



Documented Information Guidance

ISO 9001:2015



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Introduction

A robust document control process invariably lies at the heart of any compliant quality management system (QMS); 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 on-going maintenance of an efficient document management system must not be overlooked.

Your organization must control the documentation required by the QMS and ensure that a suitable process is implemented to define the controls needed to; approve, review, update, identify changes, identify revision status and provide access. The document control procedure that is included with this document will help you to define the scope, purpose, method and responsibilities required to implement these parameters.

The procedure also defines the controls needed for the identification, storage, protection, retrieval, retention and disposition of records and ensuring that they remain legible and identifiable throughout their retention period. This is because records are an important organizational asset; as they provide the primary route for evidence based verification and traceability since they demonstrate compliance with customer and regulatory requirements. Records will prove the efficacy of your QMS:

1. Records prove compliance against requirements;
2. Develop and implement the control of records procedure;
3. 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 in this document, if you feel that your business 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.

Existing ISO 9001:2008 Documents

While there is no requirement for a management system manual or documented procedures in ISO 9001:2015, it is suggested that if they add value to operations, then your ISO 9001:2008 documents should not simply be binned. You will be expected to maintain the integrity of your QMS and its documentation when transitioning from ISO 9001:2008 to ISO 9001:2015, this can be evidenced using management review meeting minutes, SWOT analysis documents or risk and opportunity trackers.

You need to restructure your management system to follow the sequence of and titles of the requirements. Providing all of the requirements contained in ISO 9001:2015 are met, your organization's quality management system will be compliant.

1. If your system manual fits your business and your customers require it, keep it!

2. If your procedures are effective and define how your key processes operate, keep them!
3. If the quality policy and related objectives align with business strategy, and they are communicated and adding value, keep those too!

You do not need to renumber your existing documentation to correspond to the new clauses. It is down to each organization to determine whether the benefits gained from renumbering will exceed the effort involved.

Interpreting ISO 9001:2015 Clause 7.5

In order to comply with ISO 9001:2015 Clause 7.5 Documented Information, it is essential that all personnel understand what type of documents should be controlled and more importantly, how this control should be exercised.

The type and extent of documented information that your organization should retain and maintain, in order to be compliant with ISO 9001:2015, clearly depends on the nature of your organization's products and processes. The following criteria can be used to assess the different types of documentation and information that your organization should retain and maintain as documented information by determining whether the information:

1. Communicates a message internally or externally;
2. Provides evidence of process and product conformity;
3. Provides evidence that planned outputs were achieved;
4. Provides knowledge sharing.

If any of the above criteria apply to any type of document or information within your organization's domain, then it should be retained and maintained as a form of 'documented information' as per Clause 7.5 of ISO 9001:2015.

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. For multi-site/corporate certifications the auditor will expect to see that system documentation and changes are centrally managed (usually performed at the headquarters location) with further control of documents at the local level, as applicable.

Clause 7.5.1 - General

Clause 7.5.1 of ISO 9001:2015 is **identical** to the requirements from ISO 9001:2008 – Document Control. It should be noted that there is no need to maintain a documented procedure but your organization may still chose to operate one. You should ensure that you organization's management system includes documented information required to be maintained and retained by ISO 9001:2015, and the documented information required identified by your organization to demonstrate the effective operation of its QMS.

Clause 7.5.2 - Creating & Updating

Clause 7.5.2 of ISO 9001:2015 is **comparable** to the requirements from ISO 9001:2008 – Document Control. You should seek to confirm that when documented information is created or updated, your organization has ensured that it is appropriately identified and described (e.g. title, date, author, reference number). It must be