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in an appropriate format (e.g. language, software version, graphics) and on appropriate media (e.g. paper, electronic). Confirm that documented information is reviewed and approved for suitability and adequacy.

## Clause 7.5.3 - Controlling Documented Information

Clause 7.5.3 of ISO 9001:2015 is **comparable** to the requirements from ISO 9001:2008 – Control of Records. A robust document control process invariably lies at the heart of any compliant management system; almost every aspect of auditing and compliance verification is determined through the scrutiny of documented information. 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 documented information required by the QMS. A suitable process must be implemented to define the controls needed to; approve, review, update, identify changes, identify revision status and provide access. The documented information process should define the scope, purpose, method and responsibilities required to implement these parameters.

Departmental managers should always be responsible for promoting good documented information practices in their area whilst supporting overall compliance to the requirements. Individuals and their line managers should be responsible for the information that they create, as well as being responsible for their retention and disposal in line with legislative requirements and organizational needs.

## How to Develop Your Documentation

### Step 1: Determine how QMS documentation can be integrated into existing documents

Before you dive into your documentation, learn how deep the water is. Find out what documentation already exists, what its purpose is, and whether it works. The goal of this search is to locate materials you can use to begin your QMS implementation and documentation. Many facilities use the same format for all of their documents. An example of existing documentation might be a quality plan or tracking report.

### Step 2: Tailor the documentation to your organization's needs

You will probably have to compromise in producing documentation that meets your needs while also meeting your budget. Here are some questions to help you determine what fits your needs:

1. How can we use or revise existing documents rather than creating new ones?
2. Does our business operate in a single location or many? This will affect who creates some of the documents and where they are located. It may also affect how many versions of a document might be necessary to cover different circumstances.
3. What is our current computer capability? Many companies use an electronic system to maintain documents.
4. What security precautions do we need? While computer systems are handy, they often can be accessed by a number of people. Electronic documentation can be edited or destroyed. Security, or at least restrictions on who can change data, can be a critical issue for many companies that use electronic documentation systems.

### Step 3: Determine a standard format for all documents

Before developing your QMS documents, plan the format (document and page appearance) for the documents. If a company standard exists, use it. If not, the need for QMS documentation provides an