TECHNICAL LEARNING AND ASSESSMENT DOSSIER

Auditor/Lead Auditor ISO 15189 (Medical laboratories)

Price / certificate issuance
99,00 €
VAT excluded

Course code	Minimum duration	Final pass score	Dossier issue
ISO15189_LA	60 min	70%	28/11/2026

1. Course identity, purpose and scope

The "Auditor/Lead Auditor ISO 15189 (Medical laboratories)" course is designed to train professionals in performing internal and external audits in compliance with the ISO 15189 standard, specific to medical laboratories. Participants will gain in-depth skills in interpreting and applying quality management and technical competence requirements within diagnostic laboratory settings. Knowledge areas include specimen pathway analysis, risk management, biosafety, data integrity, and accreditation compliance procedures. The course also equips learners with practical tools to plan, conduct, and report audits, emphasizing ISO 19011 guidelines for effective audit processes. Intended for current or aspiring auditors and quality managers in clinical laboratories, the program explores realistic case studies and critical scenarios to prepare attendees for certification. The 60-minute duration offers a focused and efficient learning experience, concluding with an assessment featuring questions based on real professional situations. Passing the final exam ensures robust theoretical knowledge essential for supporting compliance and continuous improvement in healthcare diagnostic facilities.

This extended technical dossier describes the pathway as published in CIWZ Academy on the issue date. It consolidates purpose, references, learning architecture, module contents, assessment system, passing criteria and certificate conditions. It does not replace the official texts of the standards, laws, guidelines or schemes referenced.

2. Normative, regulatory and technical references

ISO 15189; ISO 19011

References are used as the learning and assessment framework within the limits of published content and available sources. For professional application, the official and current versions of the referenced documents always prevail.

3. Learning architecture and assessment system

- minimum tracked time: 60 min

- active final-exam bank: 200 questions
- final exam: 30 questions selected from the bank
- passing threshold: 70%

- Direct access to the final assessment under the published rules for the exam-only pathway.
- Exam assembly from the active course bank and scoring against the published pass threshold.
- Recording of the result and, where applicable, request for the final certificate.

4. Official catalogue technical information

Learning Objectives

Acquire skills to conduct audits in medical laboratories according to ISO 15189; understand related standards and guidelines; develop critical analysis and non-conformity identification abilities.

Competencies Obtained

Audit planning and execution; interpretation of ISO 15189; evaluation of specimen pathways; risk and biosafety management; verification of IT procedures and documentation.

Target Audience

Healthcare and diagnostic professionals, auditors, quality managers, laboratory technicians, and staff involved in medical laboratory certification.

Prerequisites

Basic knowledge of laboratory processes and quality management standards; recommended work experience in healthcare settings.

Course Content

- Introduction to ISO 15189 and ISO 19011
- Structure and requirements of ISO 15189
- Audit planning and conducting
- Specimen handling and risk management
- Biosafety and process validation
- Documentation, reporting, and data integrity
- Non-conformity assessment and management

Teaching Methodology

Theoretical lessons combined with case studies, real scenario analyses, practical exercises, and audit simulations.

Assessment Method

Final exam with multiple-choice questions based on practical scenarios; minimum passing score 70%.

Duration

60 minutes.

Certification

Certificate of attendance upon passing the exam.

Expected Outcomes

Ability to perform ISO 15189-compliant audits; identify critical issues in specimen pathways and laboratory management; implement effective corrective actions.

7. Assessment system, final exam and passing criteria

- The final assessment consists of 30 questions selected from the active course bank. The platform applies an anti-repetition logic for new attempts when the bank size allows it.
- Final question-bank size detected at generation time: 200 active questions.
- Published passing threshold for the course: 70%.
- Questions are intended to assess not only recall but also interpretation, application, evidence selection, scenario assessment and quality of decision-making, depending on the subject matter.

8. Tracking, learning continuity and session integrity

- Path status, completed modules and recorded time are managed server-side when the course uses the Academy learning mode.
- The platform allows the pathway to resume from the recorded point and retains the results of required checks.
- Assessment sessions may be subject to the integrity and proctoring controls enabled by the platform and described in the applicable usage rules.
- Technical and integrity events support assessment and do not replace professional judgement where human review is required.

9. Certificate, use and limitations

The CIWZ certificate, where provided by the pathway and requested after passing, records the result achieved in the stated CIWZ pathway or assessment. It does not automatically replace personnel certification, professional registration, statutory licence, legal qualification or credentials issued by third-party bodies where such requirements are imposed by the applicable scheme.

10. Commercial and tax conditions

- Price / certificate issuance: 99,00 € VAT excluded.
- UAE VAT is applied to UAE customers according to billing data and the applicable tax rules.
- Any specific commercial terms, agreements or corporate orders override the public price only when formally accepted by Certificato IWZ FZCO.

11. Dossier document control

- Document automatically generated by CIWZ Academy from the course data published at the time of the request.
- Course code: ISO15189_LA
- Document language: EN

- Generation date: 28/11/2026
- For normative and professional application, the current official sources and any applicable procedures/schemes prevail.