Content Sheet 16-1: Introduction to Documents & Records

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 (SOP), 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.

Content Sheet 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.

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.

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[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.

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.
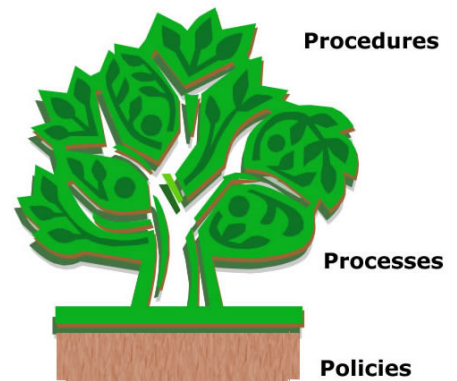
The quality manual is the overall guiding document that defines the quality system through policies established by the laboratory. Next in the hierarchy of documents are the processes, the sets of activities. Procedures either flow from processes, or make up a part of a process; these will generally be described as standard operating procedures (SOP). 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 content sheets 16-3 and 16-4).

- Standard Operating Procedures (SOP)—SOP 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/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 programs;

- 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 work space where testing is performed.

The testing personnel need immediate access to quality control charts and trouble-shooting instructions for equipment. All staff must have access to safety manuals.

Content Sheet 16-3: The Quality Manual

What is a quality manual?

The quality manual is a document that describes the quality management system of an organization (ISO 15189). Its purpose is to:

- clearly communicate information;

- serve as a framework for meeting quality system requirements;

- convey managerial commitment to the quality system.

As the quality manual is an important guide or roadmap, all persons in the laboratory should be instructed on its use and application. The manual must be kept up to date, and responsibility for the updating should be assigned.

Writing a quality manual

Although ISO 15189 standards require that laboratories have a quality manual, the style and structure are not specified. There is considerable flexibility in how to prepare it, and a laboratory can construct the manual so that it is most useful and suited to the needs of the laboratory and its customers.

When writing a quality manual, it is a good idea to use a steering committee. Because the quality manual needs to be tailored to the specific needs of the laboratory, each facility should carefully consider how to best involve those who are needed. Involve the policy makers for the laboratory. It is also essential to involve the bench technologists, to take advantage of their expertise and get their buy-in.

The quality manual should state policies for each of the twelve essentials of the quality system. Also describe how all the related quality processes occur, and make note of all versions of procedures (SOP), and where they are located. For example, SOPs are a part of the overall quality system. Although there are usually too many to include directly in the quality manual, the manual should specify that SOPs be developed, and indicate that they be compiled in the SOP manual.

Annex 16-A and Annex 16-B show examples of the table of contents from quality manuals provided by ISO 15189 and CLSI, respectively. These examples give suggestions for topics to include when developing a quality manual.

Key Points

The key points to remember about the quality manual are:

- there is only ONE official version;

- the quality manual is never finished; it is always being improved;

- it should be read, understood, and accepted by everyone;

- it should be written in clear, easily-understood language;

- the quality manual should be dated and signed by the management.

Developing a quality manual is a very big job, but it is also very rewarding and useful for the laboratory.

Content Sheet 16-4: Standard Operating Procedures (SOP)

What is an SOP?

Standard Operating Procedures (SOP) are also documents, and contain written step-by-step instructions that laboratory staff should meticulously follow when performing a procedure. A laboratory will have many SOPs, one for each procedure conducted in the laboratory.

Written SOPs ensure the following.

- Consistency—Everyone should perform the tests exactly the same so that the same result can be expected from all staff. Consistency enables people who use laboratory results to observe changes in a particular patient's results over time; if different laboratories use the same SOPs, comparisons of their results can be made; it should be emphasized that all laboratory staff must follow the SOPs exactly.

- Accuracy—Following written procedures help laboratory staff produce more accurate results than relying on memory alone because they won't forget steps in the process.

- Quality—Together, consistent (reliable) and accurate results are primary goals of the laboratory, and could be considered as the definition of quality in the laboratory.

A good SOP should be as follows.

- Detailed, clear, and concise, so that staff not normally performing the procedure will be able to do so by following the SOP. all necessary details, for example, ambient temperature requirements and precise timing instructions, should be included.

- Easily understood by new personnel or students in training.

- Reviewed and approved by the laboratory management. Approval is indicated by a signature and a date; this is important to assure that the procedures being used for testing in the laboratory are those that are up-to-date and appropriate.

- Updated on a regular basis.

Standardized format

It is a good idea to standardize the formats of SOPs so staff can easily recognize the flow of the information.

Headers are a very important part of the format. Below are examples of two different types of headers that could be used when writing an SOP.

- Complete Standardized Header—Typically the standardized header would appear on the first page of each SOP. The standardized form makes it easy for staff to quickly note the pertinent information.

TML\MSH Microbiology Department Policy & Procedure Manual	Policy # MI\RESP\11\v05	Page 1 of 5
Section: **Respiratory Tract Culture Manual**	Subject Title: **SPUTUM (Including Endotracheal Tube and Tracheostomy Specimens)**	
Issued by: **LABORATORY MANAGER**	Original Date: September 25, 2000	
Approved by: Laboratory Director	Revision Date: September 14, 2006	
	Annual Review Date: August 13, 2007	

- Reduced Standardized Header—This standardized form includes a smaller version of the header that would appear on all pages other than the first.

TML\MSH Microbiology Department Policy & Procedure Manual **Respiratory Tract Culture Manual**	Policy # MI\RESP\11\v05	Page 2 of 5

An example of a SOP is provided in Annex 16-C.

Preparing SOPs

There are a few things to keep in mind when preparing an SOP. Firstly, it is important to assess the scientific validity of the procedure. Then, when writing the procedure, include all steps and details explaining how to properly perform the procedure. The SOP should refer to any relevant procedures that may be written separately, such as instructions for sample collection or quality control. Finally, a mechanism should be established for keeping SOPs updated.

SOPs should include the following information.

- Title—name of test.

- Purpose—include information about the test—why it is important, how it is used, and whether it is intended for screening, to diagnose, or to follow treatment; and if it is to be used for public health surveillance.

- Instructions —detailed information for the entire testing process, including pre-examination, examination and post-examination phases.

  Pre-examination instructions should address sample collection and transport to the laboratory, and conditions needed for proper sample handling. For example, instructions should indicate whether the sample needs a preservative, whether it should be refrigerated, frozen, or kept at room temperature. Instructions should also reflect laboratory policies for sample labelling, such as requirements to verify more than one type of patient identification, to write the collection date on the sample label, and to make sure all information needed is included on the test request form.

  Examination instructions should address the actual step-by-step laboratory procedures to follow and the quality control procedures needed to ensure accuracy and reliability.

  Post-examination instructions should provide information on reporting the results, including the unit of measurement to be used, the normal (reference) range, ranges that are life-threatening (sometimes called "panic values"), and instructions for how

to deal with an urgent report. They should also include references to the published sources of the procedures, including published evidence that the procedures are scientifically valid.

- Name of the person preparing the SOP.

    signatures of approving officials and dates of approval—It is necessary to follow the laboratory's quality policy and regulatory requirements.

Manufacturer's instructions

The instructions that manufacturers provide in their product inserts tell how to perform the test, but do not include other important information that is specific to laboratory policy, such as how to record results, algorithms outlining the sequence of testing, and safety practices. The manufacturer's instructions may describe recommended quality control procedures for the test, but the recommendations may not be as comprehensive as protocols that a laboratory has put into place. **Do not rely solely on manufacturer product inserts for SOPs. Use information from these inserts, but develop SOPs specific to your laboratory.**

What is a Job aid?

A job aid is a shortened version of an SOP. It is designed for use directly at the testing site. It should be placed in a visible location, and serves as a reminder of the steps that need to be completed. The job aid and the SOP must include the same instructions. If a job aid is distributed to sources outside the laboratory, ensure that the information illustrated matches that which is instructed in the SOP. External laboratory assessors often check to see if job aids and SOPs are in accordance.

- shortened version of SOPs
- hand written or printed
- visible location at testing site
- useful tool to assure all testing steps are correctly performed

Job aids supplement–not replace–the SOP. They do not include all the details that are provided in the SOP.

An example of a job aid is provided in Annex 16-D.

Content Sheet 16-5: Document Control

Purpose of document control

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:

- assure that the most current version of any document is the one that is in use;

- ensure the 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

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:

- 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

All documents that are produced by and/or used in the laboratory must be included in the control system. Some important examples include:

- Standard Operating Procedures (SOP)—It is essential to have all SOPs up-to-date, showing the procedures that are in current use. Also, 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

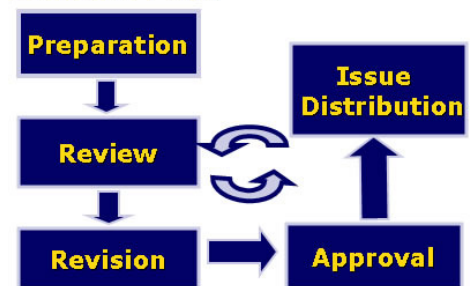While establishing a document control program, the following should be considered.

- 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.

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.

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.

Document Preparation and Control Process

- Accessibility—The document control plan must provide a process for assuring 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/destruction.

Implementing document control

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 the following.

- 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.

Content Sheet 16-6: Overview of Records

Importance of records
Remember that records are laboratory information, either written by hand or computer-printed. They are permanent, and are not revised or modified. They should be complete, legible and carefully maintained, as they are used for many purposes, such as:

- continuous monitoring—without access to all the data collected as a part of a quality system process, continuous monitoring cannot be accomplished;

- tracking of samples—well-kept records allow for tracking of samples throughout the entire testing process; this is essential for troubleshooting, looking for sources of error in testing, and investigating identified errors;

- evaluating problems—well-kept equipment records will allow for thorough evaluation of any problems that arise;

- management—good records serve as a very important management tool.

- etc.

Never change a record. If new information needs to be added to a record, it should be noted as an addition, with a date, and signature or initials.

Examples of laboratory records
Many kinds of records are produced in a laboratory. Some examples include:

- sample log book, registers;
- laboratory workbooks/sheets;
- instrument printouts –maintenance records
- quality control data
- EQA / PT records
- patient test reports
- personnel records
- results of internal and external audits
- continuous improvement projects
- incident reports
- user surveys and customer feedback
- critical communications: i.e. letters from regulatory agencies, from government, or maybe from administrative offices within the healthcare system.

A method to record any information that must be kept should be established. The following type of records could be easily forgotten.

- Information on the management and handling of rejected samples.

- Data needed on any sample referred to another laboratory; to include when the sample was transported, where it was sent, and when the report was issued. The sample should be able to be tracked throughout the referral process.

- Information about adverse occurrences or problems. Include all information that is pertinent, such as the results of any investigation of the problem (see Module 14 - Occurrence Management).

- Inventory and storage records. These help keep track of reagents and supplies; (see Module 4 - Purchasing and Inventory).

- Equipment records.

Test report contents

Test reports should be designed so that all information that is needed by the laboratory, the laboratory users, and for any accreditation requirement, is included.

The following is a list of test report contents required by ISO 15189:

- identification of test;
- identification of laboratory;
- unique identification and location of patient, where possible, and destination of the report;
- name and address of requestor;
- date and time of collection, and time of receipt in laboratory;
- date and time of release of report;
- primary sample type;
- results reported in SI units or units traceable to SI units, where applicable;
- biological reference intervals, where applicable;
- interpretation of results, where appropriate;
- applicable comments relating to quality or adequacy of sample, methodology limitations, or other issues that affect interpretation;
- identification and signature of the person authorizing release of the report;
- if relevant, notation of original and corrected results.

Many of the items listed above are used by laboratories for their report forms. Some may be used less often, depending on the test and the context. For some tests, the report form may also need to include the patient's gender, as well as the date of birth (or age).

Content Sheet 16-7: Storing Documents and Records

Where to keep documents and records

Storage must be given careful consideration, as the main goal of documentation is finding the information when it is needed.

Using a paper system

It is important to consider the following when using a paper system for records.

- Permanence—paper records must last for as long as needed. This should be ensured by binding pages together, or using a bound book (log register). Pages should be numbered for easy access, and permanent ink used.

- Accessibility—paper systems should be designed so that information can be easily retrieved whenever needed.

- Security—documents and records must be kept in a secure place. Security considerations include maintaining patient confidentiality. Care should be taken to keep documents safe from any environmental hazards such as spills. Consider how records can be protected in the event of fires, floods, or other possibilities.

- Traceability—it should be possible to trace a sample throughout all processes in the laboratory, and later to be able to see who collected the sample, who ran the test, and what the quality control results were for the test run including issuing of the report.

  This is important in the event there are questions or problems about any reported laboratory result. All records should be signed, dated, and reviewed to ensure that this traceability throughout the laboratory has been maintained.

Using an electronic system

Electronic systems have essentially the same requirements as paper systems. However, the methods for meeting these requirements will be different when using computers. The following are factors to consider.

- Permanence—backup systems in case the main system fails are essential. Additionally, regular maintenance of the computer system will help to reduce system failures and loss of data.

- Security—it is sometimes more difficult to assure confidentiality with a computer system, as many people may have access to the data.

- Traceability—electronic record systems should be designed in a way that allows for tracing the specimen throughout the entire process in the laboratory. Six months after performing an examination, it should be possible to look at the records and determine who collected the specimen and who ran the test.

Record retention Retention times for records should be determined in each laboratory, based on a number of factors:

- the length of time the laboratory will need to have access to its records;

- government requirements or standards that dictate record retention times;

- whether the laboratory is engaged in ongoing research requiring many years of data;

- the time interval between the laboratory's assessments or audits.

Content Sheet 16- 8: Summary

Summary   Documents include written policies, processes, and procedures, and provide a framework for the quality system. They need to be updated and maintained.

Records include information captured in the process of performing and reporting a laboratory test. This information is permanent, and does not require updating.

Having a good document control program assures that the most current version of a document is used, and ensures availability and ease of access when a document is needed.

Key messages
- Information is our product.
- Documents are essential for assuring accuracy and consistency in the laboratory.