

Module 10:

Documents and Records

Management

Key Message ...

My lab maintains documents and records

Desired Outcome

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

You document because

- “The palest ink is clearer than the best memory.”

Chinese Proverb

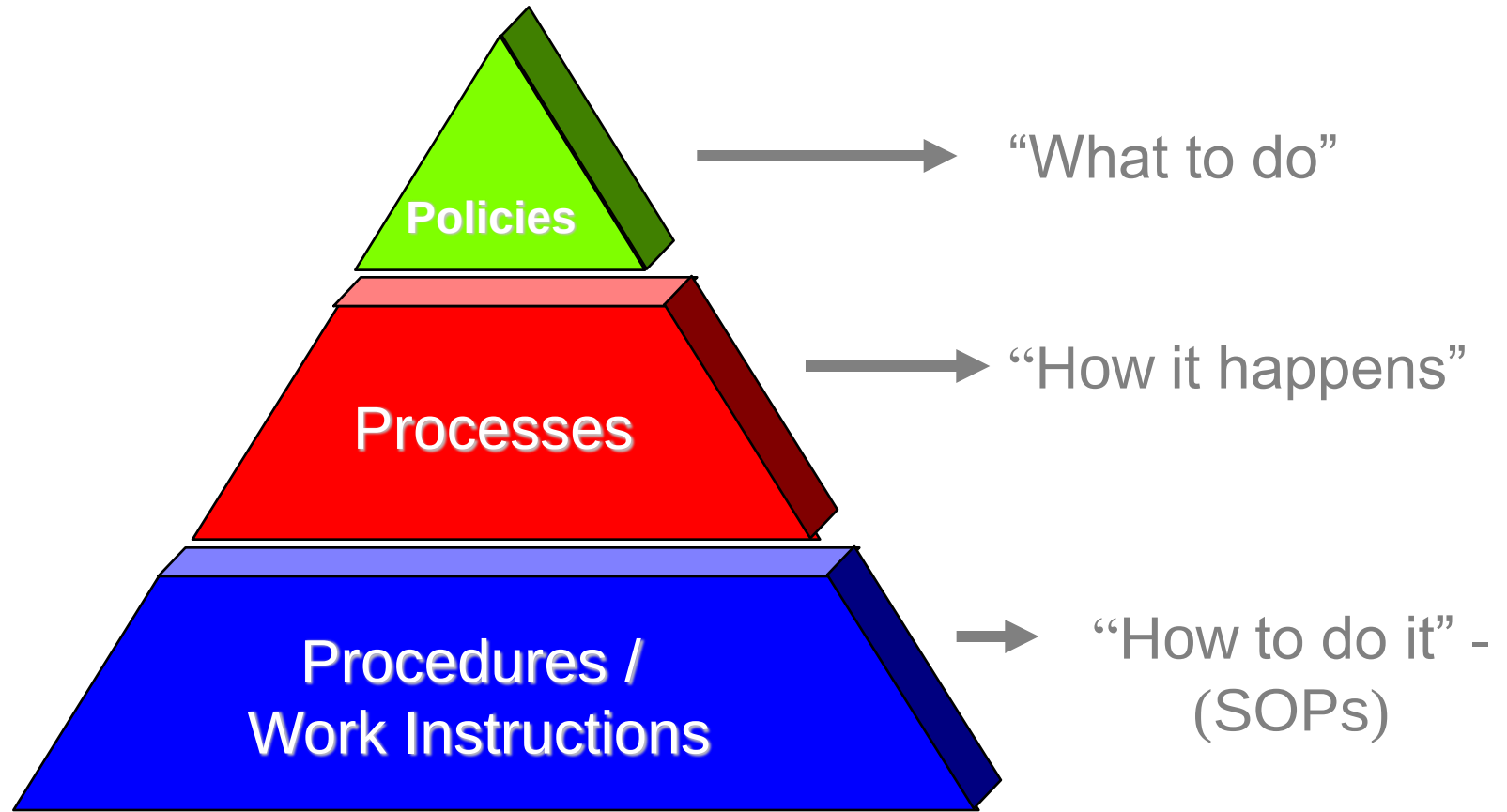
- Not documented – Not done!

Conviction held by clinical laboratory scientists worldwide

Document and Records

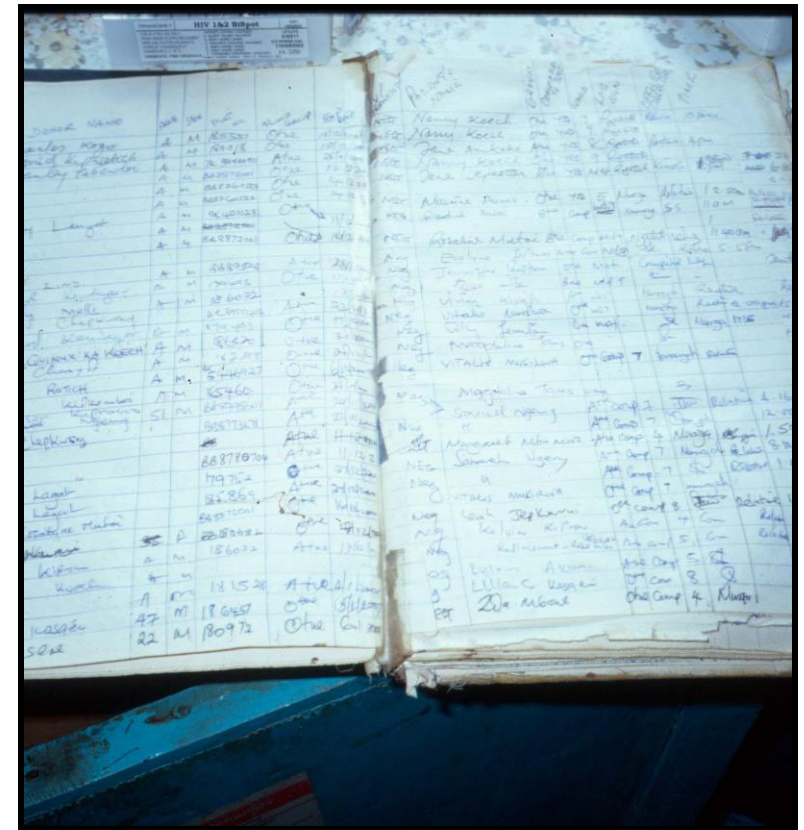
- Documents provide the policies and procedures to guide the work of the laboratory.
- Records provide the evidence that this work is accomplished.

Documents



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



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

Test	JAN	FEB	MAR	Total
ALT				
AST				
CD4				
FBC				
TB Smears				

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Why Was the Outdated Procedure Used?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 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

[illegible]

CAPE CLINIC LABORATORY

MASTER FILE INDEX

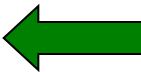
Document Name	Version		Effective Date	Distribution Location(s)
	#	Date		
Serum Glucose - Cobas c111 Analyzer Procedure	1	June 4, 2006	June 4, 2006	#1 Master File
	2	January 15, 2007		#2 Chemistry Department
	3	April 15, 2009		#3 Cobas c111 Analyzer Workstation

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<i>Date Reviewed:</i>	<i>Date Revised:</i>	<i>Initials:</i>
<i>November 30, 2006</i>		<i>JH</i>
	<i>January 15, 2007</i>	<i>AL</i>
<i>December 15, 2007</i>		<i>JH</i>
<i>December 2, 2008</i>		<i>JH</i>
	<i>April 15, 2009</i>	<i>AL</i>
<i>December 20, 20XX</i>		<i>WSM</i>
<i>Distribution:</i>		<i>Document Number:</i> SGC35v3
#1 Master File		
#2 Chemistry Department		
#3 Cobas c111 Analyzer Workstation		
<i>Date of Discontinuation:</i>		Page 1 of 5





CAPE CLINIC LABORATORY
MASTER FILE INDEX: Standard Operating Procedures - General Chemistry



Number	Document Name	Version		Effective Date	Distribution Location(s)
		#	Date		
SGC35	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
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?

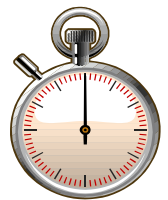
- Worksheet 1: Master File Index
- Worksheet 2: Scenario
- Worksheet 3: Scenario A (AFB)
- Worksheet 4: Scenario B (Critical)
- Worksheet 5: Scenario C (Hgb)

What will you do?

Divide into groups of 4-6 to:

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

15 minutes



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

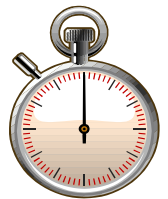
To create and organize an efficient and productive workstation using elements developed from each module.

What will you do?

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

What will you need?

Laboratory Accreditation
Preparedness Checklist



15 minutes

Activity: What Would You Do?

Purpose

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

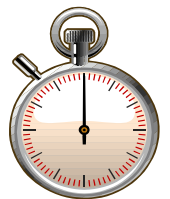
What will you need?

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 Handout.
- 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