

## Quality System: Document Management Creating and Managing User-Friendly Documents

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## Why document management?

- 2004, CAP laboratory inspectors cited 6.3% of laboratories for failure to implement a document control system (One of the highest rates of citation in the CAP Laboratory Accreditation Program)

## Why document management?

- Of the 6.3%
  - 1.0% - 4.5% cited for failing to perform annual review
  - 1.2% - 2.0% cited for failing to make a complete procedure manual available at the work bench

## Why document management?

- Two significant quality risks\* related to policies and procedures are: \*Quality Management in the Clinical Laboratory by Paul Valenstein, MD
  - Steps performed by laboratorians may diverge from steps specified in written procedures, creating distinct and separate worlds of "practice" and "paper".

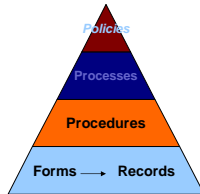
## Why document management?

- Many laboratory processes are never documented at all and have never been formally reviewed or authorized

## Plan for this hour:

- List the key requirements to writing user-friendly technical documents
- Edit a document to make it more user-friendly using the key requirements
- Discuss why user-friendly documents and document management are the basis for standardized work
- Describe the necessary elements for a complete document management system

## 4 Levels of Documents



## Policies



- A documented statement of overall intentions and directions defined by those in the organization and endorsed by management

## Policy Statements

- Statements of **what** the laboratory does
- Policy statements should be declarative.
  - The Department of Pathology identifies patients using two patient identifiers before collecting any type of specimen.
  - Not, the Department of Pathology will identify patients using two patient identifiers...
- May be stand alone documents or contained in the body of a process description or a procedure

## Policy Statements

- For each policy statement there are numerous process documents, procedures and forms.

## Process Document



- Depicts or describes “**how something happens**”
  - Use flowcharts or tables
- Key work processes interlink to transform an examination into a result report for a patient's health record
- Provide the means to identify problematic activities that can be improved to help prevent medical errors

## Procedures (SOPs)



- **How** to do it
- Present step-by-step instructions that a single individual needs to take to successfully complete one activity in the process
- One process document refers to a number of supporting procedure documents

## Forms



- Forms are blank documents or computer screens onto which the results generated from the performance of a given procedure are recorded

## Standardized Formats

- Template ensures that essential information will be in every document
- Consistent look for the end-user to read
- Ensure that format will be compatible if posting on an intranet or website

## CLSI GP2-A5

### Laboratory Documents: Development and Control

- Suggested contents of laboratory procedures, depending on type of document
- Encourages users to write procedures using laboratory's work processes and work flow

## Standardized Format

- Unique identification system
  - Alpha/numeric combinations
- Title – clearly states the intent of the document

## Effective Technical Writing

- Know your audience
  - Write for the novice or cross-trained staff member
  - Write to EXPRESS not to impress
- Use ACTIVE verbs:
  - **Do Not Write:** The mixture is allowed to reach 200 degrees.
  - **DO WRITE:** Allow the mixture to reach 200 degrees.

## Effective Technical Writing

- Use present tense
- Use white space (break up blocks of text)
- Avoid wordiness
- Use flowcharts, tables
- Begin instructions with an imperative
  - **Do not write:** It is necessary to record ...
  - **Do write:** Record....

## Standardized work – why?

- Eight Wastes
  - Overproduction
  - Waiting
  - Excess motion
  - Transport
  - Overprocessing
  - Inventory
  - Defects
  - Unused expertise

## Standardized work – reduce variability – so can improve

- Best, easiest, safest method today
- Only one standard
- Documentation of know-how
- Consistent with quality, cost, and deliverables requirement

## Standardized work and documents?

- Essential to incorporate technical writing guidelines
- Visual is best
  - Use a process flow diagram instead of a 5 page procedure
    - Easier for staff member to use
    - More likely to use the document
    - Easier to audit the work to ensure they are following the standard

## Standardized work and documents?

- Document Control process needs to be more agile and flexible
- Eliminate waste in process

## Document Control – Step 1

- Initiate a Document Change Control Form (DCCF)
  - Rationale for new or changed the document
  - New or changed document
  - Name, number, version number, requestor, date, change number

## Step 1

- Document Change Control Form cont'd
  - Related documents affected? Y/N
  - Process validation affected? Y/N
  - Training needed? Type of training
  - Approval section
  - Annual review section
  - Distributed locations section

## Step 1

- Document control should be controlled by limiting the number of people
  - Document control person
  - Keep track of who is working on what procedures (avoid duplication)
  - Assign new numbers

## Step 2

- Write the procedure or other type of document
  - Follow formatting procedure
  - Ensure following manufacturer's package insert or operator's manual
  - Follow Technical Writing guidelines

## Step 3

- Are there related documents that need to be reviewed and revised?
  - Have a Related Document section
    - Lists other procedures, forms or process documents that contain information associated with the document being revised

## Step 4

- Validate procedure:
  - Have 1-2 staff members follow procedure exactly as written and write comments, questions on the document

## Step 4

- Ask Quality staff member or another member of management to:
  - Compare the procedure to the manufacturer's directions and/or operator's manual to ensure that it is accurate
  - Ensure that it is the standardized work that was agreed upon

## Step 5

- Determine if process validation testing needs to be done and perform as necessary
- Examples include:
  - New reagent
  - Change in kits
  - Package insert change
  - Change in critical supplies (new butterfly needle for collections)

## Step 6

- **Send procedure for approval signatures**
  - Signatory list is determined by Laboratory Medical Director
  - Should be at least:
    - Laboratory Medical Director
    - Appropriate member of management team
    - Quality Representative or someone that serves in that role, mandated by FDA for Blood Establishments
    - Author

## Step 7

- **Train on the procedure**
  - On the CCF it is noted the type of training to be done – this could be:
    - Read and sign off
    - Read and in-service training
    - Read and competency assessment

## Step 7

- **Training must be documented regardless of the type of training performed**
- **Training of all staff must occur before patient testing using the new or revised procedure is ever performed**

## Step 8

- **Log the following information into the Master Index (Control Log) at a minimum:**
  - Document name
  - Effective date
  - Document number
  - Version
  - Distribution locations of each working copy of the document

## Step 8

- **Master Index may also include:**
  - Annual review date (when it should be performed) and
  - Date annual review actually performed

## Step 9

- **Refer to the Document Change Control Form and/or the Master Index for the number of copies of the document to be made**
- **Prepare copies**
- **Distribute the copies to the appropriate procedure manuals – remove previous versions of the document and discard**

## Step 10

- Update the Master File (paper file)
  - The current and all previous versions of the document
  - Includes the Document Change Control Form or other type of approval page for the document

## Step 11

- Archival of documents:
  - When a document is changed, new version becomes the new master document
  - Note on the previous version in the Master File via a stamp or other method:
    - That the document is archived
    - Include the date of archival
    - This prevents its unintended use

## Step 12

- **Storage of Archived Documents must have a method:**
  - To prevent loss, damage, or unauthorized access
  - Must be able to retrieve easily
  - Retention times for archived documents are defined by regulations, accreditation requirements, and organizations

## Document Management

All of the preceding steps must be outlined in procedure(s) and handled just like any other procedure, including validation and training.

## Annual Review

- **Purpose:**
  - To review unchanged documents to detect errors, oversights, or work practices that have diverged from formal procedures
  - Date for annual review changes, if the document is revised during the course of the year
    - Annual review to be done in April but procedure is revised in February, then annual review not needed until the next February

## Annual Review cont'd.....

- Methods used to ensure this process gets done each year:
  - If Master List is in Excel - use the sorting function to determine which controlled documents need to be reviewed for the upcoming month.
  - Split up your Master List of controlled documents into 12 lists, so 1/12 of documents are reviewed each month.

## Annual Review cont'd...

- Methods to ensure this gets done:
  - Assign Annual Review as a bench on the CLS schedule
  - Others?

## Job Aides

CAP calls them Derivative Documents

- Index card files, posted diagrams, forms, instruction sheets, wall charts
  - Need review to ensure they are current, complete, correct, and traceable to the parent document
  - Effective date must be listed

## Job Aides cont'd...

- Must control them
- Initiate a Document Change Control Form, if revisions are needed
- Uniquely identify them (alpha/numeric)
  - JAxxxx (JobAide with the procedure #)
- List them as a Related Document in the parent document
- Prepare a Master File for each of these documents and include in the Master Index
- Include a completed example of form in each procedure, where used

## Table of Contents

- CLSI GP2-A5 has examples of TOCs that make finding the right document easy
  - They arrange the procedures into subgroups that represent the sequence of work activities rather than alphabetically or numerically
- Must ensure that TOCs are up-to-date

## In review...

- Create appropriate documents based on their purpose
- Create user-friendly documents
  - Its midnight on Christmas Eve and you are putting that toy together – did the directions help?
- Create documents based on standardized work
- Ensure document control process is complete and at the same time agile and flexible

## Document Management

may seem like it's a big headache now...



But its absolute panic in the middle of night when...

- Your newest CLS is using the old version of a procedure and the Troponin result they just sent to the ED is wrong!

