COURSE OVERVIEW LE0195
ISO 15189 Medical Laboratories Lead Auditor

Course Title
ISO 15189 Medical Laboratories Lead Auditor

Course Date/Venue
Session 1: April 20-24, 2025/Boardroom 1, Elite Byblos Hotel Al Barsha, Sheikh Zayed Road, Dubai, UAE
Session 2: October 20-24, 2025/ Fujairah Meeting Room, Grand Millennium Al Wahda Hotel, Abu Dhabi, UAE

Course Reference
LE0195

Course Duration/Credits
Five days/3.0 CEUs/30 PDHs

Course Description

This practical and highly-interactive course includes real-life case studies and exercises where participants will be engaged in a series of interactive small groups and class workshops.

Medical laboratory services are essential to patient care and therefore have to be available to meet the needs of all patients and the clinical personnel responsible for the care of those patients. Such services include arrangements for requisition, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent validation, interpretation, reporting and advice, in addition to the considerations of safety and ethics in medical laboratory work.

The “core business” of the clinical laboratory is the production of reliable test results. The development of automation and the availability of ready-to-use test kits for most of the analytes may induce the wrong idea that high quality results can be easily produced. This is not true and a considerable effort must be dedicated to the control of the analytical aspects in order to provide to the clinicians results useful for the patient’s care.

Medical laboratories wishing to have some verification of their quality and performance have for years used ISO 17025. While this standard provides a generic framework for a laboratory quality management system, essential elements relative to clinical laboratories are missing. ISO 15189 is the medical laboratory version of ISO 17025. ISO 15189 incorporates the essential elements of ISO 9001 and adds technical competency factors relevant to medical laboratories. Its primary application is to improve the structure and function of medical laboratories. The ISO 15189 accreditation includes both the certification of the QMS and the evaluation of the competency of the laboratory functions.

This course is a comprehensive look at the latest revision of the ISO 15189:2007 and its documentation and internal auditing requirements. You will gain critical insight on the interpretation of the requirements of this medical laboratory standard and you will also receive a detailed review of the accreditation process.

You will learn how to design and develop laboratory documents and quality manuals. The quality manual will be examined as to its impact on laboratory operations and what purpose it serves. You will learn what information it should contain, what writing style is most effective and how to keep your documents and quality manual up to date.

This course also gives attendees the knowledge needed to establish an internal quality audit program as required by ISO 15189:2007, and to initiate the sequence of activities involved in scheduling, planning, conducting, reporting on and closing out internal quality audits. Participants will be able to employ effective techniques of auditing and the ability to develop the auditing procedures, scheduling and recording systems needed to sustain the program. Further, participants will receive practical instructions on the development, implementation and long-term maintenance of an effective medical laboratory quality system.

In addition to the updated knowledge provided to course participants during the course, each participant will go back to his/her laboratory equipped with an **outstanding manual that includes typical SOPs that can be modified and used within participant's laboratory**. Further, participants will be given **12 video tapes, compressed in one CD** that can be used by the participant in training colleagues and subordinate on laboratory safety.

Course Objectives

Upon the successful completion of this course, each participant will be able to:-

- Get certified as a *"Certified ISO 15189 Medical Laboratories Lead Auditor"*
- Interpret the requirements of the medical laboratory standard and receive a detailed review of the accreditation process
- Design and develop laboratory documents (SOP) and quality manuals and what information they should contain, what writing style is most effective and how to keep documents and quality manual up to date
- Establish an internal quality audit program as required by the ISO 15189:2007 standard, and initiate the sequence of activities involved in scheduling, planning, conducting, reporting on and closing out internal quality audits

- Employ effective techniques of auditing and develop the auditing procedures, scheduling and recording systems needed to sustain the auditing program
- Implement practical instructions on the development, implementation and long-term maintenance of an effective medical laboratory quality system in compliance with the requirements of ISO 15189:2007

Exclusive Smart Training Kit - H-STK®

*Participants of this course will receive the exclusive "Haward Smart Training Kit" (**H-STK®**). The **H-STK®** consists of a comprehensive set of technical content which includes **electronic version** of the course materials conveniently saved in a **Tablet PC**.*

Who Should Attend

This course is intended for medical laboratory managers, superintendents, supervisors, chemists, analysts and technicians. Further, this course will be of great value for quality managers, quality officers, quality auditors and management representatives.

Training Methodology

All our Courses are including **Hands-on Practical Sessions** using equipment, State-of-the-Art Simulators, Drawings, Case Studies, Videos and Exercises. The courses include the following training methodologies as a percentage of the total tuition hours:-

30% Lectures
20% Practical Workshops & Work Presentations
30% Hands-on Practical Exercises & Case Studies
20% Simulators (Hardware & Software) & Videos

In an unlikely event, the course instructor may modify the above training methodology before or during the course for technical reasons.

Course Fee

US$ 5,500 per Delegate + **VAT**. This rate includes H-STK® (Haward Smart Training Kit), buffet lunch, coffee/tea on arrival, morning & afternoon of each day.

Accommodation

Accommodation is not included in the course fees. However, any accommodation required can be arranged at the time of booking.

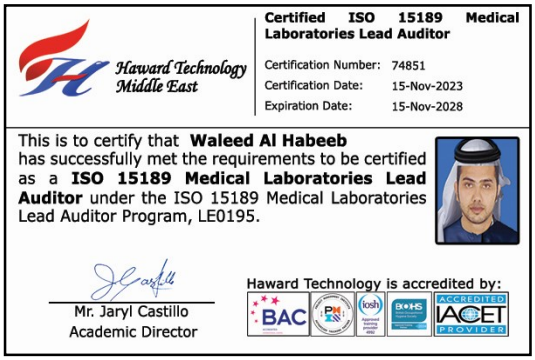
Course Certificate(s)

(1) Internationally recognized Competency Certificates and Plastic Wallet Cards will be issued to participants who completed a minimum of 80% of the total tuition hours and successfully passed the exam at the end of the course. Successful candidate will be certified as a "*Certified ISO 15189 Medical Laboratories Lead Auditor*". Certificates are valid for 5 years.

Recertification is FOC for a Lifetime.

Sample of Certificates

The following are samples of the certificates that will be awarded to course participants:-



(2) Official Transcript of Records will be provided to the successful delegates with the equivalent number of ANSI/IACET accredited Continuing Education Units (CEUs) earned during the course.

Haward Technology Middle East

Continuing Professional Development (HTME-CPD)

CEU Official Transcript of Records

TOR Issuance Date: 15-Nov-23

HTME No. 74851

Participant Name: Waleed Al Habeeb

Program Ref.	Program Title	Program Date	No. of Contact Hours	CEU's
LE0195	ISO 15189 Medical Laboratories Lead Auditor	November 11-15, 2023	30	3.0

Total No. of CEU's Earned as of TOR Issuance Date **3.0**

TRUE COPY

Jaryl Castillo
Academic Director

Haward Technology has been approved as an Accredited Provider by the International Association for Continuing Education and Training (IACET), 2201 Cooperative Way, Suite 600, Herndon, VA 20171, USA. In obtaining this approval, Haward Technology has demonstrated that it complies with the ANSI/IACET 1-2018 Standard which is widely recognized as the standard of good practice internationally. As a result of their Authorized Provider membership status, Haward Technology is authorized to offer IACET CEUs for programs that qualify under the ANSI/IACET 1-2018 Standard.

Haward Technology's courses meet the professional certification and continuing education requirements for participants seeking Continuing Education Units (CEUs) in accordance with the rules & regulations of the International Association for Continuing Education & Training (IACET). IACET is an international authority that evaluates programs according to strict, research-based criteria and guidelines. The CEU is an internationally accepted uniform unit of measurement in qualified courses of continuing education.

Haward Technology is accredited by

P.O. Box 26070, Abu Dhabi, United Arab Emirates | Tel.: +971 2 3091 714 | E-mail: info@haward.org | Website: www.haward.org

Certificates Accreditations

Certificates are accredited by the following international accreditation organizations:-

- British Accreditation Council (BAC)

  Haward Technology is accredited by the **British Accreditation Council** for **Independent Further and Higher Education** as an **International Centre**. BAC is the British accrediting body responsible for setting standards within independent further and higher education sector in the UK and overseas. As a BAC-accredited international centre, Haward Technology meets all of the international higher education criteria and standards set by BAC.

- The International Accreditors for Continuing Education and Training (IACET - USA)

  Haward Technology is an Authorized Training Provider by the International Accreditors for Continuing Education and Training (IACET), 2201 Cooperative Way, Suite 600, Herndon, VA 20171, USA. In obtaining this authority, Haward Technology has demonstrated that it complies with the **ANSI/IACET 2018-1 Standard** which is widely recognized as the standard of good practice internationally. As a result of our Authorized Provider membership status, Haward Technology is authorized to offer IACET CEUs for its programs that qualify under the **ANSI/IACET 2018-1 Standard**.

  Haward Technology's courses meet the professional certification and continuing education requirements for participants seeking **Continuing Education Units** (CEUs) in accordance with the rules & regulations of the International Accreditors for Continuing Education & Training (IACET). IACET is an international authority that evaluates programs according to strict, research-based criteria and guidelines. The CEU is an internationally accepted uniform unit of measurement in qualified courses of continuing education.

  Haward Technology Middle East will award **3.0 CEUs** (Continuing Education Units) or **30 PDHs** (Professional Development Hours) for participants who completed the total tuition hours of this program. One CEU is equivalent to ten Professional Development Hours (PDHs) or ten contact hours of the participation in and completion of Haward Technology programs. A permanent record of a participant's involvement and awarding of CEU will be maintained by Haward Technology. Haward Technology will provide a copy of the participant's CEU and PDH Transcript of Records upon request.

Course Instructor(s)

This course will be conducted by the following instructor(s). However, we have the right to change the course instructor(s) prior to the course date and inform participants accordingly:

Dr. Tarek Awad, PhD, MSc, PGDip, BSc, is a **Senior Analytical Chemist** and an **International Expert** in **Instrumentation & Control Engineer** with proven experience in **Oil**, **Gas**, **Refinery** & **Petrochemical** industries. He is well-experienced in **Analytical Measurement**, **Field Bus & Communications**, **Field Indication Instruments**, **P&ID Reading & Interpretation**, **Process Control Loop**, **Control Valves**, **Control** Systems, **Actuators & Valve** Selection, **Process Control & Automation**, Batch Process & Sequential Control, **Analog** Control, **Operator Interfaces**, **Data Communication**, System Checkout & Testing, Advanced Control with **PLC's**, **Ladder Logic**, **Process Instrumentation & Control**, **Control Valve** Maintenance, **Mercury** Analysis Techniques, **Mercury** (Hg) Analyzer, **Mercury Vapor** Analyzers, **Natural Gas & LNG**, **Analytical Laboratory** Management, **Gas Chromatography** (**GC**), **Laboratory Quality** Management, **Lab Management** Systems, **Product & Chemical Analysis**, **QA/QC**, **Analytical** Management Activities/Techniques, **Crude Oil Testing & Equipment**, **IP/ASTM Test Methods**, **Crude Oil Sample Analysis**, Analysis of **Water Quality Specification**, **Water Sampling** Techniques, **Water Analysis & Quality Control**, **Laboratory Environmental** Analysis (Soil, Water, Air), **Health & Safety** and **Laboratory** Operations. Further, he is well-versed in **Six Sigma** Analysis, **Six Sigma** Technology, Tool Landscape, **Lean Six Sigma**, **DMAIC**, **Statistical Process Control**, **Measurement System** Analysis, **Business Analysis**, **Corporate Strategies**, Budget Preparations & Follow-Up, Capital & Resources Planning & Management, Planning Claims Management, **Quality Assurance & Control**, **Total Quality** Management, **Project** Management, **Quality Management** System, Analytical **Problem-Solving & Decision Making** and **Communication & Leadership** Skills. He is a **Certified Data Analyst**, **Lean Six Sigma Black Belt** (**LSSBB**), and **Certified Lead Auditor** in accordance with ISO 9001, ISO14001, OHSAS 18001 and **ISO 17025**.

Dr. Tarek gained his expertise through his long-term dedication as a **Senior Laboratory Analyst** in **SEGAS LNG**. He was in-charge of plant optimization, Quality, Environmental & OHSAS Standards. Prior to this, he was an **Advisor** for a reputable oil, gas and LNG company in the Middle East and was the **Senior Corrosion & QC Chemist** of **WEPCO** wherein his duties involved quality control, corrosion control and chemical optimization for oilfield. He has built-up a formidable reputation with his professionalism and practical problem-solving abilities and has performed significant contribution to his fields.

Dr. Tarek has **PhD** in **Analytical Chemistry**, a **Post Graduate Diploma** and **Master** degree in **Material Science** (**Corrosion**) and a **Bachelor** degree in **Chemistry**. Further, he is a **Certified Instructor/Trainer**, a **Certified Internal Verifier/Assessor/Trainer** by the **Institute of Leadership & Management** (**ILM**), a **Certified CLSSBB Lean Six Sigma**, a **Certified ISO Auditor/Lead Auditor** (**QMS**), a **Certified IEMA Auditor** (**EMS**) and an active member of International Register of Certificated Auditors (I**RCA**), American Center Library, Egyptian Accreditation Council (**EGAC**), Technical Assistance Center (**TAC**), Egyptian Corrosion Society, Egyptian Arab Society of Material Science, Egyptian Syndicate of Scientific Profession and Egyptian Petroleum Association. He has further published various scientific papers, technical journals as well as delivered numerous trainings, courses, seminars and workshops worldwide.

Course Program

The following program is planned for this course. However, the course instructor(s) may modify this program before or during the course for technical reasons with no prior notice to participants. Nevertheless, the course objectives will always be met:

Day 1

0730 – 0800	*Registration & Coffee*
0800 – 0815	*Welcome & Introduction*
0815 – 0830	***PRE-TEST***
0830 – 0930	***Accreditation*** *Quality System ● Medical Laboratory Accreditation, National and International Dimension*
0930 – 0945	*Break*
0945 – 1100	***Accreditation (cont'd)*** *Accreditation Benefits*
1100 – 1230	***ISO 15189:2007 What the Standard Requires*** *Management Requirements 4.1 - 4.7*
1230 – 1245	*Break*
1245 - 1420	***ISO 15189:2007 What the Standard Requires (cont'd)*** *Management Requirements 4.8 - 4.15*
1420 – 1430	***Recap***
1430	*Lunch & End of Day One*

Day 2

0730 – 0930	***ISO 15189:2007 What the Standard Requires (cont'd)*** *Technical Requirements 5.1 - 5.2*
0930 – 0945	*Break*
0945 – 1100	***ISO 15189:2007 What the Standard Requires (cont'd)*** *Technical Requirements 5.3*
1100 – 1215	***ISO 15189:2007 What the Standard Requires (cont'd)*** *Technical Requirements 5.4*
1215 – 1230	*Break*
1230 – 1420	***ISO 15189:2007 What the Standard Requires (cont'd)*** *Technical Requirements 5.5 - 5.7*
1420 – 1430	***Recap***
1430	*Lunch & End of Day Two*

Day 3

0730 – 0930	***Reporting of Results*** *Technical Requirements 5.8*
0930 – 0945	*Break*
0945 – 1100	***Preparation of Documentation*** *Effective Documentation Control ● How to Design a Quality Manual ● Auditing a Sample Quality Manual*
1100 – 1215	***Internal Audits of the Lab*** *What is an Internal Audit; Why it's Important*
1215 – 1230	*Break*
1230 – 1420	***Internal Audits of the Lab (cont'd)*** *What Should it Accomplish ● How Should the Program be Organized; Steps*
1420 – 1430	***Recap***
1430	*Lunch & End of Day Three*

Day 4

0730 – 0930	***Internal Audits of the Lab (cont'd)*** *How Should Effort be Coordinated ● Establishing/Managing Audit Program*
0930 – 0945	*Break*
0945 – 1100	***Internal Audits of the Lab (cont'd)*** *Planning/Conducting the Audit ● Effective Questioning Techniques*
1100 – 1215	***Laboratory Safety Procedures*** *Employee Safety and Health ● Waste Disposal*
1215 – 1230	*Break*
1230 – 1420	***Laboratory Safety Procedures (cont'd)*** *Internal Safety Program ● Safety Manual & OSHA*
1420 – 1430	***Recap***
1430	*Lunch & End of Day Four*

Day 5

0730 – 0830	***Preparation for the Exam***
0830 – 0930	***COMPETENCY EXAM***
0930 – 0945	*Break*
0945 – 1045	***Exam Reviews and Correction***
1045 – 1200	***Open Forum***
1200 – 1215	*Break*
1215– 1415	***General Discussion***
1415 – 1430	*Presentation of Course Certificates*
1430	*Lunch & End of Course*

Practical Sessions

This practical and highly-interactive course includes real-life case studies and exercises:-

Course Coordinator

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