THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

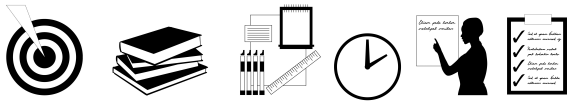
UGANDA Supranational® Reference Laboratory
Timely Accurate Diagnostics for a TB-Free Africa

Laboratory Quality Management System (LQMS)

(Module 5)

Documents and Records

Part 5.0: Documents and records



PURPOSE: To provide the participants with information for managing documents and records.

LEARNING OBJECTIVE:

At the end of this module, participants will be able to:

explain the difference between documents and records;
describe the hierarchy of documents and the role of each level;
outline the content that should be included in a standard operating procedure;
explain the important steps, or elements, of a laboratory document management system;
outline the contents of a quality manual;
describe methods and tools to properly store documents and records.

MATERIALS:

1. PowerPoint slides or transparencies
2. Overhead projector or computer with an LCD projector
3. Prepared flipchart, white board, or chalk board
4. Paper cards, markers, and tape
5. Additional handouts as required.

TIMELINE: 120 Minutes

METHODOLOGY:

1. Lecture
2. Discussion
3. Exercise

ADVANCE PREPARATION:

1. Printing Activities 5-1 and 5-2
2. Familiarize oneself with the slides
3. Read facilitators Notes and ISO 15189 Standard

FACILITATORS STEP-BY STEP INSTRUCTIONS:

1. Welcome and Introduction
2. Present module overview
3. Ask Questions in between the presentation to actively involve participants.
4. Continue the presentation
5. Recap presentation using the Assessment questions
6. Ask if there is any question.

FACILITATORS NOTES

Refer to the trainers notes attached
Refer to the trainer's activity guide attached

SLIDE OF POWERPOINT PRESENTATION

SITUATION ANALYSIS/ EXERICES

Give the participants a copy of the following scenario and/or show it as a slide (Presentation 5, slide 3). Allow 2 minutes for them to read.

"You have found all these papers lying on a desk."

Ask the question:

Which of these are documents and which are records?

ASSESSMENT REVIEW

Suggested questions for this module (with answers bolded) include:

1. Written policies, processes, and procedures are necessary for all of the following reasons EXCEPT:
   a. verbal instructions may be misunderstood
   b. laboratory inspectors require it
   c. they record data or information about what happened, and are not revised or modified
   d. reproducibility of results is improved

2. Procedures:
   a. tell "what to do", and define the overall intentions and directions of the organization
   b. tell "how it happens", and can generally be represented in a flow

chart indicating how events should occur over a period of time

c. tell "how to do it", and show the step-by-step instructions that laboratory staff should meticulously follow to produce accurate and consistent results

3. The following is an example of a document:

a. a Quality Manual

b. a log of patient results

c. a chart showing the temperatures of a refrigerator over the last month

d. a graph plotting quality control results

REFERENCES

- CLSI – Standards, guidelines, and best practices for quality in medical testing
- WHO – Laboratory Quality Management System - Handbook
- ISO 15189 – Medical laboratories – Requirements for quality and competence