Guidelines for Training Courses for Assessors Used by Accreditation Bodies

About ILAC

ILAC is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

It is a representative organisation that is involved with:
- the development of accreditation practices and procedures,
- the promotion of accreditation as a trade facilitation tool,
- supporting the provision of local and national services,
- the assistance of developing accreditation systems,
- the recognition of competent testing (including medical) and calibration laboratories, inspection bodies, proficiency testing providers and reference material producers around the world.

ILAC actively cooperates with other relevant international organisations in pursuing these aims.

ILAC facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement – the ILAC Arrangement - among Accreditation Bodies (ABs). The data and test results issued by laboratories, and inspection bodies, collectively known as Conformity Assessment Bodies (CABs), accredited by ILAC Accreditation Body members are accepted globally via this Arrangement. Thereby, technical barriers to trade, such as the re-testing of products each time they enter a new economy is reduced, in support of realising the free-trade goal of "accredited once, accepted everywhere".

In addition, accreditation reduces risk for business and its customers by assuring that accredited CABs are competent to carry out the work they undertake within their scope of accreditation.

Further, the results from accredited facilities are used extensively by regulators for the public benefit in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services.

Accreditation Bodies that are members of ILAC and the CABs they accredit are required to comply with appropriate international standards and the applicable ILAC application documents for the consistent implementation of those standards.

Accreditation Bodies having signed the ILAC Arrangement are subject to peer evaluation via formally established and recognised regional cooperation bodies using ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

The ILAC website provides a range of information on topics covering accreditation, conformity assessment, trade facilitation, as well as the contact details of members. Further information to illustrate the value of accredited conformity assessment to regulators and the public sector through case studies and independent research can also be found at www.publicsectorassurance.org.

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INTRODUCTION

1.   GENERAL

1.1   Preamble

An essential feature of all accreditation schemes is that conformity assessment bodies (CAB) seeking accreditation are assessed for compliance with specified accreditation criteria. Such assessments are carried out by competent assessment personnel employed or contracted by the Accreditation Body (AB) to act on its behalf. These personnel may be appointed in the role of team leader, assessor or technical expert to fulfil the assessment requirements of the AB's accreditation scheme. In all cases, the personnel utilized for these assessment activities play a vital role in determining the credibility of the accreditation scheme.

Each role should have defined duties within an assessment team, and the personnel fulfilling the roles should have the appropriate professional qualifications as well as the knowledge of and experience in the conformity assessment activities they are going to assess.

All personnel involved in assessment activities should undergo appropriate training, regardless of background, experience or qualifications. The need for training should take into account an AB's competence criteria and/or knowledge requirements for its specific personnel. In some cases, training may be mandatory based on this criteria and/or requirements.

Training should aim to familiarize the candidate with the accreditation methodologies, accreditation criteria, and assessment techniques. Expected professional behaviours may also be addressed as part of the training.   The training provider is normally the AB itself, but services of other organizations can be used, provided that they are competent in carrying out training courses according to the AB's criteria.

To achieve an effective training course, the AB, for each type of role on an assessment, should;

♦   establish criteria to accept candidates (regarding knowledge, experience, education, personal attributes, etc.);
♦   design an appropriate training process;
♦   formally evaluate candidates after finalization of the training process;
♦   formally authorize assessors according to their role in the assessment team (team leader or assessor or technical expert), to the type of CAB they are authorized to assess (testing, calibration, inspection, etc.) and to the technical area they will assess (food, chemistry, elevators, etc.);
♦   organize periodical activities to update and harmonize assessors;
♦   establish processes to monitor assessors and technical experts (including onsite monitoring).

Upon successful completion of training, participants should be familiar with the specific requirements of ISO and ISO/IEC standards, any additional AB requirements, and the criteria for the application of these requirements to the specific accreditation schemes based on their assigned role in an assessment. In particular, the participant should have

gained sufficient knowledge and experience from the training to enable them to identify, record and classify nonconformities and to develop effective information gathering techniques and interpersonal skills for use during assessment.

An assessment team often includes a team leader who is responsible for the overall assessment, including the management of the assessment team. A candidate team leader should have assessment experience as a team leader trainee, experience with various assessment techniques, knowledge of the AB's accreditation processes as well as competencies in leadership and management.

1.2 Purpose

These guidelines have been prepared to assist ABs in setting up training courses that are in line with international practice and that will enable them to generate the team leaders and assessors that they need. While these guidelines are focused on traditional face-to-face settings, the principles can be adapted for development of other learning methodologies such as online learning courses. The training courses depicted in these guidelines are intended to cover management system and AB related training for new assessors. It is preferable that each training course be conformity assessment standard specific (i.e. ISO/IEC 17025, ISO 15189, ISO/IEC 17020, ISO/IEC 17043, ISO 17034), if possible. These guidelines are not intended to cover refresher training or technically specific training of veteran assessors.

1.3 Authorship

This publication was prepared by the Accreditation Committee of ILAC. The guidelines were initially published in 1994. Updates to the publication were made in 2011 and 2012. All future revision history is located in the Revision Table found in Appendix B of this publication.

2. SELECTION OF TRAINERS

The trainers chosen to conduct assessor training courses will determine the quality of the potential assessors generated by the course. The main course trainers should have knowledge of the accreditation standards being used, assessment experience, and have operated as a team leader managing an assessment team and assessing management systems. They should also have the ability, through training or experience, to design, manage and conduct training courses of this type.

Any supporting trainers should be suitably qualified and knowledgeable in the course topics they are to present, through experience in the relevant conformity assessment activity associated with the training course.

All course trainers need to be knowledgeable about quality assurance (QA) and conformity assessment 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 the assessment of CABs.

3. TRAINING COURSE

3.1 Number of participants and trainers

Experience has shown that with more than 20 participants in a course, opportunities for the participants to become fully involved are significantly reduced and, in addition, it is more difficult for the trainers to assess their potential. With fewer than 15 participants some of the benefits of the interaction between potential assessors from quite different disciplines may be lost and it is more difficult to operate the course on a full cost recovery basis. It is recommended, therefore, that the number of participants be restricted to a maximum of 20 and that the course is arranged so that:

(a)　participants work in teams/groups of approximately 5 persons;

(b)　persons representing a mixture of disciplines are invited to the course.

3.2 Practical arrangements

When making arrangements for a training course, the following items should be considered, but not limited to:

(a)　Facilities:

    (i)　Lecture room with space for 20 that allows all participants to see one another and work together in group activities (U-shape works well),

    (ii)　Audio-visual needs - a computer and projection screen, whiteboard/flip chart. Internet access and photocopying equipment may also be needed;

    (iii)　Breakout rooms or areas for team/group work.

(b)　Duration:

    (i)　The duration of the course will depend upon the established objectives and whether or not there is self-study required to be completed in advance. Overall, it is recommended that team leader training course(s) be in total a minimum of 36 hours and assessor training course(s) be in total a minimum of 16 hours. There are many ways to conduct the training course(s). For example, training can be delivered over the course of 4-5 days, or may be split between self-study and 3 days in a training course.   Ultimately, the AB should ensure that the assessors have sufficient knowledge of the accreditation criteria, sufficient training in assessment techniques and the AB has sufficient time to evaluate the likely performance of the participant as an assessor;

    (ii)　Participants should be required to complete the full course. In exceptional cases where a participant is unable to attend the full course, alternate arrangements should be made to ensure the individual has a full grasp of the course content missed;

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

(iv)   Shorter courses covering selected elements may be run if they are for assessors who have already received QA training or will not be required to assess management systems.

(c)   Location:

(i)   Hotel, training center or conference center convenient for public transport, equipped with WIFI, restaurant, meeting area/bar, photocopying facilities;

(ii)   If the course location is in the offices of the AB, trainers shall avoid interruptions from AB staff.

4.   COURSE PROGRAM AND DOCUMENTATION

4.1   Course program

4.1.1   On receipt of completed registration forms and the payment of any fees charged, participants should be sent a course program and relevant documentation/self-study materials.

4.1.2   The course program should contain the course objectives, including titles of lectures and exercises with timetables for each.

4.1.3   The course program, including directions for travel to the training venue, should be sent to participants in sufficient time to allow for completion of any assignments required in advance of the course.

4.1.4   The AB may choose to test the participants before and/or after the course.

4.2   Documentation to be supplied to participants

Documents may be supplied before the course, but, at a minimum, documents (g) and (h) should be supplied during the course:

(a)   Course description and expectations;

(b)   Copy of the relevant accreditation standard unless the participant is required to obtain their own copy (or the respective checklists if they contain the full text of the standard), any AB specific accreditation criteria and any other essential documents;

(c)   Documents describing the accreditation scheme;

(d)   Documents describing steps in the accreditation process;

(e)   Documents describing the conduct of different types of assessments and assessment techniques;

(f)   Samples of forms used during assessment (e.g., nonconformity form, preliminary report form, checklists);

(g)   Case studies describing example assessments to demonstrate acceptable and unacceptable assessor practice, identification of nonconformities and communication difficulties with the CAB. One case study should be in the form of required documented information for a CAB (see Appendix A for information for available case studies);

(h)   Description of exercises to be used during the course (e.g., for management system and technical reviews).

5.   COURSE CONTENT

5.1   Introduction

(a)   Welcome participants.

(b)   AB staff and/or course trainer introduces themselves and provides a brief description of their technical, management, and/or assessment related experiences.

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

(d)   Describe administrative arrangements (e.g. lunches, telephone and WIFI access, timing, safety and emergency procedures).

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

5.2   Program

5.2.1   The program should consist of a mixture of lectures, discussions, team/group exercises and case study review exercises. The topics that should be covered are given 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. Case studies that mimic real-life situations 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, see appendix A.

5.2.2   Lectures, discussions and team/group 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 AB is located. Development of CAB accreditation. Role of ILAC and other relevant bodies such as AFRAC, APAC, ARAC, EA, and IAAC as appropriate. Information on regional trade organisations and their interactions with the accreditation community, e.g. interaction between the European Union (EU) and EA;

(b)   Introduction to the background of the accreditation scheme and to accreditation in general. Include details of structure, staffing, general procedures of the AB and its relationship with external national and

international bodies, including certification bodies and other approval bodies;

(c)   Introduction to accreditation scheme requirements, that is, ISO/IEC 17025, ISO 15189, ISO/IEC 17020, ISO 17034, ISO/IEC 17043, and/or ISO 20387 and any ILAC policies/guidelines, regional requirements, and regulatory requirements associated with the conformity assessment activity, explanation of key requirements and conditions with examples, discussion of concepts;

(d)   Exercises with case studies for example assessments, including the use of verbal and nonverbal communication - group discussion;

(e)   Management system:

(i)   Relationship between ISO 9000 series and ISO/IEC 17025, ISO 15189, ISO/IEC 17020, ISO 17034, ISO/IEC 17043, and/or ISO 20387 as appropriate, when applied to the conformity assessment bodies;

(ii)   Documentation of management system with reference to different types of CABs - operating procedures, documentation control and records;

(iii)   Typical management system documentation;

A team/group exercise should be conducted using a case study covering the assessment of a management system. This case study can be used to emphasize the importance of key management system elements specific to the conformity assessment standard. The exercise should include a report back from the teams/groups of the conclusions such as possible nonconformities with accreditation criteria and bad practice. Analysis by trainers, where necessary, is suggested.

(f)   Calibration and metrological traceability (ILAC P10 and ILAC P14):

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

(ii)   Measurement uncertainty *(Guidance on uncertainty in testing can be found in ILAC G17.)*;

(iii)   Examples of cases where metrological traceability is difficult or not possible (e.g., chemical, biological). Use of reference materials and quality control measures;

(iv)   Verification of metrological traceability through calibration certificates, certified reference material (CRM)/reference material (RM) certificates, and internal calibration records;

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

(g)   Medical laboratory assessments (ISO 15189):

(i)   Pre-examination phases;

(ii)   Post-examination phases, including reporting of results.

(h)   Inspection Body assessments (ISO/IEC 17020 and ILAC P15):

(i)   Witnessing of inspectors;

(ii)   Assessment of key locations.

(i)   Interlaboratory comparison (proficiency testing/external quality assessment) and internal quality control schemes (ISO/IEC 17043 and ILAC P9):

(i)   Definitions;

(ii)   Mechanisms, criteria, current programs, follow-up actions;

(iii)   Participation plans.

(j)   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 CAB'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;

(v)   Managing conflict during an assessment.

(k)   Administrative and pre-assessment procedures:

(i)   Application, appointment of team leader, examination of management system documentation and preliminary reports to CAB;

-      Performing a document review;
-      Preparing an agenda.

(ii)   Preliminary visits;

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

(iv) Preparation for assessment (e.g., provision of latest management system documentation to team leader and assessors, as appropriate).

(l) Conduct of assessments:

(i) Purpose, type and approach (evidence-based vs. risk-based) of the assessment - implications for assessors;

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

(iii) Opening meetings;

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

(v) Role of technical assessors/technical experts;

- assessment of documented test/calibration/inspection procedures and their validation;

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

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

- use of computers, and software validation;

- performing a vertical assessment and witnessing;

- performance in proficiency testing programs/external quality assessment schemes or other relevant interlaboratory and/or intralaboratory comparisons.

(vi) Closing meeting, and reporting of findings, including nonconformities;

(vii) Post-assessment activities;

a. Review of analysis of cause and the extent of nonconformities, and the corrective actions to address any nonconformities identified;

b. Assessment deliverables (e.g. report, draft scope, checklists, etc.).

(viii) Process for granting accreditation;

(ix) Assessment cycle: periodic onsite assessment and reassessment.

(m) Drafting the wording of nonconformities - practical exercise or this can be done during reports on findings from case study exercises;

(n) Mock assessment (team/group exercise):

(i) Team/group examination of case study(ies) for assessment of example CAB 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 management systems requirements.)

(ii) Guidance of team/group on preparations for report-back to management of CAB;

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

(o) Feed-back by course trainers:

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

(p) Questions and answer session:

(i) Trainers invite course participants to critique course and to ask points of clarification. It is recommended that this be documented in a written course evaluation questionnaire.

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 monitoring of performance during the training course and written examination.

6.2 For effective appraisal through continuous monitoring of performance, more than one trainer may be necessary, depending on the number of participants in the course.   The trainers should evaluate, through the contributions made during the course, 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 take a written examination as a means of demonstrating their attainment of the level of knowledge required for work as assessor/team leader. The examination should be written to assess the mastery of the course objectives, i.e. the length of the examination will vary based on the established objectives. The use of notes, texts and/or resource materials should be considered during the development of the examination.

6.4   It is recommended that participants be classified as suitable/unsuitable or suitable with additional training immediately after the course has been completed. The AB 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.   CERTIFICATE OF COMPLETION/ATTENDANCE

7.1   If the course includes both a formal system for continuous monitoring of performance during the training course 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 fulfil the requirements of 7.1 or to participants in courses where a written examination is not provided.

8.   EVALUATION OF COURSE BY PARTICIPANTS

8.1   ABs should monitor the effectiveness of their trainings using the feedback from the participants. This can be achieved by a questionnaire/short survey filled out immediately at the end of the course or a short period after;

8.2   This questionnaire should seek the input on the course content, the competence of the trainers, the documentation and the practical arrangements;

8.3   ABs should use the results of such feedback for continual improvement of the training process.

9.   UPDATING ASSESSORS

In addition to the formal monitoring of the performance of assessors on a regular basis, ABs should ensure that assessors are made aware of current accreditation criteria and practices. ABs should establish criteria necessary for their assessors to maintain competency. All assessors should be supplied with or have access to documentation issued by the AB, and should be required to attend courses at prescribed intervals to maintain the appropriate knowledge. At these courses, current policies and practices, including interpretations of criteria, can be discussed to ensure consistency is achieved in the assessment process.

10.   REFERENCES

ISO/IEC 17011 *Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies*

ISO/IEC 17020 *Conformity assessment – Requirements for the operation of various types of bodies performing inspection*

ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*

ISO 17034 *General requirements for the competence of reference material producers*

ISO/IEC 17043 *Conformity assessment – General requirements for proficiency testing*

ISO 15189 *Medical laboratories –Requirements for quality and competence*

ILAC-P9 *ILAC Policy for Participation in Proficiency Testing Activities*

ILAC-P10 *ILAC Policy on Metrological Traceability of Measurement Results*

ILAC-P14 *ILAC Policy for Uncertainty in Calibration*

ILAC-G8 *Guidelines on Decision Rules and Statements of Conformity*

ILAC-G17 *Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025*

ILAC-G27 *Guidance on measurements performed as part of an inspection process*

APPENDIX A

ILAC/Laboratory Committee (LC) Case Study guidance

In an effort to address concerns with harmonization between regions and ABs, the ILAC LC developed case studies as a tool to help train assessors and to assist in maintaining uniformity between ABs. As a result of the case study project, several case studies have been developed and grouped in the following categories:

- Quality management;
- General laboratory matters,
- Testing laboratory specific matters,
- Calibration laboratory specific matters,
- Medical laboratory specific matters, and
- Other.

Case studies will be made available from a repository on the ILAC website for use by ILAC Members and Associates to facilitate the harmonization of accreditation practices. Additionally, a mechanism has been developed to allow for submission of new case studies. If you would like to submit a new case study, please use the *Guidelines for submitting a new Case Study* to be made available from the ILAC website.

APPENDIX B

REVISION TABLE – The table provides a summary of the key changes to this document from the previous version.

Section	Amendment
About ILAC introductory text	Replaced with new version
Copyright text	Replaced with new version
Whole document	The document is updated to the new terminology in ISO/IEC 17011:2017. Besides this, changes are minor and editorial.
10.References	Updated
APPENDIX A	Grading of NCs removed
APPENDIX B	Updated as Appendix A, reference to the ILAC LC Case studies added.
APPENDIX B	New. Revision table added.