



Accreditation Standard ISO 15189:2012 and Internal Auditing

Training Schedule (19th to 26th September, 2020 Online Classes)

Medical Laboratory Quality Manager Training Course

(in accordance with ISO 15189:2012)

Course Rationale:

Medical Laboratory plays a very integral role in the efforts at improving quality and safety of care outcomes. It is therefore very essential to ensure that medical laboratory professionals are sufficiently equipped with the requisite knowledge and competencies in quality management systems to compliment efforts by various stakeholders and actors in healthcare delivery to provide quality and safe care.

This course is organized as a collaboration between the Africa Institute of Healthcare Quality Safety & Accreditation (AfHQSA) and the Quality and Accreditation Institute (QAI) in India.

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.

CPD Accreditation awarded by the Allied Health Professions Council (AHPC) for 8-CPD Points

Course Design

This course is designed to be delivered in 3 different categories:

Category A: This is an eight (8)-day (19th to 26th September, 2020) intensive online (virtual) session three hours each day. The course is delivered in a form of a lecture, presentation, discussions and case studies.

Package: Tuition; Course materials; Course Participation Certificate; 8-CPD Points from AHPC

Cost: Eight Hundred and Fifty Ghana Cedis (GHS850)

Category B: In addition to Category A, participants will have a practical 2-hour session where they will visit a medical laboratory (of their choice preferably where they are working) and undertake an internal audit with a checklist of the ISO 15189:2012 standards and write a report. Participants will present their reports to the class and faculty after which same is shared with the laboratory where the assessment was done.

Package: Tuition; Course materials; ISO 15189:2012 Assessment tool; Course Participation Certificate; 8-CPD Points from AHPC; Certification Exam (MCQ+written); 6-weeks practical field work (Facility Assessment plus report); 6-weeks mentorship; Certification (Certificate of Competence)

Cost: One Thousand Five Hundred Ghana Cedis (GHS1,500)



Category C: This will normally apply to somebody who has completed the theoretical work and would like to do the competency to become certified.

Package: ISO 15189:2012 Assessment tool; Certification Exam (MCQ+written); 6-weeks practical field work (Facility Assessment plus report); 6-weeks mentorship; Certification (Certificate of Competence)

Cost: One Thousand Two Hundred Ghana Cedis (GHS1,200)

What is covered in the course for Quality Manager for Medical Laboratory as per ISO 15189?

(a) Quality Management System as per ISO 15189:

Management Requirements	Technical Requirements
Organisation and Management responsibility	Personnel
Quality management system	Accommodation and environmental conditions
Document control	Laboratory equipment, reagents and consumables
Service agreements	Pre-examination, examination and post-examination processes
Examination by referral laboratories	Ensuring quality of examination results
External services and supplies	Reporting of results
Advisory services	Release of results
Resolution of complaints	Laboratory information management.
Identification and control of nonconformities	
Corrective action	
Preventive action	
Continual improvement	
Control of records	
Evaluation and audits	
Management review	

(b) Internal Audit:

- What is audit
- Types of audits
- What is Internal Audit
- Process of Internal Audit including planning and execution
- Internal Audit Report writing
- Follow-up and Closing the loop



Course Evaluation (Applicable to Category B&C)

At the end of the first phase of the training program (i.e. course work) participants are assessed by answering a set of Multiple-Choice Questions and a written test in one (1) hour. This is the QMS-MLS-IA-ISO 15189:2012 Certification Examination. This component of the assessment takes 30% of the overall assessment (100%). Participants are also expected to share their internal audit findings and report. This takes a total score of 70%. A participant is expected to score 80% or more to be certified. He/she is expected to score at least 20 out of 30 (in the written test) and 60 out of 70 in the experiential aspect of the assessment.

Renewal

Certified QMS & Internal Auditors (Medical Laboratory) will be expected to renew their certification every two (2) years with AfHQSA at a cost of USD50. There will have to be evidence of practice as part of the renewal process.

Intended Course Participants

As per accreditation requirements, it is important for the Quality Manager of a Medical Laboratory or any Biomedical Scientist who is interested in a career in Healthcare Quality and Safety to get trained in a course which covers Quality Management Systems (QMS) and Internal Auditing. It is also equally useful for:

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1. Biomedical Scientists
 2. Pathologists
 3. Medical Directors
 4. Microbiologists
 5. Biochemists
 6. Technicians working in Medical laboratories to understand this international standard and sustain the quality and accreditation framework.
 7. Healthcare Managers
 8. Quality Managers
 9. Clinical, industrial and academics with interest in medical laboratory are also invited to attend
 10. Other stakeholders in health interested in quality and safety of medical laboratories

NB: Participants will have to be practicing Medical Laboratory Personnel with not less than two (2) years post-qualification experience.

Learning outcomes: At the end of successful completion of the course, participants will learn and be exposed to the following:

- Appreciate their role and their ability to advance patient safety through medical diagnostics
- Understand the fundamentals of healthcare quality & safety
- Understanding and interpretation of the requirements of the standards
- Basic quality management systems as per ISO 15189
- Identify documents and records required by ISO 15189



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- Understanding of a risk management plan
- Understanding of auditing principles
- Knowledge of internal auditing process including planning
- How to perform an internal audit
- Compose audit findings
- Preparation of audit report, follow-up and closing the loop
- Characteristics of an effective internal auditor

Course Faculty

BK Rana | PhD: The first expert on ISO 15189 from India, Dr. B.K. Rana is the Founding CEO of Quality & Accreditation Institute (QAI) and former Director of NABH, the national healthcare accreditation body. He served International Society for Quality in Health Care (ISQua) as elected Vice-Chairman- Accreditation Council (2008-2014) and Chairman- Accreditation Council (2014-2016). He was appointed member on ISQua Board from 2014 to 2016, and now **elected as Member of the ISQua Board for 2017-19**. Concurrently, he served as President of Asian Society for Quality in Healthcare (ASQua) in 2011 & 12 and now serving as Member on its Board. He has many honours to his credit such as ISQua Expert, Assessor and Advisor. He also served as External Consultant of WHO on setting hospital accreditation program and also served as temporary advisor. He achieved rare distinction by becoming part of United Nations Framework Convention on Climate Change (UNFCCC) as an Expert/Assessor for Clean Development Mechanism (CDM). **He is a former APLAC Evaluator**. He sits on many national and international committees including **ISO/ TC 210 WG1**. **He is also appointed** ISQua Fellowship Program Curriculum Advisor. He is the Chief Advisor of the "Academy of Medical Laboratory Auditors (AMLA)".

Buckle, Gilbert | MB.CHB, MPH, ODCC: Gilbert is a Public Health Physician and Consultant in Health Systems Strengthening & Healthcare Quality, with over 22 years of experience (in both the public and private sectors). He is an accomplished and resourceful executive, with experience in designing healthcare programs and leading healthcare systems and organisations to enhanced performance. He is adept at strengthening health systems and healthcare organisations, with a focus on improving the quality of health outcomes, in resource-limited environments. His additional competencies include critical thinking, analysis, & strategic planning; Health Systems Strengthening & Optimisation; Healthcare Quality Improvement Initiatives; Leadership Coaching & Capacity Development; and Organisational System Transformations. Gilbert is the Executive Director of the Africa Institute of Healthcare Quality Safety & Accreditation (AfHQSA). He is a certified executive coach with the International Coach Federation as well as an Organizational Development Certified Consultant. Gilbert is an inaugural/founding member of the ISQUA Academy of Quality and Safety in Healthcare (IAQS).

Raymond Donbezier Fatchu is the Director of Frayd Consulting. He is committed to shaping health outcomes by promoting the value and contributions of quality health systems through continual improvement of such health systems and practices. He holds a bachelor's degree in Medical Laboratory Technology from the Kwame Nkrumah University of Science and Technology. He has worked extensively in the field of health systems strengthening with focus to laboratory quality management systems. He is the first Ghanaian resident



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mentor to lead the first public sector medical laboratory in Ghana to ISO 15189 accreditation. He has assessed, mentored and provided technical assistance to several medical laboratories in both public and private laboratories throughout Ghana.

OTCHI, Elom Hillary | PhD, FISQua, MPH, MA (Org. Devt.): Elom is a National and International Consultant in Organizational Development and Healthcare Quality & Patient Safety. He is a conference speaker and been on discussion panels of several quality & patient safety conferences. He has served as the National Consultant on Quality Improvement (QI) for UNICEF. A role in which he supported twenty-four (24) health facilities (*including a regional hospital*) in implementing the Mother-Baby Friendly Health Facility Initiative (MBFHI) in the Upper East Region of Ghana. He was also the International Consultant for the WHO Country office in Sierra Leone in supporting the Ministry of Health & Sanitation (MoHS) setup national quality of care structures, developed training manuals and quality of care policy and strategy. He also built the capacity of various cadres to lead the quality improvement program at various levels of the health system of the country. Elom is the Technical Director of the Africa Institute of Healthcare Quality Safety & Accreditation (AfHQSA). He is also an Expert of the International Society of Quality Healthcare (ISQua). Elom is a Fellow of International Society of Quality in Healthcare (ISQua) and a Certified Hospital Surveyor (CHS). He is a member of the WHO Global Learning Laboratory on Quality of Care and Universal Health Coverage. Elom currently also works as an International Consultant supporting the WHO to explore mechanisms for private sector engagement towards the provision of quality maternal and newborn deaths in Ghana.



Course Outline

Time	Activities	Facilitator
Day 1		
0900 – 0930	Registration (Entry into the class room) and Introduction of Participants	Dr. Elom OTCHI
0930 – 1000	Introduction to the training course Internal Audit Requirements as per ISO 15189:2012	Dr. Gilbert BUCKLE Dr. BK RANA
1000 – 1030	Laboratory Accreditation: International Scenario	Dr. BK RANA
1030 – 1100	ISO 15189:2012 – Clause 4: Management Requirements (4.1 - 4.3 clause)	Dr. BK RANA
1100 – 1115	Break	ALL
1115 – 1200	ISO 15189:2012 – Clause 4: Management Requirements (4.4 - 4.7 clause)	Dr. BK RANA
Day 2		
0900 – 1100	ISO 15189:2012 – Clause 4: Management Requirements (4.8 - 4.15 clause)	Dr. BK RANA
1100 – 1115	Break	ALL
1115 – 1200	Exercise No. 1: Clause identification (reference clause 4)	Dr. BK RANA
Day 3		
0900 – 0930	Review of Day 1 & 2	ALL
0930 – 1100	ISO 15189:2012 – Clause 5: Technical Requirements (5.1 - 5.4 clause)	Dr. BK RANA
1100 – 1115	Break	ALL
1115 – 1200	ISO 15189:2012 – Clause 5: Technical Requirements (5.5 - 5.6 clause)	Dr. BK RANA
Day 4		
0900 – 0930	ISO 15189:2012 – Clause 5: Technical Requirements (5.7 - 5.10 clause)	Dr. BK RANA
0930 - 1100	Exercise No. 2: Clause identification (reference clause 5)	Dr. BK RANA



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1100 - 1115	Break	ALL
1115- 1200	Internal Audit and its associated activities (what is audit/ why audit is done/ How audit is done/ Planning and Execution	Raymond FATCHU
Day 5		
0900 – 0930	Review of Day 3 & 4	ALL
0930 - 1100	Internal Audit and its associated activities (what is audit/ why audit is done/ How audit is done/ Planning and Execution	Raymond FATCHU
1100 - 1115	Break	ALL
1115- 1200	Internal Audit- Findings and report writing	Dr. BK RANA
Day 6		
0900 - 1100	Conduct of mock audit: Group Exercise	Dr. BK RANA/ Raymond FATCHU
1100 - 1115	Break	
1115 - 1200	Process of Accreditation	Dr. BK RANA
Day 7		
0900 – 0930	Review of Day 5 & 6	Dr. Elom OTCHI
0930 - 1100	Leadership skills for improvement	Dr. Gilbert BUCKLE
1100 - 1115	Break	ALL
1115 - 1200	Professional Regulation of Allied Health Practice in Ghana: What every Practitioner must Know	Rep from AHPC
Day 8		
0900 – 1030	Post-test and/or Certification Examination (MCQ + Written) (Applicable to category B&C	Dr. Elom OTCHI
1030 - 1130	Planning of Field Work (6 Weeks) plus Laboratory Audit Report Submission for Grading	Raymond FATCHU/ Dr. Elom OTCHI
1130 - 1115	Course Evaluation & Feedback	ALL
1115 - 1200	Award of Certificates of Participation & Valedictory	Dr. Gilbert BUCKLE/ Dr. BK RANA
Day 9 to 42 (6 weeks)		
	Field Work	ALL