ISO 9001: Mandatory Documentation Required by ISO 9001:2008

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WHITE PAPER

June 11, 2014

BASIC OVERVIEW

Many companies go overboard with documentation in the belief that they need to document every single process that is in place in their organization, without realizing that this is not necessary to meet the requirements of the ISO 9001 standard. In the standard, only a Quality Manual, Quality Policy, Quality Objectives and six documented procedures are needed, with any remaining procedure documentation being at the discretion of the company (under certain guidelines). What is really important is that the documentation works for the company, not just to satisfy what someone thinks the standard needs. So, you may ask, "What should I document?"

1) What documentation does the ISO 9001 Standard Require?

Mandatory Documents	ISO 9001 Clause
Quality Manual	4.2.2
Quality Policy Statement	5.3
Quality Objectives Statements	5.4.1
Control of Documents	4.2.3
Control of Records	4.2.4
Internal Audit	8.2.2
Control of Non-Conforming Product	8.3
Corrective Action	8.5.2
Preventive Action	8.5.3

Quality Manual: The ISO 9001 Quality Management System first requires a Quality Manual be written. This document is the backbone of the Management System, and is where you announce your intentions. What does your company do, and are there any parts of the ISO 9001 standard that you are not doing (such as Design)? What documented procedures have you created to govern the Quality Management System? How do your company processes, both documented and undocumented, interact to form your Quality system? This is often the document where the company records the Quality Policy and Objectives, and sometimes adds the company's Mission and/or Vision Statement. Learn more about a Quality Manual in this article about Writing a short Quality Manual.

Quality Policy: The Quality Policy is intended to be a company's documented intention to meet requirements placed on the company and to continually improve. The policy is a focus for the company to work toward meeting the customer requirements and should readily convey the goal of the organization. It is often documented in the Quality Manual and sometimes posted throughout the organization as a way of communicating to all employees, since it is important that every employee understand how the Quality Policy relates to his or her job. For more information, see How to Write a good Quality Policy.

Quality Objectives are derived from the goal stated in the Quality Policy, and are the main method used by companies to focus this goal into plans for improvement. The objectives are intended to be S.M.A.R.T. (specific, measurable, achievable, realistic and time-based) and should have relevance at all levels of the company, meaning that all employees should understand how their jobs support meeting the Quality Objectives. The article How to Write good Quality Objectives gives more information on this process.

Along with the Quality Manual, Quality Policy and Quality Objectives there are requirements for documented procedures. As stated above, there are only six required documented procedures in the ISO 9001 standard. These are:

Control of Documents: How do you approve, update and re-approve your documents? When a document is changed, how do you identify changes, and make sure that people who need the current document have it and stop using older documents? How do you make sure the documents can be read and how do you control documents that come from outside of your organization for use? Find out more about documentation with Some Tips to make Document Control more useful for your QMS.

Control of Records: How do you maintain your records that show your product is acceptable to use, including how you identify, store and protect the records so that they can be retrieved as necessary, for the correct amount of time, and destroyed when no longer needed but not before? Follow this link to discover Some Tips to make Control of Records more useful for your QMS.

Internal Audit: How do you audit your Quality Management System to make sure that it is performing as planned and is effective? Who is responsible for planning and carrying out the audits? How do you report results and what records are kept? How do you follow up Corrective Actions noted in Audits? Learn more in this article about the Five main steps in ISO 9001 Internal Audit.

Control of Non-Conforming Products: What controls are in place, and who is responsible, to make sure that non-conforming product is not used? Are there terms that can be put in place to allow the use of non-conforming product such as Rework, Repair or Acceptance by Customer? How do you ensure that corrected product is re-verified, and what records are kept of the process? Find out about Five Steps for ISO 9001 Non-conforming Products here.

Corrective Actions: How do you review non-conformities, determine causes, and evaluate the need for actions to correct them? How do you implement the necessary actions, review that the actions were effective, and keep records of the actions taken?

Preventive Actions: How do you apply the same process used for Corrective Actions to non-conformities that are identified before they occur? Learn how to do this with Seven Steps for Corrective and Preventive Actions to support Continual Improvement.

As a minimum, these are the documented procedures that are necessary to meet the requirements and are all that is needed to document a simple Quality Management System. However, there is often a need to provide written documents for more, and the trick is in knowing what else your company needs to document. If you are implementing a Quality Management System you may struggle with the decision of what needs to be written down. This is common, but wisely answering the question "What should I document?" can avoid complexity in your Quality Management System, saving time and money.

2) Required Records

Mandatory Records	ISO 9001 Clause
Management Review	5.6
Education, Training Skills & Experience	6.2.2
Evidence that Processes and Product Meet Requirements	7.1
Review of Requirements Related to the Product	7.2.2
Inputs Related to Product Requirements	7.3.2
Design and Development Reviews	7.3.4
Design and Development Verification and Action	7.3.5
Design and Development Validation and Actions	7.3.6
Review of Design and Development Changes	7.3.7
Evaluation of Supplier Selection	7.4.1
Identification and Traceability (when required)	7.5.3
Damage to Customer Product (where applicable)	7.5.4
Results and Standards for Equipment Calibration and Verification	7.6
Internal Audit Records and Results	8.2.2
Release of Product to Customer (including person)	8.2.4
Nonconformities and Actions Taken	8.3

Results of Corrective Actions	8.5.2
Results of Preventive Actions	8.5.3

The purpose of records, apart from being proof that the process creating the record worked as planned and answering questions arising from faulty products or services, is to provide data for your company to use toward improvement of the processes. By ensuring that you have records that include relevant data of the process, you can return to analyze that data to help you improve the processes your company uses. The above listing of records includes those required by the ISO 9001 standard as the minimum necessary to demonstrate compliance to customer requirements and to provide data for working on and demonstrating improvement of the Quality Management System. These records are to be maintained in accordance with the documented procedure identified in section 4.2.4 of the standard.

3) Criteria for deciding which other documents are to be written

In addition to the six required procedures, there is a requirement to create documented procedures when non-conformances would occur if the procedure was not written down. Simply put, if you need to have a written procedure to make sure that mistakes are not made, you need to have a written procedure. There are a few simple things to think about when deciding if a documented procedure is needed, and those below are a good start.

Does the order of operations matter? If there are several ways to get the same outcome, and the important thing is the outcome, then there is no need to write down what process to use. An example would be certain design analyses. There are several ways to analyze the mechanical design of a product, and many different computer design tools to use, but all give very similar results. If the result of any of the available processes is acceptable, then why prescript which to use?

Can any simple requirements be covered by training or forms? As a corollary to the first question, there are other ways to ensure things are done properly. If you have a standard form (paper or electronic) for purchasing that highlights all the required information to be sent to a supplier for the purchase of product, do you really need a written procedure to tell someone how to fill out the form to place the order? If the important thing is for the required information to be there, the form can stand for itself. Any additional information such as how to find a part number in your system to fill in the form may be able to be acquired through training without needing to write a document.

Does the process need the same level of change control that is afforded Quality Management System documents? Some companies like to document all of their Human Resource Policies as part of the Quality Management System, but you need to think that there are costs to having a procedure as part of that system. Does the procedure need to have change control that is as strict as other documents, or could having controlled change access on a computer drive be just as effective? Does every detail of the procedure need to be audited, or is it there mostly for the information of employees when they need it (such as a travel policy)? Remember that just because some information is important doesn't mean that it needs to be controlled in the Quality Management System documentation; other avenues are also available.

This is also a good question to ask when deciding if something needs to be a controlled form or not. Often, a company's Documentation Procedure will specify the change control on forms, whereas some checklists can be more effective if their content is controlled more easily by the few people who use it rather than through a more complicated change control system. For example the shipping department may have a checklist for

what they need to do to ship product. If a problem occurs and they all agree to add an additional check to make sure the problem doesn't happen again this change can happen more quickly and can help prevent the same problem from recurring in the meantime.

How many people are doing the job? Using purchasing as an example again, if you only have a few people doing the job, then they can very likely ensure that between them the process outputs are consistent, meaning that the information going to the suppliers is always similar enough to make sure that good product is received. This also allows those few people to share process improvements to help the process flow better.

Does competence of the workers make a written procedure unnecessary? One beneficial addition to the ISO 9001 standard separates Competence from Training. If your hiring practices for a machine shop comprise only hiring licensed machinists or their apprentices, then you don't really need written instructions on how to use a lathe. This is part of the competence of a machinist. The old ISO 9001 adage of "write what you do, do what you write" need not apply. Discover more about Using Competence, Training and Awareness to replace documentation in your QMS.

Why written documentation for every process may be bad

When you document a specific order of operations for a process you can limit the participants in the process from using any flexibility in how they do their job. This can potentially lower job satisfaction, employee engagement and indeed can hinder any efforts to find process improvements. In the worst case, the effort to try to change the process for the better can be seen as greater than just continuing to use the flawed or imperfect process. Sharing of best practices should be encouraged, and by writing a prescriptive process, you may hinder employees' desire to improve what they do.

4) What are other common Documented Procedures?

Documented Procedure	ISO 9001 Clause
Purchasing	7.4
Design	7.3
Production/Service Operations	7.5
Monitoring & Measurement	8.2
Sales (Customer-Related Processes)	7.2
Customer Satisfaction	8.2.1
Management Review	5.6

As stated, you do not need to capture any other processes in documented procedures if you can prove that no mistakes will be made by not doing so. There are several procedures that are often documented in order to ensure that there is easy access to some important information to govern that process. Some examples are:

Purchasing: What information is needed for a supplier, and who is responsible for generating it? Who needs to approve various levels of expense? (You may not want a buyer to be responsible for committing the company to pay for large purchases without other approvals.) How do you decide on what standard requirements to place on your suppliers, and how do you approve and control these suppliers? For some more information, read Purchasing in QMS – The Process & the Information Needed to Make it Work.

Design: This is often turned into a documented procedure in order to capture what reviews and approvals are required to ensure a good design every time. Where do all of your requirements come from? Who can approve a design to proceed? How do you control your design changes, and who can approve a change to the design? To find out more, see The ISO 9001 Design Process Explained.

Production/Service Operations: For complicated products or services it is easy to see why the process would be documented. How do you control the flow of parts and documentation to your production area for use? How do you track your service from customer order to completion to ensure customer requirements are met? How do you ensure that product status can be identified, such as what has or has not been tested? How do you track customer acceptance of your service?

Monitoring and Measurement: How do you control the equipment you use to test that your product meets the requirements and is fit for use? How do you manage measurement equipment brought in by employees (such as machinist's tools that are owned by the machinist)?

Sales (Customer-Related Processes): The ISO 9001 standard does not include a section on sales, but the requirements on Customer-Related Processes are the main element in a documented sales process. How do you determine requirements related to the product by considering: what the customer specifies (including delivery & post-delivery activities); what the customer does not specify, but is necessary (such as the requirement for a lifejacket to float, even if this is not in the customer requirements); what the legal requirements are for the product (such as legally allowed colors for a lifejacket); and any additional requirements the company knows are needed? How do you review these requirements to make sure the product requirements are all known, any contract questions are resolved, and the company can meet all requirements? Finally, how do you control communication with your customer?

Customer Satisfaction: This clause talks about measuring an important, but often overlooked aspect of the business, and that is customer perception. How do you measure how well your customers think you met the requirements? This is not just about measuring how you think you did in meeting the needs of your customer, but knowing how well *they* think you did. What methods are you going to use to obtain this information?

Management Review: How do you conduct your review of the system to ensure that all areas of the system are functioning and improvements are happening where planned and expected? How do you control the flow of information on Management Decisions out to the company? Learn more in this article about How to make Management Review more practical.

5) Documentation is important, but make it uncomplicated

Documentation in the Quality Management System is important to ensure that critical processes, where you need to make sure that all employees consistently do the same thing, are understood and repeatable. In order to make this work, it is wise to have these processes as uncomplicated as possible and presented in the simplest manner to make them easy to understand; often, using a graphical flow chart can suffice to relay all the relevant information quickly and easily. The less complicated the process documentation, the easier it

will be to ensure that all employees can deliver repeatable, quality outcomes for the processes. In the long run, the old adage is often right: "The simpler the better."

It is important to note that even if you have chosen to document a procedure, this does not mean that the details of the procedure need to absolutely define everything. One example of this is found in a process for software design. In this process it would be important to define the steps that a piece of software code need to follow, especially including where reviews by peers need to take place; however, it would be wise to realize that different programmers may structure their code differently and it will likely not be important to have the procedure tell the programmers how to code. Guidance on making the code reviewable by peers should be all that is needed.

Sample Documentation Templates

Here you can download a free preview of the ISO 9001 Documentation Toolkit – in this free preview you will be able to see the Table of Contents of each of the mentioned documented procedures, as well as a few sections from each document

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