16. Documents and records

16-1: Introduction

Role in quality management system

The management of documents and records is one of the 12 essential elements of the quality system. The management system addresses both use and maintenance of documents and records. A major goal of keeping documents and records is to **find information whenever it is needed.**

Documents and records—what are the differences?

Documents provide written information about policies, processes and procedures. Characteristics of documents are that they:

- communicate information to all persons who need it, including laboratory staff, users and laboratory management personnel;
- need to be updated or maintained;
- must be changed when a policy, process or procedure changes;
- establish formats for recording and reporting information by the use of standardized forms—once the forms are used to record information, they become records.

Some examples of documents include a quality manual, standard operating procedures and job aids.

Records are the collected information produced by the laboratory in the process of performing and reporting a laboratory test. Characteristics of records are that they:

- need to be easily retrieved or accessed;
- contain information that is permanent, and does not require updating.

Some examples of records include completed forms, charts, sample logs, patient records, quality control information and patient reports.

Information is the major product of the laboratory, so manage it carefully with a good system for the laboratory's documents and records.

16-2: Overview of documents

Documents include all the written **policies, processes and procedures** of the laboratory. In order to develop laboratory documents, it is important to understand each of these elements and how they relate to each other.

What is a policy?

A policy is "a documented statement of overall intentions and direction defined by those in the organization and endorsed by management".[1] Policies give broad and general direction to the quality system. They:

- tell "what to do", in a broad and general way;
- include a statement of the organizational mission, goals and purpose;
- serve as the framework for the quality system, and should always be specified in the quality manual.

Although there are national policies that affect laboratory operations, each laboratory will develop policies specific to its own operations.

What is a process?

Processes are the steps involved in carrying out quality policies. ISO 9000 [4.3.1][2] defines a process as a "set of interrelated or interacting activities that transform inputs into outputs".

Some examples of laboratory inputs include test requests, samples, and requests for information. Examples of laboratory outputs include laboratory data and reports of results. Using these examples, one process might be how to transform a test request (input) into a test result (output).

Another way of thinking about a process is as **"how it happens".** Processes can generally be represented in a flow chart, with a series of steps to indicate how events should occur over a period of time.

What are procedures?

Procedures are the specific activities of a process (ISO 9000 [3.4]). Procedures are very familiar to laboratorians—a procedure is easily described as the performance of a test.

A procedure tells **"how to do it"**, and shows the step-by-step instructions that laboratory staff should meticulously follow for each activity. The term **standard operating procedure (SOP)** is often used to indicate these detailed instructions on how to do it.

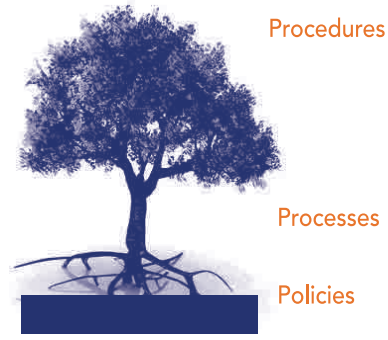
Job aids, or work instructions, are shortened versions of SOPs that can be posted at the bench for easy reference on performing a procedure. They are meant to supplement, not replace, the SOPs.

1 CLSI/NCCLS. *A quality management system model for health care; approved guideline—second edition.* CLSI/NCCLS document HS1-A2. Wayne, PA, NCCLS, 2004.

2 ISO 9000:2005. *Quality management systems—fundamentals and vocabulary.* Geneva, International Organization for Standardization, 2005.

Document hierarchy

A good way to represent the relationship of policies, processes and procedures is as a tree. The policies are represented by the roots, and they form the base for all the other parts. The processes can be viewed as the trunk of the tree, representing a series of steps or flow of actions through the laboratory. The leaves of the tree can be thought of as the procedures; there will be many procedures in the laboratory for accomplishing the activities or the work.



The quality manual is the overall guiding document that defines the quality system through policies established by the laboratory. Next in the hierarchy of documents are the processes, the sets of activities. Procedures either flow from processes, or make up a part of a process; these will generally be described as SOPs. Work instructions or job aids are shortened versions of SOPs. Finally, forms are used to record results; when completed, they become records.

Why are documents important?

Documents are the essential guidelines for all of the laboratory operations. Some of the important documents that every laboratory should have include:

- Quality manual—this is the overall guiding document for the quality system and provides the framework for its design and implementation. A laboratory is required to have a quality manual for ISO accreditation (the quality manual is discussed further in sections 16-3 and 16-4).
- SOPs—SOPs contain step-by-step written instructions for each procedure performed in the laboratory. These instructions are essential to ensure that all procedures are performed consistently by everyone in the laboratory.
- Reference materials—good reference materials are needed in order to find scientific and clinical information about diseases, laboratory methods, and procedures. Sometimes, there are difficult interpretive issues, for which references or textbooks will be needed. As an example, when examining samples microscopically for parasites, photographs and descriptive information can be very helpful.

Written documents are required by formal laboratory standards, including those leading to accreditation. Standards generally require that policies and procedures be written and available. Most inspection or assessment activities include an examination of the laboratory's documents. The documents are an important element on which the laboratory is assessed.

Documents are the communicators of the quality system. All policies, processes and procedures must be written, so that everyone will know the proper procedures and can carry them out. Verbal instructions alone may not be heard, may be misunderstood, are quickly forgotten and are difficult to follow. Everyone, both inside and outside the laboratory, must know exactly what is being done and what should be done at each step. Therefore, all of the guidelines must be written so that they are available and accessible to all who need them.

Documents are a reflection of the laboratory's organization and its quality management. A well-managed laboratory will always have a strong set of documents to guide its work.

A good rule to follow is "Do what you wrote and write what you are doing".

What makes a good document?

Documents communicate what is done in the laboratory. Good documents are:

- written clearly and concisely—it is better to avoid wordy, unnecessary explanations in the documents;
- written in a user-friendly style—it might be helpful to use a standard outline so the general structure will be familiar to staff and easily used by new personnel;
- written so as to be explicit and accurate, reflecting all implemented measures, responsibilities and programmes;
- maintained to ensure that it is always up to date.

Accessibility

The documents needed in the work process must be accessible to all staff. Persons managing samples should have the procedures for sample management directly available to them. Testing personnel will need the SOPs in a convenient place, and perhaps a job aid posted in clear view of the workspace where testing is performed. The testing personnel need immediate access to quality control charts and troubleshooting instructions for equipment. All staff must have access to safety manuals.