Strengthening Laboratory Management Toward Accreditation

Module 10: Documents and Records Management

Key Message ...

My lab maintains documents and records

Desired Outcome

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

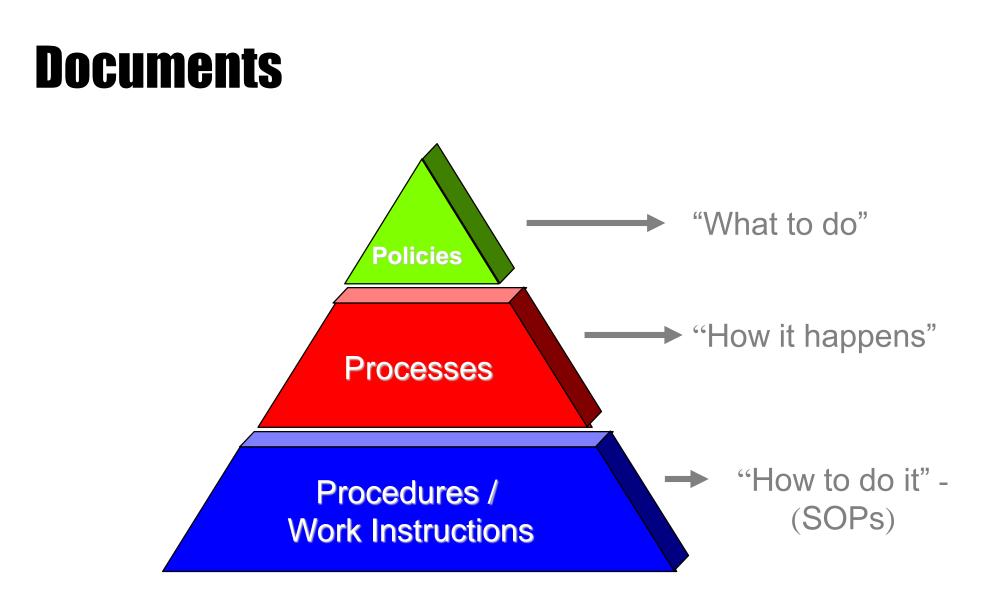
You document because

- "The palest ink is clearer than the best memory."
 Chinese Proverb
- Not documented Not done!

Conviction held by clinical laboratory scientists worldwide

Document and Records

- Documents provide the policies and procedures to guide the work of the laboratory.
- Records provide the evidence that this work is accomplished.



Records

- Patient Records
 - Specimen Log
 - Patient Reports
- Specimen Records
 - Specimen Rejection Log
 - Specimen Referral Log
- Equipment Records
 - Equipment Inventory
 - Maintenance Logs
 - Temperature Logs
 - Instrument Printouts

Module 10: Documents	&	Records	Management
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Records

Quality Assurance Records

- Daily Quality Control (QC)
- EQA External Quality Assurance results
- Improvement Projects
- Adverse Occurrences
- Patient Satisfaction Surveys
- Internal Audits
- Personnel Records
 - Competency Assessment / Training
- Inventory / Supply Records

Records -Management Reporting

- Statistics
- Important for:
 - monitoring progress
 - documenting the work
 that you do
 - detecting problems or trends
 - planning/projecting for the future

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Task

 10.1 - Maintain a library of documents (policies, guidelines, SOPs, references, etc.); review and update annually

Ensuring the information is current whenever it is needed.

Why Was the Outdated Procedure Used?

Cape Clinic Medical Facility Department of Clinical Laboratory

Document: Serum Glucose	- Cobas c111 Anal	lyzer Procec	lure				
Approved by: Date:							
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Prepared by: Anne Lugo, MT (ASCP ⁱ)	Date Adopted: June 4, 2006		^{ent:} ectrophotometer cedure				
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#2 Chemistry Department							
#3 Cobas c111 Analyzer Workstation							
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CAPE CLINIC LABORATORY

MASTER FILE INDEX

Document Name		Version	Effective Date	Distribution Location(s)	
	#	Date			
Serum Glucose - Cobas c111 Analyzer	1	June 4, 2006	June 4, 2006	#1 Master File	
Procedure	2	January 15, 2007		#2 Chemistry Department #3 Cobas c111 Analyzer	
	3	April 15, 2009		Workstation	

Cape Clinic Medical Facility Department of Clinical Laboratory

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#1 Master File #2 Chemistry Department			
3 Cobas c111 Analyzer Workstatio	n		
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CAPE CLINIC LABORATORY MASTER FILE INDEX: Standard Operating Procedures - General Chemistry



Number	Document Name	#	Version Date	Effective Date	Distribution Location(s)
SGC35	Serum Glucose - Cobas c111 Analyzer Procedure	1 2	June 4, 2006 January 15, 2007	June 4, 2006	#1 Master File #2 Chemistry Department
		3	April 15, 2009		#3 Cobas c111 Analyzer Workstation
SGC36	AST/SGOT - Cobas c111 Analyzer Procedure	1	June 4, 2006	June 4, 2006	#1 Master File #2 Chemistry Department #3 Cobas c111 Analyzer Workstation

Activity: Why was the Outdated Version Used?

Purpose

To perform document control for three common laboratory scenarios involving: a current procedure, a revised procedure, and a new procedure.

What will you need?

- <u>Worksheet 1</u>: Master File Index <u>Worksheet 2</u>: Scenario
- Worksheet 3: Scenario A (AFB)
- Worksheet 4: Scenario B (Critical)
- Worksheet <u>5</u>: Scenario C (Hgb)

What will you do?

Divide into groups of 4-6 to:

- Select a spokesperson for your group
- Answer questions relating to <u>Worksheet 2</u>
- Update the Master File Index (<u>Worksheet 1</u>) and the procedure coversheets (<u>Worksheets 3-5</u>)
- The group's spokesperson presents a summary of the document control steps for one scenario during the 2 minute class report.



Tasks

- 10.2 Maintain integrity, organization, and confidentiality of records (client test results, specimen transfer logs, maintenance logs, inventory logs, etc.)
- 10.3 Assure proper record retention, rotation to storage, and disposal according to protocol

Activity: Workstation Set-up

Purpose

To create and organize an efficient and productive workstation using elements developed from each module.

What will you need?

Laboratory Accreditation Preparedness Checklist

What will you do?

- Participate in the classroom's discussion
- Integrate key concepts from earlier activities



15 minutes

Activity: What Would You Do?

Purpose

To integrate the module's lessons and apply them to the case scenario.

What will you need?

Handout: Case Study Scenarios

What will you do?

Divide into groups of 4-5

- Select a spokesperson for your group
- Formulate specific action steps to address the scenario from the <u>Handout</u>.
- The group's spokesperson presents the proposed steps during the 2 minute class report.



5 minutes

What Would You Do?

You recently updated a policy to prevent the reoccurrence of a serious issue. Later in the month, the same situation occurred again resulting in a serious injury to a patient. When you questioned the staff member, you discovered he/she only had access to the old version of the policy that did not reflect the updated changes. You realize there are several copies of this policy, but you cannot recall where they are all located.

What actions can you take in managing your documents and records?

What Would You Do?

You have heard rumors that patients in your community are hesitant to come to your facility because of confidentiality issues.

- What actions do you take to ensure the confidentiality of the laboratory results?
- When asked, how will you assure your patients that the laboratory maintains confidentiality?

Tasks

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