



Laboratory Quality Management System (LQMS)

(Module 14)

Accreditation Norms

Acknowledgements

This Module was prepared by Beatrice Orena



PURPOSE: To provide the participants with information on laboratory standards, the organizations that develop them, and how the processes of accreditation and certification are conducted

LEARNING OBJECTIVE:

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

- Compare and contrast accreditation, certification and licensure;
- Describe the process involved in the development of standards;
- Discuss the need for laboratory norms and standards.

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: 45 Minutes

METHODOLOGY:

1. Lecture
2. Discussion
3. Exercise

ADVANCE PREPARATION:

1. Printing Participant activity 14-1
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/ EXERCISES

Give the participants a copy of the following scenario and/or show it as a slide (Presentation 14, Slide 4). Allow 2 minutes for them to read.

“Your hospital administrator has asked you, the laboratory manager, to examine the possibility of having the laboratory accredited.”

Ask the following questions:

What does to be accredited mean?

Where can you obtain information?

How would you obtain start?

ASSESSMENT REVIEW

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

1. Which of the following statements is true?
 - a. standards organizations can never serve as accrediting bodies
 - b. certification is the procedure by which an independent body gives written assurance that a product, process or service conforms to specific requirements**
 - c. most standards for laboratory practice are developed by local government agencies
 - d. only one international standards organization is recognized by all countries for quality management of laboratories

2. In order to be accredited, a laboratory must do all of the following EXCEPT:
 - a. be visited by representatives of the accrediting body which observes the laboratory's policies and practices
 - b. be enrolled in a proficiency testing or other EQA program
 - c. pay a fee for the accreditation process
 - d. adhere to international standards rather than local standards**

3. The main focus of ISO 15189 standard is
 - a. improving the quality of medical laboratories**
 - b. minimizing the harmful effects of the environment
 - c. addressing laboratory safety issues
 - d. improving the status of the quality manager

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