

ISO 9001:2008
Document Management Guidance

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Introduction

About the Document Management Solution

The document and record control procedures and their associated forms included in this package are to be used as templates in developing your own document management system. The following documents are provided and are intended to help you develop, implement and manage your document management processes.

Ref	Title & Description
P001	Document Control Procedure
F001-1	Master Document Index
F001-2	Document Issue Sheet
F001-3	Document Change Request
P002	Control of Records Procedure
F002-1	Master Quality Record Index

Forms & Records

The forms provided and are referenced from within the respective procedure documents. You can replace these forms with those currently by your organization. You can also add more forms to suit your requirements but ensure that you make the necessary amendments within the procedures.

Document Reference Numbering

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 procedure and forms.

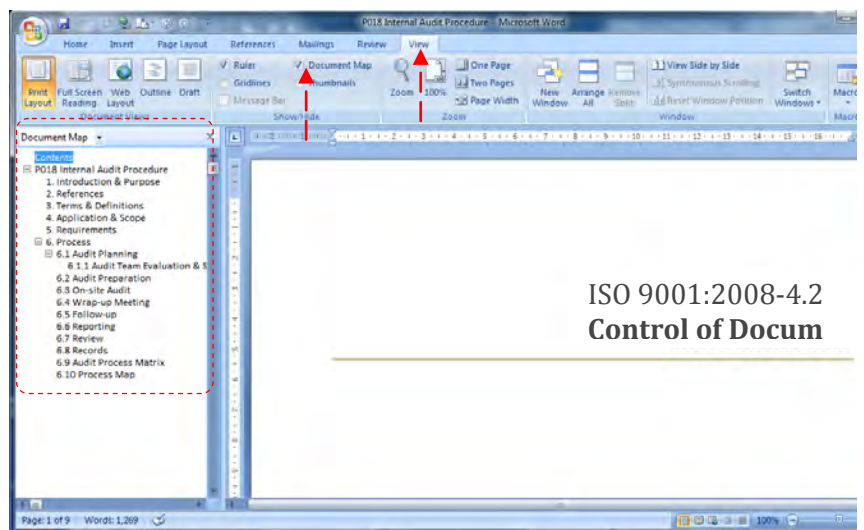
Navigating the Documents

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.

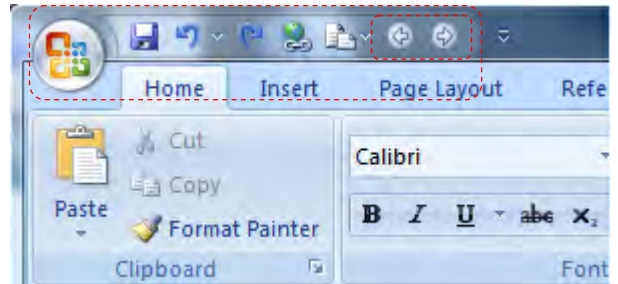
Please see your Microsoft Word **'Help'** to enable this feature.

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



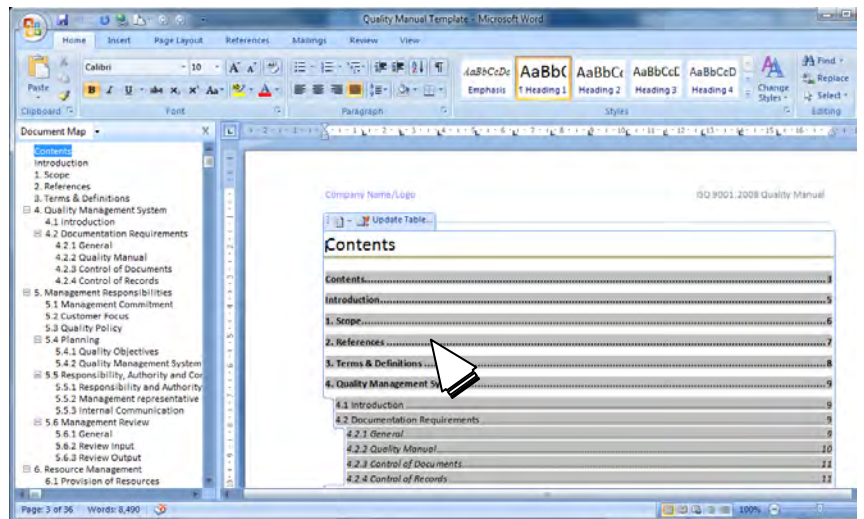
If you're using **MS Word 2003** you can use the 'back' and 'forward' arrow buttons to navigate between the various sections of the manual and the contents page; please select the 'Web' toolbar within 'Microsoft Word'. If you're using **MS Word 2007** or later, you can also navigate the documents using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

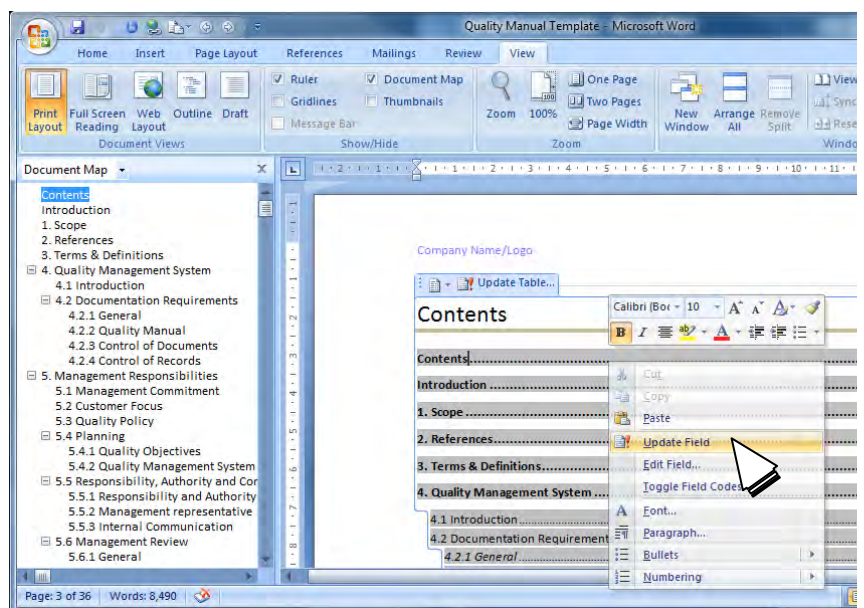


Updating the Contents Pages Dynamically

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.



Documentation Requirements

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.

Document Control Procedure

The document control procedure (P001) defines the following controls:

- How to approve documents before distribution
- Ensuring a system exists to control document revisions
- Ensuring that correct versions are available where needed by employees
- How to determine the current revision documents
- How to record and distribute external documents
- How to maintain the legibility of QMS documents and records
- How to remove obsolete documents from circulation

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.

Documentation Hierarchy

We suggest using this common 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