

# **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

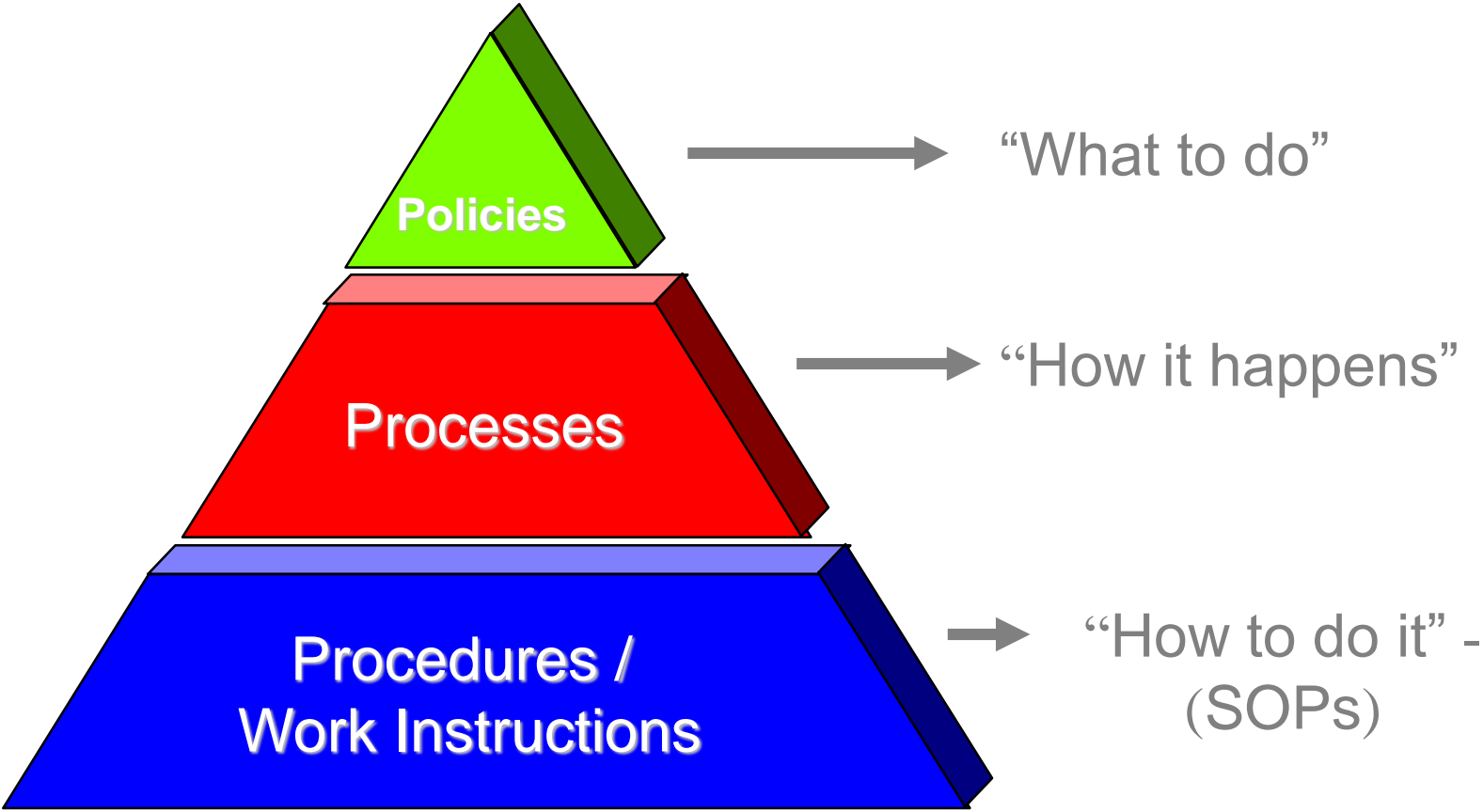
- **Not documented – Not done!**

Conviction held by clinical laboratory scientists worldwide

# Document and Records

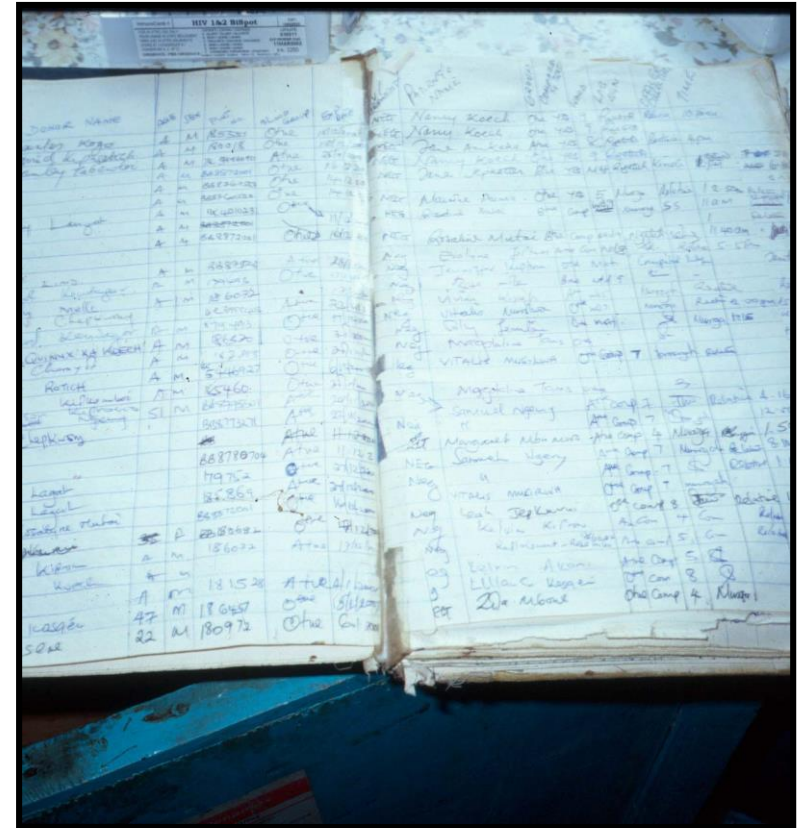
- Documents provide the policies and procedures to guide the work of the laboratory.
- Records provide the evidence that this work is accomplished.

# 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

<b>Test</b>	<b>JAN</b>	<b>FEB</b>	<b>MAR</b>	<b>Total</b>
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## **Why Was the Outdated Procedure Used?**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 LABORATORY

### MASTER FILE INDEX

Document Name	#	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





**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 Chemistry Department #3 Cobas c111 Analyzer Workstation
		2	January 15, 2007		
		3	April 15, 2009		
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

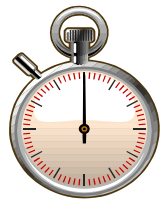
To create and organize an efficient and productive workstation using elements developed from each module.

## What will you 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 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