Guidelines for Training Courses for Assessors Used by Laboratory Accreditation Schemes

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PREAMBLE

ILAC resolution No. 2/92 resolved that ILAC Committee 2 should undertake to prepare Guidelines for the content of laboratory assessor training courses, taking into account existing documents.

The aim of this work was to establish if laboratory assessor training courses could be based on a similar program of training to ensure the consistency of assessment of accredited laboratories. This aspect is increasingly important with the increase in the number of bilateral and multilateral agreements between accreditation bodies. All ILAC Members were asked to submit their laboratory assessor training course programs to the Working Group for comparison. These documents together with the WELAC document were analysed and a draft Guide on the content of training courses has been produced. The draft was considered in Washington and some minor changes have been incorporated.

Through ILAC resolution No. 14/94, the Conference endorsed the *Guidelines for Training Courses for Assessors* as an ILAC Guidance Publication.

These guidelines are based upon the content of courses currently run by ILAC members and the guide WGD51 produced by WELAC* for the content of assessor training courses. They comprise a number of discrete elements and the content of the training course to be used may be varied to provide the emphasis needed.

* WELAC - Western European Accreditation Cooperation - now incorporated within the European Cooperation for Accreditation of Laboratories (EAL).

PURPOSE

These guidelines have been prepared to assist laboratory accreditation bodies to set up training courses that are in line with international practice and which will enable them to generate the lead assessors and technical assessors that they need.

AUTHORSHIP

These guidelines were prepared by an ILAC Working Group of Committee 2 (Accreditation Practice).

The convenor of the Working Group was Dr J.A. Rogers from UKAS in the United Kingdom.

1. INTRODUCTION

1.1 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. Training courses should aim to familiarise assessors with the accreditation criteria to be used, assessment techniques and the human aspects of assessment. At the end of a training course successful participants should be familiar with the specific requirements of ISO/IEC Guide 25 or other requirements used by the Accreditation Body and know how to apply these requirements to specific calibration and testing laboratories. They should also be in a position where, with the guidance and supervision of an experienced lead assessor, they are able to plan, organise, conduct and report on assessment of a laboratory. In particular they should have gained sufficient knowledge and experience from the course to enable them to identify, record and classify non-compliances and to develop effective information gathering techniques and interpersonal skills for use during assessment.

1.2 Laboratory assessment often involves a team of assessors with one of the team designated to concentrate upon the assessment of the quality system and the management and operation of the laboratory. This person, who may or may not be, a technical expert like the rest of the team is usually also the lead assessor (team leader). To become a lead assessor an assessor has to have experience of assessment as a team member and have received intensive training in quality systems, assessment techniques and the criteria the accreditation body uses.

1.3 The tutors used to run assessor training courses will determine the quality of the potential assessors generated by the course. The main course tutors should have knowledge of the standards being used, experience in calibration and testing, experience in technical assessment, and shall have operated as a lead assessor managing a team and assessing quality systems. They should also have the ability, through training or experience, to design, manage and conduct training courses of this type.

Any supporting tutors should be suitably qualified and knowledgeable in the course topics they are to present.

All course tutors need to be enthusiastic and knowledgeable about quality assurance (QA) and accreditation and be able to work with a wide range of people. They should have good communication skills and be able to convey their knowledge effectively to the participants. It is essential that they be able to form effective judgements about the suitability of course participants for laboratory assessment.

2. SELECTION OF PARTICIPANTS

2.1 Accreditation bodies need to have available documentation setting out the basic qualifications/ criteria (see following note) for the acceptability of assessors, dealing

with their technical competence, qualifications, experience and ability to communicate verbally and orally. ISO 10011, *Guidelines for Auditing Quality Systems*, is useful for selecting lead assessors used to examine quality systems, but the standard needs to be supplemented to cover the requirements for technical assessors and assessment of laboratories.

(NOTE Committee 2 of ILAC is currently preparing guidelines for the qualification and performance monitoring of assessors.)

2.2 Documentation should be used to establish age, qualifications (academic and professional), working experience in testing, calibration, quality assurance and assessment, previous training in QA, expertise in testing/calibration and personal references.

2.3 The completed documentation and the criteria of acceptability should be used to choose suitable candidates.

2.4 If the potential assessor is not known, an interview, where necessary, should be held with two members of the accreditation body staff, one of whom is involved in the training programme.

2.5 Recommendations should be made for training or rejection. If participants are assessed carefully before attendance, failure rates on the course should be low.

3. TRAINING COURSE

3.1 Number of participants and tutors

3.1.1 Experience has shown that with more than 20 participants on a course, opportunities for the participants to become fully involved are significantly reduced and, in addition, it is more difficult for the tutors to assess their potential. With fewer than 16 participants some of the benefits of the interaction between potential assessors from quite different disciplines are lost and it is more difficult to operate the course on a full cost recovery basis. It is strongly recommended, therefore, that the number of participants is restricted to a maximum of 20 and that the course is arranged so that:

(a) there are at least two tutors when the number of participants exceeds 8 and that at least one of these tutors fulfills the requirement for a main tutor described in the *Introduction* to these guidelines;

(b) participants work in syndicates/groups of 4 to 5;

(c) a mixture of disciplines is invited to the course.

3.2 Practical arrangements

(a) Facilities:

(i) Lecture room with space for 20 tables and chairs in U-shape, an overhead projector and blackboard or whiteboard;

(ii) Syndicate rooms large enough for 5 participants sitting around one table.

(b) Duration:

(i) The duration of the course will depend upon the objectives set but in order to ensure sufficient knowledge of the accreditation criteria, sufficient training in assessment techniques and time to evaluate the likely performance of the participant as an assessor, it is strongly recommended that courses be of a minimum of 36 hours duration spread over 4 to 5 days;

(ii) Participants should be required to stay at the course centre to ensure that they attend evening sessions and gain maximum benefit from interaction with other course members;

(iii) Courses may be split into modules each of 1 to 2 days if preferred.

(iv) shorter courses covering selected elements may be run if they are for assessors who have already received QA training or will not be asked to do quality systems assessment.

(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 the offices of the accreditation body to avoid tutors being interrupted by accreditation body staff.

4. COURSE PROGRAMME AND DOCUMENTATION

4.1 Course programme

4.1.1 On receipt of completed registration forms including fees where charged, candidates should be sent a course programme and relevant documentation.

4.1.2 The course programme should contain titles of lectures and exercises with time-table for each.

4.1.3 The 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.

4.1.4 As a minimum, participants should be sent the accreditation criteria (eg ISO/IEC Guide 25) and general information about the accreditation body [see paras 4.2(b) & 4.2(c)].

4.1.5 The accreditation body may choose to test or examine the participants before and after the course.

4.2 Documentation to be supplied to participants

Documents (a) to (g) may be supplied before the course, but documents (h) to (j) should only be supplied during the course:

(a) Programme for course;

(b) Copy of ISO/IEC Guide 25 and/or EN 45001, ISO 9000 series and ISO 10011 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 and surveillance visits;

(f) Guide to preparing a quality manual, if available;

(g) Guide to conducting internal audits and reviews, if available;

(h) Samples of forms used during assessment (eg, non-compliance form, preliminary report form, checklists);

(i) Case studies describing assessments at an imaginary laboratory written so as to provide examples of acceptable and unacceptable assessor practice, identification of non-compliances and communication difficulties with the laboratory. One case study should be in the form of a quality manual for a laboratory;

(j) Examples of acceptable and unacceptable calibration certificates and quality system audit records and an agenda for a quality system review by top management.

5. COURSE CONTENT

5.1 Introduction

(a) Welcome participants.

(b) Introduce course content; describe method of assessment of participants.

(c) Describe administrative arrangements (eg lunches, telephone, timing).

(d) Have participants introduce themselves to rest of course, including their name, organisation and technical expertise.

5.2 Programme

5.2.1 The programme should consist of a mixture of lectures, discussions and group or syndicate exercises. The topics that should be covered are given in (a) - (o) in 5.2.2, but they need not be dealt with in the order given. Group exercises are essential in order to be able to evaluate the participants' ability to work as part

of a team or as a team leader. They are also necessary to permit evaluation of the participants' likely performance in real-life situations, that is, his or her potential suitability as an assessor.

5.2.2 Lectures, discussions and syndicate exercises with case studies, as appropriate, covering the following topics are recommended:

(a) Common introduction: Concepts of QA and QC and their importance particularly in relationship to the marketplace relevant to the country in which the accreditation body is located. Development of laboratory accreditation. Role of ILAC and other relevant bodies such as APLAC, EAL, EU and EOTC as appropriate;

(b) Introduction to the background of the 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, including certification bodies and other approval bodies;

(c) Introduce accreditation criteria, that is, ISO/IEC Guide 25 and any regulations, and explain key requirements and conditions with examples. Discussion of concepts;

(d) Exercise with case study for an imaginary initial assessment - group discussion;

(e) Quality system and quality manual:

(i) Relationship between ISO 9000 series and ISO/IEC Guide 25:1990 and/or EN 45001, as appropriate, when applied to calibration and testing laboratories;

(ii) Documentation of quality system with reference to different types of laboratory - operating procedures, calibration/test procedures, documentation control and records;

(iii) Content of a quality manual;

(iv) A syndicate exercise should be conducted using a case study covering the assessment of a quality manual for an imaginary laboratory. This case study can be used to emphasis the importance of key quality system elements such as organisation and management, audit and review, staff, equipment, traceability policy, calibration/test procedures, accommodation and environment, handling of test items, records, certificates and reports, complaints, sub-contracting and purchasing;

(v) Report back of findings to course - presented by one member from each syndicate. Syndicates should be asked to indicate possible non-compliances with accreditation criteria and bad practice. Analysis by tutors where necessary;

(f) Procedures for, and performance of, internal audits and review:

(i) Include examples of completed internal audit records;

(ii) Include example of agenda for review meeting;

(g) Calibration and traceability of measurement:

(i) Calibration hierarchy - concept of traceability of measurement and its application;

(ii) Calibration management systems in the laboratory;

(iii) Uncertainty of measurement;

(iv) Examples of cases where measurement traceability is difficult or not possible (eg, chemical, biological). Use of reference materials and quality control measures;

(v) Syndicate/individual exercise using examples of acceptable and unacceptable calibration certificates and internal calibration records.

(h) Proficiency testing and internal quality control schemes (ISO/IEC Guide 25: 1990 Para 5.6):

(i) Definitions;

(ii) Mechanisms, criteria, current programmes, follow-up actions.

(i) Human aspects of assessment, (see Clause 9 WGD83) 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 - questioning techniques;

(iii) Skills needed to gather information in an objective, friendly and professional manner;

(iv) Conflicts of interest and ethical concerns.

(j) Administrative and pre-assessment procedures:

(i) Application, appointment of lead assessor, examination of quality manual and preliminary reports to laboratory;

(ii) Pre-assessment visits and reports;

(iii) Composition, selection and appointment of assessment team;

(iv) Preparation for assessment (eg, provision of latest quality manual and other relevant documentation to lead assessor and assessors as appropriate).

(k) Conduct of assessments:

(i) Purpose and type - implications for assessors;

(ii) Preparation of programme and agenda for assessment. Briefing of assessment team;

(iii) Opening meetings;

(iv) Examination of quality system, gathering information and recording observations;

(v) Role of technical assessors;

- assessment of documented test procedures and their validation

- assessment of technical competence - this should cover the need for technical assessors to talk to testing staff, to observe them performing tests and to look at all aspects of the testing process from sample preparation, equipment and environment used, methods, method validation, standards, calibration, reference materials, data recording and analysis, quality control and reporting procedures.

- assessment of calibration arrangements, including traceability of measurement and uncertainty, internal calibration procedures and calibration intervals.

- use of computers, and software validation

- performance in proficiency tests

(vi) Final meeting, and reporting non-compliances;

(vii) Post-assessment activities;

(viii) Accreditation process;

(ix) Surveillance and re-assessment.

(l) Reporting of non-compliances (individual exercise) - practical exercise or this can be done during reports on findings from case study exercises

(m) Dummy assessment (syndicate exercise):

(i) Group examination of case study(ies) for assessment of imaginary laboratory against accreditation criteria noting quality of assessor performance and practice;

(Note: The case studies need to contain examples of assessors assessing compliance with the technical requirements of the accreditation criteria as well as the quality systems requirements.)

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

(iii) Report-back by team leader and individual members of each syndicate in turn to management with presentation of outcome of assessment and noncompliances identified.

(n) Feed-back by course tutors:

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

(o) Questions and answer session:

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

6. APPRAISAL OF COURSE PARTICIPANTS

6.1 It is essential to assess the performance of participants in training courses to ensure that they have the necessary personal qualities and are able to acquire the knowledge needed to carry out assessments to the desired standards. It is recommended that appraisal be done by a combination of continuous assessment and written examination.

6.2 For effective appraisal through continuous assessment at least two tutors must be present for the majority of the course. The tutors should form a judgement, through the contributions made during the course, about the participant's:

(a) knowledge and understanding of the accreditation criteria and accreditation procedures;

(b) ability to work as a member of a team;

(c) ability to communicate and deal with the human relations aspects of assessment;

(d) leadership potential.

6.3 Participants should be offered an opportunity of taking a written examination as a means of demonstrating their attainment of the level of knowledge required for work as assessor/lead assessor. The examination should test the participant's knowledge of:

(a) the content and practical application of ISO/IEC Guide 25 and/or EN45001 and ISO 9002 in respect to laboratories;

(b) the steps involved in planning, organising and conducting assessments against the requirements of these standards;

(c) identifying, classifying and reporting non-compliances;

(d) the human relations aspects of assessments and,

(e) if appropriate, the regulations/rules of the local accreditation body.

6.4 It is recommended that participants be classified as suitable/unsuitable to work as an assessor immediately after the course has been completed. The accreditation body should inform the participant in writing of the outcome of the course and, if appropriate, place the participant on its register of potential assessors.

7. ATTENDANCE CERTIFICATE/DIPLOMA

7.1 If the course includes both a formal system for continuous assessment and a written examination the course providers may issue a 'Certificate of Successful Completion' to those participants who demonstrate the required levels of achievement in both respects.

7.2 A Certificate of Attendance containing a brief description of the course may be issued to participants who do not fulfill the requirements of 7.1 or to participants in courses where a written examination is not provided.

7.3 Such certificates should clearly state that they relate only to the fact that the participant attended all of the course and should not infer that the holder is a fully qualified assessor.

7.4 Participants who already have some assessment experience will still need to demonstrate by participation in assessments that they have gained the necessary knowledge of laboratory accreditation criteria and laboratory assessment techniques.

8. UPDATING ASSESSORS

In addition to the formal monitoring of the performance of assessors on a regular basis, accreditation bodies should ensure that assessors are made aware of current criteria and practices. All assessors should be supplied with documentation issued by the accreditation body on a controlled basis, and should be required to attend updating courses at laid down intervals. At these courses, current policies and practices, including interpretations of criteria, can be discussed to ensure a consistent standard is achieved in assessment.

9. REFERENCES

1. (EAL) WELAC Guidance document WGD5 September 1993 - *Guidelines for Training Courses for Assessors used by Laboratory Accreditation Schemes*.

2. ILAC Seminar on Laboratory Assessor Training Programmes at ILAB, Dublin 21 October, 1987 Paper entitled *Human Aspects of Assessment* by Dr J A Rogers, NAMAS.

3. EAL (WELAC) Guidance Document WGD8 September 1993 - *Programme for Course for Tutors for Assessor Training*.