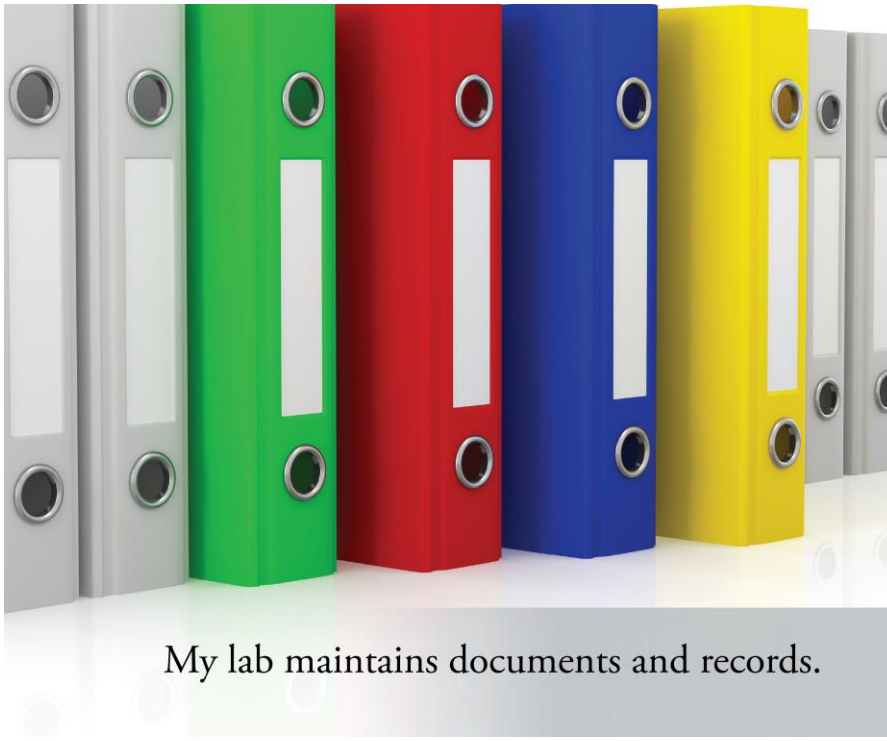
MODULE 10

Documents and Records

2015 Version



SLMTA Trainer's Guide

Overview

MODULE 10. DOCUMENTS AND RECORDS MANAGEMENT

Performance Outcome

With satisfactory participation in the training and successful implementation of laboratory improvement projects, a participant's laboratory should achieve the following outcome:

- Permanent, secure, and traceable records
- Approved, up-to-date, and easily accessible documents

Checklist Items Supported by this Module

This module supports the requirements for the following items from the SLIPTA Checklist:

1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9

Learning Objectives (Management Tasks)

By the end of this module, participants should be able to perform the following management tasks:

1. Maintain a library of documents (policies, guidelines, SOP's, references, etc.); review and update annually
2. Maintain integrity, organization, and confidentiality of records (client test results, specimen transfer logs, maintenance logs, inventory logs, etc.)
3. Assure proper record retention, rotation to storage, and disposal according to protocol

What's in this Module?

ACTIVITY TITLE	PURPOSE	DURATION
Why Was the Outdated Version Used?	Document control ensures staff members have the current, correct, and consistent information to perform their work. In this activity, participants utilize a master file index to control common documents used in the laboratory. Record management is addressed during the cross-cutting activity, Workstation Set-up.	50 min
	TOTAL ACTIVITY TIME:	**50 min**

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ACTIVITY Why Was the Outdated Version Used? Module 10

PURPOSE:

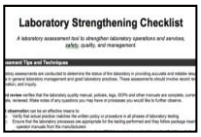
Document control ensures staff members have the current, correct, and consistent information to perform their work. In this activity, participants utilize a master file index to control common documents used in the laboratory.

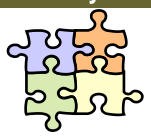
RESOURCES FOR FACILITATOR:

- ❑ PowerPoint slides: 10.10 to 10.15
- ❑ Tool: Key Points
- ❑ File folder
- ❑ Tape, flipchart and markers

RESOURCES FOR PARTICIPANT:

- ❑ Handout: Glucose Coversheet (1001)
- ❑ Worksheet 1: Master File Index (1002)
- ❑ Worksheet 2: Scenarios (1003)
- ❑ Worksheet 3: Scenario A (AFB) (1004)
- ❑ Worksheet 4: Scenario B (Critical) (1005)
- ❑ Worksheet 5: Scenario C (Hgb) (1006)
- ❑ Job Aid: Documents and Records (1007)

This activity supports the following laboratory management tasks and SLIPTA checklist items	
Management Tasks 	10.1 Maintain a library of documents (policies, guidelines, SOPs, references, etc.); review and update annually
Checklist Items 	1.2 Laboratory Quality Manual Is there a current laboratory quality manual, composed of the quality management system's policies and has the manual content been communicated to, understood and implemented by all staff? 1.3 Document and Information Control System Does the laboratory have a system in place to control all documents and information from internal and external sources? 1.4 Document and Records Is there a list that details all documents used in the quality management system indicating their editions and distribution? 1.5 Laboratory Policies and Standard Operating Procedures Are policies and/or standard operating procedures (SOPs) for laboratory functions, technical and managerial procedures current, available and approved by authorized personnel? (Document Control) 1.6 Policy and SOPs Accessibility Are policies and SOPs easily accessible/ available to all staff and written in a language commonly understood by respective staff? 1.7 Policies and SOPs Communication Is there documented evidence that all relevant policies and SOPs have been communicated to and are understood and implemented by all staff as related to their responsibilities? 1.8 Document Control Log Are policies and procedures dated to reflect when it was put into effect, its location, when it was reviewed and when it was discontinued? 1.9 Discontinued Policies and SOPs Are invalid or discontinued policies and procedures clearly marked / identified and removed from use and one copy retained for reference purposes?

This activity is related to the following activities:	
	Cross-cutting: Workstation Set-Up Module 1: Creating a Management Calendar Module 1: What are the Benefits of a Standardized Process? Module 1: Planning and Conducting a Staff Meeting Module 6: Using Standard Operating Procedures

ACTIVITY AT-A-GLANCE				
Step		**Time**	**Resources**	**Key Points**
1	Explain why documents need to be controlled	10 min	Slides 10.10 to 10.14 Job Aid Handout Worksheet 1 File folder	
2	Introduce the activity	5 min	Slide 10.15 Worksheet 2 Worksheet 3 Worksheet 4 Worksheet 5	
3	Conduct the activity	15 min	Job Aid Worksheet 1 Worksheet 2 Worksheet 3 Worksheet 4 Worksheet 5	
4	Debrief the activity	15 min	Worksheet 1 Worksheet 2 Worksheet 3 Worksheet 4 Worksheet 5 Tool	
5	Conclude the Activity	5 min		
	TOTAL TIME:	**50 min**		

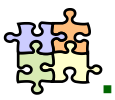
PROCESS

Preparation

- Consider printing Worksheets 1-5 using a single-sided format and not a double-sided format to make this activity more user-friendly for the participants.

Step 1. Explain why documents need to be controlled 10 min

- Project Slide 10.10 to introduce the activity.
- Distribute Job Aid: Documents and Records. Introduce the job aid indicating that documents describe the work to be done and records capture the results of doing the work. Review and explain the job aid with the participants. Indicate that for this activity, the focus will be on document control. Record management will be explored during the activity, *Workstation Set-Up*.



- Share a personal story regarding document control problems that led to variations in quality which affected patient care (i.e. the revised procedure was distributed to all manuals except the one located at the workstation resulting in the wrong dilution factor being used for the patient's result.)
- Project Slides 10.11 to 10.12 while referring participants to Handout: Glucose Coversheet and Worksheet 1: Mater File Index. Discuss the following points and relate them to the job aid:
  - Review the required elements for document identification.
  - Indicate the page numbers identified as page 1 of 5.
  - Indicate the discontinuation date is blank since the procedure is in-use.
  - The date is used as the version number with version 1 being the effective (adopted) date.
  - Emphasize the documentation of the periodic review. The last review date, December 20, 20**XX**, was chosen to represent the performance of annual reviews.
  - Discuss how the master index file resembles a table of contents and reflects the coversheet.
  - Discuss which documents for this procedure would be contained in the master file (i.e. the original version, each revision, attestation record for the original and each revision) Hold the file folder and explain how individual folders can be used to manage their master file.
- Project Slides 10.13 to 10.14 and discuss the usefulness of establishing a numbering or coding system for all documents as part of their document control system.
- Present a scenario where another revision was needed to the "Serum Glucose – Cobas c111 Analyzer Procedure" and work through the example with the class how the coversheet, index, and file would be updated. Discuss how a numbering or coding system would be beneficial since frequently documents require updating to remain current. Discuss the distribution step so that the current version is made available. Discuss ways the revision would be communicated to the staff members.

Step 2. Introduce the activity 5 min

- Project Slide 10.15 to provide an overview of the activity.
- Distribute or refer participants to Worksheets 2 through 5. Explain that participants will perform the document control for three common laboratory scenarios involving: a current procedure, a revised procedure, and a new procedure.
- Divide the class into groups of 4-6.
- Instruct the groups to answer the questions and update the index and coversheets as needed for all three scenarios. Indicate the groups have 15 minutes to discuss all three scenarios.
- Mention that each scenario will be presented as a 2-minute summary by a group to explain their document control approach for that scenario. Indicate that each group must select a spokesperson to present their group's responses.

Step 3. Conduct the activity 15 min

- Monitor and provide assistance during this activity.
- Select the scenario to be summarized for each group towards the end of this activity. Remind each group that the presentation should last no more than 2 minutes.

Step 4. Debrief the activity 15 min

- Facilitate the presentation of Scenario A.
- Provide any insight or feedback you may have to add. Refer to Tool: Key Points to assist you. Solicit any additional feedback from the other participants.
- Facilitate the other two scenarios in the same fashion.

Step 5. Conclude the Activity 5 min

- Highlight or reiterate the key messages below.
- Make sure participants achieved objectives of the activity.

KEY MESSAGES

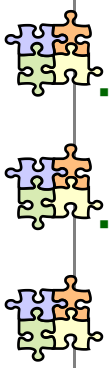
- Document control ensures staff members have the current, correct, and consistent information to perform their work.
- The Master File serves as a historic record of a single document from its inception to the present.
- The Master File Index serves as a table of contents for all documents and their distribution.

Can they:

- Identify the areas needed for document control?
- Update the Master File Index to reflect current documents?
- Propose the necessary actions needed for document control for a revised or a new document?

ACTIVITY OBJECTIVES MET?

➤➤ Connections and Applications



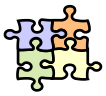
- Documents consist of policies, processes and procedures. To avoid variation in quality, the documents must be standardized and controlled to ensure only the current document is used as a resource by the staff. Reinforce the importance of standardization by connecting this idea to the activity, *What are the Benefits of a Standardized Process?*
- By utulizing a standard format for all procedures at your site, the staff members will become familiar with the same format and be able to locate and refer to the desired information more quickly. Link this to the activity, *Using Standard Operating Procedures*.
- Since procedures can be several pages in length, it is helpful to highlight the specific change in a copy of the revised document during the communication process with employees. (Link this to the *Planning and Conducting a Staff Meeting* activity.) This allows the employees to easily locate and focus on the change when signing the attestation record.

Tool: Key Points

Scenario A (AFB)

The AFB Direct Smear Procedure was created, approved and adopted in 2006. A master file was created which contains the original approved and signed version and the attestation record. No revisions have been made since its adoption date.

This currently in-use procedure has not been subject to a periodic review since 2006. Since this procedure has not been revised, no change to the index or distribution needs to be done. The only action needs to be the documentation of the periodic review on the coversheet. Discuss the importance of performing periodic reviews. Suggest to participants that they could add a reminder on their management calendar to bring this procedure with them to their next meeting with the laboratory director. Link this to the activity, *Creating a Management Calendar*.



(Optional) Consider describing the following scenario to highlight the importance of periodic review: A microbiology staff member attended an AFB Direct Smear Microscopy Workshop in 2008. Upon returning, the staff member indicated that she learned different techniques to reduce the aerosolization potential while preparing the slide. Unfortunately, this information was never captured and incorporated into the procedure. Even though current resources support these improvements, no one considered a revision to be necessary. Newly trained staff members using the 2006 version are not aware of these improvements.

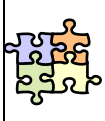
Scenario B (Reporting Critical Results)

Last week patient care was seriously jeopardized when a phoned critical value was transcribed incorrectly by the patient's nurse. Upon reviewing the occurrence report and discussing the incident with your QA manager, the corrective action now requires staff members to request the critical value be read-back to them. Today you have completed the revision to the "Reporting Critical Results Procedure" to reflect this change.

The coversheet and index must be updated with the new revision date to reflect version 2. A copy of the revised policy needs to be added to the master file along with the attestation record that staff has been notified. The master file should now contain the original version and its attestation record, followed by the revised version and its attestation record.

Each distribution location must have the outdated version removed and the revised version inserted. Five copies must be made and distributed to the manuals that currently contain the old version.

The revision needs to be communicated with staff. The weekly staff meeting provides an opportunity to discuss this revision. Link this to the *Planning and Conducting a Staff Meeting* activity.



Suggest to participants that they could add this topic on their management calendar to ensure this revision is discussed. Link this to the activity, *Creating a Management Calendar*.

Tool: Key Points

Note: If the training workshop is conducted after December, 2009, then participants may also note the need for a periodic review.

Scenario C (Hemoglobin and Hematocrit)

Your laboratory has just completed the method validation and training for the new hematology analyzer, the pocH-100i. You were assigned to write all the necessary procedures for this new instrument.

The first step is to obtain approval for a newly created document. Since the laboratory director approved it this morning, the coversheet should be completed with the adopted date being today's date and a participant's name inserted in the 'Prepared By' area. The index needs to be updated. The master file should contain the original version and attestation sheet. Three copies of the procedure need to be distributed.

Discuss how to handle the archiving of the obsolete HemoCue procedure if it will not be used as the backup procedure for hemoglobin. Explain how this discontinued HemoCue procedure must have the date it was discontinued and must be retained according to the defined retention schedule in the Master File. Even though the HemoCue procedure does not appear on the provided Master File Index worksheet, discuss how participants can update the index to reflect its archival status.

Remind participants to update the table of contents that are in the different manuals with the addition and removal of procedures.

Master File Index			
Document Name	**Version**	**Effective Date**	**Location(s)**
Hemoglobin and Hematocrit – pocH-100i Analyzer Procedure	1 (*today's date*)	(*today's date*)	#1 Master File #2 Hematology Department #3 pocH-100i Workstation

Job Aid: Documents and Records

Documents – Policies, processes, and procedures that describe the work to be done.

Document Control - The mechanism that ensures only the latest version of an approved document is available and used as a resource. Obsolete documents are removed and archived so that they can no longer be used but only referenced.

Areas of Document Control

- ❑ Required elements for document identification
  - Title that designates it is a policy, process or procedure (i.e. Quality Control **Policy**, Reporting Critical Results **Procedure**)
  - Version Number such as the effective date or revision number
  - Number of pages
  - Authority for use
  - Laboratory name
- ❑ Creation, approval for use, and distribution of a new document
- ❑ Revisions (changes) to an approved document and its distribution
- ❑ Periodic review of current documents (annual review is recommended).
- ❑ Archiving and retaining obsolete documents
- ❑ Maintaining a master file that contains:
  - Original signed version that all other copies are made
  - Archived master copy of all previous versions
  - A copy of the completed document change form, if required
  - Original copy of the attestation record (list of applicable employee signatures attesting that they have read and understood the new or revised document)

Document Attestation Record

I have read and understood the following document (*insert document title*):

Name	Signature	Date

- ❑ Maintaining a master index that lists:
  - Title Name
  - Version
  - Effective Date
  - Distribution Location(s)

Master File Index

Document Name	Version	Effective Date	Location(s)

Job Aid: Documents and Records

To Address Document Control

Step 1. Create a laboratory policy regarding documents with your laboratory director or QA manager

Step 2. Create a process map and table to address the areas involving document control. For each step in the process determine the procedures needed and the responsible person.

Step 3. Develop the needed procedures.

- For example, the step-by-step instructions for "How to Write a Procedure" may specify:
  - Font size and font type used
  - Required elements of the cover page
  - Required elements of a procedure
  - Cover page template and procedure template
- Standardizing the look and format of all procedures used at your site allows staff members to become familiar with and locate the information needed more readily.

Step 4. Place the document policy, process maps, and procedures in the Quality Manual.

Step 5. Designate a storage area for the master file

Records – Written or electronic information that captures the results of doing the work. They provide the evidence that a task was performed or a result was obtained. Examples of records include the following: requisitions, reports, logs, labels, charts, and tags.

Record Management- The mechanism that ensures that information is captured correctly on the current version, kept confidential, and is available and accessible when needed.

Areas of Record Management

- ❑ Creation or revisions to records that support the work processes and procedures
  - Required elements for record identification, such as title
  - Referenced by title name in the appropriate procedure
- ❑ Distribution of blank records (i.e. blood bank tag for completed crossmatch) or availability of in-use records (i.e. current temperature chart) to support work processes as they occur
- ❑ Active review of records by supervisor or designate person
- ❑ Maintain a record filing system that allows information to be readily located
- ❑ Ability to access and retrieve records when needed while protecting confidentiality
- ❑ Sufficient storage capability to retain records according to the record retention schedule
- ❑ Destruction and disposal of records that ensures confidentiality

Handout: Glucose Coversheet

Cape Clinic Medical Facility
Department of Clinical Laboratory

Document:	
Serum Glucose - Cobas c111 Analyzer Procedure	
Approved by:	Date:
H. Grady Hines, PhD, MT (ASCP^{i})	June 3, 2006

Prepared by:	Date Adopted:	Supersedes Document:
Anne Lugo, MT (ASCP^{i})	June 4, 2006	Glucose by Spectrophotometer Procedure

Date Reviewed:	Date Revised:	Initials:
November 30, 2006		HH
	January 15, 2007	AL
December 15, 2007		HH
December 2, 2008		HH
	April 15, 2009	AL
December 20, 20XX		WSM

Distribution:
#1 Master File
#2 Chemistry Department
#3 Cobas c111 Analyzer Workstation

Date of Discontinuation:		Page 1 of 5

Worksheet 1: Master File Index

CAPE CLINIC LABORATORY

MASTER FILE INDEX

Document Name	Version #	Version Date	Effective Date	Distribution Location(s)
Serum Glucose - Cobas c111 Analyzer Procedure	1	June 4, 2006	June 4, 2006	#1 Master File
	2	January 15, 2007		#2 Chemistry Department
	3	April 15, 2009		#3 Cobas c111 Analyzer Workstation
Acid Fast Bacilli (AFB) Direct Smear Procedure	1	August 3, 2006	August 3, 2006	#1 Master File #2 Microbiology Department
Reporting Critical Results Procedure	1	February 3, 2006	February 3, 2006	#1 Master File #2 Chemistry Department #3 Hematology Department #4 Urinalysis & Serology Department #5 Microbiology Department

Worksheet 2: Scenarios

Scenario A (AFB)

The AFB Direct Smear Procedure was created, approved and adopted in 2006. A master file was created which contains the original approved and signed version and the attestation record. No revisions have been made since its adoption date.

1. What changes, if any, need to be done to the Master File Index? If needed, update the index to reflect the changes.
2. What changes, if any, need to be done in the Master File? If needed, update the procedure's coversheet and list any information to be added or changed in the file.
3. What changes, if any, need to be done with the distribution of this procedure?
4. What information, if any, needs to be communicated with staff members? If needed, how will this be communicated and documented?

Scenario B (Reporting Critical Results)

Last week patient care was seriously jeopardized when a phoned critical value was transcribed incorrectly by the patient's nurse. Upon reviewing the occurrence report and discussing the incident with your QA manager, the corrective action now requires staff members to request the critical value be read-back to them. Today you have completed the revision to the "Reporting Critical Results Procedure" to reflect this change.

1. What changes, if any, need to be done to the Master File Index? If needed, update the index to reflect the changes.
2. What changes, if any, need to be done in the Master File? If needed, update the procedure's coversheet and list any information to be added or changed in the file.
3. What changes, if any, need to be done with the distribution of this procedure?
4. What information, if any, needs to be communicated with staff members? If needed, how will this be communicated and documented?

Scenario C (Hemoglobin and Hematocrit)

Your laboratory has just completed the method validation and training for the new hematology analyzer, the pocH-100i. You were assigned to write all the necessary procedures for this new instrument.

1. Finding no mistakes after proof-reading your written procedure, what are your next steps?
2. The laboratory director approved your procedure this morning, what are your next steps regarding the Master File and Master File Index? Update the procedure's coversheet and list any information to be added in the file. Update the index to reflect the changes.
3. What are your next steps with this new procedure regarding distribution and communicating with staff members?

Worksheet 3: Scenario A (AFB)

Cape Clinic Medical Facility
Department of Clinical Laboratory

Document:	
Acid Fast Bacilli (AFB) Direct Smear Procedure	
Approved by:	Date:
H. Grady Hines, PhD, MT (ASCP^{i})	August 1, 2006

Prepared by:	Date Adopted:	Supersedes Document:
Anne Lugo, MT (ASCP^{i})	August 3, 2006	Not Applicable

Date Reviewed:	Date Revised:	Initials:
November 30, 2006		HH

Distribution:
#1 Master File
#2 Microbiology Department

Date of Discontinuation:		Page 1 of 8

Worksheet 4: Scenario B (Critical)

Cape Clinic Medical Facility
Department of Clinical Laboratory

Document:	
Reporting Critical Results Procedure	
Approved by: H. Grady Hines, PhD, MT (ASCP^{i})	*Date:* February 1, 2006

Prepared by:	*Date Adopted:*	*Supersedes Document:*
Anne Lugo, MT (ASCP^{i})	February 3, 2006	Not Applicable

Date Reviewed:	*Date Revised:*	*Initials:*
December 19, 2006		HH
December 15, 2007		HH
December 2, 2008		HH

Distribution:

#1 Master File	#4 Urinalysis & Serology Department
#2 Chemistry Department	#5 Microbiology Department
#3 Hematology Department	

Date of Discontinuation:		Page 1 of 3

Worksheet 5: Scenario C (Hgb)

Cape Clinic Medical Facility
Department of Clinical Laboratory

Document:	
Hemoglobin and Hematocrit - pocH-100i Analyzer Procedure	
Approved by:	*Date:*

Prepared by:	*Date Adopted:*	*Supersedes Document:*
		Hemoglobin by HemoCue Procedure

Date Reviewed:	*Date Revised:*	*Initials:*

Distribution:
#1 Master File
#2 Hematology Department
#3 pocH-100i Analyzer Workstation

Date of Discontinuation:		Page 1 of 5