TRINIDAD AND TOBAGO LABORATORY ACCREDITATION SERVICE

UNDERSTANDING ISO 15189:2012

Date: 2019 April 29 – May 01

8:30 a.m. – 4:00 p.m.

Venue – Maracas Room, PQSL, Trinidad and Tobago Bureau of Standards, 1-2 Century Drive, Trincity Industrial Estate, Macoya.

PREAMBLE:

Accreditation is the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.[1] As a result of the magnitude of the activity of accreditation, it is important that the process employed is objective, unbiased, and competence-based.

Laboratory Accreditation is a process which gives formal recognition to the technical competence of a laboratory to perform specific tests or calibrations. The process requires the maintenance of a documented quality management system and identification of personnel qualified and authorized to perform tasks related to the scope of accreditation. The added value of laboratory accreditation far outweighs the necessary investment in human resources, finances and time.

The process is an independent method of monitoring competence and performance, and assures the validity of results to users. It is expected that the information provided by the workshop will result in an understanding and working knowledge of the standard *ISO 15189 – Medical laboratories – Requirements for quality and competence*. Participants will be provided with some basic tools for implementation of management system within their facilities.

AIM

The aim of the program is to provide a basic understanding of ISO 15189 and a working knowledge of the implementation of a management system.

COURSE DESCRIPTION:

This course is a comprehensive look at the requirements of the International Standard, *ISO 15189 – Medical laboratories – Requirements for quality and competence*. The subject matter enables an understandable explanation of the standard and an introduction to the documentation employed in management systems. The tools to be employed in the implementation of management systems will be introduced.

Participants will learn how to interpret the requirements of the standard so that the process of development of the management system can begin.

[1] ISO/IEC Guide 2: 2004 – Standardization and related activities – General vocabulary

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TOPICS

Course Introduction

- Pre-course Quiz
- Overview of Conformity Assessment and Accreditation concepts

Quality system documentation

- Documentation hierarchy
- Document control, maintenance, storage and disposal
- Quality system structures
- Evaluating the compliance of documents and the control system

ISO 15189

- Requirements examined and explained

Introduction to Management System Tools

- SPO Analysis
- Quality Project plans
- Gap analysis

End of course quiz

LEARNING OBJECTIVES:

At the end of the training, participants would be able to:

- Identify and describe the requirements of ISO 15189
- Describe the types of documentation to be employed in developing a management system
- Identify tools to be used in management system development
- Identify the steps in the accreditation process

TRAINING MATERIAL:

Material needed for the duration of the course:

1. ISO 15189 *Medical Laboratories – Requirements for Quality and Competence*
2. Power point presentations (Handouts)

3. Sample documents (Handouts)
4. Document describing accreditation scheme, and steps in the accreditation process
5. Course CD with additional resources

OVERVIEW:

The workshop will be conducted using a combination of "interactive" lecture style, Power Point presentations, and group exercises using application exercises and role playing.

An evaluation form will be provided to the participants at the end of the programme to rank the course content, training material, facilitator and overall level of the programme using a numbered scale.

TARGET GROUPS:

- ❑ Laboratory Directors
- ❑ Laboratory managers
- ❑ Quality managers
- ❑ Technical laboratory staff

PARTICIPANT CRITERIA:

In order to ensure success, the following criteria are key:

- ❑ Hands-on laboratory experience
- ❑ Quality Management experience

EXAMS:

Two quizzes will be administered:

a) Pre-Course quiz to evaluate the attendee's current awareness of ISO 15189 and accreditation; and
b) Final quiz to demonstrate the attendee's ability in applying the knowledge gained from this course.

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WORKSHOP AGENDA

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FACILITATOR:

- **Karlene Carolyn Lewis** – Manager, TTLABS

COFFEE BREAKS: 10:30 am – 10:45 am

LUNCH: 12:30 PM – 1:30PM

PROGRAMME OUTLINE:

Day 1: 9:00 am – 4:30 pm

1. Introductions and review of Objectives
2. Pre-Course Quiz
3. Course Introduction
4. Overview of Conformity Assessment and Accreditation process
5. Quality system documentation
6. Requirements of ISO 15189
7. Exercises 1 & 2

Day 2: 9:00 am – 4:30 pm

1. Summary of Day 1
2. Requirements of ISO 15189
3. Exercises 3, 4 & 5
4. Introduction to SPO Analysis
5. Introduction to Quality Project Plans

Day 3: 9:00 am – 4:30 pm

1. Summary of Day 2
2. Gap Analysis
3. Exercises 6 & 7
4. End of course quiz
5. Course Evaluation

END OF AGENDA