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Guidelines for Training Courses for Assessors Used by Laboratory Accreditation Schemes

PURPOSE

This document has been produced to provide guidance to laboratory accreditation bodies on the organisation and content of assessor training courses (ATCs). It is designed to cover the training of both lead assessors and quality systems/technical assessors.

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Authorship

This publication has been written by WELAC Working Group 2.

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

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0 Background

0.1 An essential feature of all third-party laboratory accreditation schemes is that laboratories seeking accreditation are assessed on site for compliance with specified accreditation criteria. Such assessments are carried out either by assessors directly employed by the accreditation body or, more commonly, by part-time assessors appointed by the body to act on its behalf. In either case, the assessor plays a vital role in determining the credibility of the scheme. Assessors should hold appropriate technical and professional qualifications and should have recent experience in the activities they are going to assess. All potential assessors should undergo intensive training, regardless of background, experience or qualifications, by attending an appropriate training course. This training course should aim to familiarise assessors with the accreditation criteria to be used, assessment techniques and the human aspects of assessment.

1 Selection of ATC participants

- 1.1 Use the basic criteria for acceptability of assessors dealing with their technical competence, qualifications, experience and ability to communicate verbally and orally.
- 1.2 Use documentation to establish age, qualifications (academic and professional), working experience in testing/calibraton, quality assurance and assessment, previous training in QA, expertise in testing/calibration, personal reference.
- 1.3 Use completed documentation plus criteria of acceptability to choose suitable candidates.
- 1.4 If the potential assessor is not known, an interview, where necessary, is to be held with two members of accreditation body staff, one of whom is involved in the training programme.
- 1.5 Make recommendation for training or rejection.

2 Training course

2.1 Number of participants

- 2.1.1 Experience has shown that more than 20 participants on the course does not give sufficient opportunity for the participants to take part fully or for the tutors to assess their potential. Fewer than 16 participants loses some of the benefits of the interaction between potential assessors from quite different disciplines. Further, smaller numbers of delegates raises economic course fees to unacceptable levels. Therefore it is suggested that the number of participants is kept at a maximum of:
 - (a) 20 people working in syndicates/groups of 4 5.
 - (b) A mixture of disciplines is highly recommended.

2.2 Practical arrangements

(a) Facilities:

(i) Lecture room with space for 20 tables and chairs in U-shape and overhead projector and blackboard.

- (ii) Syndicate rooms large enough for 5 people sitting around one table.
- (b) Minimum duration 3 days with participants staying at course centre and not permitted to return home.
- (c) Location:

Hotel, training centre, conference centre convenient for public transport equipped with study bedrooms, restaurant, meeting area/bar, photocopying and conference secretary.

- (d) Course location should be reasonably remote from offices of accreditation body to discourage tutors from attending duties at the office.
- (e) Evening work should be confined to syndicate activities.

3 Course programme and documentation

3.1 Course programme

- 3.1.1 On receipt of completed registration forms including fees where charged, candidates should be sent a course programme and relevant documentation.
- 3.1.2 Course programme should contain titles of lectures and exercises with timetable for each.
- 3.1.3 Course programme should be sent to candidates in sufficient time, together with directions for travel to course centre and material to be read before the course and brought to the course.
- 3.1.4 As a minimum, attendees should be sent the accreditation criteria (eg EN 45001) and general information about accreditation body [see paras 3.2(b) & 3.2(c)].
- 3.1.5 The accreditation body may chose to test or examine the attendees before and after the course.

3.2 Documentation to be supplied to ATC attendees

- (a) Programme for course.
- (b) Copy of EN 45001 or national criteria and any other essential documents.

- (c) Document describing accreditation scheme.
- (d) Documentation describing steps in accreditation process.
- (e) Documentation describing conduct of assessments.
- (f) Guide to preparing quality manual, if available.
- (g) Samples of forms used during assessment (eg, non-compliance form, preliminary report form, checklists).
- (h) Case studies describing assessments at imaginary laboratory written so as to provide examples of acceptable and unacceptable assessor practice, identification of non-compliances and communication difficulties with laboratory. One case study in form of quality manual for laboratory.
- (i) Examples of acceptable and unacceptable calibration certificates and quality system audit ecords.

4 Course content

4.1 Introduction

- (a) Welcome course attendees.
- (b) Introduce course content; describe method of assessment of attendees.
- (c) Administrative arrangements, eg lunches, telephone, timing.
- (d) Attendees introduce themselves to rest of course:

Name, organisation and technical expertise.

4.2 Programme

4.2.1 All points (a) – (n) below should be covered, not necessarily in this order, through the use of:

Syndicate exercise with case study covering:

assessment of quality manual for imaginary laboratory

or assessment of text of initial assessment of imaginary laboratory

with

Report back of findings to course — presented by one member from each syndicate. Syndicates are asked to indicate possible non-compliances with accreditation criteria and bad practice

and

Lectures as appropriate.

- (a) Common introduction: EC, EFTA and EEA, EC documents as New Approach, Global Approach, etc.
- (b) Introduction to background to accreditation scheme and to accreditation in general. Include details of structure, staffing, general procedures for the accreditation body and its relationship with external national and international bodies.
- (c) Introduce accreditation criteria and explain key features with examples.
- (d) Quality system and quality manual

(i) Relation between ISO 9000 and EN 45000 (and ISO/ IEC Guide 25:1990)

- (ii) Documentation of quality system
- (iii) Content of a quality manual
- (e) Procedures and performance of audits and reviews
 - (i) Include examples of completed audit records
- (f) Calibration and traceability of measurement
 - (i) Calibration hierarchy
 - (ii) Uncertainties

(iii) Examples of cases where measurement traceability is difficult or not possible (eg chemical, biological)

(iv) Include examples of acceptable and unacceptable calibration certificates

- (g) Proficiency testing
 - (i) Definition
 - (ii) Mechanisms, criteria, current programmes, follow-up actions
- (h) Human aspects of assessment tailored to national characteristics

(i) Techniques for conducting the assessment to establish the method of working and the degree of compliance with the laboratory's own procedures and the accreditation criteria

- (ii) Advice on methods of communication
- (iii) Skills needed to establish information in an objective, friendly and

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professional manner

- (i) Administrative procedures
 - (i) Application, notification of arrangements for assessment
 - (ii) Composition and selection of assessment team

(iii) Preparation for assessment — eg, provision of quality manual and other relevant documentation to lead assessor

- (j) Conduct of assessments
 - (i) Preparation of programme and agenda for assessment
 - (ii) Examination of quality system
 - (iii) Assessment of technical competence
 - (iv) Reporting non-compliances
 - (v) Post-assessment activities
- (k) Reporting of non-compliances practical exercise or this can be done during reports on findings from case study exercises
- (l) Dummy assessment

(i) Examination of case study for assessment of imaginary laboratory against accreditation criteria noting quality of assessor performance and practice

(ii) Guidance of syndicates on preparations for report back to management of laboratory

(iii) Report-back by each syndicate in turn to management with presentation of outcome of assessment and non-compliances identified

(m) Feed-back by course tutors

(i) Content of notes taken by course tutor during report-back exercises reflecting observations on assessment practice relayed to course members. Emphasis on constructive comments to ensure good assessor practice

(n) Questions and answer session

(i) Tutors invite course members to criticise course and to ask points of clarification

5 Appraisal of course attendees

- (a) Continuous assessment by course tutors during course
- (b) Classification of attendees immediately after course
- (c) Where appropriate, letter to attendees describing outcome of course
- (d) Placement on register of potential assessors

6 Attendance certificate/diploma

6.1 An attendance certificate may be handed over to the course attendees. It should contain a brief description of the content of the course and should not infer that the holder is a fully qualified assessor.