

[WCH Professional Services, LLC](http://www.wchservices.com)

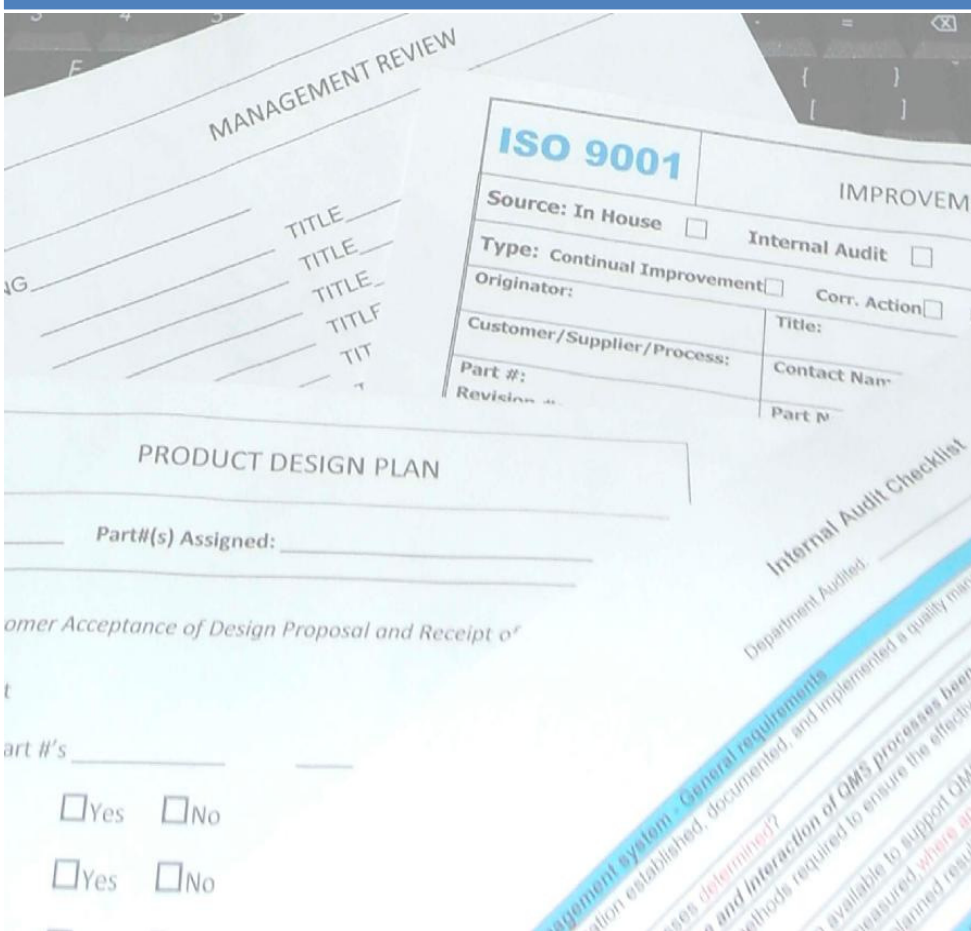
Phone: 570-30-9256

Email: support@wchservices.com

ISO 9001:2008



DOCUMENTATION INSTRUCTIONS



INTRODUCTION

ISO 9001 can be applied to any organization, including manufacturers, hospitals, schools, temporary employment agencies, etc. Your organization can become certified to ISO 9001:2008. This guide and the accompanying documents will help you to achieve your goal.

Before continuing, you will need to purchase a copy of the standard. Electronic versions may be purchased and downloaded from www.techstreet.com and www.ansi.com as well as other similar websites. WCH recommends that you purchase an electronic version, rather than a hard copy.

ISO 9001 is a Quality Management System standard. Companies often “lock in” on the word “Quality.” The most appropriate way in which to interpret the word “Quality” is to substitute it with the word “Business.” ISO 9001 is about Business Management Systems.

Why are you in business? What are your business goals? How is your business run?

WCH Professional Services, LLC has created the **ISO 9001:2008 Implementation Set** to help companies implement a Quality Management System that is based on the ISO 9001:2008 standard. This set includes the all of the mandatory documents that are required by the standard and additional supporting forms and spreadsheets that will help your company to achieve ISO 9001:2008 certification.

OVERVIEW

The documents and worksheets supplied by WCH Professional Services, LLC are in Word and Excel (97-2003) format. There is no need to create an overly complicated system in order to comply with the standard. That is why we have chosen to use popular software platforms and simple documents.

Per ISO 9001:2008, “the extent of quality management system documentation can differ from one organization to another due to the size of the organization . . . the type of activities, the complexity of processes and their interactions and the competence of personnel.” ISO 9001:2008 requires a minimum set of documents that includes the following:

Quality Manual ^{Section 4.2.2}, Quality Policy ^{Section 5.3}, Quality Objectives ^{Section 5.4.1}

The following documented procedures can be referenced or contained within the Quality Manual. We have chosen to separate them from the manual and provide a reference to them within the manual.

1. Document Control ^{Section 4.2.2}
2. Records Control ^{Section 4.2.4}
3. Internal Audits ^{Section 8.2.2}
4. Nonconforming Material ^{Section 8.3}
5. Corrective Action ^{Section 8.5.2}
6. Preventive Action ^{Section 8.5.3}

Note that Items 5 and 6 may be combined.

So, in total, a company can be certified with only eight (8) documents. (Actually, 3 documents will suffice if the procedures shown above are contained within the Quality Manual.) Records are a different form of documentation and will be discussed later. Your company may choose to create more documents based on your needs.

ISO 9001:2008 also says that, “documentation can be in any form or type of medium.” WCH recommends that documentation be stored electronically, preferably on a server that is backed up regularly (with backups that are taken off-site to protect the company’s data in the event of a fire.) All of our templates have the following sentence in the footer: **The CONTROLLED version is stored electronically. Printed copies are for REFERENCE ONLY.** When a copy is printed, it is not controlled and cannot be considered to be the latest version without verifying that it is the same as the CONTROLLED version that is stored electronically. This is a fantastic method to ensure that outdated documents are not “laying around” your facility.

WCH has provided a Controlled Documents directory and a Records directory. If you mirror this system on your company server (or computer for very small businesses,) you will find that this is a very easy way to centralize all of your company’s Controlled Documents and Records. You may modify the Records subdirectories to suit your needs.

DOCUMENTS AND INSTRUCTIONS

You will find the following documents within this package:

1. Quality Manual ^{Section 4.2.2}

Review all highlighted sections and modify to suit your company’s needs. Delete any **helpful instructions** provided within the manual and remove all yellow highlights while keeping necessary text before finalizing the manual.

Use Microsoft Word’s “Find and Replace” function to replace the words “our company” with your company’s name. This gives ownership for the ISO program.

ISO 9001:2008 requires that the quality manual contain:

- a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),
- b) references to the documented procedures established for the quality management system, and
- c) a description of the interaction between the processes of the quality management system.

2. Quality Policy ^{Section 5.3}

Refer to Section 5.3 of the ISO 9001:2008 standard. The Quality Policy that is provided with this package complies with ISO 9001:2008 but it is a generic policy. You may wish to make the policy more unique. Be careful not to lose sight of the requirements outlined in Section 5.3 when you modify the Quality Policy.

Review all highlighted sections and modify to suit your company's needs. Delete any **helpful instructions** provided within the Quality Policy and remove all yellow highlights while keeping necessary text before finalizing the document.

As noted earlier, WCH encourages electronic versions of Controlled Documents rather than hard copies. If there are computers located throughout your organization, you might consider making the policy the screen saver on the computers. If this does not reach all employees, you will want to post hard copies that are printed with the words "Controlled Document" in red. A hard copy sample has been provided with this document set. You will need to keep a record of where these copies are posted. Generally, companies post them above time clocks, in the cafeteria and/or in the lobby.

Hint: An easy way to keep track of hard copies is to note where hard copies are located in the "Properties" associated with the document. By left-clicking on the document icon in the server directory, you can add to the "Comments" of the "Properties." This method is noted in the Document Control procedure, referenced in Item 4, below.

3. Quality Objectives ^{Section 5.4.1}

WCH has provided a Quality Objectives worksheet in Excel, which lists three objectives that can be applied to most organizations. These may be changed to suit your organization. It is important that objectives are measurable. You will note that each of the objectives has a specific numeric goal (or percentage) and a time frame in which to achieve said objective. Remember to replace the word "Quality" with "Business." What are your Business Objectives?

WCH has also provided a fictitious, sample chart that your company should copy and fill in with the company's own objectives and data.

Your company may choose to chart more objectives, although this is not required.

- Objectives should be set at each appropriate level within the organization. They should support the higher level objectives. For example, if the company has an objective to “Increase the Profit Margin by 5% per year,” then some supporting objectives might be:
- “Decrease scrap by 2% per year.”
- “Improve employee productivity by 7% per year.”
- “Decrease material costs by 2% per year.”
- “Investigate three new suppliers per year, in an effort to decrease material costs while maintaining quality and delivery.”
- And so on.

Your company may or may not achieve these objectives. Objectives should be reviewed during Management Review meetings. If they need to be reevaluated, they can be adjusted or eliminated as appropriate.

4. Five procedures and supporting forms, including:

a) Document Control ^{Section 4.2.2}

b) Records Control ^{Section 4.2.4}

- Records Matrix – this matrix outlines all of the records that are required by ISO 9001:2008. Complete this matrix with your company’s information. Where are and how are records stored? Be sure not to delete columns in this document as they are required by the standard. If you are taking any exclusions to the ISO 9001:2008 standard (see Section 1.2 of your Quality Manual,) you can delete the appropriate row. For example, if your company does not have a Design Group (Section 7.3 of the ISO 9001:2008 standard,) you will not have records related to Design and Development.

c) Internal Audits ^{Section 8.2.2}

- Internal Audit Schedule
- Internal Audit Checklist
- Internal Audit Matrix
- Internal Audit Summary
- Improvement Action Request (IAR) (used with Items c, d, e and f in this list)

Note: When modifying the Internal Audit Checklist, be sure to change the filename to reflect the current date after the word “UPDATED.”

- d) Nonconforming Material ^{Section 8.3}
 - Improvement Action Request (IAR) (used with Items c, d, e and f in this list)
- e) Corrective Action ^{Section 8.5.2} & Preventive Action ^{Section 8.5.3}
 - Improvement Action Request (IAR) (used with Items c, d, e and f in this list)

A note about IARs: An easy way to keep track of IARs when they are filled in and become records is to name each IAR by its number (in the following example 2010 is the year, 03 is March, 01 is the 1st day of the month and 1 is the first IAR of the day) and then either enter it in a log or add a brief description to the filename. For example: a filename might be: “IAR 2010-03-01-1 LEAKY ROOF.” Then you could simply look through the IAR directory on the server to easily find the IAR by initiation date or subject. This also eliminates the need for double data entry, i.e. filling out the IAR and then entering information on a log. This method can be used in other areas as well – perhaps ECNs (Engineering Change Notices,) Management Review Minutes (example: MR 2010-04-01,) Internal Audits (example: IA 2010-04-01-1 PURCHASING, IA 2010-04-01-2 CALIBRATION,) etc. This method is not required by ISO 9001:2008, it is just a helpful hint.

WCH does not recommend modifying these procedures or forms without fully understanding the requirements of the standard. It is possible to delete a key requirement of the standard by simply deleting something that you believe doesn’t apply to your organization.

- 5. WCH has provided additional forms to assure compliance with the standard including:
 - a) Management Review Minutes ^{Section 5.6} – use this form to hold Management Review meetings as often as you like but at least a minimum of once per year. You must cover every item on the agenda. The Agenda should be distributed before each meeting so that managers have time to prepare for the meeting and bring the appropriate data to the meeting. There is a sample of a Management Review meeting (for the ISO 14001 standard) on WCH’s website at www.wchservices.com/samples. This may help your team to understand what the outputs of a Management Review meeting might look like.
 - b) Sample Job Descriptions ^{Section 6.2.2} - a few Job Descriptions have been included. You can use this format to create your own.

- c) Training Matrix & Needs Assessment spreadsheet^{Section 6.2.2} – use this spreadsheet to assess and record employee training needs, to record training and effectiveness of training. This sheet is designed for a small company and can be expanded. Larger companies may choose to find another way to accomplish something similar with a more robust software platform than Excel.

When modifying this spreadsheet, be sure to change the filename to reflect the current date after the word “UPDATED.” Archive old versions (for two years or as specified on the Records Matrix.

- d) Additional supporting forms and spreadsheets as described in the “DOING” section of this manual.

DOING (SECTION 7 OF ISO 9001:2008)

WCH considers Section 7 of the ISO 9001:2008 standard to be the “DOING” section of the standard. With the exception of subclause 7.3, “Design and Development,” Section 7 is not highly prescriptive. It has been WCH’s experience that most successful companies who have figured out how to make money by providing a product or service are between 60 and 75% compliant with Section 7, especially if they have been in business for five or more years. Section 7 covers the process from receiving a Customer Order through to Shipping and Servicing. There are a few areas within Section 7 that create extra work for organizations that are ISO 9001:2008 compliant as opposed to organizations that aren’t.

WCH has provided optional forms and spreadsheets that your company can use to address any gaps between your current system and the requirements of the ISO9001:2008 standard. You can use these or substitute them with your own.

Optional forms and spreadsheets that WCH offers are as follows:

1. Design and Development Form^{Section 7.3} – use this form to control the design and development process and to ensure compliance with the ISO 9001:2008 standard. It is not necessary to use a Design and Development Form. WCH recommends that you keep all Design-related documents together in a file (electronic or hardcopy.) One file per product / part number is recommended.

One of the criteria of ISO 9001:2008 is that Design Review “include[s] representatives of functions concerned with the design and development stage(s.)” Companies should consider including representatives from manufacturing and field service in Design Reviews.

Companies often have difficulty discerning the difference between Design Verification and Design Validation. The best way to understand this is as follows:

- Design Verification is done without a finished product. It is a paper review that compares the Design Outputs to the Design Inputs and makes sure that the Outputs will create a product that meets the Inputs.
 - Design Validation is done with a finished product. After one or more products are produced, the product(s) should be tested according to planned criteria to ensure that it is compliant with the appropriate Design Outputs (such as an Engineering drawing) and meets the Design Inputs, including any customer requirements / expectations. Additionally, the product should be tested in its expected final-use environment. In some cases, this is not possible. The product should then undergo a series of tests that emulate the intended final-use environment as closely as possible.
2. Approved Supplier - Subcontractor List ^{Section 7.4.1} – use this simple spreadsheet to record activities associated with periodic supplier evaluation. This spreadsheet defines very basic criteria for evaluation. The best way to evaluate suppliers is with data that is collected throughout the year that demonstrates quality, delivery and service. Your company can then determine what acceptable levels are. The spreadsheet provided herein assumes that your company is in the early stages of data analysis and that supplier performance data is not being collected. You may want to change this criteria to suit your company’s needs. If your company has 100 or more suppliers that contribute to your company’s final product or service, it may be better to select a different software platform than this Excel spreadsheet.

ISO 9001:2008 does not require that you re-evaluate ALL of your suppliers. Section 7.4.1 in the Quality Manual indicates that key suppliers are re-evaluated (this should occur at least once per year.) So, a company with 100 suppliers may choose to evaluate a subset of these suppliers. For example, you may choose to evaluate suppliers of critical components or suppliers who represent the Top 10 in spending. You can also choose to randomly select 10 suppliers. Or you can combine these and other criteria. This should be defined. Progressive companies use their MRP/ERP systems to constantly evaluate suppliers and kick out warnings to Purchasing. This is not necessary but it is cool.

It is globally expected that your company maintain a list of Approved Suppliers that Purchasing refers to when making a purchase. The Registration Auditor may ask to see a list of your Approved Suppliers. Another way to ask this question is, “How do you know which suppliers are approved for use?” Your company needs to be able to answer this question. You may have another way of doing this. The Approved Supplier - Subcontractor List provided by WCH is much more than a list of suppliers. Review it carefully and determine if your company can use this simple method to set criteria for evaluation, evaluate and re-evaluate suppliers.

When modifying this spreadsheet, be sure to change the filename to reflect the current date after the word “UPDATED.” Archive old versions (for two years or as specified on the Records Matrix).

3. Receiving Inspection Form ^{Section 7.4.3} – use this form to record the results of Incoming Inspection of Purchased Product. This form shows the sampling plan to be used and which products are to be inspected. You may want to change this criteria to suit your company’s needs.
4. Process Validation Spreadsheet ^{Section 7.5.2} – use this spreadsheet to record the validation of special processes. There is only one worksheet tab for one employee. The assumption in the sample Process Validation Spreadsheet is that you are qualifying an individual who is a welder. Copy this worksheet tab for as many employees and operations as you need.

When modifying this spreadsheet, be sure to change the filename to reflect the current date after the word “UPDATED.” Archive old versions (for two years or as specified on the Records Matrix).

5. Calibration Schedule ^{Section 7.6} – use this spreadsheet to inventory all measuring tools and keep calibration records of same.

When modifying this spreadsheet, be sure to change the filename to reflect the current date after the word “UPDATED.” Archive old versions (for two years or as specified on the Records Matrix).

When calibration is performed by qualified In House personnel, your company might consider calibrating to Work Instructions to ensure that the calibration method is applied consistently. Auditors will look for this. At the time of this writing, WCH Professional Services, LLC currently recommends that its clients visit the Long Island Indicator website. They have posted a nice set of Work Instructions that your company should review for free at <http://longislandindicator.com/p7.html>. This site location is not controlled by WCH and is subject to change.

6. Customer Satisfaction Survey ^{Section 8.2.1} – refer to www.wchservices.com/survey to view a sample Customer Satisfaction Survey.

There are many ways to monitor customer perception. Your customers may perceive that your company is doing an excellent job even though deliveries are late, quality is poor and service is mediocre. (This would be unusual, but it will also be a cause for celebration.) The opposite is also true. Even if your company is shipping a quality product on time at a competitive cost, the customer may be unhappy with your company’s performance. Knowing this might cause your

company to investigate it further. An example of how this might occur is that the customer's Purchasing Agent is not performing his/her job properly or the customer's Material Requirements Planning system is using faulty data to drive demand.

WCH has found that Customer Satisfaction Surveys that are mailed or emailed to customers are not an effective means of monitoring Customer Satisfaction. Often, these surveys are discarded. Customer Surveys can be effectively applied by asking the survey questions when the customer places an order or by soliciting responses through a survey form set up on a website.

If you would like for WCH to create an online survey for your company where the customer responses are sent directly to your email address, please give us a call at 570-350-9256.

DISCLAIMER

ISO 9001:2008 is a standard for Quality Management Systems and ISO Registrars are accredited. However, all Quality Management Systems, Registration Organization and Auditors are unique systems, organizations and people, respectively. WCH cannot guarantee that your company will come through the registration audit free and clear of any and all non-compliances. Your company will be certified if you work with your registrar to resolve audit non-compliances in a timely fashion.