



Laboratory Quality management system

MODULE 12 Quality Control for Quantitative Tests

Version: 1.0

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Acknowledgements

This Module was prepared by Beatrice Orena.

Part 12.0: Process control quantitative test

LQMS/FG/012

Version 1.0

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Page 1 of 4



OBJECTIVE: To understand how quality control methods are applied to quantitative laboratory examinations, and how to organize a quality control program for quantitative tests.

Learning Objectives

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

- differentiate accuracy and precision;
- select control material for a specified examination method;
- establish acceptable control limits for a method when only one level of control material is available;
- explain the use of a Levey-Jennings chart;
- give two examples of rule violations using Westgard Multi rule System;
- Describe how to correct "out of control" problems.

MATERIALS:

1. Handouts,
2. Slides
3. Computer
4. Over head projector
5. Flip chart
6. Markers and pens
7. Note books
8. Exercise: stickers for equipment placement and lab flow diagram
9. Additional handouts as required.

TIMELINE: 120 Minutes

METHODOLOGY:

1. Lectures
2. Discussion
3. Group exercise

ADVANCE PREPARATION:

1. Print participant activities 12-1 and 12-2
2. Ensure that adequate exercise materials are available, i.e each group should have at least two exercise materials/ drawings

3. Make sure that adequate instructions are printed and issued out to the various groups, i.e. each group member should have a copy of the exercise instructions.
4. Confirm that the stickers are appropriate and adequately stick onto the diagrams prior to starting the class

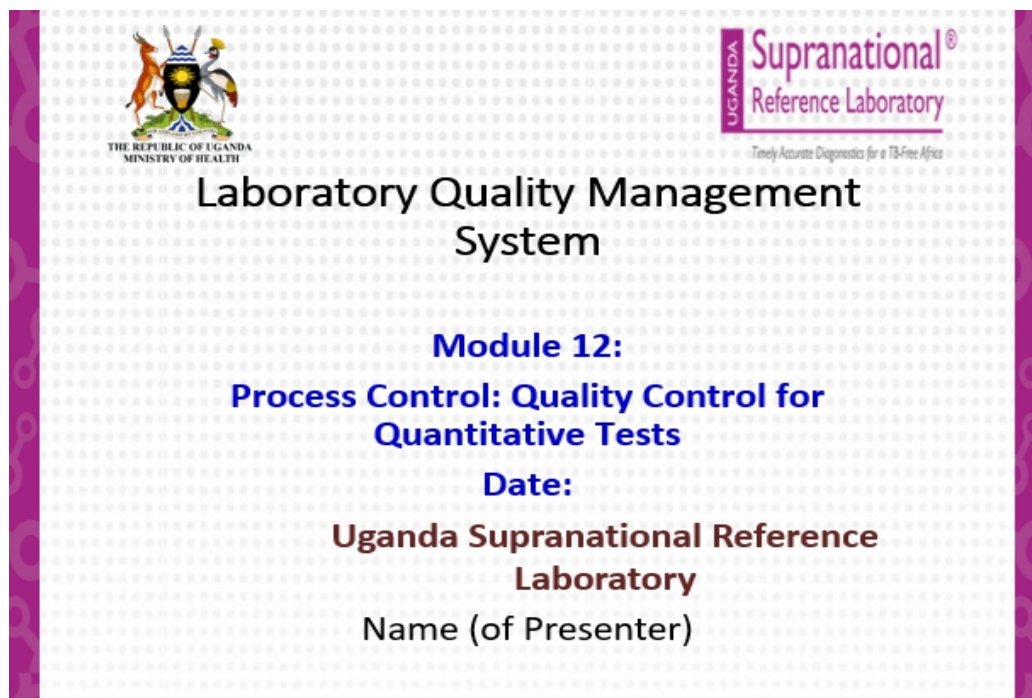
FACILITATORS STEP-BY STEP INSTRUCTIONS:

1. Welcome and Introduction
2. Present module overview
3. Break the class into 5 groups composed of not more than 5 participants each at least and issue out the exercise sheets.
4. Proceed with slide presentation

FACILITATORS NOTES

1. Put more Emphasis on quality control of all tests in the lab, and why this is important.
2. Encourage active participation from the class.
3. Use relevant examples and illustrations from the slides to help participants understand.

SLIDE OF POWERPOINT PRESENTATION



SITUATION ANALYSIS/ EXERCISES

- 1) Organize participants in groups of five
- 2) **Ask participants:** Calculate the mean and SD using Annex 7-A and the two Standard Deviation Worksheets provided as per the trainer's activity guide.

ASSESSMENT REVIEW

1. Differentiate between accuracy and precision.
2. What factors to consider when Selecting control material for the laboratory.
3. Name three sources of Control Materials.
4. Explain the use of a Levey-Jennings chart.
5. Describe how to correct “out of control” problems

REFERENCES

- GLI TB training package (<http://www.stoptb.org/wg/gli/trainingpackages.asp>)
- 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