

16-5: Document control

Purpose of document control	<p>Documents, by definition, require updating. A system must be established for managing them so that current versions are always available. A document control system provides procedures for formatting and maintaining documents and should:</p> <ul style="list-style-type: none">• ensure that the most current version of any document is the one that is in use;• ensure availability and ease of use when a document is needed;• provide for the appropriate archiving of documents when they need to be replaced.
Elements of document control	<p>A document control system provides a method for formatting documents so that they are easily managed, and sets up processes for maintaining the inventory of documents. In this system the laboratory will need:</p> <ul style="list-style-type: none">• a uniform format that includes a numbering system, to include a method for identifying the version (date) of the document;• a process for formal approval of each new document, a distribution plan or list, and a procedure for updating and revising laboratory documents;• a master log or inventory of all documents of the laboratory;• a process to ensure that the documents are available to all who need them, including users outside the laboratory;• a method for archiving documents that become outdated but need to be kept for future reference.
Controlled documents	<p>All documents that are produced by and/or used in the laboratory must be included in the control system. Some important examples include:</p> <ul style="list-style-type: none">• SOPs—these must be up to date, showing the procedures that are in current use and, when work instructions or job aids are used, they must exactly match the SOPs for the tasks described;• texts, articles and books that are part of the documents referenced in a laboratory;• documents of external origin, such as instrument service manuals, regulations and standards, and new references (that may change over time).
Developing the document control system	<p>While establishing a document control programme, the following should be considered.</p> <ul style="list-style-type: none">• A system for standardizing the format and/or numbering—it is very useful to have a numbering or coding system that applies to all documents created within the organization. Because documents are “living” and require updating, the numbering system should indicate the document version.<ul style="list-style-type: none">- One suggestion for a numbering system is to use a letter for the type of document, then an incremented number for each of the documents of this type. All pages of the documents would contain the appropriate number. For example, B1, B2, B3, ... for books ; T1, T2, ... for official texts. A location code could be used, and would be useful for the master log or file. For example, “Book number 2, pages 188–200, on bookshelf 1” → B2, 188–200, BS1.

Implementing document control

- Establishing a document numbering system can be a difficult and time-consuming process. If the laboratory already has an effective system in place, there is no need to change it.
- Approval, distribution and revision process—control of documents requires that they be reviewed on a regular basis, with revision as needed, followed by approval and distribution to those who need them. The review and approval process is generally performed by laboratory management, and approval is indicated by signatures with appropriate dates. Policies for the approval, distribution and revision of documents should be clearly established as a part of the documents and records policy.
- Master log—this will allow the person responsible for document control to know exactly what is in circulation and where copies can be found. The log should be kept up to date at all times.
- Accessibility—the document control plan must provide a process for ensuring that relevant versions of documents are available at the point of use. This may include provision for having current sample collection information available outside the laboratory if collection is performed in other places, such as hospital wards or physician offices.
- System for archiving—remember that archiving old versions of documents will be very important. It is frequently necessary to refer to older versions of documents when researching a problem or when reviewing quality practices. As a part of the distribution process, it will be necessary to collect all old versions of the documents for archiving or destruction.

When implementing a new document control system, the following steps will be needed.

- Collect, review and update all existing documents and records—usually a laboratory without a document control system will find many outdated documents that will need to be revised.
- Determine additional needs—once all documents have been collected, it should be possible to determine needs for new process or procedure descriptions. If the quality manual has not yet been developed, this should probably be done at that time, as it serves as the framework for all the efforts.
- Develop or obtain examples of documents, including forms and worksheets, if needed—remember that forms of all kinds are documents, but once they have information added they become records. In order to help with formatting, examples from other laboratories or from published materials can be used.
- Involve stakeholders—it is useful when creating documents to be used in the laboratory to involve all staff who will be using them. For documents that will be used outside the laboratory, such as reports, it is very helpful to seek input from those who will use the reports.

Common problems

Some of the common problems found in laboratories that do not have document control systems, or that do not manage their document control systems include:

- Outdated documents in circulation.
- Distribution problems—if multiple copies of documents are dispersed throughout different areas of the laboratory, it will be cumbersome to gather all copies when it is time to update them, and some could be overlooked. For this reason, multiple copies should be avoided. Documents should not be distributed more widely than needed and a record should be kept of where all documents are located.
- Failure to account for documents of external origin—these documents may be forgotten in the management process, but it is important to remember that they may also become outdated and need to be updated.