

ISO 9001:2008  
**Internal Audit Guidance**

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## Introduction

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### About the Internal Audit Solution

The information provided with the internal audit solution is based on the following reference documents:

Standard	Title	Description
ISO 9000:2005	Quality management systems	Fundamentals and vocabulary
ISO 9001:2008	Quality management systems	Requirements
ISO 19011:2002	Quality management systems	Guidelines for Quality Management System Auditing

### Forms & Records

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

Ref	Title & Description
F018-1	Internal Audit Schedule
F018-2	Internal Audit Plan
F018-3	Internal Audit Assignment
F018-4	Internal Audit & Gap Analysis Checklist
F018-5	Internal Audit Report
F018-6	Internal Audit Feedback
F020-1	Non-conformance Report
F020-2	Non-conformance Report Log
F023-1	Corrective Action Request
F023-2	Corrective Action Request Log
F024-1	Preventive Action Request
F024-2	Preventive Action Request Log

### Internal Audit Procedure

The internal audit procedure that accompanies this package comprises a detailed text based narrative that describes each step in the audit process:

1. Introduction and purpose
2. References
3. Terms and definitions
4. Application and scope

5. Requirements
6. Audit Process

An abbreviated process matrix is provided for quick reference that shows each step in the audit process and clearly defines the actions required, the people responsible and the records required for output. An editable process map showing the relationship between each step in the audit process is also included.

Remember, if you make any changes to the text based procedure; be sure to amend the process matrix and process map accordingly. If the process matrix or process map does not add value to your organization's internal audit process, you are free to delete them from the procedure.

## Document Reference Numbering

The procedure 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

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.

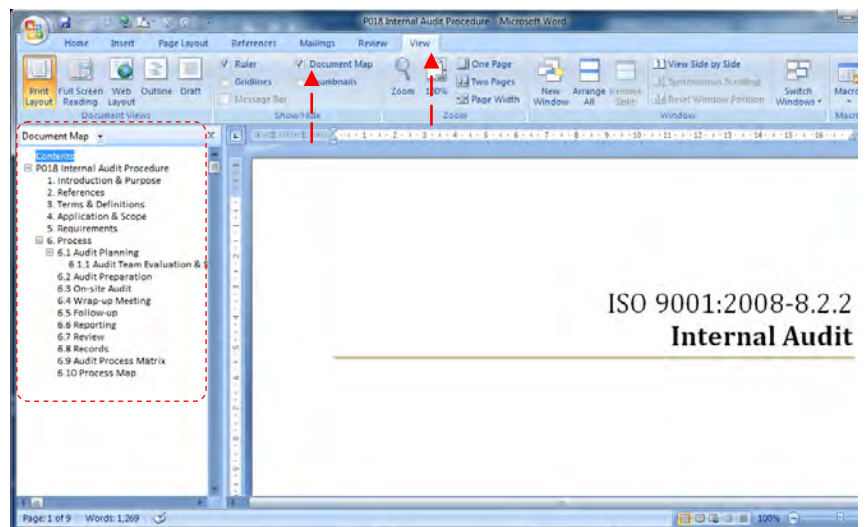
## Navigating the Documents

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.

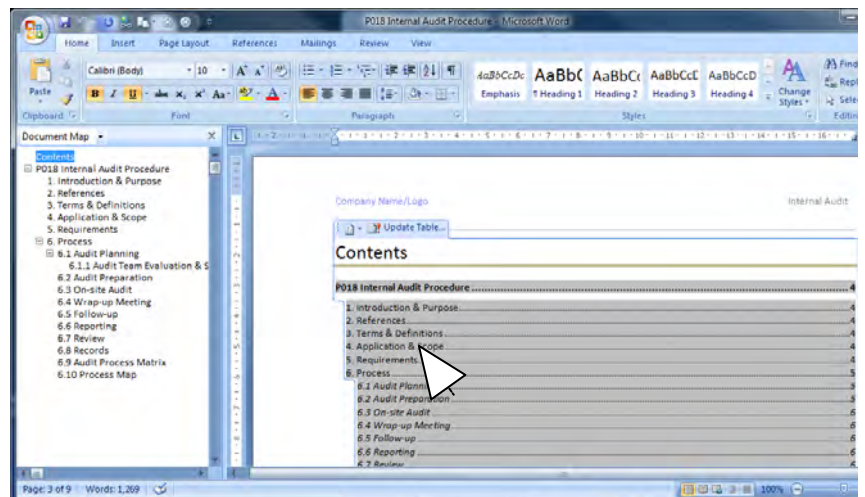
Please see your Microsoft Word **'Help'** to enable this feature.

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




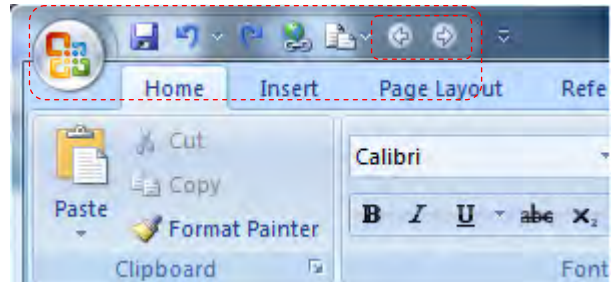
Alternatively you can navigate the quality manual using the **'Contents'**; the headings shown in the contents pages are hyperlinked to the relevant sections of the quality manual:

- Open the 'Audit Procedure 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



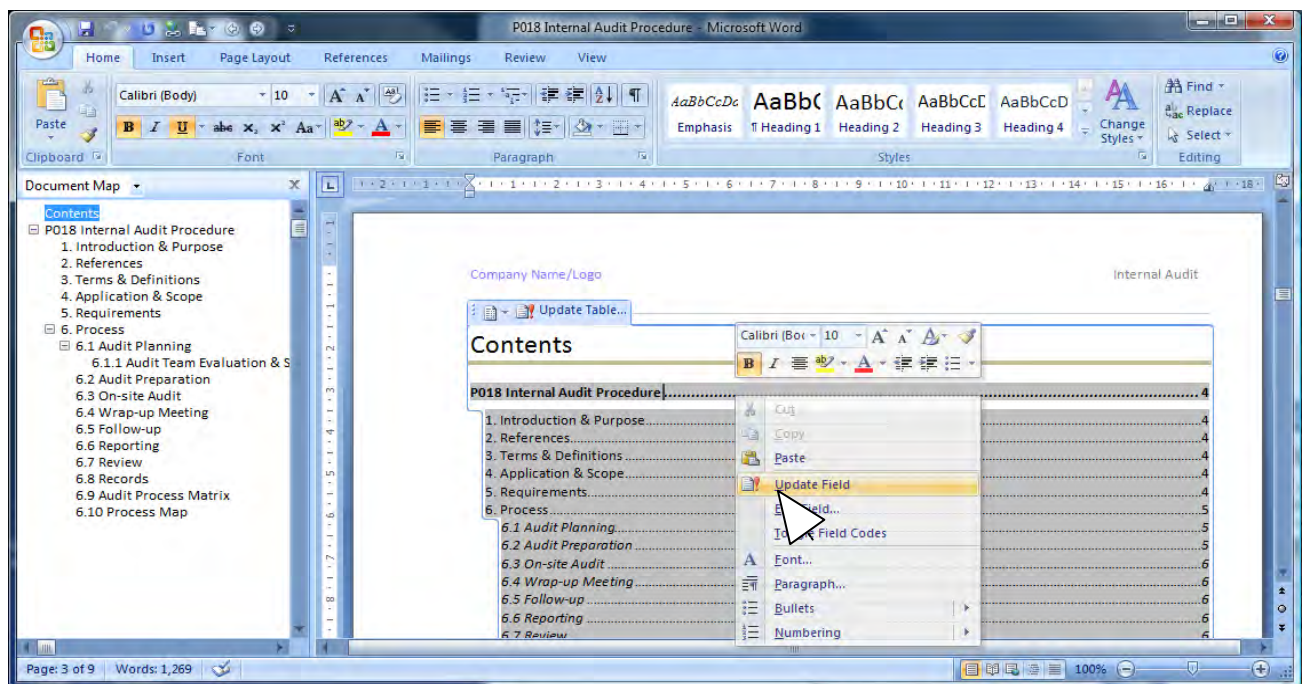
If you're using **MS Word 2003** you can use the 'back' and 'forward' arrow buttons to navigate between the various sections of the manual and the contents page; please select the 'Web' toolbar within 'Microsoft Word'. If you're using **MS Word 2007** or later, you can also navigate the documents using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



## Updating the Contents Pages Dynamically

If you add new sections using heading Styles, you can automatically update the 'Contents' pages using the **Update Field** feature of MS Word (this will save you time). This is done in different ways depending on your version of MS Word – please see your MS Word Help for more information about this feature.



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## Internal Auditing

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The purpose of internal auditing is to assess the effectiveness of the quality management system and the organization's overall performance. ISO 9001:2008 Clause 8.2.2 requires that your internal audits demonstrate compliance with your 'planned arrangements', e.g. quality manual, procedures or process maps and that the planned arrangements are implemented and maintained.

The auditor's role is to gauge how well this system is functioning by gathering of objective evidence of conformance. The auditee will often be a processes owner; they are the experts of that process and as such will provide an invaluable insight into the mechanics of the process.

The auditor will verify that processes are documented, implemented and understood. He will also seek confirmation that each process complies with the necessary requirements, that the process is effective and demonstrates continual improvement.

Implement an internal audit programme by:

- Developing the audit procedure (P018)
- Establishing audit schedule (F018-1)
- Planning your audits (F0182)
- Assigning audit duties (F018-3)
- Reviewing and amending the audit checklist (F018-4)
- Preparing the audit report (F018-5)
- Obtaining feedback from auditees (F018-6)

## Principles of Auditing

Auditing relies on a number of principles whose intent is to make the audit become an effective and reliable tool that supports your company's management policies and procedures whilst providing suitable objective information that your company can act upon to continually improve its performance.

Adherence to the following principles are considered to be a prerequisite for ensuring that the conclusions derived from the audit are accurate, objective and sufficient. It also allows auditors working independently from one another to reach similar conclusions when auditing in similar circumstances.

The following principles relate to auditors.

1. Ethical conduct: Trust, integrity, confidentiality and discretion are essential to auditing
2. Fair presentation: Audit findings, conclusions and reports reflect truthfully and accurately the audit activities
3. Due professional care: Auditors must exercise care in accordance with the importance of the task they perform. Having the necessary competence is an important factor
4. Independence: Auditors must be independent of the activity being audited and be objective
5. Evidence-based approach: Evidence must be verifiable and be based on samples of the information available

## Auditor Training

Formal training in internal auditing will provide your auditors with a broad understanding of the various organizational processes that comprise the QMS and how it is implemented. The aim of such training is to provide participants, who intend on performing internal audits, with the knowledge and skills needed to assess and report on the conformance and implementation of processes, and to contribute to the continual improvement of the quality management system.

Internal auditor courses are normally two-days in duration and topics include:

- An introduction to ISO 9001