FACILITATOR GUIDE

Training on Proficiency Testing Scheme (GeneXpert DTS)

Module 17: ISO 17043:2010 Requirements

Acknowledgements

This Module was prepared by SRL-Uganda training team.

The inputs provided by the representatives of SRL-Uganda are acknowledged.

Part 17.0: ISO 17043:2010 Requirements

- **OBJECTIVE:** To acquit and refresh participants with the knowledge on the Requirements for conformance to the ISO 17043:2010 standard

MATERIALS:
1. Handouts,
2. Slides
3. Computer
4. Over head projector
5. Flip chart
6. Markers and pens
7. Note books

TIMELINE: 45 Minutes

METHODOLOGY:
1. Lecture
2. Discussion

ADVANCE PREPARATION:
1. Printing notes,
2. Familiarize oneself with the slides
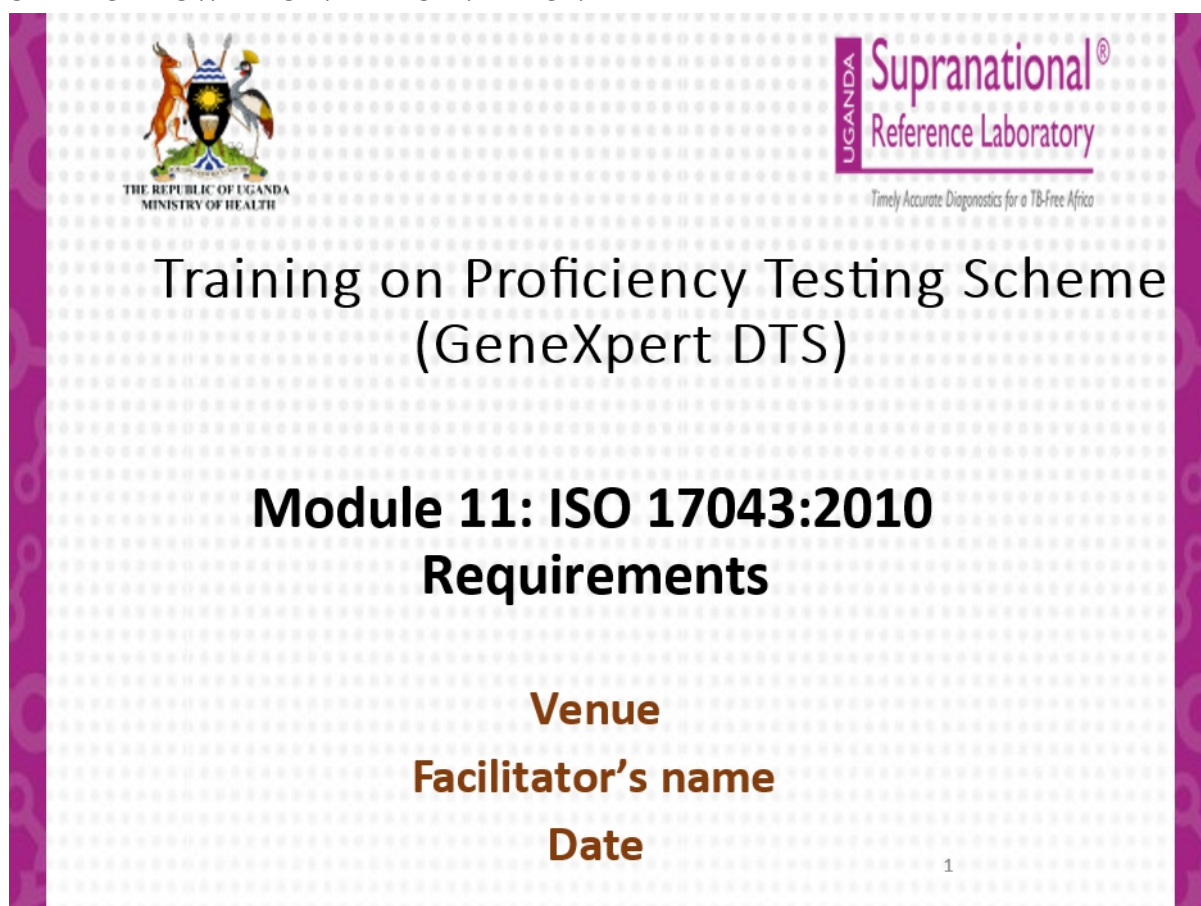
FACILITATORS STEP-BY STEP INSTRUCTIONS:
1. Welcome and Introduction
2. Present module overview
3. Ask question about module expectations
4. Distribute handouts
5. Start the presentation
6. Recap presentation using discussion questions
7. Ask if there is any question.

FACILITATORS NOTES
1. Make sure you go slow with the presentation chronologically as in the ppt file;

2. Encourage some of the participants to answer some of the questions that may arise during the presentation as this may create active participation from most of the class

3. Make sure the Uganda SRL journey of PT provision and ultimate accreditation is well highlighted in your preparation for this module

4. Command knowledge in the ISO 17043:2010 standard requirements; Technical and Managerial considerations

SLIDE OF POWERPOINT PRESENTATION

SITUATION ANALYSIS/ EXERCISES

What is the difference between accreditation and certification? (5 minutes) (Group activity with direct engagements)

ASSESSMENT REVIEW

1. What are the Issues to consider when establishing an EQA scheme?

2. What are the objectives of EQA schemes to the laboratory network?

REFERENCES

ISO 13528:2005, Statistical methods for use in proficiency testing by interlaboratory comparisons

ISO 15189:2012, Medical laboratories — Particular requirements for quality and competence

ISO Guide 34, General requirements for the competence of reference material producers

ISO Guide 35, Reference materials — General and statistical principles for certification

ISO/IEC 17043 First edition 2010-02-01

Guide 34, ISO Guide 35 and ISO 13528 (homogeneity and stability)

ISO/IEC Guide 98-3, Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)