CAP Document Control Course – Sample Content

Background

What is a document?

A document is an information source and its supporting medium. The medium can be paper, magnetic, electronic, or photographic.

Documents are important because they:

- Make the ideas and discoveries of experts available to a broad audience
- Facilitate training
- Make it possible for a large number of people to implement a process in the same way, and get consistent results
- Provide objective evidence of activities and results

What is document control?

To "control" documents means to ensure that the documents workers need and use on the job are:

- Accessible
- Accurate
- Current

Document control is a set of processes and procedures that govern the way documents are:

- Developed
- Approved
- Made available for use
- Revised
- Taken out of the system and archived

Why is document control important?

Effective document control has significant benefits. For example:

- Ensures consistency
  - Testing is being done the same way among all staff, all shifts, and all locations. This means better patient care.
- Reduces errors and cycle times
  - Workers have ready access to the right documents. They get their work done more efficiently and accurately, taking out the guess work. This means better turn-around-times.

David Wolfe on the risk of inconsistency

Christine Christopher on document-related occurrences

- Lowers operating costs
  - The process for approving new or revised documents is organized and streamlined. This means new methods can be implemented more quickly and take up less time for the reviewers.
- Lowers compliance costs
  - Preparing for inspections and audits takes less time if the document control system is easy to use and robust.

A lack of document control poses significant risks:

- Wrong document use
  - A single occurrence due to inaccurate or unapproved document can result in a costly liability.
- No defined procedure
  - Lack of guidance for critical steps in a process can lead to inaccurate test results and ultimately poor patient care
- Inaccessibility of documents
  - Patient safety and employee safety may be at risk during a fire or other disaster if approved instructions are difficult to locate.

What must be controlled?

In determining what documents to control, keep in mind the goal: to perform critical tasks in a consistent way.

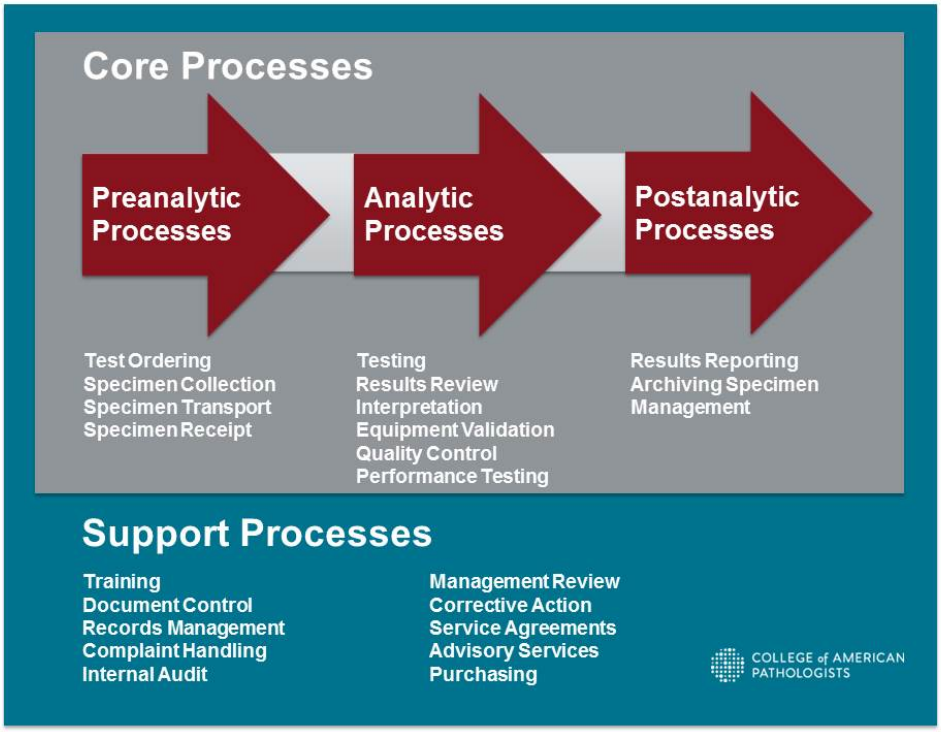
In a nutshell, documents must be controlled if they contain the following:

- Key details requiring update
- Details that affect quality of patient care

David Wolfe on using feedback loops to find gaps

Christine Christopher on missing information

The document control system must control all documents that are part of the QMS. This means all documents that describe, or are used in, core processes and support processes.



A quality management system includes the following types of documents:

- Process, procedure, and policy documents that describe how to do work
- Records of activities performed or results achieved
- Contracts
- Standards or regulations
- The quality manual, which describes the elements of the quality system

Each of these document types will require periodic changes. Document control is crucial anytime critical documents go through revisions because they directly affect quality and patient care.

Note: This includes documents of external origin such as regulations, standards, or procedures such as manufacturer's instructions.

David Wolfe on using internal audit results

Many documents that laboratory workers create and use do not need to be controlled. For example, documents that are created for specific short-term purposes (emails, agendas, and meeting notes) or that are used as part research and development (journals and/or white papers), do not need to be controlled.

Need to control	**Don't need to control**
Documents supporting core and support processes containing: • Key details requiring update • Details that affect quality of patient care	Documents created for short-term purpose (for example, emails, agendas, and meeting notes) Research and development documents

Is document control the same as record control?

No. A record is a specific type of document. Most documents say what to do. A record says what has been done.

Examples of records:
- Temperature charts
- Instrument maintenance logs
- Patient reports
- Management review reports

A record enables the laboratory to reconstruct what has occurred in the past and ensures critical information is not dependent on the memory or availability of an individual.
Some documents become records. This is true in the case of forms. A form provides a checklist of things to do. Once the procedure is complete and the form has been filled out, it becomes a record.

Records have their own quality requirements and need to be controlled. A laboratory needs to create a separate records control procedure. The organization needs to state what records it creates, the environment in which they are stored, how long it keeps them, who is responsible for them, and how it disposes of them.

Records need to be controlled because they provide evidence of conformity to requirements and of the effective operation of the quality management system. The organization needs to establish a documented procedure to define
- How records are identified, collected, and indexed
- How they are stored to prevent damage, loss, or unauthorized access
- How long they are kept
- How it disposes of them

Records need to remain legible and retrievable.

How should documents be structured?

Structure documents into a hierarchy.

High-level documents should describe and help locate low-level documents. High-level documents provide a general description of what to do. Low-level documents say exactly what to do.

The top document in the hierarchy is the Quality Manual. This manual provides an index of key processes, policies, and procedures. It also contains a high-level map of the organization's processes and their interactions. Individual procedures may reference more specific work instructions and forms.

What is the difference between a policy, a process, a procedure, a form, and a record?

These terms are confusing because organizations often use the word *procedure* in a vague way to refer to any kind of document.

David Wolfe on the problems caused by poor definitions

But these terms have specific meanings. Here are the definitions:

Term	Definition
Policy	A documented statement of overall intentions, endorsed by management and chosen from among alternatives to guide and determine present and future decisions. Example: a quality policy statement
Process	A documented set of interrelated or interacting activities that transform inputs into outputs. These activities occur over time with starts and stops and involve more than one person or group. Examples: test order entry to specimen storage; external regulation or standard.
Procedure	A documented set of instructions that describe specified way to perform an activity. A procedure can be done from start to finish by one person or a closely working team in one place and time. Examples: receiving and processing patient specimens; external documents such as manufacturer's instructions or package inserts Note: Often the term procedure is used more generally to refer to a specified way to carry out an activity *or a process*. So the documented description of a process is sometimes referred to as a "procedure," even though process and procedure are technically two different things.
Work Aid	A procedure, or a portion of a procedure, created to serve as a reference while the worker performs the task.
Form	A blank document that is used to capture results of the performance of a procedure.
Record	A document that captures results or other critical information from the performance of a procedure.

What about work aids?

Often workers in the lab do not need the full procedure to do their work. They need a key portion of the procedure, sometimes called a "recipe card" or a work aid.

David Wolfe on analyzing the need for work aids

Work aids play an important role because it is difficult to remember factual details such as procedure steps – it is better to be able to view the key steps while performing the task.

Christine Christopher on integrating work aids

Sometimes it is convenient to create a note and post it, so it can be read while doing the task. It is not recommended to use documents in this way, but it's acceptable as long as they are controlled. This means they are:

- Legible
- Identifiable
- Traceable to an approved, current procedure

If documents are identified, linked, and controlled, all documents will reflect any changes to methodology. In this way, practice and results will be consistent.

Note: Sticky notes are not reliable for long-term use. Use laminated sheets or cards as a better approach.

Some work aids are simply copies of existing documents. Here is an example of an approach for controlling such work aids or "secondary documents."

Secondary Document Log Example

Note: Miller-Latif Laboratory is a fictitious example to illustrate best practices and one possible approach.

Document Readability

In the effort to develop and organize documents, it is possible to lose sight of their purpose: to make work easier and more accurate by clearly communicating steps and information.

Too many laboratory documents are developed in haste, are never reviewed for readability, and are understandable only to the person who created them.

Here are some common writing/design issues:

- Documents are too long and wordy.
- Documents are unclear, complicated, or difficult to understand.
- Documents are too generic, general, or simplistic.
- Documents are poorly designed or hard to navigate.
- Documents are inconsistent using different formats.

Keep your procedures short and succinct so it is easier to update them. Use pictures, graphics, and examples to illuminate what you expect.

Documentation efforts that follow standardized methods are most successful (for example, the Information Mapping standards and principles [informationmapping.com]).

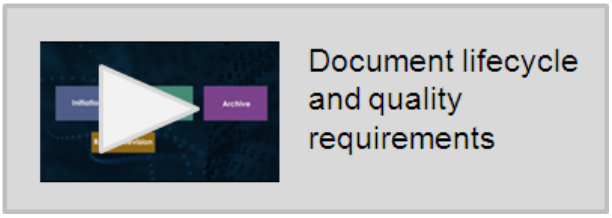
Note: We encourage you to go through the demo on the Information Mapping home page (informationmapping.com). Consider how much time you could save in your laboratory by having well-written and structured documents.

CLSI Guideline QMS02, Quality Management System: Development and Management of Laboratory Documents, 6th Edition, provides some excellent principles and examples of good laboratory documentation. Order page for QMS02. Accessed September 30, 2019.

Lifecycle and Requirements

Document Lifecycle and Quality Requirements

Documents follow a predicable lifecycle in organizations. Each phase of the lifecycle has associated quality requirements and pitfalls.



Summary of Requirements and Pitfalls

Document Lifecycle Stage	Quality Requirements	Common Pitfalls
Initiation	• Approve prior to use • Uniquely identify with o Title o Edition, current revision date, or revision number o Number of pages o Source identification • Maintain master list • Identify and track external documents	• Incomplete or nonexistent bench procedures • Unofficial documents (eg, sticky notes) are created and used in lab without approval • Inadequate identification • Forms not linked to procedures • Inadequate master list o Missing documents o Number of copies not indicated o Locations not identified
Implementation	• Provide training/education to staff if necessary • Make available at point of use • Provide access to current versions only • Ensure documents are legible and identifiable • Prevent use of obsolete documents	• All staff not adequately trained • Obsolete documents creep into use o Old editions not removed o Forms printed out in bulk and used despite being superseded o Old work aids or “sticky” notes • Personalized procedures in use • Workers can’t get to documents easily (eg, difficult system) • Procedures not used or followed

Document Lifecycle Stage	**Quality Requirements**	**Common Pitfalls**
Review/Revision	• Review periodically • Have a process for revising and updating • Identify changes • Show current revision date or revision number on document • Update master list • Approve substantive changes • Implement/distribute	• Reviewers assume that procedures are OK and don't perform a thorough review and rubber stamp revisions • Reviewers don't do review at all • Revised but unapproved documents in use in the lab (handwritten notes and changes on document) • All staff not adequately trained or informed of changes
Archive	• Remove obsolete documents • Mark as obsolete • Retain according to quality management system requirements	• Not removing all copies—especially forms—from point of use • Not making electronic obsolete copies inaccessible • Relying on memos and communications about what should not be used versus making it inaccessible • Discarding documents inappropriately

Note: For ISO certification or accreditation, you must not only do these things, but also you must prove that you have done them. For this reason, you need to document what you do. Specifically, you will need to ensure you have records of the following:

- Sign-offs of reviews
- Requested changes and evidence of review
- Sign-offs for release
- History of changes
- Updated master lists
- Sign-offs that the end users have received document, read it, and agreed to comply
- Periodic review
- Review/approval and distribution for any documents that are modified either from review or changes to the process

Case Examples

The following three laboratories uncovered document control issues during external audits.

Laboratory 1 – Confusing Online System

Document control problem:
Accession staff has difficulty accessing procedures online, so they use a hard copy in the manager's office. Only the Quality Office can have hard copies of procedures. The manager's office also contains some obsolete copies.

Impact on quality:
Staff has access to obsolete procedures, which might omit critical steps in processing, resulting in less than optimal samples for testing.

	**Auditor**	During my assessment of the pre-analytic process of Miller-Latif Laboratory, I asked one of the accession staff to locate the written procedure for the activity she was performing. She looked for several minutes in the online document control system, but she was unable to locate it. She told me there is a manual in the supervisor's office that she uses. I checked the manual and found that several procedures were not the current, approved procedures.

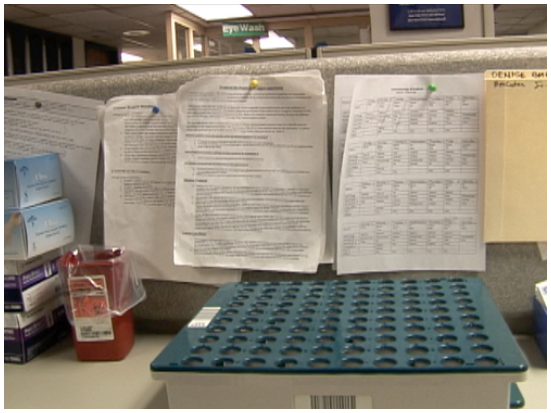
Root cause analysis results:
Search function brings up too many procedures making it difficult to locate the one that is needed.

Countermeasures:
Quality department created controlled department-specific table of contents that helps with the limitations of the system's search function. It also created a Quick-Search User's Guide.

	**Accessioner**	The new table of contents and the guide make it easy to quickly pull up any procedure we need.

Laboratory 2 – Uncontrolled Work Aid

Document control problem:
Chemistry supervisor put together key information from three different chemistry procedures as a work aid. This is not referenced to approved procedures, only the date it was posted. Procedures are both online and in manuals in the department.



Impact on quality:
This work aid is not included under document control. It may go unrevised if there are changes made to the original procedures. In this case, staff might access inaccurate work instructions when making critical decisions.

	**Chemistry supervisor**	I want the techs to have important information at their fingertips. It takes time to look up procedures. Some things we do in chemistry have decision points based on certain clients. We've had some problems recently, so I put together a couple of key procedures into one document and dated it.

Root cause analysis results:
The supervisor noticed some repetitive problems in chemistry and decided to compile some key information to assist the technologists. He thought that by dating the document it was under document control.

Countermeasures:
Staff are allowed "controlled" copies of procedures but only through the document controller. The controller prints the copy, stamps it *Controlled*, and logs it into the Master List. The recipient initials are also documented.

	**Chemistry Tech**	I'm glad we're allowed to have some information posted at the work stations; it makes it easier to do the right thing.

Laboratory 3 – Lack of Awareness of a Confidentiality Procedure

Document control problem:
Not all staff has reviewed the revised procedure Patient Information Confidentiality. Three months have lapsed since it was released. This is a paper document control process.

Impact on quality:
All staff may not be aware of critical information related to patient confidentiality.

	**Quality manager**	At our CAP15189 Gap Assessment, the assessor found all staff in Client Services had not read the Patient Information Confidentiality procedure. This information is critical for Client Services staff to perform their jobs correctly. We'll have to look at our process lab-wide to ensure this doesn't happen elsewhere.

Root cause analysis results:
No standardized process exists for capturing documentation of review of revised procedures by staff.

Countermeasures:
The laboratory Performance Improvement Committee created a form for recording review of new/revised procedures. The form captures the procedure name, a listing of pertinent staff, and their signatures and dates. The form also lists an expected turnaround-time for completion.

	**Medical Director**	This new process provides better communication throughout the laboratory and ensures compliance with regulatory agencies.

For more information on root cause analysis and internal auditing, see QMEd online courses, Root Cause Analysis and Internal Auditing.