CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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QMS02-A6

Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition

This document provides guidance on the processes needed for document management, including creating, controlling, changing, and retiring a laboratory's policy, process, procedure, and form documents in both paper and electronic environments.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition

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Abstract

Clinical and Laboratory Standards Institute document QMS02-A6—*Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition* presents the important components of creating, evaluating, approving, controlling, changing, and retiring documents used in the laboratory environment. This guideline describes the processes needed in a document management system, whether paper-based or electronic. Key features of electronic document management systems are described. Several examples of process and procedure documents for preexamination, examination, and postexamination laboratory activities are included.

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Foreword

Control of documents and records (DR) is critical to optimizing the effectiveness of a QMS and sustaining quality. This guideline encourages using an organized process-based approach for implementing and managing a program to develop and control the medical laboratory's many documents. In an environment of document management, only approved versions of paper-based or electronic documents are available for use by staff in all locations where they are needed.

DR is one of the 12 quality system essentials (QSEs) in CLSI document GP26,[1] which describes a structured approach to organizing, creating, and maintaining the necessary information for the QSEs. The QMS model depicted in Figure 1 demonstrates how each QSE, such as DR, is a building block to quality that is necessary to support any laboratory's path of workflow (POW) from preexamination to examination to postexamination. This document is designed to guide the user in the development and implementation of a document management system.

Figure 1. The Quality Management System Model (see CLSI document GP26)[1]

If a QSE is missing or not well implemented, problems may occur in any or all preexamination, examination, and postexamination laboratory activities, as well as laboratory management activities. For example, when the laboratory lacks defined processes for properly installing, calibrating, and maintaining its instruments so they work effectively, problems will occur in examination processes.

The requirements for QSE DR can be summarized as:

- Development and maintenance of a document management system
- Development and maintenance of a record management system

The current edition of QMS02 will focus only on the processes within a document management system.

Overview of Changes From GP02-A5

Previous editions of QMS02 have focused on essential elements to include in laboratory examination procedures.

This edition of QMS02 has been reorganized to provide guidance for:

- Using an overall process for document management and control
- Using flow charts to depict the sequence of activities in laboratory processes
- Preparing instructions for performing procedures in the preexamination, examination, and postexamination processes in the laboratory's POW
- Preparing process and procedure documents specifically for multitest automated analyzers
- Writing procedures for the LIS
- Managing and controlling paper-based and electronic laboratory documents after they are approved for use

Key Words

Computer procedure, document, document control, document management, electronic procedures, laboratory procedure, laboratory process, procedures manual, technical procedures

Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition

1 Scope

This guideline presents evidence-based suggestions for preparing different types of laboratory documents. In addition, a process is described for how laboratory documents can be managed and controlled from the time a need is recognized for a new or revised document, through the document's use and control, until the time it is retired.

This guideline is applicable to documents used by medical laboratories of any size, complexity, or specialty, including point-of-care testing.

QMS02 is intended for use by the following:

- Administrative and technical personnel who develop laboratory documents
- Manufacturers
- Educators
- Regulatory and accreditation organizations

QMS02 is a *guideline* for how to implement requirements established in international standards, and by regulatory and accrediting organizations for laboratory documents and procedures manuals. ***QMS02 is not a standard;*** that is, this guideline does not set requirements for laboratory documents and procedures. **Instead, this guideline describes what laboratories need to do to meet published regulations, accreditation requirements, and international standards[2-13] for documents and document management, and provides suggestions and examples for fulfilling the requirements.**

2 Introduction

All work happens in processes—that is, sequences of activities that a laboratory needs to perform in a specific order, and correctly, to transform a given input into the desired output. Laboratories need to communicate both the sequence of activities (ie, process) as well as the instructions for how to perform a given process activity (ie, procedure). Documented processes and procedures provide essential information for both new and experienced employees about how to perform all of their job tasks—including tasks not related to directly performing examinations, such as training, competence assessment, collecting blood samples, and using the laboratory's computer system.

To provide structure for the document management system described in this guideline, a process for how a laboratory can manage and control its documents is introduced. The flow chart starts with awareness of a need for a new document and proceeds through the lifespan of a document from development, evaluation, approval, distribution, review, change, and finally retirement. Figure 2 shows the activities and decisions in an effective document management process. Each main activity in the process is shown in a box; decisions made regarding documents are shown in a diamond as a question with a yes/no answer. Each activity, with its respective decisions and actions, is discussed in a separate section of this guideline; section numbers are shown to the left of the respective activities. Additional information to assist with developing a document management system is found in later sections.

This guideline provides several examples of common laboratory processes and procedures. Laboratories are encouraged to use these examples as starting points for documenting their own processes and procedures. Although there are specified international standard, regulatory, and accreditation requirements for needed contents of laboratory procedures manuals, *there are no specific requirements*

for the formats of laboratory documents. Therefore, this guideline presents evidence-based suggestions for document formats that effectively communicate management's message to staff about how to do the laboratory's work.[14]

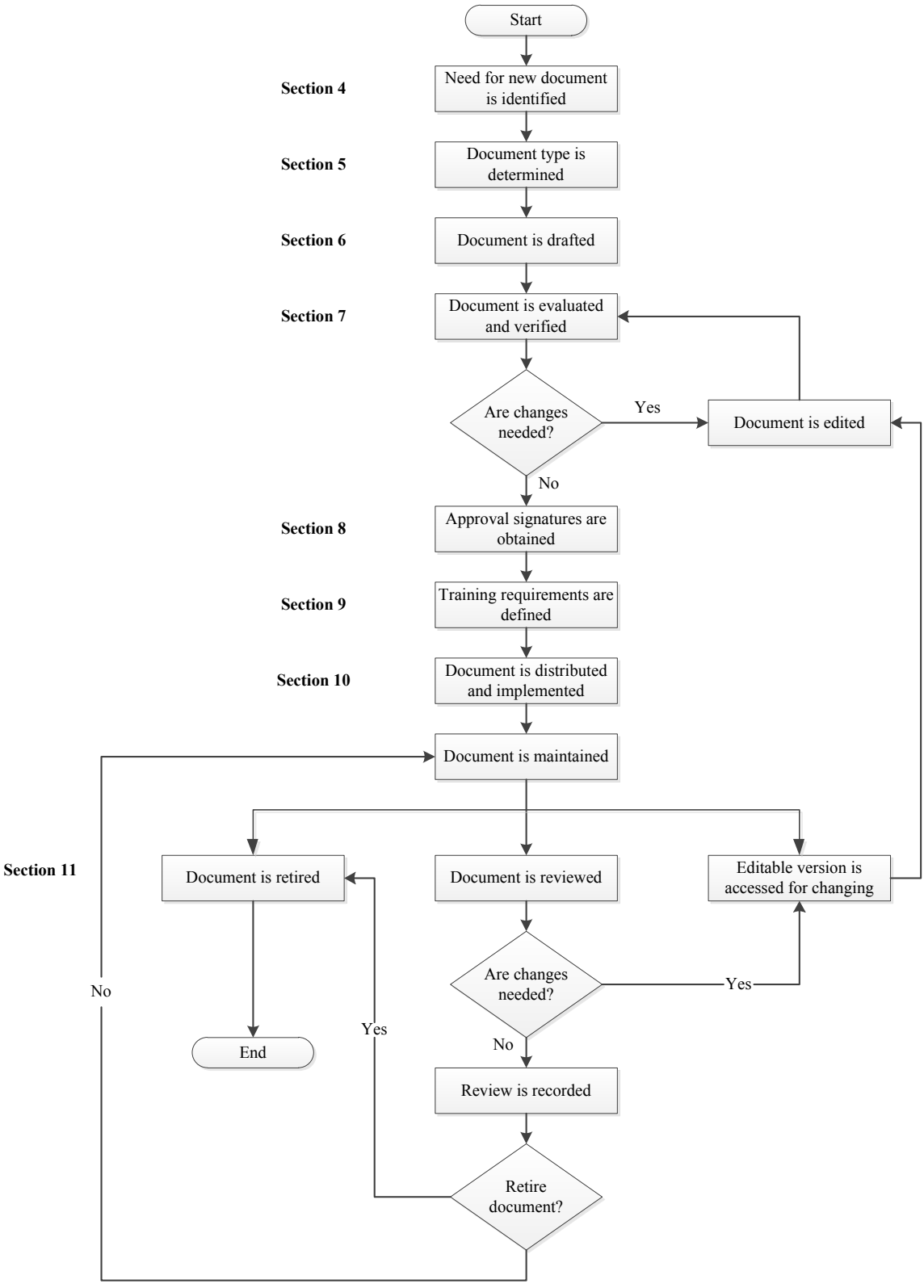

Figure 2. Document Management Process. This process shows the activities performed and decisions made throughout the lifespan of a document.

3 Terminology

3.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in CLSI, International Organization for Standardization (ISO), and European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. In light of this, CLSI's consensus process for development and revision of standards and guidelines focuses on harmonization of terms to facilitate the global application of standards and guidelines.

The words "must" and "shall" reflect language used in the requirements of regulatory and accreditation organizations; therefore, these words do not appear in the text of this guideline. Where the phrase "needs to" appears in this document, the statement in which it appears is a restatement of a published requirement for medical laboratories. This deliberate convention is used to make it clear to the reader that the activity described is not optional and assessment is likely during licensure and accreditation inspections.

Where other words are used such as "should," "could," or "recommended," the statements in which they appear are intended as guidance and offer options for how a laboratory can meet the published requirement. These are intended as suggestions only and do not constitute a laboratory's only option.

3.2 Definitions

conformance – fulfillment of a requirement (ISO 9000).[15]

controlled copy – an approved document that bears all appropriate document control markings such as identification and revision status; **NOTE:** Controlled copies are distributed for use within the facility and are accounted for when revisions are made, to ensure that obsolete copies are removed from potential use.

document – information and its supporting medium (ISO 9000).[15]

document control coordinator – person responsible for managing document creation, review, editing, and distribution.

draft – a rough or preliminary piece of writing.

examination – set of operations having the object of determining the value or characteristics of a property (ISO 15189)[2]; **NOTE 1:** In some disciplines (eg, microbiology), an examination is the total activity of a number of tests, observations, or measurements (ISO 15189)[2]; **NOTE 2:** In this document, the term "examination" replaces the term "test"; however, for the purposes of this guideline, readers can consider the terms equivalent.

flow chart – diagram, often using geometric symbols, showing the sequence of activities and decisions made in a process; also commonly referred to as "process map."

form – a paper or electronic document on which the results from the performance of a procedure or other information are captured; a completed form becomes a record.

job aid – information excerpted from an approved procedure that is presented in a more readily viewable format; job aids are subject to document control.

policy – set of basic principles or guidelines that directs or restricts the facility's plans, actions, and decisions.

procedure – a specified way to carry out an activity or a process (ISO 9000)[15]; **NOTE:** For a QMS, a procedure is a set of instructions that describes the stepwise actions taken to complete activities identified in processes.

process – set of interrelated or interacting activities that transforms inputs into outputs (ISO 9000)[15]; **NOTE:** A process may be documented as a flow chart or table that describes operations in the laboratory's path of workflow or activities within a quality system essential.

process map – see **flow chart.**

record – (noun) evidence of results achieved or activities performed (ISO 9000).[15]

record – (verb) the action of documenting activities performed or results achieved.

sample – one or more parts taken from a primary sample (ISO 15189)[2]; **NOTE 1:** For example, a volume of serum taken from a larger volume of serum (ISO 15189)[2]; **NOTE 2:** In this document, the term "sample" replaces the term "specimen"; however, for the purposes of this guideline, readers can consider the terms equivalent.

sorting – act of dividing a group of persons or things related by having something in common.

template – design, mold, or pattern of an item or group of items that serves as a basis or guide for designing or constructing similar items.

uncontrolled copy – copy of an approved document for use within a specified time period, or for a special use (eg, approved distribution outside the facility to a regulatory or accreditation organization) *and* that is marked in a manner (eg, not controlled) to indicate that the copy will not be accounted for when making revisions or retiring the document.

workflow – progression of tasks, events, or interactions that comprise a work process, involve two or more persons, and create or add value to the organization's activities; in a sequential workflow, an activity is dependent on the activity that precedes it, and in a parallel workflow, two activities can take place concurrently[16]; **NOTE:** The laboratory's path of workflow is sequential.

3.3 Abbreviations and Acronyms

CEN	Comité Européen de Normalisation (European Committee for Standardization)
DR	documents and records
ID	identification
ISO	International Organization for Standardization
LIS	laboratory information system
NCE	nonconforming event
PDF	portable document format
POW	path of workflow
QC	quality control
QMS	quality management system
QSE	quality system essential
SOP	standard operating procedure

4 Need for New Document

4.1 International Influence

International standards have influenced organizations worldwide to understand and manage their operations as both work processes that produce the organization's products and services, and quality processes that support the organization's QMS.[2-4] A QMS helps to ensure accuracy and consistency in all organizational functions, and requires that organizations control and continuously improve their work processes.

4.2 The Quality Management System and Documentation Management

A QMS is a systematic, process-oriented approach to meeting a laboratory's quality objectives. CLSI document GP26[1] introduced the concept of the building blocks of a QMS—the Quality System Essentials (QSEs)—as shown in Figure 1 in the Foreword.

This guideline focuses on QSE Documents and Records (DR), and the requirements for an effective document management system. Documentation serves multiple purposes, supporting high-quality operations for all laboratories regardless of size, and all personnel from the newest employee to the laboratory director, regardless of their lengths of service. The first step in understanding document management is to understand the types of documentation used in a laboratory QMS.

4.3 Documentation Hierarchy

A common conceptual structure for documentation is shown in Figure 3. Usually, four tiers of documents are used in a typical medical laboratory: policies, processes, procedures/job aids, and forms. *Policies* describe the organization's goals and intentions—the "what is done and why." *Process* maps show the sequence of events that produce a product or service—the "how it happens." *Procedures* (and corresponding job aids) provide step-by-step instructions—the "how to do it." *Forms* capture information and results generated as the process proceeds. The documents behave in a downward cascade so that a policy on the first tier sets the intent and direction for the process or processes to fulfill it, the processes describe the activities needed to turn the intent into action, and the procedures provide instructions for the activities in the processes. It is possible that when there is a change in policy, the corresponding processes, procedures, and forms in the lower tiers may need to be revised as well. However, when a procedure or job aid is revised, it may not necessarily affect its corresponding process map or policy.

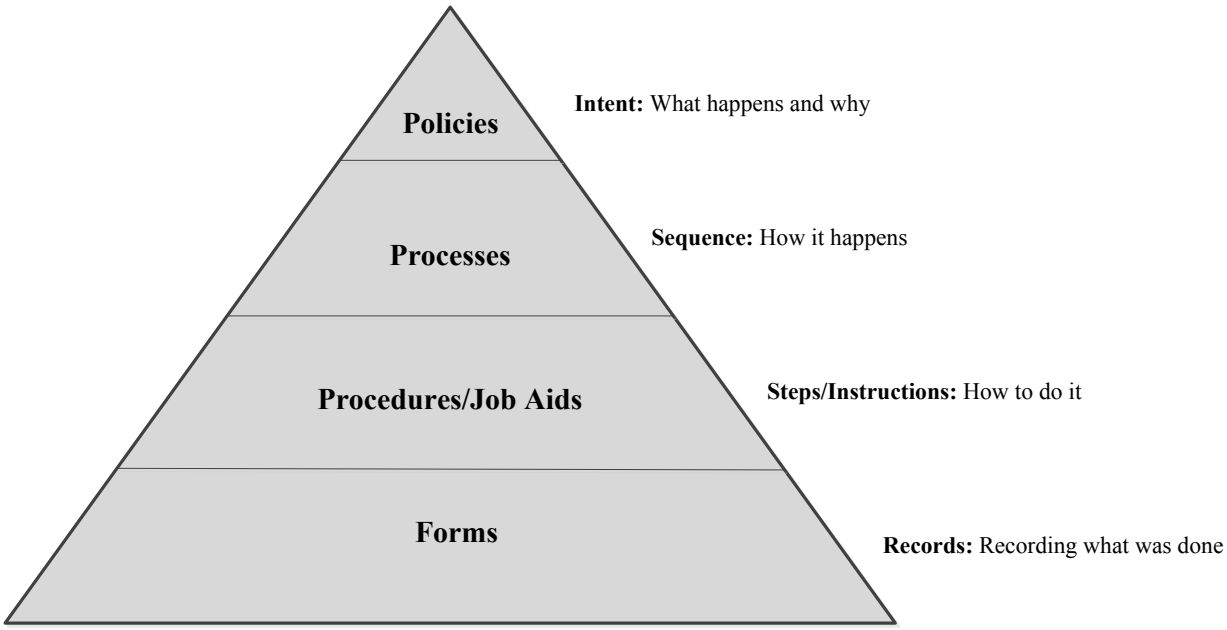

Figure 3. Document Hierarchy Pyramid

4.4 Documentation Categories

In a medical laboratory, there are two families of documents: those related to the activities of the QMS (quality documents) and those that describe the laboratory's technical activities (operations documents). Whereas quality documents may be similar between laboratories, operations documents are usually more facility-specific. In addition, much information contained in operations "policy" documents usually consists of rules, cautions, or warnings that are best presented in the respective portions of operations procedures documents. These concepts are shown in a more detailed version of the document hierarchy (see Figure 4).

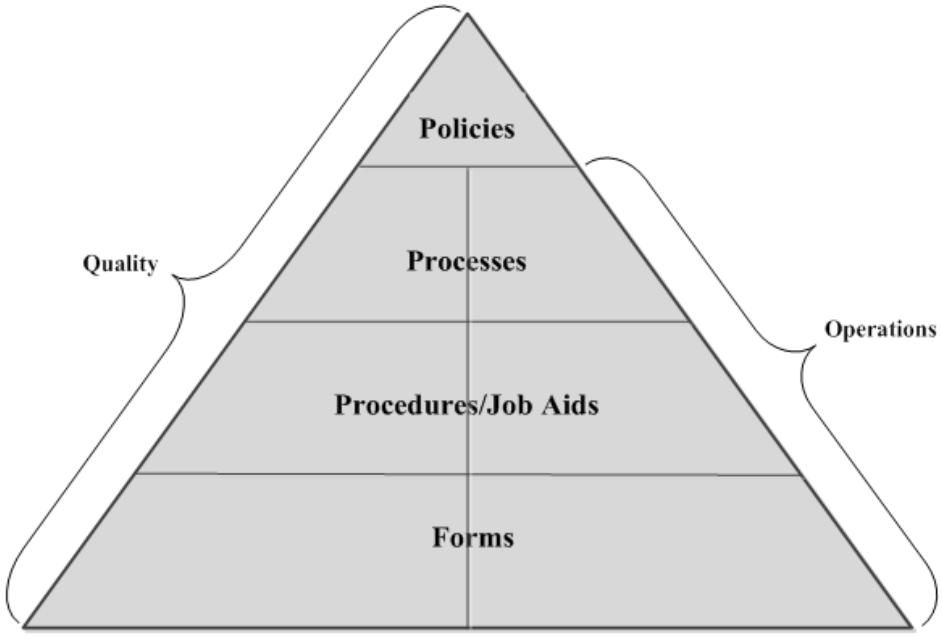

Figure 4. Document Hierarchy Pyramid With Documentation Categories

4.4.1 Quality Documents

A well-designed, documented, and implemented QMS reflects the laboratory's commitment to operate according to practices that have been shown to produce high-quality outcomes. Compared to operations documents, quality management documents usually include more policies and fewer processes and procedures; however, the need for training and reliable delivery of quality activities is as important as for technical activities.

Laboratories usually have operations procedures in place for their technical staff because the examinations and testing work need clear instructions. However, laboratories have been historically less attentive to documenting nontesting, nontechnical, quality management, and support processes and related procedures. Developing and implementing missing quality management documents can help focus and standardize activities even in the most mature laboratory operation.

4.4.2 Operations Documents

Operations documents detail how laboratory-specific activities at a particular facility are done. When used for training, operations documents ensure that staff are getting the same instructions and are prepared to seamlessly fit into the work processes according to their roles. Operations documents serve as reminders and resources for staff when questions arise, and can be used to define how things are supposed to happen so that deviations can be readily identified when problems occur.

5 Document Type Is Determined

In this section, each document tier is described in more detail. The definitions and uses of each document type are identical for both quality and operations documents. In general, each tier of the document pyramid can be easily defined by one word or simple phrase, as detailed in Figure 3, while Figure 5 illustrates where more information can be found in Section 5 for each tier.

NOTE: Specific contents of policy, process, procedure, and form documents are discussed further in Section 6; useful examples are provided as appendixes to that section.

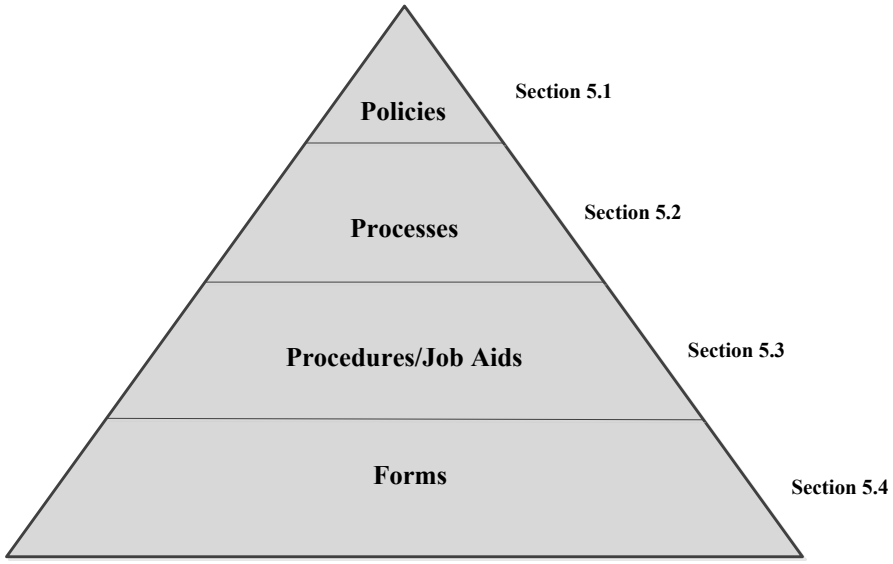

Figure 5. Document Types and Related QMS02 Sections

5.1 Policies

The starting point for all laboratory documents is tier 1 of the documentation hierarchy pyramid. In the laboratory environment, policy documents reflect the laboratory's intent to fulfill requirements it must meet to obtain an operating license or achieve accreditation. Tier 1 policy documents are typically written by laboratory leadership and describe what happens and why it happens, as well as state the laboratory's intent to deliver these actions. It is recommended that, at a minimum, each laboratory should have a policy that states its intent for the requirements contained in each QSE. In a formal QMS, these policies are compiled into a collection known as "the Quality Manual" (see CLSI document GP26).[1] Additional policies may be created, where needed.

Appendixes A and B provide examples of policies for QSEs Facilities and Safety and Nonconforming Event (NCE) Management. An example of a policy for QSE DR is included in CLSI document GP26.[1]

5.2 Processes: Quality and Operations

Each laboratory needs to identify key quality management and work operations processes, and determine whether these are already well documented or if there is a gap. CLSI document GP26[1] contains a list of key quality management processes that every laboratory should have for the 12 QSEs. By identifying the tier 2 key processes, a laboratory will then be able to determine what type of documentation is needed to support these activities.

5.2.1 Process Maps and Flow Charts: Quality and Operations

As the laboratory identifies key quality and work operations processes, these processes should be documented. A flow chart or process map is highly recommended for each process because such a document serves as a high-level overview of the work being performed. Flow charts define sequential process activities and serve as a roadmap for identifying key activities and decision points for which instructions are needed. Flow charts also assist in identifying connections to other processes. Instructions on how to create a flow chart can be found in Section 6.5.3.

Traditionally, laboratories have been functionally, and often physically, divided into specific clinical disciplines such as chemistry, hematology, microbiology, and transfusion services for specialized examination methods. More recently, many laboratories have segregated along manual and automated examination methods. Each laboratory or clinical discipline—however it is organized—needs to identify all of its automated and manual examination processes.

5.2.2 Quality Processes

Quality processes are described in the QSEs, and are mandated by international, national, regional, and organizational requirements. A list of process examples for each QSE is shown in Table 1. Note that this list is not all-inclusive. A complete list of quality processes is provided in CLSI document GP26.[1] An example of a quality process for QSE Assessments is provided in Appendix C.

Table 1. Examples of Processes for Each QSE

QSE	Process Examples
Organization	• Quality Planning Process • Management Review Process
Customer Focus	• Complaints Tracking Process • Obtaining Customer Feedback Process
Facilities and Safety	• Disaster Management Process • Health Risk Assessment Process
Personnel	• Work Operations Training Process • Ongoing Competence Assessment Process
Purchasing and Inventory	• Supplies Replenishment Process • Laboratory Inventory Management Process
Equipment	• Preventive Maintenance Process • Equipment Decommission Process
Process Management	• Laboratory-Developed Method Validation Process • QC Plan Development Process
DR	• Document Creation, Review, and Approval Process • Document Management Process (as shown in Figure 2)
Information Management	• Fulfilling Request for Release of Patient Records Process • LIS Downtime Process
NCE Management	• Investigating an NCE Process • Analyzing NCEs Process
Assessments	• Proficiency Testing Process • Quality Indicator Development Process • Internal Laboratory Audit Process
Continual Improvement	• Root Cause Analysis Process • Plan-Do-Check-Act Process

Abbreviation: DR, documents and records; LIS, laboratory information system; NCE, nonconforming event; QC, quality control; QSE, quality system essential.

5.2.3 Operations Processes

Operations processes are laboratory-specific and based on the laboratory's respective functions, methods, and instrumentation. All operations processes have a place in the laboratory's overall path of workflow (POW). All laboratory work is a sequence of key processes in which the laboratory uses resources such as people, methods, materials, and instruments to transform orders for laboratory examinations into results and reports for patient management. Key processes for the laboratory are also referred to as the "total testing process," and are shown in Figures 6 through 9.

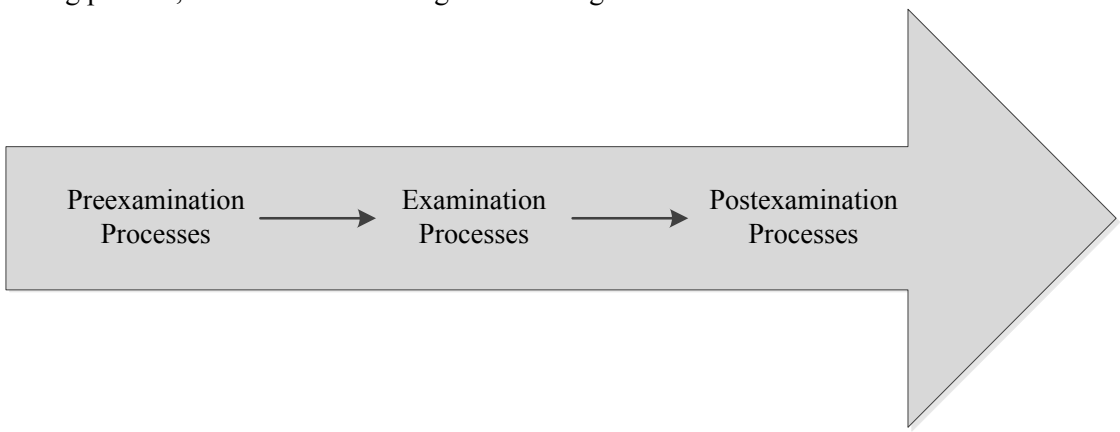

Figure 6. Laboratory POW (see CLSI document GP26)[1]

5.2.3.1 Path of Workflow: Preexamination Processes

Preexamination processes include all activities from the time the laboratory examinations are ordered through the time that the samples are processed and delivered to the workstation for analysis or, for referred testing, transported to outside laboratories. For surgical pathology and cytology, preexamination activities extend from the time the tissue or sample is removed or collected from the patient to the point at which the slides are prepared, stained, and ready for diagnostic assessment and interpretation. The preexamination portion of the laboratory's POW is shown in Figure 7. In some countries, preexamination activities may also include the laboratory's provision of consultations and/or advice given about selecting examinations.

In some laboratories, there may be a process for charging a fee for examinations, as applicable; charging may also be a postexamination activity.

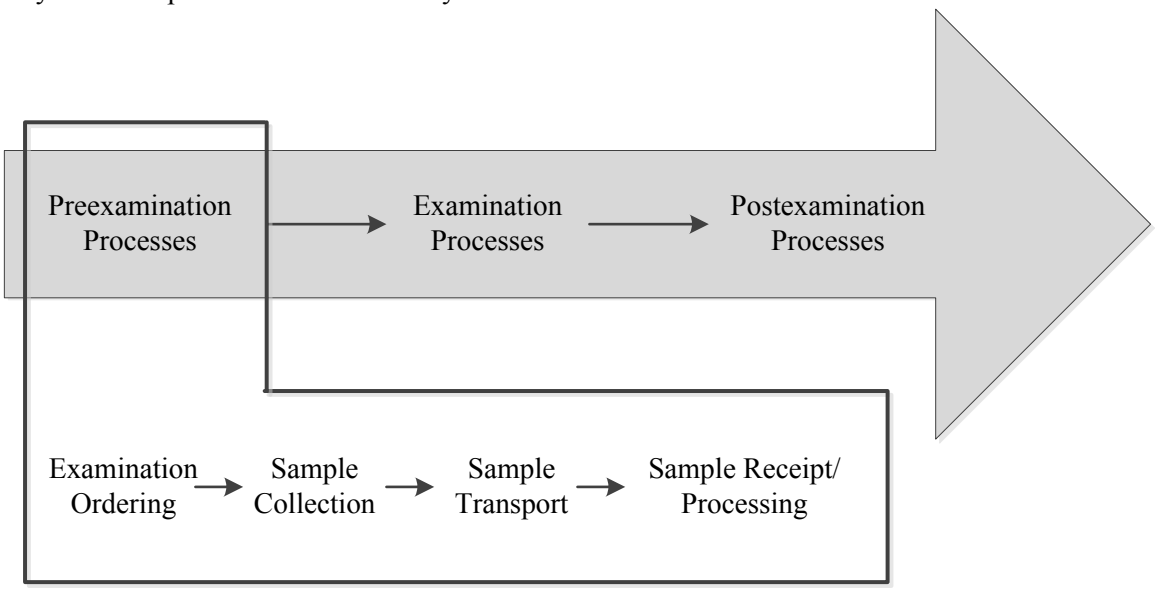

Figure 7. Key Laboratory Preexamination Processes (see CLSI document GP26)[1]

An example of a preexamination process for inpatient blood sample collection is provided in Appendix D.

5.2.3.2 Path of Workflow: Examination Processes

Laboratory examination processes include the activities of performing the testing, which often involve operating an automated analytical instrument and verifying the results; interpreting the results or findings, which may include a physician's evaluation; and recording the results, in either or both written or electronic formats. In the anatomic pathology specialties, examination includes the diagnostic assessment of the samples and/or slides, peer consultation, and recording the findings.

Examination key processes for the laboratory's POW are shown in Figure 8.

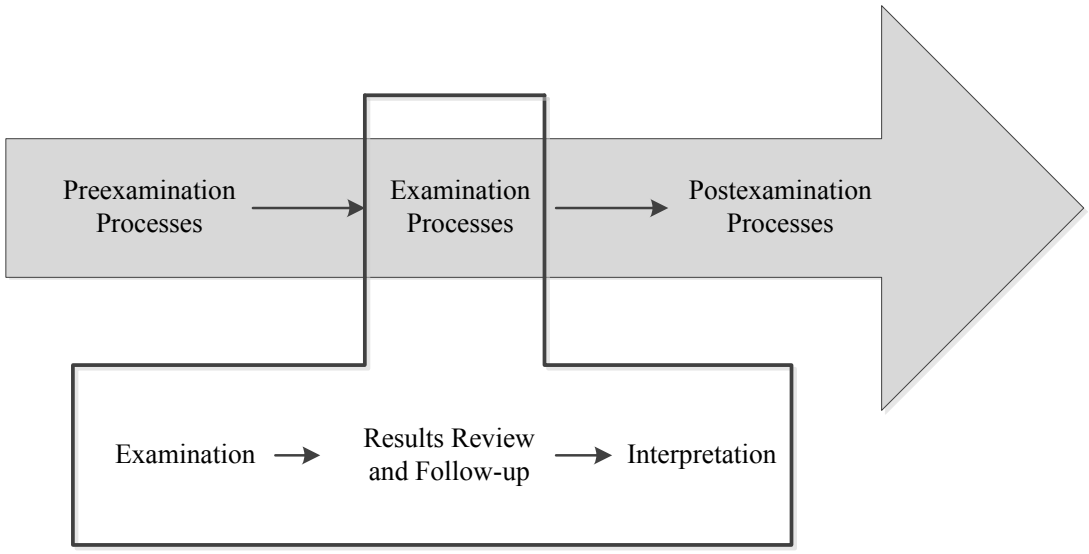

Figure 8. Key Laboratory Examination Processes (see CLSI document GP26)[1]

Examples of the examination process for analyzer setup and run and surgical pathology are provided in Appendixes E1 and E2, respectively.

5.2.3.3 Path of Workflow: Postexamination Processes

Postexamination key processes in the laboratory's POW include activities related to reporting results, including any critical or alert values, as well as archiving results and sample material. Postexamination processes are shown in Figure 9. An example of a postexamination process for critical value handling is provided in Appendix F.

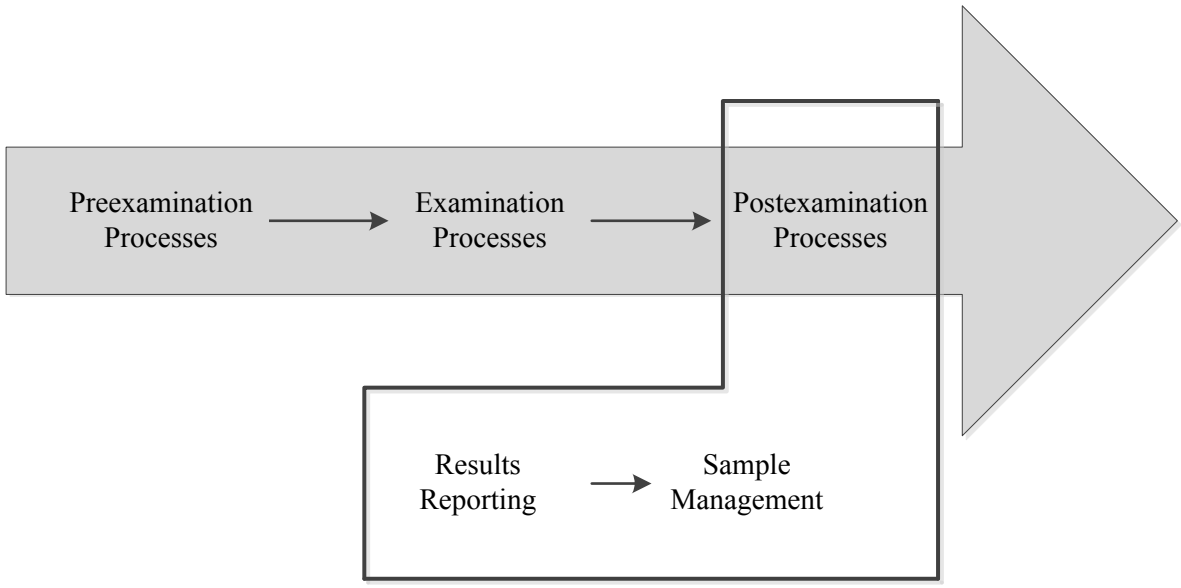

Figure 9. Key Laboratory Postexamination Processes (see CLSI document GP26)[1]

5.2.3.4 Example of Interconnected Paths of Workflow

Some POWs may be interconnected, as shown in Figure 10. For example, in a transfusion service, the POW for receiving and managing blood components is separate from that for the preexamination, examination, and postexamination activities of patient compatibility testing. The two POWs interconnect at the point at which a patient's blood type is determined and blood components of a compatible type are

selected, allocated, and reserved for potential transfusion. Thus, mapping processes is beneficial in developing a clear understanding about how work happens in a laboratory.

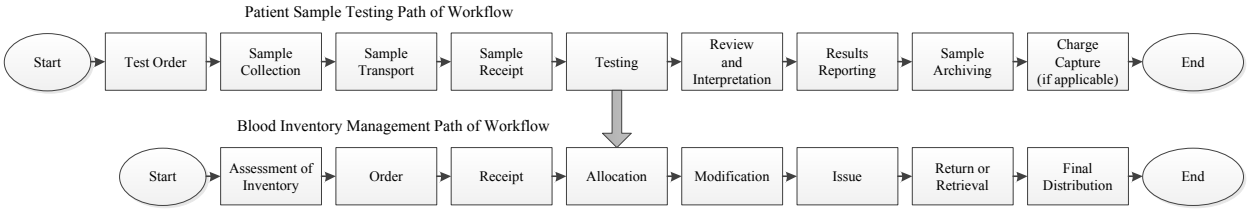

Figure 10. Interconnected POWs in a Transfusion Service

5.3 Procedures and Job Aids: Quality and Operations

Tier 3 of the documentation hierarchy represents procedures and related job aid documents. Procedures and job aids support both a laboratory's quality and operations processes by detailing how to perform the activities described in the process. Each activity in a process usually needs a procedure that provides stepwise instructions for how to perform that activity. Job aids are used to condense procedure information into a shorter format for more rapid access to and review of the instructions.

5.3.1 Procedures

Procedures are documents that provide written step-by-step instruction on how to perform activities in a process. Procedures are typically used internally by laboratory personnel. Examples of quality and operations procedures are listed in Table 2 and provided in Appendixes G1 through G6.

Table 2. Examples of Quality and Operations Procedures

Quality Procedures	Operations Procedures
• Creating a New Document • Determining Training Requirements • Performing Validation Activities • Performing a Method Comparison	• Collecting Blood Cultures • Using the Pneumatic Tube System • Calibrating the XYZ Analyzer • Entering Results Into the Laboratory Reporting System

5.3.2 Job Aids

Job aids are instructions, lists, or quick reference materials derived from the main document and used when reference to the full procedure may not be needed at the time the task is being performed. Their abbreviated nature demands simplicity in format as well as function. Job aids may be given to patients or used by laboratory personnel at their work areas to assist them in performing a procedure. Depending on the activity being described, job aids may be either written, graphical, or a combination. Job aids are considered as documents and thus are subject to document management system processes and procedures. Some examples of job aids for quality and operations processes are listed in Table 3 and shown in Appendixes H1 and H2.

Table 3. Examples of Quality and Operations Job Aids

Quality Job Aids	Operations Job Aids
• Document Management Form • Examples of Effective Training Tools • Validation Testing Form • Method Comparison Testing Form	• Document Template Graphic • Decision Charts for Bacteriology • Fire Extinguisher Use Diagram • Call Center Script Card

5.4 Form Identification

Tier 4 of the documentation hierarchy represents forms. Forms are a place to record results or actions for both quality and operations procedures. They may be created for the entire process or for individual activities in a process; there is no limit to how many forms one's laboratory may use. Forms often capture original data, and are used to record examination results or to log important laboratory activities. Some examples of forms for quality and operations procedures are listed in Table 4 and provided in Appendixes I1 and I2.

Table 4. Examples of Quality and Operations Forms

Quality Forms	Operations Forms
• Document Management Form • Training Form • Validation Results Report Form • Method Comparison Results Form	• Critical Value Call Log • Daily Maintenance Logs • Refrigerator and Freezer Temperature Charts • ABO/Rh Discrepancy Worksheet

Forms are considered documents and are therefore subject to document management system processes and procedures.

5.5 Putting It All Together

As this section has described, creating documentation is a process. Understanding the documentation hierarchy and the types of documents within each tier of the pyramid provides a solid foundation for each laboratory to create a complete documentation catalog.

As shown in this section, a minimum number of policies may be created by referring to the list of QSEs provided in Figure 1. Once the policies are created, the laboratory can then identify key quality and operations processes and create flow charts for each process. Subsequent procedures and jobs aids for the laboratory's processes are composed and, finally, forms are produced to complete the document pyramid. Refer to Figure 11 for an example of the document pyramid for the document management process. Please note that the document list provided in Figure 11 is not all-inclusive.

A possible and sometimes required manner in which to structure documentation is to develop a quality manual. This manual contains the laboratory's quality management policies, but may also include QMS processes, procedures, and forms such as the examples provided in Section 5, and Tables 1 through 4. More information on the contents of and uses for a quality manual is presented in CLSI document GP26.[1]

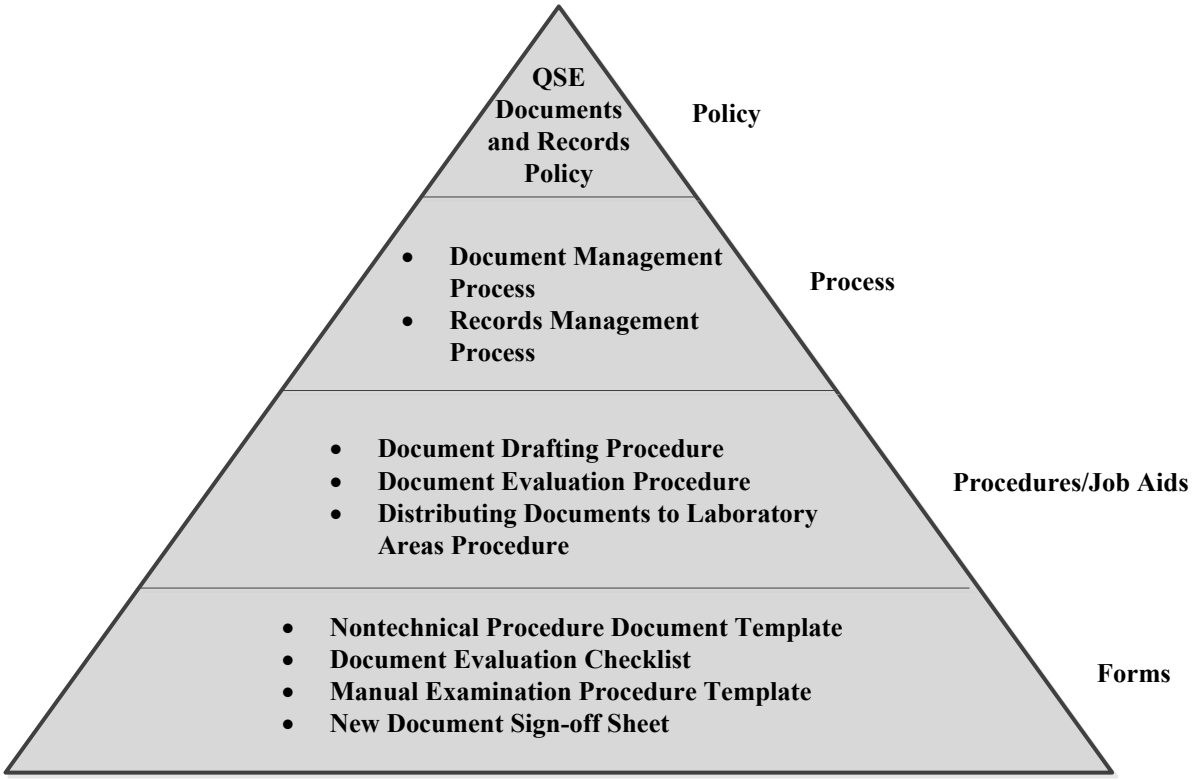

Figure 11. Document Hierarchy for the Document Management Process. (**NOTE:** The procedures/job aids and forms lists in this figure are not all-inclusive.)

6 Document Is Drafted

Written information should be presented in a manner that makes it easily understood by readers. Therefore, when creating documents, it is essential to consider structure as well as content; that is, *how the information is presented is as important as the wording itself.*

Consistent document formats can be achieved through the use of document templates, which also improve readability and comprehension of the content. In addition to content, the document needs to include control information that allows users to know that the document has been approved and is the most current version.

6.1 Use of Document Templates

A template is a standardized document used as the basis for creating multiple documents with the same kind of information. Templates are often facilitated by electronic word processing software that provides a consistent look to—and structure for—documents containing the same type of information—ie, all policy documents would be developed in a single policy template.

6.1.1 Benefits

Both the structure and the content of documents are best controlled by the use of document templates. Templates provide the following advantages:

- Standardization: Because formats and other parameters are predefined in templates, many different people can develop documents, or one person can create many different types of documents, and the end products will look quite similar. Standardization makes it easier for readers to find information

they are looking for when reading multiple documents or scanning a document for specific information.

- Completeness: Including elements in a template ensures that they will not be forgotten or overlooked when the document is created. Elements identified as requirements can be included in templates to ensure they are considered when creating the document, thus helping the laboratory meet regulatory, accreditation, and organizational requirements.

- Document management: Consistent use of fields for document control information helps readers know they are using a document that has been approved and is the most current version.

6.1.2 Elements That Can Be Standardized

Format elements that can be standardized include:

- The placement of information in document headers
- The placement of information in document footers
- Font type and size, and attributes such as bold, italics, and underline
- Formatting of tables
- Placement and size of any organization logo(s)
- Height and width of margins
- Numbering of instruction steps

Content elements that can be standardized include:

- Headings within the body of the document (see Section 6.5.1)
- Some wording, such as purpose statements
- Acronyms, abbreviations, and units of measure

6.1.3 Other Considerations

The following considerations also improve use and understanding of the information being presented. These items may not all have international applicability.

- Legibility—text needs to be easily read by the human eye.

- Use of white space—in the form of blank lines, should be used to separate various types of information, thus making the document more easily scanned and readable.

- Fonts—as there is no agreement about using fonts with serifs (eg, Times New Roman and Baskerville fonts) and those without serifs (eg, Arial and Helvetica fonts), the laboratory should select a font type that is easily readable in any document type or part of a document. Font size is important because reading becomes difficult when the font size is too small or when multiple font types or sizes are used within a section. Very large fonts may occupy space in the document without adding to the readability. Depending on the specific font selected, sizes 10 to 12 are recommended.

- Step-action tables—see examples in Section 6.5.6. Include step-action tables in templates if this format has been selected as the format of choice for presenting a procedure's stepwise instructions.

6.2 Template Types and the Document Hierarchy

Different types of documents contain different types of information; therefore, templates should be created for each type of document:

- Policies
- Processes
- Procedures/Job aids
- Forms

Each template should be created in a way that clearly presents the particular type of information needed to fill it. Suggestions for the content of document templates are provided in Appendix J.

6.3 Contents of Template Types

Figure 12 depicts key parts of a document. Descriptions of these document parts and their contents follow.

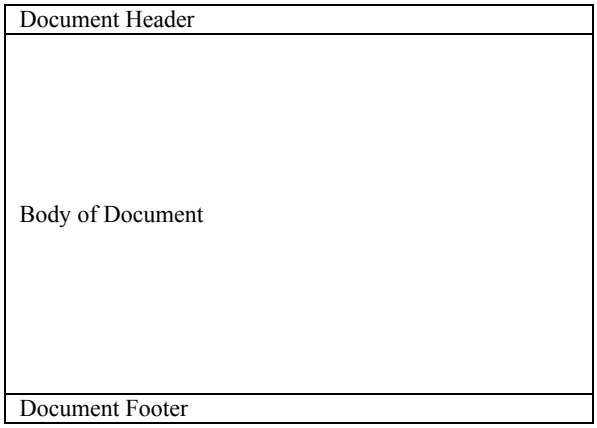

Figure 12. Parts of a Document

6.3.1 Headers and Footers

The header contains information within the top margin of the page; the footer contains information within the bottom margin of the page. Header and footer information is usually repeated on each page. Headers and footers are convenient places for locating required information so that it does not take up space in the body of the document.

Document headers and footers can include required and important information for identifying the document, such as the:

- Name and location of organization or laboratory
- Name of procedures manual or section of the laboratory or organization
- Document title
- Unique document number, if used
- Version identification
- Effective date
- Approval date, if used
- Author, if needed
- Approval signature(s), when a document master sheet or electronic signature is not used

- Location of the document in the electronic library, such as file name and pathway
- Controlled copy number, for paper copies
- Inclusive page numbers in the document (eg, "page x of y")

Forms, job aids, and attachments may not need all elements for the header and footer that would be included in policy, process, and procedure documents, but there should be some way to connect these document supplements with the procedure to which they are related and to manage them.

Appendix F shows one way that information can be included in a document header and footer.

6.3.2 Format for the Body of a Document

Section headings should be included in a document template and reflect the type of information needed in the document. For example, all policy documents should have headings for Policy and Purpose; process documents should have a heading for Process (flow chart or table); and testing/examination procedure documents should always have headings for Equipment, Reagents, Supplies, and Instructions.

Ideally, the sections should appear in the order in which the information is needed. For example, in a procedure document, it is important to provide information about special safety precautions to take when performing the procedure—such as use of special freezer gloves, respirators, or fume hoods—*before* providing the instructions in which the precautions are needed. The same is true for any limitations of the examination method, such as not using hemolyzed or lipemic samples.

A numbered or number-and-letter outline format has not been shown useful or esthetically pleasing for presenting laboratory policy, process, and procedure information. Research has shown that readers prefer, and can more easily navigate, a document that reserves numbers only for stages in a process or steps in a procedure.[14] Appendixes G1 through G6 show how these concepts are applied.

Templates may include standardized text that can be modified as needed for the content of the particular document being created. For example, the words, "This procedure provides instructions for how to…" can be used in the Purpose section of every procedure document to inform readers that procedures provide instructions. See examples in Appendixes G1 through G6.

Ideally, forms should be designed in a manner that captures the data, information, or results to enter in the order in which they are obtained; that is, in the order following the sequence of the process activities or procedure steps. This helps ensure that entry of required data, information, or results is not overlooked or forgotten.

Although the information contained in laboratory document appendixes may vary substantially, defining a standardized format for these also helps to maintain the look and readability of the information.

6.4 Sources of Information for Content for the Different Document Template Types

Several sources of information should be considered in order to ensure that the content of any document is appropriate and correct. Sources may include, but are not limited to:

- Policy documents. Regulations, standards, and accreditation requirements should be consulted for the wording to use in developing the policy statements.

- Process documents. Staff members performing the process are usually the best source of information about the proper sequence of activities. Process flow charts are best developed by the people who perform the tasks.

- Technical procedures. Formal documents such as instrument/equipment operators' manuals, manufacturers' inserts, and textbooks should be referenced. Online resources may also be considered, but a process is needed to ensure the appropriateness and reliability of the website and its information.

6.5 Composing the Draft Using the Selected Template

One of the most difficult tasks for those writing documents is determining where to start and where to end the document; that is, the document's scope. Documents often duplicate information contained in other documents, thereby introducing inconsistencies when something is changed in one document and not in the others. This problem is solved when documents are separated into the categories described in the document hierarchy in Figure 3. The beginning and end of procedure documents is further clarified when flow charts are used to depict laboratory processes. In a properly constructed flow chart, boxes represent activities for which procedures (ie, stepwise instructions) are needed. The separation of the boxes defines the procedure's boundaries.

Once the most appropriate template is chosen for the intended document and sources of content have been assembled, the next action is to draft the content and organize it in the document template headings. The draft begins with identifying the document with a working title and completing any available header or footer information.

All documents need to be written in a language commonly understood by staff in the laboratory, including the elements necessary for proper grammar and syntax.

6.5.1 Title, Headings, and Intended Content

The document title is a descriptive name and should be unique from that of any other document. It should be as brief as possible without losing meaning. The title may be bold, and centered or left-aligned below the header and above the first heading, which is usually "Purpose." The title may also be contained in the header and thus repeated on subsequent pages. Ideally, the title should include the word "Policy," "Process, "or "Procedure" to clearly describe which of the document types it represents.

Examples of concise titles for quality documents include:

- QSE Personnel Policy
- Ongoing Competence Assessment Process
- Written Assessment Procedure
- Direct Observation Checklist

Titles of testing and examination procedures should contain the method. For example:

- Antibody Screen by Gel Technique Procedure
- Microscopic Urinalysis by Phase Microscopy Procedure
- Gram Stain Procedure
- Fingerstick Glucose Examination Procedure for the XYZ Instrument

Table 5 describes the content for each of the common headings found in policy, process, and procedure documents.

Table 5. Common Headings to Include in Policy, Process, and Procedure Documents

Document Body Heading	Description/Intent	Suggestions/Examples
Purpose	Describes what the document is meant to achieve.	Examples: • "This policy describes the elements of our laboratory's NCE management program to include identification, reporting, investigation, analysis, and referral to continual improvement." • "This document outlines the sequence of activities in the Inpatient Blood Collection Process."
Scope or Applicability	Describes the extent of the activity or the area over which the activity extends.	Examples: • "This document applies to all Company X Laboratory personnel." • "This document applies to Site X." • "This document applies when X condition exists."
*Specific headings as described in Section 6.5.2 (policy), Section 6.5.3 (process), and Section 6.5.4 (procedures) are inserted here.		
References	Names the source document from which the content was directly taken. The use of online references is acceptable. The Web link for the reference and the date accessed need to be included. This heading may be not applicable where no formal source is used. For example, many processes are unique to a specific laboratory.	• Common references are regulations, standards, and accreditation requirements (for policy documents), and operators' manuals, kit inserts, or textbooks (for process and procedure documents). See Appendixes G4 and G5 for examples of reference formats. • Suggested readings or background materials are not references but may be included under an optional heading of "Bibliography."
Related Documents	This is a list of documents referred to in the body of the document, or whose content the reader will need to complete the task or process. This section is useful to readers because it can lead them to the next procedure in a process.	Examples of Related Documents: • Forms. • Job aids. • A different procedure the reader needs to perform to be able to do this procedure; for example, one needs to know how to streak an agar plate before setting up a microbiology culture. • An antecedent or subsequent procedure needed for completion of the process.