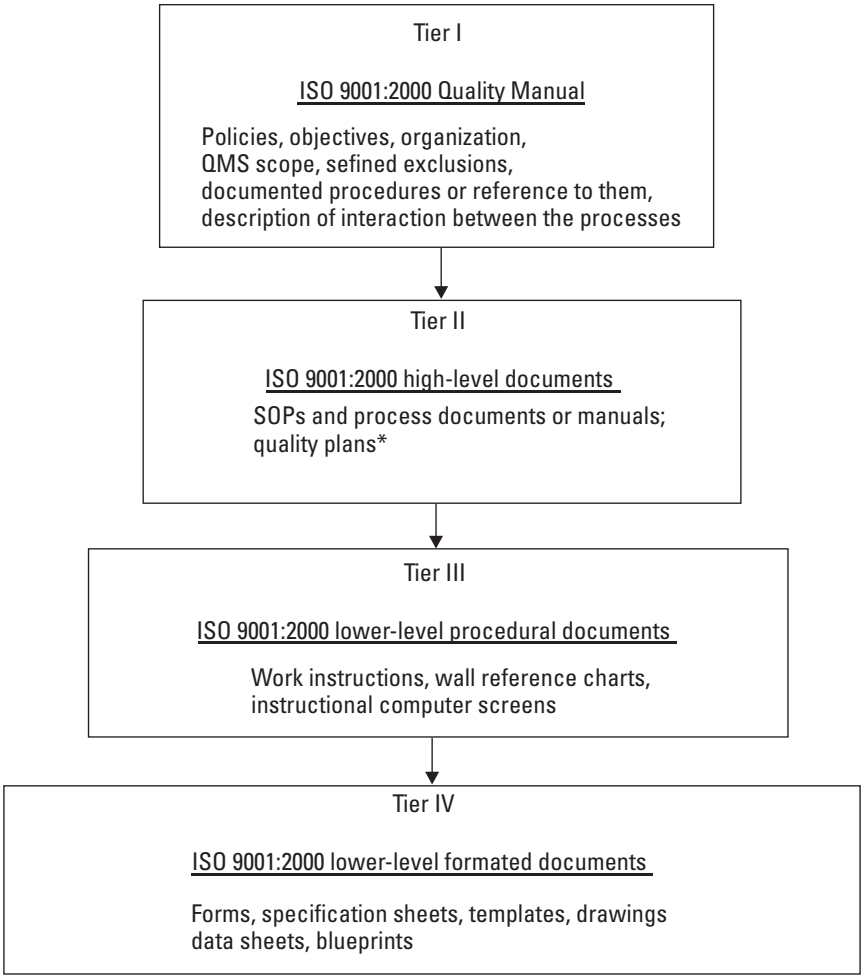


Figure 4.2
ISO 9001:2000 documentation waterfall effect [3].

*The terminology for tier II documents varies widely over different industries. We have found that SOPs, quality plans, process documents, and even low-level procedures fulfill the role of tier II documentation (i.e., that to which the tier I document sends the reader is intrinsically a tier II document).

the content of the second-tier documents, and the tier II documents drive the content of the procedures/work instructions). In this manner, the executive rules are transformed into management controls that are then transformed into operational directives.

Thus, the design of an effective QMS is holistic in that it is more than the sum of its parts. Unlike the engineering design of a personal computer's printed wiring assembly, there must be a powerful motivational element present within the QMS environment. For example, there is no need to motivate the electrons to flow efficiently within the printed circuit board's copper tracks, but there is an extremely important requirement to create a symbiotic

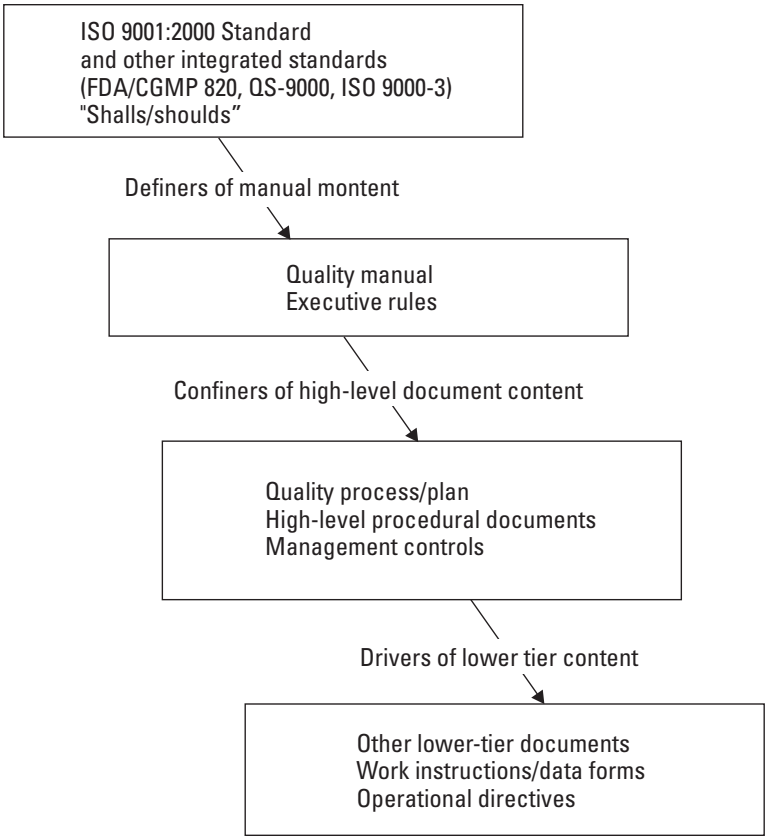


Figure 4.3
ISO 9001:2000 hierarchal drivers.

relationship between the inert document's pages and the dynamic application of those documents by human beings. Thus, there is always an affective requirement as well as an effective requirement in the design of the QMS.

The QMS acts as a living organism, and this is why it is so difficult to create the QMS in the first place and then to effectively maintain the system. However, it is the inherent ability of the four-tier structure to enhance informational flow that increases the probability of a successful QMS [4].

4.3 The ISO 9001:2000 QMS Is To Be Documented

The Standard demands a documented QMS. Within this mandated documentation are to be found the means to do the following [5]:

1. Identify QMS processes;
2. Determine process sequence and interaction;

3. Determine operational and monitoring criteria;
4. Determine operational and monitoring methods;
5. Monitor processes;
6. Measure processes;
7. Analyze processes;
8. Achieve planned results;
9. Achieve continual improvement of such processes.

So the key question here is how do you document these nine mandatory requirements? In other words, how do I document identified processes? How do I document the sequence and interaction of these processes? Our answer is to use a tier II document that can be either contained within the quality manual or referenced to another text from the quality manual. An agreement that this process document is a viable response to these nine requirements will validate the use of the proposed four-tier documentation structure.

With this assumption in mind, it is now necessary to establish that the following documents are the desired complete hierarchal set of documents, either defined or implied, in the Standard:

1. A documented quality policy (tier I);
2. Documented quality objectives (tier I);
3. A documented quality manual (tier I);
4. Six specifically defined documented procedures (tier III);
5. Documents that ensure the effective planning, operation, and control of processes (we logically conclude that this implies):
   - Process documents/SOPs/quality plans (tier II);
   - Procedures/work instructions (tier III);
   - Forms (tier IV);
6. Records (filled and filed forms that can occur at any tier level).

Of the six types of recommended global documents categorized here, records are the least understood with regard to their position in the documentation hierarchy. In fact, records (i.e., historical documents or documents used as objective evidence of activity) are distributed across the elements and can

occur at any level of the hierarchy. For example, management review minutes are generated at the tier I level, quality plans and routers/travelers in the form of medical device history formats are required at the tier II level, and inspection and test reports are introduced at the tier III level.

To term records as being a specific tier is inappropriate. Records are a separate category and, in this regard, the Standard recognizes that that they are a special type of document and require document control [6].

4.3.1 Information Channel Management

In a more graphical sense, Figure 4.4 indicates the several possible channels of information that are covered under the suggested QMS four-tier concept [7]. Documents add up very quickly—a small company will reach hundreds of documents and a larger company will reach thousands of documents by the time they apply for certification. The number of documents will be proportional to the number of organizational functions and operating divisions. In addition, it is important to include controlled documents for field sales and field service personnel who are in residence outside of the main site's location but who must be kept up to date on revisions to the controlled documentation. Many companies now use online systems for this purpose.

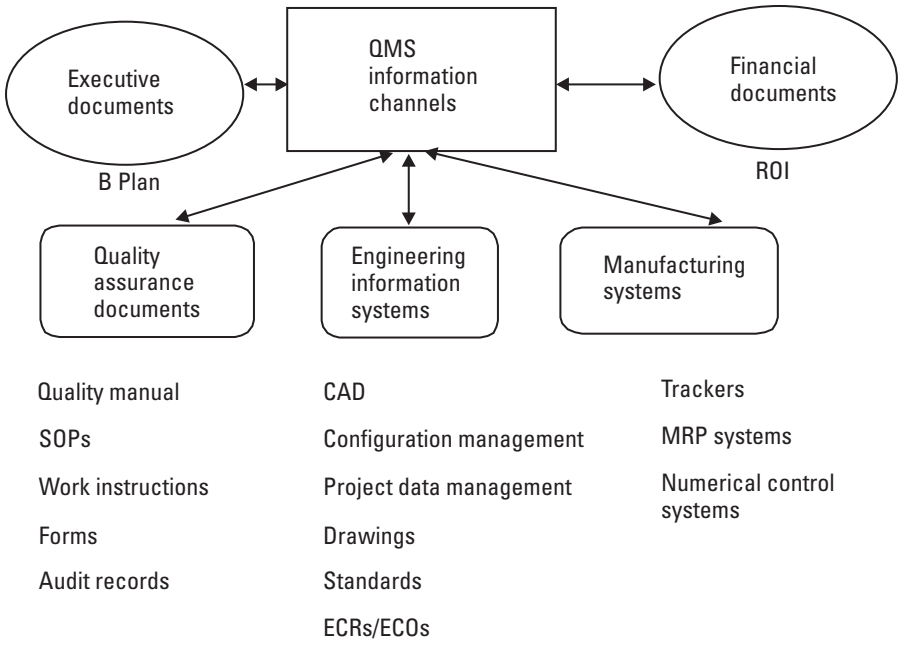
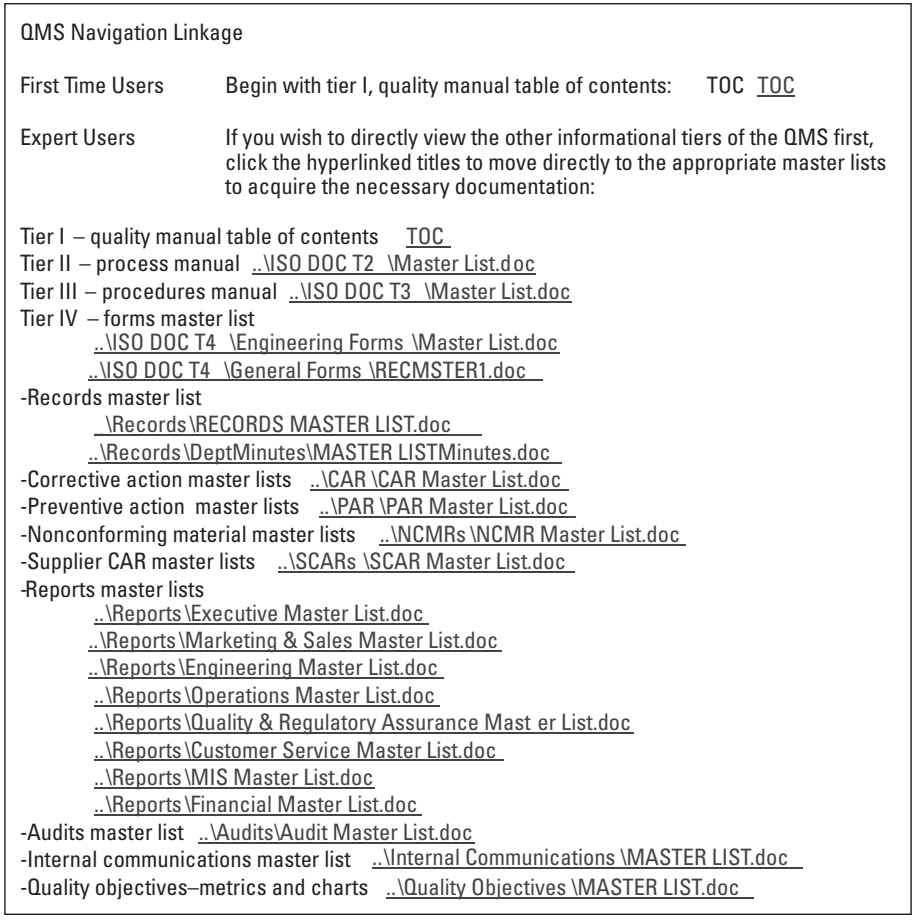


Figure 4.4 Potential QMS information channels.

4.3.2 Mandatory Tier II Linkage Requirements

Linkage is also defined in the Standard in that the quality manual is to either include the required procedures or reference them [8]. As a result, the tiers should be clearly linked so that it is possible to readily navigate throughout the documentation. One of the more effective ways to link documents is illustrated in Figures 4.5 and 4.6. In this case, the organization has used electronic media to control the quality manual. This online document exemplifies the nature in which the lower tier documents can be linked via hyperlinks and the various sections within the quality manual itself can be linked via bookmarks.

In practice, it is common to find the QMS defined primarily by the Quality Management Documents channel, with the Engineering Information Systems and Manufacturing Systems channels weakly described. The day-to-day



QMS Navigation Linkage

First Time Users — Begin with tier I, quality manual table of contents: TOC TOC

Expert Users — If you wish to directly view the other informational tiers of the QMS first, click the hyperlinked titles to move directly to the appropriate master lists to acquire the necessary documentation:

Tier I – quality manual table of contents TOC
Tier II – process manual ..\ISO DOC T2 \Master List.doc
Tier III – procedures manual ..\ISO DOC T3 \Master List.doc
Tier IV – forms master list
..\ISO DOC T4 \Engineering Forms \Master List.doc
..\ISO DOC T4 \General Forms \RECMSTER1.doc
-Records master list
\Records\RECORDS MASTER LIST.doc
..\Records\DeptMinutes\MASTER LISTMinutes.doc
-Corrective action master lists ..\CAR \CAR Master List.doc
-Preventive action master lists ..\PAR \PAR Master List.doc
-Nonconforming material master lists ..\NCMRs \NCMR Master List.doc
-Supplier CAR master lists ..\SCARs \SCAR Master List.doc
-Reports master lists
..\Reports \Executive Master List.doc
..\Reports \Marketing & Sales Master List.doc
..\Reports \Engineering Master List.doc
..\Reports \Operations Master List.doc
..\Reports \Quality & Regulatory Assurance Mast er List.doc
..\Reports \Customer Service Master List.doc
..\Reports \MIS Master List.doc
..\Reports \Financial Master List.doc
-Audits master list ..\Audits\Audit Master List.doc
-Internal communications master list ..\Internal Communications \MASTER LIST.doc
-Quality objectives–metrics and charts ..\Quality Objectives \MASTER LIST.doc

Figure 4.5 David Wayne Industries online quality manual cover page.

Figure 4.6 David Wayne Industries online quality manual partial table of contents (TOC).

ISO 9001:2000 Quality management systems
Table of Contents

interplay between engineering, operations, and quality assurance requires that all channels be equally efficient.

This was the reason, in the past editions of the Standard, that it was inefficient to certify a design and manufacturing facility to ISO 9002 and then seek a future audit to complete the certification to ISO 9001. The number of daily interfaces with engineering requires interface procedures. It is essentially the same effort to simply do the entire facility to ISO 9001 than to create all of those interface documents. The 2000 release resolves this issue because all certificates are to ISO 9001, and you are required to clearly justify why you have not complied with a specific clause required in Section 7, Product Realization.

The next step requires a careful examination of the Standard's mandatory QMS documentation requirements taken stepwise through the four tiers.

Endnotes

[1] We have just seen the hierarchy of policy, process, procedure, form used in the open literature: Bradel, Teri, "Quality Makes the Grade," *Quality Progress,* March 2002, p. 86.

[2] Although the terms *quality policy, process,* and *procedure* are defined in ISO 9000:2000, a pathological logic exists in the application of these concepts because a procedure is defined as a "specified way to carry out an activity or a process." It is a Catch 22 situation. Only six procedures are called for but we are to identify our processes, and it takes a procedure to document the process. As a result, our definitions are based on the work of Horn, Robert E., *Demystifying ISO 9000, Second Edition*, Information Mapping, Inc., Waltham, MA, 1994, pp. 5–6. In Mr. Horn's work, policy, process, procedure, and form are clearly defined.

[3] The terminology for tier II documents varies widely over different industries. We have found that SOPs, quality plans, process documents, and even low-level procedures fulfill the role of tier II documentation (i.e., that to which the tier I document sends the reader is intrinsically a tier II document).

[4] The importance of human interfacing with the QMS is extremely well documented. A source of original and lucid studies in this matter is available in the *Quality Management Journal,* a publication of the ASQ (e.g., Vol. 4, No. 2, 1997).

[5] ISO 9001:2000, Clause 4.1.

[6] ISO 9001:2000, Clause 4.2.3.

[7] The exponential increase of electronic media-based systems is concurrent with the explosion in information technology. It is now common to see electronic documentation control systems in use in parallel with MRP/ERP manufacturing control systems. Electronic calibration control systems are commonplace.

[8] ISO 9001:2000, Clause 4.2.2.