Document Control Course

Contents

Document Control Course

This document contains the text and graphics from the online course Document Control. It does not include links to video files or case example documents. For more information contact QMEd@cap.org

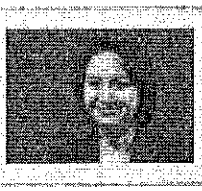
Document Control Course

Introduction

Welcome

Course Description

This "how-to" course details how to control documents in a way that meets the requirements of international quality standards such as ISO 9001, ISO 17025, and ISO 15189.



Introduction by Caroline Maurer

It provides guidance on how to achieve document control with minimal resources, such as spreadsheets, as well as sophisticated document control software. CAP 15189 assessors give examples and commentary on common pitfalls and issues.

Learning Objectives

After completing this course, participants will have a better understanding of the following:

- How document control contributes to cost containment and patient care
- Phases in document lifecycle and associated best practices and pitfalls
- How to achieve document control with simple/inexpensive tools as well as sophisticated tools

Course Length

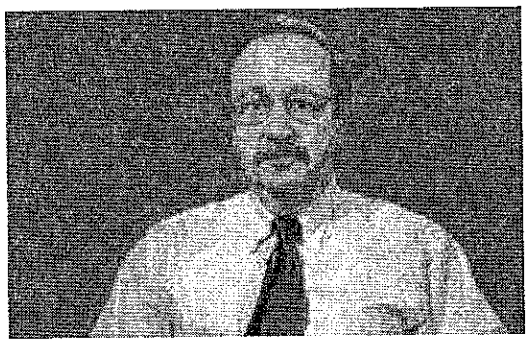
Approximately 2 hours

Course Text

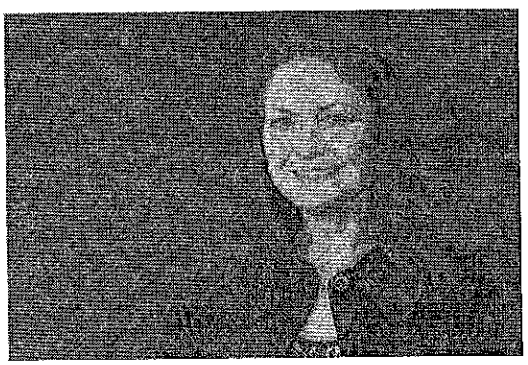
This attachment provides the text of this course in easily printable form.

Meet the Presenters

Caroline Maurer is the program director of CAP 15189. She brings 20 years of experience in health care operations for medical laboratories and other diagnostic services.



David Wolfe is a lead assessor for the CAP 15189 program. In his career in ISO 9001 and medical device auditing, he has conducted over 900 audits.



Christine Christopher is a technical assessor for the CAP 15189 program. She has 25 years experience in medical laboratories.

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:

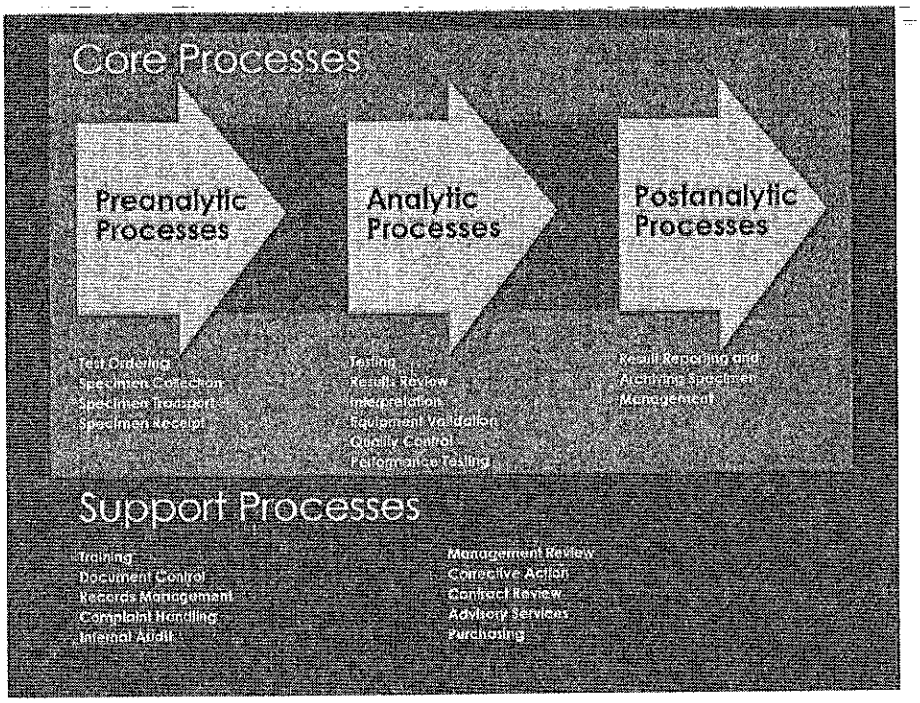
- Key details requiring update
- Details that affect quality of patient care

David Wolfe on using feedback loops to find gaps

Christine Christopher on missing information

Document Control Course

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

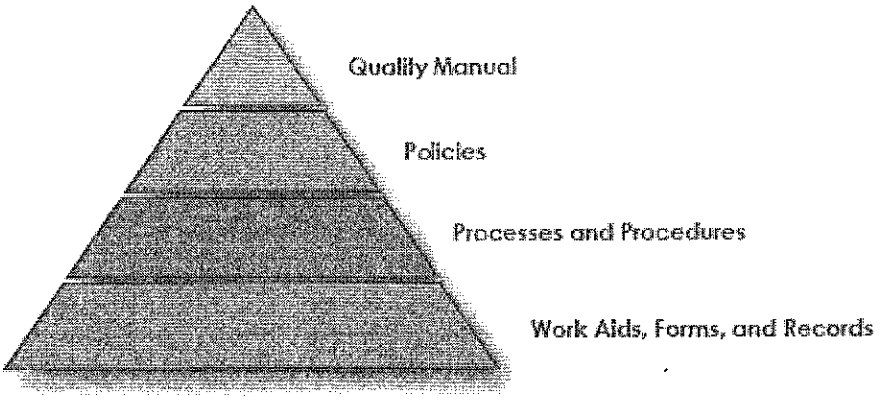
Records need to remain legible and retrievable.

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:

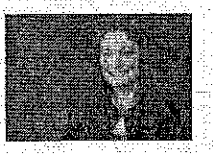
Term	Definition
Policy	A documented statement of overall intentions, endorsed by management and chosen from among alternatives to guide and determine present and future decisions. Example: a quality policy statement
Process	A documented set of interrelated or interacting activities that transform inputs 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

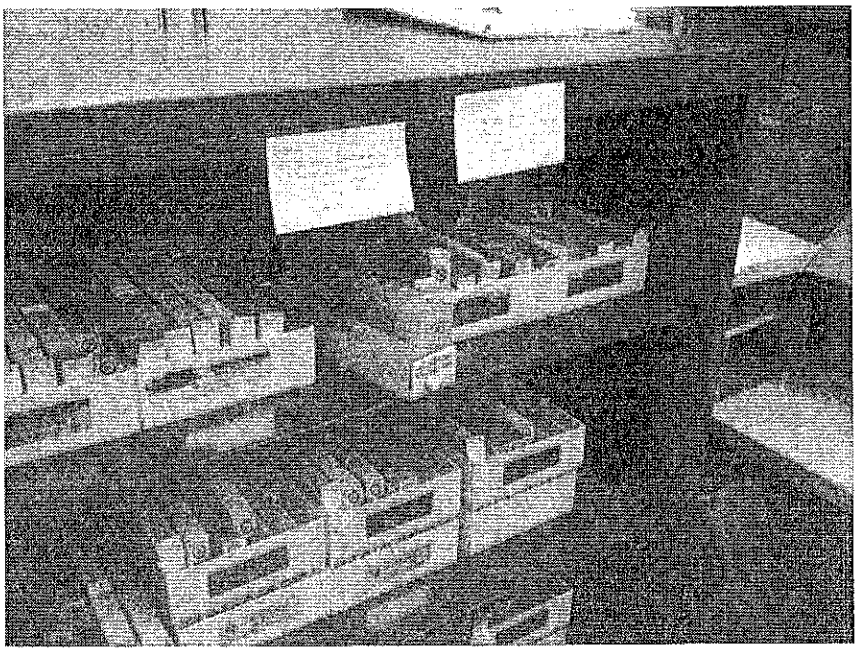
Work aids play an important role because it is difficult to remember factual details such as procedure steps – it is better to be able to view the key steps while performing the task.



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 [infomap.com]).

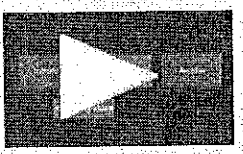
Note: We encourage you to go through the demo on the Information Mapping home page (infomap.com). Consider how much time you could save in your laboratory by having well-written and structured documents.

CLSI Guideline GP2-A5, Laboratory Documents: Development and Control; Approved Guideline - Fifth Edition, provides some excellent principles and examples of good laboratory documentation. Order page for GP2-A5. Accessed February 23, 2011.

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.



Document lifecycle and quality requirements

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

Workplace Learning

Perform an audit of your organization's document control process.

1. Does your document control procedure address all quality requirements?
2. Do you have a master list of documents?
    a. Is it correct?
    b. Have you included external documents?
3. Is your document identification process applied consistently on all documents?
4. Are only approved, current documents available at point of use?
5. Are work aids properly identified and traced?
6. Have all documents been reviewed periodically as required?
7. Is there documentation that changes? Have revisions been communicated to all pertinent staff?

Implementing Document Control

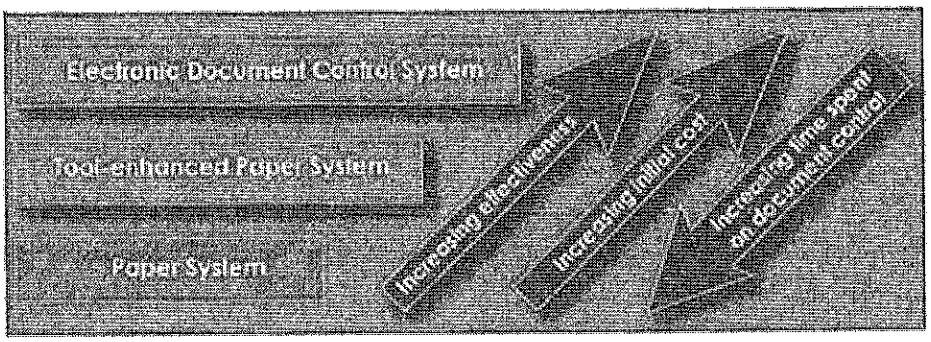
Infrastructure Options

How can laboratories meet the quality requirements and avoid the pitfalls?

There are a variety of strategies, depending on the size, complexity, and resources of the laboratory. It is possible to separate the strategies into categories based on the infrastructure employed. These strategies vary based on sophistication, cost, and effectiveness.

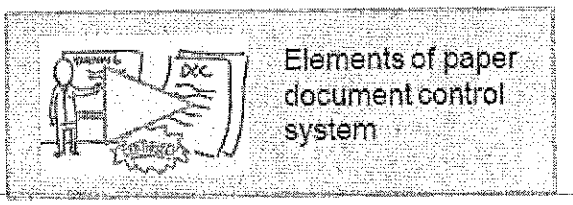
The main categories:

- Paper system
- Tool-enhanced paper system
- Electronic document control system



Paper System

Here are the key elements of a paper based system:



- Master document list
- Sign-off sheets that travel with documents until they are approved
- Education sign-off sheet indicating who has reviewed and learned new procedures or revised procedures
- Binder/repository of original/approved documents
- Manual of procedures that is available in the laboratory
- Procedure review schedule
- Binder/repository for outdated/superseded documents

Tool-enhanced Paper System

In a tool-enhanced paper system, technology tools facilitate various elements of the system.

Here are some common tools:

- Word processor for document creation and maintenance
- Scanner for creating electronic copies of external technical procedures
- Spreadsheet for master document log
- Outlook/email for review/approval process
- PDF documents for preventing unauthorized changes
- Network/intranet for document distribution and access
- Hyperlinks in documents to connect related documents
- Flash drives for backup

Electronic Document Control System

An electronic document control system is a software package that enables a user to manage the creation, approval, distribution, and archiving of all controlled documents.

The system typically automates processes such as notification, routing, and approval.

Click on the link below to see a graphic summary of EtQ, a well known system.

EtQ graphic summary

Click on the link below to see more information about the features of EtQ:

EtQ Document Control Software

Comparison of systems

Here is a table comparing these three infrastructures:

	Paper System	Tool-enhanced Paper System	Electronic Document Control System
Who drives process?	Person drives process	Person drives process	System drives process using automatic functions
Where are the documents and system elements?	Many locations (usually binders)	Somewhere on the network/intranet/ electronic folders	Central repository Accessed and controlled from within the document control software Two types: • Software/files sit on organization's network server (on-premise internal system) • Software/files sit on vendor server – accessed through Web ("cloud-based" system)
What form do the elements take?	Primarily paper	Combination of paper and electronic	All electronic Individual controlled documents can be printed for convenience
How is technology used?	To create individual documents	To facilitate the process. For example: Email/Outlook – to facilitate reviews Word/Excel – to create and maintain master document list	Technology runs the system. For example: New/revised document notifications are automatically issued & repeated until action is complete • Reviews • Training
		Hyperlinks – to ensure related documents are updated PDF copies – to prevent unapproved changes to documents in use Network folders – to store and protect documents Scanner – to create electronic copies of external technical procedures	Action items escalate if not addressed Tasks scheduled automatically Headers automatically update History of changes and evidence of reviews and approvals easily accessible Documentation of training is captured electronically

How They Meet Requirements - System Features Comparison

Here is a matrix that shows how the different infrastructure types meet document control requirements.

Comparison matrix

Project Steps

This section describes the project steps required to implement the three different infrastructure options.

Implementing a Paper System

Here is an implementation plan for a paper-based document control system that uses only the following:

- Word processing software for document creation and maintenance
- Binders for document storage

Step	Action
1	Create a process map or flowchart for document control system.
2	Create system and instructions (based on quality requirements) for: • Creating new documents • Reviewing and revising documents • Approving new/revised documents • Labeling and controlling external documents • Creating and maintaining a master list of documents • Training on new/revised documents • Distributing and accessing controlled documents • Archiving obsolete documents Example documentation Document control flowchart Note: Miller-Latif Laboratory is a fictitious example to illustrate best practices and one possible approach.
3	Train all staff on document control process: • Invite input from your employees on the process • Document training
4	Perform a focused internal audit of your document control process. Ensure all documents are: • Appropriately approved and periodically reviewed (based on accrediting bodies and institutional policy) • Uniquely identified with title, current creation/revision date, or number • Readily accessible by all staff • Current, complete, and accurate • Legible and identifiable, including "work aids" • Included on master list with number of copies available and their locations • Understood by staff (new/revised documents reviewed by pertinent staff) • Appropriately archived and marked as obsolete
5	Follow up with any needed corrective action based on input from employees and audit findings.

See online QMEd courses "Internal Auditing" and "Root Cause Analysis" for more information on auditing and corrective action.

Implementing a Tool-enhanced Paper System

Here is an implementation plan for a process that employs the following tools:

- Word processor for document creation and maintenance
- Scanner for creating electronic copies of external technical procedures
- Excel for master document log
- Outlook for review/approval process
- PDF documents for preventing unauthorized changes
- Network/intranet for document distribution and access
- Hyperlinks in documents to connect related documents

Step	Action
1	Create a process map or flowchart for document control system.

2	Create system and instructions (based on quality requirements) for:
	• Creating new documents
	  o Create/revise in Word/Excel
	  o Assign file name and extension
	  o Hyperlink referenced documents (forms and related procedures)
	  o Convert original to PDF version for on-line access
	  o Store original document in secured folder
	  o Add to master document list
	• Incorporating external documents/technical procedures
	  o Use scanner to create PDF copy of procedure
	  o Create descriptive file name
	  o Store in secured folder
	  o Add to master document list
	• Reviewing and revising documents
	  o Set up review schedule and email notification in Outlook
	  o Review original document in secured, current folders
	  o Track changes/comments on original documents
	  o Note your review completion on original documents in the Reviewed By section
	• Reviewing and approving new/revised documents
	  o Set up approving work groups in Outlook
	  o Email approving work groups
	  o Review original document in secured, current folders
	  o Note your approval on original documents in the Approved By section
	• Labeling and controlling external documents
	• Creating and maintaining a master list of documents
	  o List all documents on Excel spreadsheet
	  o Include number of copies and locations
	• Training on new/revised documents
	• Distributing and accessing controlled documents
	  o Load approved, current pdf onto intranet
	  o Provide access to all staff to pertinent documents
	  o Download current pdf documents on a USB flash drive for computer downtimes

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Step	Action
	○ Provide work aids upon request ▪ Processed through document controller ▪ Put on master list • Archiving obsolete documents ○ Store original obsolete documents in secured Discontinued/Retired folder
3	Train all staff on document control process: • Invite input from your employees on the process • Document training
4	Perform a focused internal audit of your document control process. Ensure all documents are: • Appropriately approved and periodically reviewed (based on accrediting bodies and institutional policy) • Uniquely identified with title, current creation/revision date or number • Readily accessible by all staff • Current, complete, and accurate • Legible and identifiable, including work aids • Included on master list with number of copies available and their locations • Understood by staff (new/revised documents reviewed by pertinent staff) • Appropriately archived and marked as obsolete
5	Follow up with any needed corrective action based on input from employees and audit findings.

Implementing an Electronic Document Control System

If you choose to implement an electronic document control system, one of your first challenges is to select a vendor/system. Creating a "home grown" system is rarely economical.

Here is an example of a plan for selecting and implementing an electronic document control system:

Step	Action
1	Assemble a team (physicians, medical technologists, administrators, and laboratory division heads and supervisors).
2	Create a wish list for functions and capabilities (control of any document type, automatic routing, audit trail, search capabilities, record archiving, email notification for annual review, etc).
3	Assemble a working group: • Identify software vendors • Research online • Seek recommendations • Narrow selection • Request proposals based on desired features and functions • Present to team
4	Team selects two to three top candidates.
5	Working group: • Checks out five references from each candidate. (References should come from organizations in a similar industry with similar requirements to yours.) • Selects two finalists
6	Finalists make presentation/demo to working group.
7	Base decision on: • Features and functions (see below) • What is standard versus what is customized • System or vendor host • Cost • Contracts • Business philosophy • Implementation assistance
8	Prepare for arrival/organize data.

Step	Action
9	Implement and train: • Identify implementation manager. The vendor should assign a manager who will remain with your team throughout the process. • Evaluate the standard vendor product functionality to see if you need to customize. If necessary, customize forms and workflow. • Develop plans for moving existing content into new system. Organize and clean content; identify how the move will occur; plan to put all documents on hold (make system un-editable); plan training schedule. • Move information into new system. Remove information from old system. • Perform QA check. Test workflows and escalation process; spot-check some procedures.

See article: Wagner K. Sifting through software—how one lab chooses. *CAP TODAY*. April 2008;22(4):87–88.

Follow this path for the online version of the article: CAP Home > CAP Reference Resources and Publications > CAP TODAY.

Electronic Document Control Systems - Features and Functions

Here is a list of features and functions to look for in an electronic document control system:

User-friendliness issues
- Easy to use for the end user
- Configurable by the end user (Information Technology does not need to be involved)
- Transparent accountability provisions
- History of changes and evidence of reviews and approvals need to be easily accessible
- Real time reports need to be available

Automation issues
- Notifications need to happen repeatable until action is completed
- Action items need to escalate if not addressed
- Notifications need to be automatically issued
- Automatic scheduling of tasks
- Headers need to automatically update

System flexibility issues
- Security needs to be flexible to suit the various departments and set by the system administrators.
- All document types accepted
- Is system PC-based or Web-based? How many licenses are required?
- Search capabilities

Cost/Benefit Analysis

In considering an investment in a document control system, take into account both the upside and the downside.

- How much rework is done because workers initially follow the wrong procedure, make an error, and have to redo the test?
- How much time does it take for get a document review through the system? How many people are involved? Is there rework or administrative cost because of a labor-intensive process that relies on people to check emails, route folders with sticky notes, etc?
- What would be the likely cost of significant occurrence in terms of lost reputation, lost business, and litigation? How would it affect patient care?

Here is an analysis and cost workup of typical work performed to maintain document control. This analysis will help determine whether an electronic document control system would save money and when the break-even point would come.

Cost Savings

Workplace Learning

1. Use the cost savings worksheet to create a business case for an electronic document control system for your laboratory.
2. Present this analysis to your quality manager.

Software Vendors

This section provides examples of software vendors and shows how their packages help users meet document control requirements at each phase of the document lifecycle.

PolicyStat

Background on PolicyStat:

- Cloud-based system (software/files sit on vendor server – accessed through web)
- Because it is cloud-based, laboratory does not need to implement software updates— PolicyStat takes care of maintenance
- Flexible licensure arrangements
- Easily accessible from anywhere by users

Phase	Features of PolicyStat	Demo
Initiation	• Shows flowchart of approvals • Streamlines distribution process for committee reviews • Uniquely identifies documents (title, additions) • Builds in metadata that will help later when users search (tie to clause, standard, requirement) • Maintains master list of documents • Enables creation of documents with templates • Enables scanning/import of external or existing documents	Click on the link below to see PolicyStat demo of these features. http://policystat.com/document-control
Implementation	• Notifies users of new/revised documents • Enables users to easily create record that they have reviewed new/revised documents (click button) • Provides documents at point of use, filtered by job title/responsibility (based on login) • Ensures current versions of documents— printed documents have watermark and date • Provides advanced search capabilities (eg, by clause, organization) • Accessible via URL from any web-linked computer	
Review/Revision	• Provides administrator with dashboard; informs him/her of upcoming reviews 30-60-90 • Provides structured process for updating • Provides visual flowchart of process of reviews/approvals • Updates master list • Sends notification to users when documents are revised	
Archive	• Differentiates 1) old versions of existing/in-use documents, and 2) retired documents (not in use) • Takes old/retired documents out of use, and automatically archives them	

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MasterControl

This table shows how MasterControl's features help users meet document control requirements.

Phase	Features of MasterControl	Demo
Initiation	• Electronic workspace for document editing in native format • Workflow can be assigned based on document type or by editor/initiator's choice • Automatic escalation if step approval is delayed • Streamlines distribution process for committee reviews • Allows for uniquely documents identity based on number, location, and revision • Builds in metadata that will help later when users search (tie to clause, standard, requirement) • Maintains master list of documents • Enables creation of documents with templates • Enables scanning/import of external or existing documents • Enables linking of document easy reference	Click on the link below to see MasterControl demo of these features. http://www.mastercontrol.com/downloadables/webinars/cap
Implementation	• Automatic notification of appropriate decision makers when a document is due for review Provides administrator with dashboard; informs him/her of upcoming reviews 30-60-90 • Provides structured process for updating • Updates master list • Automatically updates coversheet and signature manifest • Sends notification to users when documents are revised • Sends training task if appropriate to affected users • Automatic updates to electronic filing cabinet ensure access to latest revision	
Review/Revision	• Automatic notification of appropriate decision makers when a document is due for review • Provides administrator with dashboard; informs him/her of upcoming reviews 30-60-90 • Provides structured process for updating • Updates master list • Automatically updates coversheet and signature manifest • Sends notification to users when documents are revised • Sends training task if appropriate to affected users • Ensures access to latest revision with automatic updates sent to electronic filing cabinet	
Archive	• Takes old/retired documents out of use, and automatically archives them • Obsolete revisions are not accessible to users lacking proper rights ensuring access to active version	

Other Vendors

Here are links to other well-established vendors of electronic document control systems.

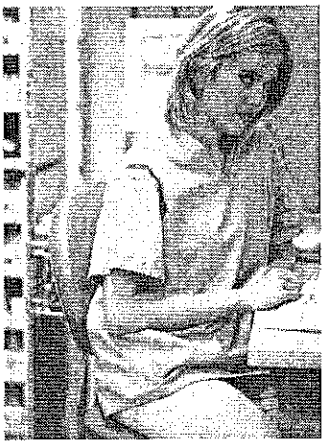
EtQ
Paradigm 3
SoftTech

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.

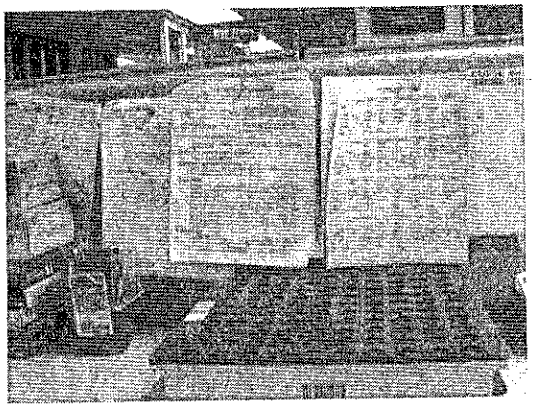
	**Auditor**	During my assessment of the pre-analytic process of Miller-Latif Laboratory, I asked one of the accession staff to locate the written procedure for the activity she was performing. She looked for several minutes in the online document control system, but she was unable to locate it. She told 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.

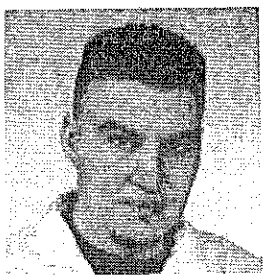
	**Accessioner**	The new table of contents and the guide make it easy to quickly pull up any procedure we need.

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.

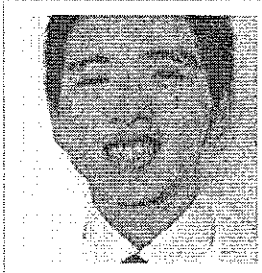
Chemistry Tech

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

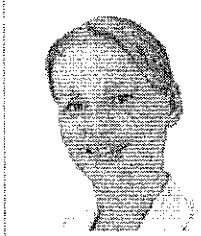
Document control problem:
Not all staff has reviewed the revised procedure Patient Information Confidentiality. Three months have lapsed since it was released. This is a paper document control process.

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.

Glossary

Term	Definition
Archive	To put in a place for storing earlier, and often historical, material. An archive usually contains documents (letters, records, newspapers, etc.) or other types of media kept for historical interest.
Corrective Action	Action to eliminate the cause of a detected problem or other undesirable situation.
Deficiency	Lack of compliance with a regulatory requirement.
Document	An information source and its supporting medium.
Document Control	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
Electronic Document Control System	A software package that enables a user to manage the creation, approval, distribution and archiving of all controlled documents. There are two types: • Software/files sit on organization's network server (on-premise internal system) • Software files sit on vendor server – accessed through web ("cloud" based system)
External Document	An information source and its supporting medium not created within the organization.
Focused Audit	An audit of a specific process, or a specific part of a process, because that process is high risk, has shown weakness in prior audits, or because of a corrective action / customer complaint.
Forms	Paper or electronic documents on which information or results are captured.
Hierarchy	Any group of objects ranked so that every one

	but the topmost is subordinate to a specified one above it.
Hyperlink	A reference to a document that the reader can directly follow, or that is followed automatically. Hyperlinks are often used in tool-enhanced paper systems or electronic systems.
Inspection	A process that checks that certain regulations or rules are obeyed
Internal Audit	Sometimes called a first-party audit, is an audit conducted by, or on the behalf of, the organization itself
Intranet	A private computer network that uses the protocols of the Internet
Network	Multiple computers and other devices connected together to share information
Obsolete	No longer in use
Outlook	An e-mail and personal information management software product from Microsoft
Policy	A documented statement of overall intentions, endorsed by management and chosen from among alternatives to guide and determine present and future decisions.
Procedure	Specified way to carry out an activity or a process
Process	A 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.
Process Map	A document to identify all the steps and decisions in a process in the form of a diagram.
Quality	Degree to which a set of inherent characteristics fulfills requirements
Quality Management System	A set of interacting parts, functions, and activities designed to ensure quality in an organization's goods and services. It typically includes: • A well-planned set of processes for providing goods or services

	• Continual improvement of processes • A set of metrics to monitor whether the processes are achieving the organization's goals • Infrastructure (eg, quality manager, management review committee, internal auditors) and ongoing activities to support quality within processes • Periodic audits of processes with subsequent plans for improvement • Risk assessment
Quality Manual	Document specifying the quality management system of an organization
Record	A document that captures results or other critical information from the performance of a procedure.
Repository	A location for storage, often for safety or preservation
Revision	The process of editing an existing text so as to produce an improved version.
Root Cause Analysis	Process to identify the basic factor(s) that underlie variation in performance and then identify the most likely basic factor (root cause) of the variation.
Software	Encoded computer instructions
System	A set of interrelated or interacting elements
Tool-Enhanced Paper System	A document control system that uses technology tools to facilitate various elements of a paper system.
Vendor	The supplier or manufacturer of a device, system, or service.
Web-based	The environment in which software in created and used on servers available to multiple users via the Internet, especially to users who may be using any of a variety of operating systems.
Work Aid	A procedure, or a portion of a procedure, created to serve as a reference while the worker is performing the task.

Self Check Quiz

1. Which of the following documents need to be controlled?

   a. Emails from the laboratory medical director
   b. Notes from the Microbiology meeting
   c. Procedures regarding accessioning
   d. Workplans for quality management system implementation
   e. All of the above

2. Which of the following characteristics must be present with "controlled" documents?

   a. Accessible
   b. Accurate
   c. Electronic
   d. Current
   e. All of the above
   f. A, B, and D

3. The terms "record" and "document" are interchangeable for all practical purposes.

   a. True
   b. False

4. Which of the following is a difference between a process and a procedure?

   a. A process typically involves starts and stops, and involves more than one person or group; a procedure can be done by one person or role at a single point in time.
   b. A process is a set of overall intentions endorsed by management; a procedure involves a specific set of interacting activities.
   c. Neither of the above. There is no practical difference between a process and a procedure.

5. What is an electronic document control system?

   a. It is a fancy name for a paper system with tools such as a spreadsheet to maintain a master list and email to facilitate distribution and approval of documents.
   b. It is a system with computer monitors for document display and automatic backup at least every four hours.
   c. It is a software package that controls creation, approval, distribution, and archiving of documents.

6. What is the first step in implementing a paper document control system?

   a. Purchasing a quality word processing system
   b. Creating a process map
   c. Performing internal audit
   d. Training staff on document control