TRINIDAD AND TOBAGO laboratory Accreditation Service

Online training on ISO 15189:2022

Medical laboratories – Requirements for quality and competence

AGENDA

Training on ISO 15189:2022

(Medical laboratories – Requirements for quality and competence)

Background

This training programme is intended to assist laboratories, that either have established or is currently establishing the International Standard ISO 15189:2022 – Medical laboratories – Requirements for the competence of testing and calibration laboratories in its organization, to understand the changes in this version of the Standard.

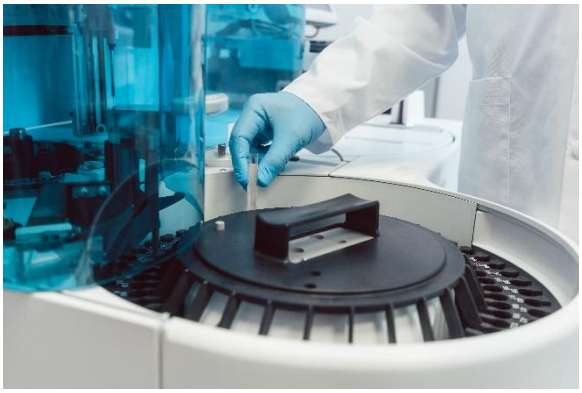
Training objectives

The ISO regional training aims to achieve the following objectives:

- Understand the importance of ISO 15189 as the basis for medical laboratory management systems
- Highlight the differences between ISO 15189:2012 and ISO 15189:2022 and explain these changes
- Understand the application of the main clauses of ISO 15189 for medical laboratories through presentations, worked examples and group exercises
- Provide a forum for exchange of experiences and to promote discussion among medical laboratories

Training format

The training is organized over four days and hosted by TTBS. It includes a set of interactive instructional methods (such as lectures, group activities and sharing experiences) to convey the information to the participants in an effective and practical manner.



Training participants

The training will target participants new to ISO 15189 and may include transition trainees.

Venue

Online

Trainers

The training will be facilitated by:
Karlene Lewis, Manager, TTLABS

Contact us

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***Cost TTD 1,980.00** Vat Inclusive. (See registration form for details)

Cost per ISO 15189:2022 (required):
TTD 1,140.00 Vat Inclusive. Visit the TTBS Web Store.

Day 1, 2023-Jun-27

08:30-09:00 • Introductions and presentation of the training agenda, objectives and outcomes

9:00 – 10:30 • **Session 1:** Terms and definitions and process

- Group activity 1: Prepare a process flow of what you do when performing a laboratory activity from receipt of items to reporting. At each of the stages, consider where risks may present themselves in the process (including feedback)

10:30-10:45 Tea/Coffee break

• **Session 2:** General and structural requirements

12:00-12:45 • Lunch break

Group activity 2: Give a brief description of how your laboratory addresses the structural requirements of the Standard and compare this with the delegates in your Group

12:45 – 14:00 • **Session 3**: Resource requirements (Part 1)

- This session will discuss the resourcing to be considered in establishing and operating a laboratory or site facility.

14:00-14:30 **End of day 1 and wrap up**

Day 2, 2023-Jun-29

08:30 **Session 4:** Process requirements (Part 1)

This session will discuss the requirements for:

- Pre-examination processes

10:30-10:45 Coffee/tea break

11:00-11:30 • Group activity 4: What makes a competent laboratory?

- Personnel
- Equipment and facilities
- Metrological traceability and equipment calibration
- Reagents and consumables
- Externally provided products and services

11:30-12:00 **Session 5**: Process requirements (Part 2)

This session will discuss the requirements for:

- Examination processes
- Post-examination processes

12:00-12:45 Lunch break

12:45-14:00 **Session 5**: Process requirements (Part 2)

- Group Activity 5: Considering the work performed in your own laboratories and in discussion with your group, outline when method verification may be applicable and when method validation may be more appropriate

14:00-14:30 **End of day 2 and wrap up**

Day 3, 2023-Jul-3

Session 6: Process requirements (Part 3)

08:30-10:30	‣ Nonconforming work ‣ Control of data and information management ‣ Complaints
10:30-10:45	Coffee/tea break
10:45-12:00	• Group activity 6: Based on the material provided generate a report which includes a statement of conformity.
12:00-13:00	Lunch break
13:00-14:00	**Session 7**: Management Requirements (Part 1) • Nonconforming work • Control of data – Information management
14:00-14:30	**End of day 3 and wrap-up**

Day 4, 2023-Jul-10

Session 6: Process requirements (Part 4)

08:30-09:30	• Group activity 7: Discuss the different scenarios provided and determine if they are instances of nonconforming work and provide the relevant clauses of the Standard.
09:30-10:30	**Session 7**: Management requirements
10:30-10:45	Coffee/tea break
10:45-12:00	**Session 7**: Management requirements • Group activity 8: Set up an internal audit plan and include a management review
12:00-13:00	Lunch break
13:00-14:00	**Session 8**: Closing/Discussion session • Q & A – Open Discussion Forum