ISO 9001:2008
Quality Manual Guidance

Contents

Introduction

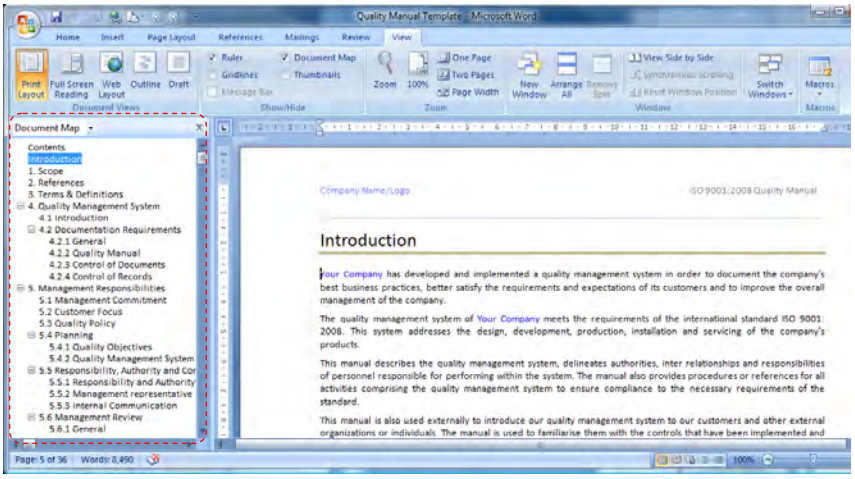
Navigating the Documents

We recommend you enable the '**Document Map'** feature of Microsoft Word.

This is accessed in different ways depending on the version of Microsoft Word that you are using.

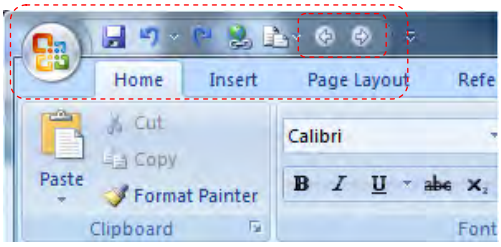
Please see your Microsoft Word '**Help'** to enable this feature.

In Microsoft Word 2007 use the **'View'** tab, and tick the checkbox '**Document Map',** just underneath the **'Mailings'** tab.



If you're using **MS Word 2003** you can use the '**back**' and '**forward**' arrow buttons to navigate between the various sections of the manual and the contents pages; please select the '**Web**' toolbar within '**Microsoft Word**'. If you're using **MS Word 2007** or later, you can also navigate the documents using the back and forward buttons via the **Quick Action Toolbar**:

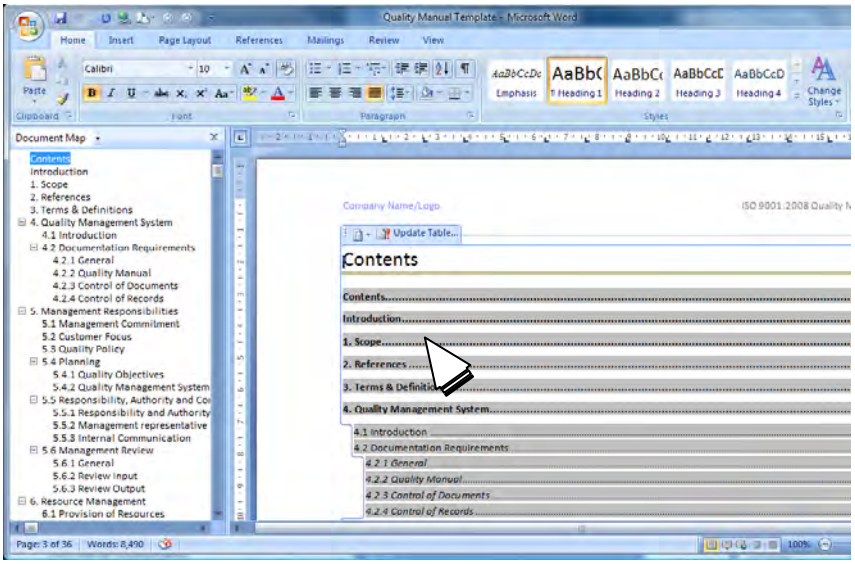
1. Click the **Microsoft Office Button** , click '***Word* Options'**, bottom right hand corner and then click **Customize**.
2. In the **Choose commands from** list, select **'All Commands'**, and then do one or more of the following:



- To add the **'Back'** button to the Quick Access Toolbar, click **'Back'**, and then click **'Add'**
- To add the **'Forward'** button to the Quick Access Toolbar, click **'Forward'**, and then click **'Add'**
- To add the **'Location'** box to the Quick Access Toolbar, click **'Document Location'**, and then click **'Add'**

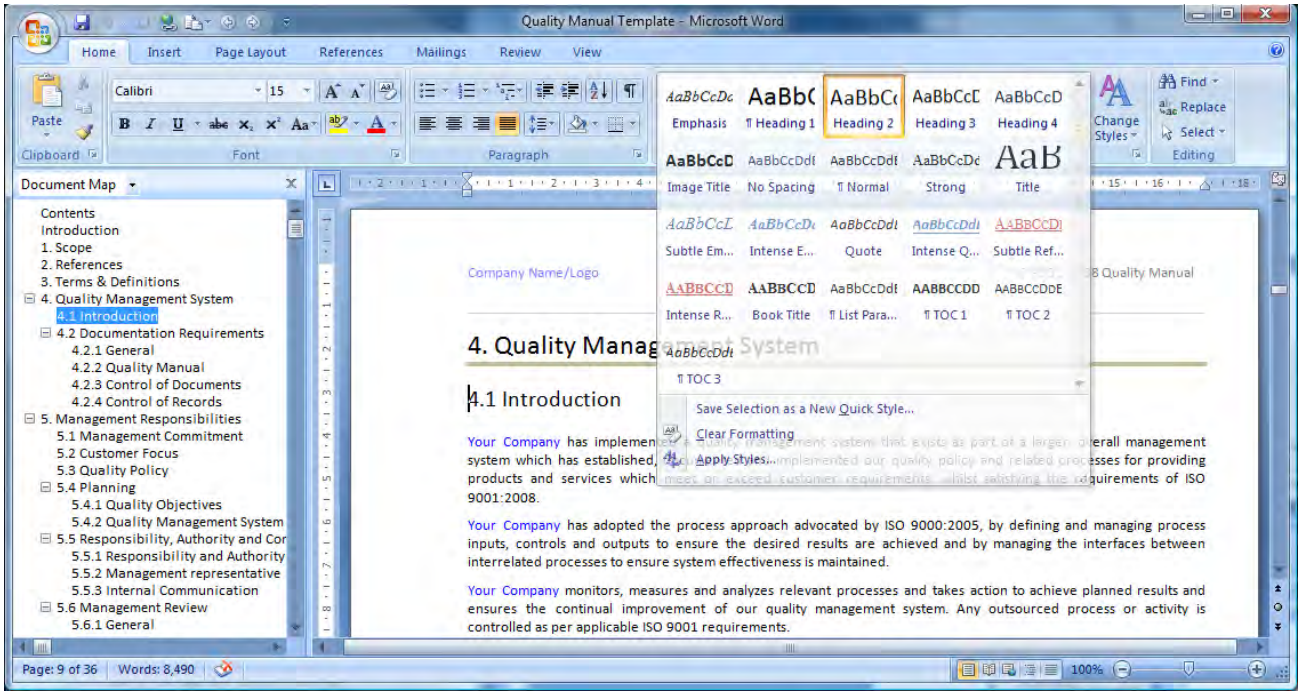
Alternatively you can navigate the quality manual using the '**Contents**'; the headings shown in the contents pages are hyperlinked to the relevant sections of the quality manual:

- Open the 'Quality Manual Template'
- Go to page 3 'Contents'
- Place your mouse cursor over the heading you wish to navigate to
- Press and hold '**CTRL'**
- **'Left Click'** your mouse



Headings and Numbering

The standard itself does not specify a numbering format, but for the sake continuity and ease of familiarity, we have used the same heading titles and numbering as the ISO 9001:2008 standard. You are free to devise an alternate format more appropriate to your organisation.



Document Styles

Styles save considerable time formatting documents. Please change the styles to your house style/branding - font, size, weight, line-spacing, line-height, etc. Styles are used throughout the documents for your convenience:

- Normal
- Heading 1
- Heading 2
- Heading 3
- Tables

Style management differs in different versions of MS Word, for more information we recommend you search and view 'how to' videos on YouTube specific to your MS Word version, e.g. www.youtube.com/watch?v=eURMxdhCC94

Adding Sections and Numbers

If you wish to add more headings please use MS Word styles. This will enable you to update the 'Contents' dynamically and will save you time. This is done differently in different versions of MS Word, for more information we recommend you search and view 'how to' videos on YouTube specific to your MS Word version, e.g.:

www.youtube.com/watch?v=6BqHH-zkzEw

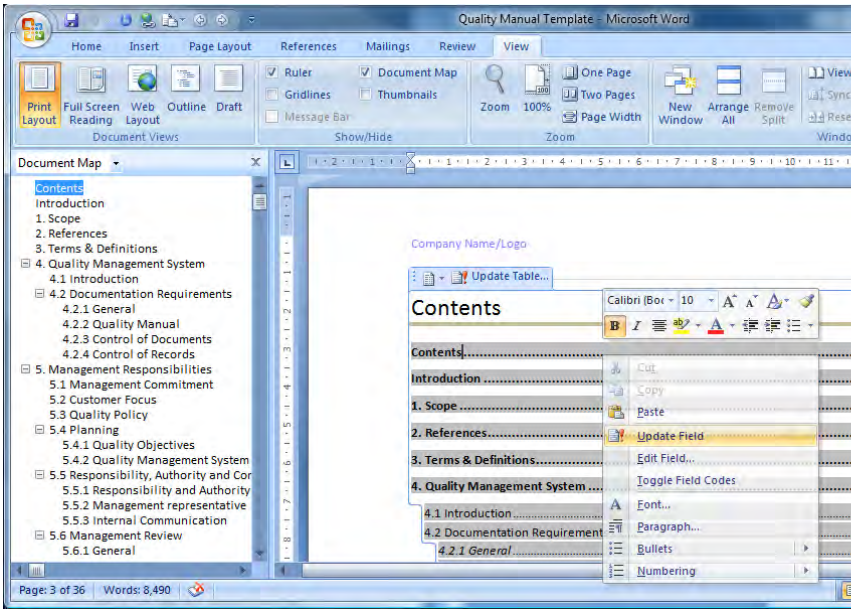
If you wish to add sections and new content we recommend you leave the heading 1 numbering the same (for reason, see above) and add subsections using styles - heading 2, heading 3, etc.

Updating the Contents Pages Dynamically

If you add new sections using heading and styles, you can automatically update the **Contents** pages using the **'Update Field'** feature of Microsoft Word (this will save you time).

This is done in different ways depending on your version of Microsoft Word.

Please see your Microsoft Word **'Help'** for more information about this feature.



What Content Should I Amend?

This document should be used as guidance when developing or upgrading your quality management system. To begin:

- Open the 'Quality Manual Template'
- Review and amend the quality policy
- Review and amend the quality manual
- Review and amend the procedures
- Review and amend the forms
- Develop work instructions where necessary
- Replace the text to match your quality system requirements
- At a minimum, blue text should be replaced with your information
- [Your Company] indicates that you should use your company's name or logo in that location

Document Reference Numbering

The procedures and forms provided have been given a basic reference numbering system which is intended to provide an immediate structure to the various components of the templates.

- Procedures are prefixed P
- Forms are prefixed F
- Work instructions are prefixed W

ISO 9001:2008 does not specify any requirements in regard to document reference numbering. You are free to change all the reference numbers to suit the format already used by your organization. Ensure that you make the necessary amendments within the quality manual, procedures and forms, etc.

4. Quality Management System

4.1 General Requirements

Your organization's quality management system is that part of an overall management system which establishes, documents and implements your quality policy and related processes necessary for providing products and services which meet or exceed customer requirements whilst satisfying the requirements of ISO 9001:2008.

4.1.1 Process Approach

Your organization should adopt the process approach advocated by ISO 9000:2005 by defining and managing:

- Process inputs, controls, and outputs to ensure desired results are achieved
- Interfaces between interrelated processes to ensure system effectiveness is achieved

Implement and develop your quality management system by:

- Determining the core processes that make up your quality management system (plan)
- Defining and mapping your organization's quality management system processes (plan)
- Implementing the quality management system by rolling out across the organization (do)
- Using the quality management system processes (do)
- Proactively managing process performance (do)

Improve your quality management system by:

- Monitoring process performance (check)
- Improving process performance (act)

4.1.2 Outsourced Processes

If your organization outsources any processes that affect product conformity, you must be able to demonstrate sufficient control over each outsourced process. This is to ensure that those processes are performed according to the relevant requirements of ISO 9001:2008 and to customer requirements.

Outsourced processes may be controlled in any number of ways; either by providing suppliers and subcontractors with product specifications, by requesting inspection and test results, certificates of conformance or by conducting product and quality management system audits.

The expectation here is that your quality management system flows down to your supplier or subcontractor; thus ensuring conformance to the same ISO 9001 requirements that you would have to implement and control had the process been performed in-house.

4.1.3 Processes Interactions

Appendix A.2 of the quality manual should describe the sequence and interaction of your organization's processes. When defining your organization's processes, think about the departments that exist and try to define those processes around the current organizational model and not around the requirements of the standard.

A good process model will reflect your business and be unique to how your organization functions. Ignore the standard, in fact put it in a draw and forget it exists and focus on your business and the way in which major departments interface with each other. Once you have defined the processes and interfaces; go back to the standard and determine which processes are responsible for which requirements.

For example; if you have an identification and traceability process, is this process the responsibility of any single person or department within your organization? You may well have a warehouse, maybe shipping and receiving, or a

production area, etc. all these processes will have responsibility, in part, for identification and traceability. It is unlikely that this is a standalone process.

4.2 Documentation Requirements

4.2.1 General

Define and document your quality management system by:

- Developing the quality policy (5.3)
- Establishing the quality objectives (5.4.1)
- Developing and establishing the quality manual (4.2.2)
- Developing procedures to implement your QMS
- Developing other documents as required by the organization

We suggest using this documentation hierarchy:

- Level 1: Policies - Key system driver of process inputs and objectives; statement of corporate vision
- Level 2: Quality Manual - Describes corporate approach and responsibilities for achieving quality
- Level 3: Procedures - Describe the methods required for process implementation
- Level 4: Work Instructions - Describe the operating practices and controls of each process
- Level 5: Forms - Key system outputs; data, records, proof of conformance, and evidence of verification

4.2.2 Quality Manual

The quality manual is the cornerstone of your organization's quality management system. It manifests and communicates top management's commitment to providing and operating an effective quality management system.

Edit the quality manual template, ensuring that it:

- Defines the scope of your QMS
- Provides reasons for any exclusions
- Documents or makes reference to reference to operational procedures
- Describes how your core organizational processes interact

Like any high level document, the quality manual must be written in such a way that it provides employees, customers, auditors and other interested parties with a sound overview of how your organization satisfies customer requirements. People throughout your organization will refer to it when they want to see the big picture of the system, or what policies have been established.

One of best ways to understand and implement ISO 9001:2008 is the actual task of compiling the quality manual. By reading through each of the requirements one-by-one and assigning each requirement a relevant document, process or procedure that exists within your organization, you'll find that more than half of the requirements have already been addressed. The quality manual will formalise the relationship between the processes, the documentation and the requirements.

4.2.3 Document Control

A robust document control process invariably lies at the heart of any compliant quality management system; almost every aspect of auditing and compliance verification is determined through the scrutiny of documented evidence. With this in mind, it becomes apparent that the ongoing maintenance of an efficient document management system must not be overlooked.

Clause 4.2.3 tells us that an organization must control the documentation required by the QMS and that a suitable procedure must be implemented to define the controls needed to; approve, review, update, identify changes, identify revision status and provide access. The document control procedure should define the scope, purpose, method and responsibilities required to implement these parameters.

In order to comply with the document control clause, it is essential that all personnel understand what type of documents should be controlled and more importantly, how this control should be exercised. To get the most out of your document control procedure, it must communicate the steps necessary to ensure that staff and other users of the organization's documentation understand what they must do in order to manage that information effectively and efficiently.

Departmental managers should always be responsible for promoting good document and record management practices in their area whilst supporting overall compliance to the document control procedure.

Individuals and their line managers should be responsible for the documents and records that they create, as well as being responsible for their retention and disposal in line with legislative requirements and organizational procedures and practices.

If you don't want to control external documents, you must specifically state this in the procedure and on the documents themselves, which are 'For Reference Only' and are not updated.

Supporting documentation:

Ref	Title & Description
P001	Document Control Procedure
F001-1	Master Document Index
F001-2	Document Issue Sheet
F001-3	Document Change Request

4.2.4 Control of Records

Clause 4.2.4 demands that an organization must implement a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records and that these records must remain legible and identifiable throughout their retention period.

This because records are an important organizational asset; they provide the primary route for evidence based verification and traceability since they demonstrate compliance with customer requirements. Records also prove the efficacy of the QMS.

- Records are used to prove compliance against requirements
- Develop and implement the control of records procedure (P002)
- Maintain the legibility and accessibility of QMS documents and records

Implementing a document management system could mean keeping certain records that your organization might not be already keeping. Some of these records may seem a little confusing until you become more familiar with the quality standard.

Of course, you are free to keep more records than those listed below, if you feel your organization needs them, but as we always preach; keep your system simple. The fewer documents and records you keep, the fewer things that will be audited, and the more time you will have to actually run your business.

Keep in mind that you are free to combine some of these records where it makes sense, for example, you could combine the corrective and preventive action request log with a simple checkbox to note which one it is. You could also combine both corrective and preventive action requests onto one form, again with a simple check box to designate its purpose.