Documented Information Guidance

ISO 9001:2015

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1 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.

2 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;

Do you need to restrict access to certain records? Should a back-up copy of critical records be maintained at another location? Should a hard copy of some records be maintained in case an inspector arrives and your computer system is down (this has actually happened to facilities).

Step 5: Prototype each new document

Prototyping means visualizing what you will need in the document and creating an outline for it before you actually have information to fill in. This is like drafting a document, but in an outline fashion. As you consider what is needed for the document, you also gain understanding about what you may need to support the QMS. It's a way of 'outlining' your QMS as well as designing documents.

The best people to prototype or provide early input to documents, are the people who will use the document. Involving them in the process should help make sure the documents are usable and applied to support the QMS. The following questions will help you plan your documents. Consider these questions for each document you identify as necessary for your company:

1. What is the document's purpose?
2. Who will use it and how will they use it?
3. How long should the document be?
4. What must be included in the document? Which information is most critical?
5. How the information is best arranged?
6. Will the user read document sequentially or randomly?

Step 6: What to maintain as documented information

Documented information is required to be controlled and maintained by your organization. Your QMS documentation should be updated as needed based on any system improvements you put in place but keep your QMS documentation simple! **Maintain** the following data as 'documented information':

Maintain the following documentation	Clause
The scope of the Quality Management System (QMS)	4.3
Information necessary to support the operation of processes	4.4
Quality policy	5.2
Quality objectives	6.2
Documented information required by ISO 9001:2015	7.5.1a

Step 7: What to retain as documented information

You may need to generate certain forms in order to implement your QMS. When these forms are filled out, they become records. Forms should be simple and understandable for the users.

Master forms should be signed by the initiator and date indicated to evidence their authority. Forms should be controlled via their unique number and revision status.

Standard forms, e.g. pre-printed material should be reference by the appropriate procedures and work instructions. **Retain** the following data as 'documented information' (A record):

4 Organizational Knowledge

4.1 What is Organizational Knowledge?

'Organizational Knowledge' is a new requirement and is closely linked with 'documented information'. You should seek and record evidence that your organization has taken steps to identify the internal and external knowledge necessary to ensure the continued product conformity.

Check that organizational knowledge is communicated as necessary and that it is maintained and retained in accordance with Clause 7.5 – Documented Information. Check that organizational knowledge is reviewed before changes to the QMS are made when responding to change.

Sources of internal knowledge often include the organization's intellectual property; knowledge gained from experience; lessons learned from failures and successes; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services. Sources of external knowledge often include other ISO standards; research papers; conferences; or knowledge gathered from customers or external parties.

You should seek to evidence to confirm how your organization has determined and made available the knowledge needed to keep up to date with changing situations and knowledge related to new products and services. You determine whether your organization has considered internal and external sources, such as:

1. Lesson learnt from non-conformities and corrective actions, near miss situations and successes;
2. Gathering knowledge from customers, suppliers and partners;
3. Capturing knowledge that exists within the organization, through mentoring or succession planning;
4. Benchmarking against competitors;
5. Sharing organizational knowledge with interested parties to ensure sustainability of the organization;
6. Updating the necessary organizational knowledge based on the results of improvement;
7. Knowledge from conferences, attending trade fairs, networking seminars, or other external events.

4.2 Sources of Organizational Knowledge

There is a strong link between organizational knowledge and the competence of employees, the latter being peoples' ability to apply knowledge to their work. Organizational knowledge can be defined as information combined with experience, context, interpretation, and insights that are useful when making decisions and taking action specific to your QMS. Examples of organizational knowledge include:

1. Documented information regarding a process, product or service;
2. Previous specifications and work instructions;
3. The experience of skilled people operating their processes;
4. Mentoring and coaching by more experienced employees;
5. Knowledge of technologies and infrastructure relevant to our organization, etc.

Sources of internal knowledge also include your business's intellectual property; knowledge gained from experience and coaching; lessons learnt from failures and successes; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services.