



ISO 15189:2012 MEDICAL LABORATORY ASSESSOR TRAINING PROGRAMME

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The purpose of the course is to provide training in the Accreditation standard(s) and UKAS methodology for UKAS Assessment Managers and potential UKAS Assessors

Day one - 09:00 for 09:15

Breaks for coffee, lunch and tea will be taken each day

09:15 Introductions

Background to accreditation, UKAS and the international scene

Purpose: *paper to provide information on the role and purpose of accreditation, both nationally and internationally and in particular the role and function of UKAS both domestically and internationally.*

Holistic approach to assessment and accreditation

Purpose: *to provide delegates with an understanding of the need to get to know the business processes of the laboratory being assessed and how to use ISO 15189:2012 as part of the means for recognising the competence of the laboratory.*

Exercise 1 - Accreditation standard exercise I – feedback on pre-course work

Purpose: *to ensure delegates have read and can apply their mind to understanding the requirements of the standard in some detail.*

Exercise 2 – Exploring organisation processes

Purpose: *a group exercise to allow an opportunity to look objectively at the processes within a medical laboratory.*

You the Assessor 1 – An Approach to Assessing

Purpose: *to give delegates a chance to consider the objectives of assessment, and how they might constructively be achieved.*

Overview of the process of accreditation

Purpose: *to provide an understanding of the structure and procedures involved in the process of accreditation of an organisation; to place in context the steps to accreditation with an overview of each step, the purpose and importance to the overall process.*

Exercise 3 - Accreditation standard exercise II

Purpose: *to allow delegates to work with the competence assessment criteria for medical laboratories to applying it in group discussion to provided case–studies. The groups will identify and present their findings of definite or possible nonconformities and of bad assessor practice. To provide an opportunity for team working and enable tutors to clarify any areas of the standard perceived to be anomalous or contentious.*

Clinical Assessment

Purpose: *to give delegates a chance to consider the objectives of a clinical assessment and how they might constructively be achieved*

Flexible Scopes

Purpose: *paper to familiarise delegates with UKAS policy and process for accreditation of flexible scopes.*

It is intended that the programme for day one will finish by 18:30

Day two - 08:45

You the Assessor 2 – The Tasks

Purpose: *To examine the activities of a UKAS Technical Assessor.*

Organisational Competence and Accreditation standards

Purpose: *Paper to help understand the structure of standards used by UKAS for accreditation activities, and to identify common elements and highlight specific requirements*

Management system documentation and documentation review

Purpose: *to encourage delegates to use the documentation of an organisation to assess the efficacy of the processes of the organisation to deliver competent services, using ISO 15189:2012 as a framework.*

Exercise 4 - Initial documentation appraisal exercise

Purpose: *to enable delegates to gain an overview of the individual applicant's processes through their documentation and to assess whether all the requirements of the standard appear to have been addressed & for technical assessors to understand how they can use the documentation.*

Exercise 5 – Detailed documentation review – group work

Purpose: *to provide an opportunity for delegates to critically review a test method and to engage in discussion with the tutors (who take the role of laboratory).*

Introductory meeting

Purpose: *to explain the process and procedure of the introductory meeting and its purpose*

Exercise 6 – Writing an Assessment Report –

Purpose: *to gain experience in writing an assessment report as relevant to a technical assessors role*

You the Assessor 3 – Person to Person

Purpose: *to note and consider some of the human aspects of technical assessing by talking with people, and by watching them work.*

Recording findings

Purpose: *to understand what a finding is, and how to be clear, factual, contextual and informative. Introduction of Improvement Action Report.*

Exercise 7 - Recording findings

Purpose: *an individual exercise to record findings from provided case studies. The results will be compared and discussed in group feedback the following morning.*

Exercise 8 - witnessing examinations

Purpose: *to provide an opportunity to witness a live examination in a simulated laboratory, and assess it in the context of its supporting documentation. The exercise will be followed by an opportunity for delegates to review their performance, to list learning points and receive feedback from tutors.*

It is intended that the programme for day two will finish by 18:15

Day Three – 08:45

Report back on Exercise 7 - Recording findings

Purpose: *Group peer review of individual findings prepared overnight. The learning outcomes identified by each groups will be presented to the other delegates.*

Calibration and traceability

Purpose: *to provide information on traceability of measurement and an understanding of the need for laboratories to have an appropriate calibration.*

Exercise 9 – Calibration and Traceability

Purpose: *An individual exercise on the assessment of calibration and traceability. Information is provided which is to be commented on in respect of meeting ISO 15189 requirements*

Estimating, Reporting and Using Uncertainty of Measurement

Purpose: *to encounter concepts of uncertainty of measurement, to understand its role in interpreting the results from medical laboratory examinations and progress knowledge and understanding.*

Evaluation, audits and management review

Purpose: *To understand the significance of this section in ISO 15189 and how to apply the requirements in an assessment context*

Private meeting of assessors and final meeting

Purpose: *to explain the format and importance of the final meeting.*



Exercise 10– Presentation of findings and agreement of improvement actions at a final meeting

Purpose: *to provide a safe environment in which to practise a final meeting, and to allow tutors to bring out more teaching points. Following the exercise, there will be an opportunity to discuss what worked and what didn't; to discuss why it didn't work and to provide an opportunity to reinforce good practice; and to note learning points.*

Post assessment activities

Purpose: *to complete the information on the steps before and after accreditation and to explain the on-going role of the assessor.*

Open forum and close course

It is intended that the course closes by 16:45

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