



**Quality & Accreditation Institute
Centre for Education & Training**

Accreditation Standard-ISO 15189:2012 and Internal Auditing

Who should attend:

As per the requirements of ISO 15189:2012, audits shall be conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system. Therefore, it is important for the Quality Manager, however named of a medical lab to get trained in an Internal Auditor's training course as per ISO 15189:2012. It is also equally useful for all those Pathologists, Microbiologists, Biochemists, Technicians, Supervisors, Managers working in Medical labs to understand the requirements of international standard ISO 15189 to sustain the quality and accreditation framework.

Learning outcomes: At the ends of successful completion of the course, participants will learn and expose to the following:

- Understanding and interpretation of the requirements of the standard
- Basic quality management systems as per ISO 15189
- Identify documents and records required by ISO 15189
- Understanding of auditing principles
- Knowledge of internal auditing processes including planning and execution
- How to perform an internal audit
- Compilation of audit findings
- Preparation of audit report, follow-up, and record keeping
- Characteristics of an effective internal auditor

Concept

Content of the course is aligned to ISO 19011: Guidelines for auditing management systems and it is tailored to be relevant to the assessment of medical laboratories.



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Training Schedule

Time	Activities
Day 1	
0900 – 0930	Registration (Entry into the class room) and Introduction of Participants
0930 – 1000	Introduction to the training course Internal Audit Requirements as per ISO 15189:2012
1000 – 1030	Laboratory Accreditation: International Scenario
1030 – 1100	ISO 15189:2012 – Clause 4: Management Requirements
1100 – 1115	Break
1115 – 1245	ISO 15189:2012 – Clause 4: Management Requirements
1245 – 1330	Lunch Break
1330 – 1500	ISO 15189:2012 – Clause 4: Management Requirements
1500 – 1515	Tea Break
1515 – 1700	Exercise No. 1: Clause identification (reference clause 4)
Day 2	
0900 – 0930	Review of Day 1
0930 – 1100	ISO 15189:2012 – Clause 5: Technical Requirements
1100 – 1115	Break
1115 – 1245	ISO 15189:2012 – Clause 5: Technical Requirements
1245 – 1330	Lunch Break
1330 – 1500	ISO 15189:2012 – Clause 5: Technical Requirements
1500 – 1515	Break
1515 – 1700	Exercise No. 2: Clause identification (reference clause 5)
Day 3	
0900 – 0930	Review of Day 2
0930 – 1100	Internal Audit and its associated activities (what is audit/ why audit is done/ How audit is done/ Planning and Execution



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1100 – 1115	Break
1115 – 1245	Internal Audit- Findings and report writing
1245 – 1330	Lunch Break
1330 – 1530	Conduct of mock audit: Group Exercise
1500 – 1515	Break
1515 – 1545	Process of Accreditation
1545-1615	MCQ Test
1615-1630	Feedback & Valedictory

Course Fee: A course fee of Rs. 6000 + GST@18% (Rs. 7080) is charged. It includes training material and certificate.

Basic Requirements:

This is a virtual (on-line platform) course. Participants require access to a computer, a microphone, webcam and stable internet in order to take this training. A headset with microphone is highly recommended.

It is strongly advised that the participant keeps a copy of the standard ISO 15189:2012. A copy may be procured from Bureau of Indian Standards <https://standardsbis.bsbedge.com/>

Seats are limited to maintain ideal size of the batch and are available on first cum first serve basis. Interested professionals for the above training course are requested to complete the registration form given at www.qai.org.in.