Guidelines for Training Courses for Assessors Used by Accreditation Bodies

ILAC-G3:08/2012

The ILAC Secretariat
PO Box 7507
Silverwater NSW 2128
Australia
Fax: +61 2 9736 8373
Email: ilac@nata.com.au

TABLE OF CONTENTS

INTRODUCTION

1. GENERAL

1.1 Preamble

An essential feature of all accreditation schemes is that Conformity Assessment Bodies (CAB) 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 (AB) or, more commonly, by part-time assessors appointed by the AB to act on its behalf. In either case, the assessor plays a vital role in determining the credibility of the scheme. It is common practice for ABs to make use of different types of assessors such as lead assessor and technical assessor. In this case, each type of assessor should have different duties within the assessment team. Each type of assessor should hold appropriate technical and professional qualifications and should have recent experience in the activities they are going to assess.

To achieve an effective training course, the AB, for each type of assessor, should;

- establish criteria to accept candidates (regarding experience, education, personal attributes, etc.);
- design an appropriate training process;
- formally evaluate candidates after finalisation of the training process;
- formally classify/qualify assessor according to their position in the assessment team (leader, technical assessor), to the type of CAB they are qualified to assess (testing, calibration, inspection, etc.) and to the technical area they will assess (food, chemistry, elevators, etc.);
- organise periodical activities to update and harmonise assessors;
- establish criteria to monitor assessors (including on-site monitoring).

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. The course provider is normally the AB itself, but services of other organizations can be used, provided that they are competent in carrying out training courses for the assessors according to the AB's criteria.

At the end of a training course successful participants should be familiar with the specific requirements of ISO/IEC standards or other requirements used by the AB and know how to apply these requirements to specific calibration and testing laboratories, or inspection bodies, respectively. 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 CAB. In particular they should have gained sufficient knowledge and experience from the course to enable them to identify, record and classify non-conformities and to develop effective information gathering techniques and interpersonal skills for use during assessment.

An assessment of a CAB often involves a team of assessors with one of the team members designated to concentrate upon the assessment of the quality management system and the management and operation of the CAB. 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 management systems, assessment techniques and the criteria the AB uses.

1.2 Purpose

These guidelines have been prepared to assist ABs to set up training courses that are in line with international practice and that will enable them to generate the lead assessors and technical assessors that they need. The training courses depicted in these guidelines are intended to cover management system and AB related training for new assessors. It is intended that each training course be conformity assessment standard specific (i.e. ISO/IEC 17025, ISO 15189, ISO/IEC 17020), not combined. These guidelines are not intended to cover refresher training or technically specific training of veteran assessors.

'Guidelines on Grading of Non-Conformities', previously included in ILAC G20, have been added as an Annex to this document.

1.3 Authorship

ILAC G3:1994 was prepared by an ILAC Working Group of Committee 2 (Accreditation Practice).

ILAC G3:2011 was revised by the ILAC Accreditation Committee.

2. SELECTION OF INSTRUCTORS

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

Any supporting instructors should be suitably qualified and knowledgeable in the course topics they are to present, through experience in calibration, testing, inspection, and/or quality management systems.

All course instructors need to be enthusiastic and 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 instructors

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 instructors 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 strongly recommended, therefore, that the number of participants is 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

(a) Facilities:

(i) Lecture room with space for 20 around a table that allows all participants to see one another (U-shape works well), a computer and projection screen and blackboard or whiteboard. Internet access and photocopying equipment may also be provided;

(ii) Breakout rooms or areas for team/group work with space enough for 5 participants sitting around one table.

(b) Duration:

(i) The duration of the course will depend upon the objectives set and whether or not there is required self-study to be completed in advance. 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 consist of 36 hours' duration, at least for the training of lead assessor(s). This can be delivered over the course of 4-5 days, or may be split between self-study and 3 days of classroom training;

(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;

(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:

(i) Hotel, training centre, conference centre convenient for public transportation equipped with bedrooms with work space/desks, restaurant, meeting area/bar, photocopying and conference secretary;

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

4. COURSE PROGRAM AND DOCUMENTATION

4.1 Course program

4.1.1 On receipt of completed registration forms including fees where charged, candidates should be sent a course program and relevant documentation/self study materials.

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

4.1.3 The course program 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 (e.g. checklists to ISO/IEC 17025, ISO 15189, ISO/IEC 17020) and general information about the AB [see paras 4.2(b) & 4.2(c)].

4.1.5 The AB may choose to test or examine the participants before and after the course. A final written exam is recommended.

4.2 Documentation to be supplied to participants

Documents may be supplied before the course, but documents (g) to (i) should be supplied during the course:

(a) Course description and expectations;

(b) Copy of ISO/IEC 17025, ISO 15189, ISO/IEC 17020 and/or ISO 9000 series (or their representative checklists if they contain the full text of the standard), ILAC G11, any AB specific 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) Samples of forms used during assessment (e.g., non-conformity form, preliminary report form, checklists);

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

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

5. COURSE CONTENT

5.1 Introduction

(a) Welcome participants.

(b) AB staff and/or course instructor introduce themselves and provide a brief description of their technical, management, and/or assessment related experience.

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

(d) Describe administrative arrangements (e.g. lunches, telephone, timing).

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

5.2 Program

5.2.1 The program should consist of a mixture of lectures, discussions and team/group 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. 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 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 APLAC, EA, and IAAC 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 AB and its relationship with external national and international bodies, including certification bodies and other approval bodies;

(c) Introduction to accreditation criteria, that is, ISO/IEC 17025, ISO 15189, and/or ISO/IEC 17020 and any regulations. Explanation of key requirements and conditions with examples. Discussion of concepts;

(d) Exercises with case studies for imaginary assessments - group discussion;

(e) Quality management system and quality manual:

(i) Relationship between ISO 9000 series and ISO/IEC 17025, ISO 15189, and/or ISO/IEC 17020, as appropriate, when applied to

calibration and testing laboratories, medical laboratories, and inspection bodies, respectively;

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

(iii) Content of a quality manual;

(iv) A team/group exercise should be conducted using a case study covering the assessment of a quality manual for an imaginary CAB. This case study can be used to emphasis the importance of key quality management system elements such as organisation and management, audit and review, staff, equipment, traceability policy, calibration/test/inspection 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 team/group. Teams/groups should be asked to indicate possible non-conformities with accreditation criteria and bad practice. Analysis by instructors where necessary;

(f) Calibration and traceability of measurement (ILAC P10 and ILAC P14):

(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 (e.g., chemical, biological). Use of reference materials and quality control measures;

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

(g) Medical laboratory assessments (ISO 15189):

(i) Specific issues;

(ii) Pre and post examination phases.

(h) Inspection Body assessments (ISO/IEC 17020):

(i) Witnessing of inspectors;

(ii) Assessment of key locations.

(i) Inter-laboratory comparison (proficiency testing/external quality assessment) and internal quality control schemes:

(i) Definitions;

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

(iii) Risk assessment and 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.

(k) Administrative and pre-assessment procedures:

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

- Performing a document review;
- Preparing an agenda.

(ii) Pre-assessment visits and reports;

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

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

(l) Conduct of assessments:

(i) Purpose and type - implications for assessors;

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

(iii) Opening meetings;

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

(v) Role of technical assessors;

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

- assessment of technical competence - this should cover the need for technical assessors to talk to testing/calibration/inspection 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, 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;

- performing a vertical assessment;

- performance in proficiency testing programs/external quality assessment schemes or other relevant inter-laboratory comparisons.

(vi) Closing meeting, and reporting findings, including non-conformities;

(vii) Post-assessment activities;

a. Following up corrective actions to address any non-conformities identified;
b. Assessment deliverables (e.g. report, draft scope, checklists, etc.).

(viii) Process for granting accreditation;

(ix) Surveillance and re-assessment.

(m) Grading of non-conformities, when applicable (See Appendix A);

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

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

(i) Team/group examination of case study(ies) for assessment of imaginary 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 laboratory;

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

(p) Feed-back by course instructors:

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

(q) Questions and answer session:

(i) Instructors 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 assessment and written examination.

6.2 For effective appraisal through continuous assessment more than one instructor should be present for the majority of the course. The instructors 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/lead assessor. The examination should test the participant's knowledge of:

(a) the content and practical application of ISO/IEC 17025, ISO 15189, and/or ISO/IEC 17020 in respect to laboratories or inspection bodies, where applicable;

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

(c) identifying, wording, classifying and reporting non-conformities;

(d) the human relations aspects of assessments;

(e) if appropriate, the requirements of the local AB.

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 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. 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/Diploma of Successful Completion to those participants who demonstrate the required levels of achievement in both respects.

7.2 A Certificate/Diploma 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/diplomas should clearly state that they relate only to the fact that the participant attended the entire course and should not imply 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 CAB accreditation criteria and CAB assessment techniques.

8. EVALUATION OF COURSE BY PARTICIPANTS

8.1 ABs should monitor the effectiveness of their trainings using the feed back from the participants; this can be achieved by a questionnaire filled out immediately at the end of the course or a short period after;

8.2 This questionnaire should seek the appreciation of the course content, the competence of the instructors, the documentation and the practical arrangements;

8.3 ABs should use the results of such feed back 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 criteria and practices. ABs should establish criteria necessary for their assessors to maintain competency. All assessors should be supplied with documentation issued by the AB on a controlled basis, and should be required to attend updating courses at prescribed intervals. At these courses, current policies and practices, including interpretations of criteria, can be discussed to ensure a consistent standard is achieved in assessment.

10. REFERENCES

ISO/IEC 17020 General criteria for the operation of various types of bodies performing inspection

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

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

ISO 15189 Medical Laboratories – Particular requirements for quality and competence

ISO/IEC 17011 Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies

ISO 19011 Guidelines for quality and/or environmental management systems auditing

ILAC-P9 ILAC Policy for Participation in Proficiency Testing Activities

ILAC-P10 ILAC Policy on Traceability of Measurement Results

ILAC-P14 ILAC Policy for Uncertainty in Calibration

ILAC-G11 ILAC Guidelines on Qualifications and Competence of Assessors and Technical Experts

APLAC TR001 Guidelines on Training Course for Laboratory and Inspection Body assessors

APPENDIX A

GUIDELINES ON GRADING NON-CONFORMITIES

1. Nature Of Non-Conformities

One aspect of the assessment of a CAB is to ensure that the management system is in conformance with the standard and that staff members are following the procedures. However, the key aspect of the assessment is the determination of competence and validity of technical operations. This assessment process requires the professional judgment of the technical assessors and / or experts. Where it is considered that aspects of technical activities are not in compliance with accreditation requirements that are based on the applicable standard(s) and/or regulation(s), one or more non-conformities will need to be raised.

For accredited CABs there is another type of non-conformity to be considered. The AB will have rules and requirements that its accredited CABs follow, such as claims of accreditation status or use of the accreditation mark. When these rules are violated, the AB will also raise a non-conformity.

Thus for accreditation the nature of a non-conformity may include:

- documentation not conforming with the requirements of accreditation criteria
- staff not following documented procedures
- operational procedures lacking technical validity
- a breakdown in the operation of the CAB
- the CAB not conforming to the rules of the AB.

It is the responsibility of the AB to decide which non-conformities are so serious as to require immediate suspension of accreditation, which are serious enough to require prompt attention with the presentation of objective evidence to the AB, and which are minor and may be corrected by the next assessment. The AB will need to take into account the nature of those non-conformities in establishing its criteria for grading non-conformities.

Accreditation provides assurance to the customers of CABs that their management systems, operations and technical activities are competent and valid (based on compliance with requirements). Therefore, the most serious non-conformities are:

- Those related to technical activities suggesting incompetence or invalid practices;
- Management non-conformities that jeopardize the whole quality management system.
- In the case of medical laboratories, those that directly impact examination results and therefore pose an immediate threat to patient safety.

The seriousness of the non-conformity is the degree to which the CAB fails to comply with requirements of the AB. Contributing factors to the seriousness of a non-conformity could be determined by the actions that the CAB may need to take in order to correct it or by the impact on the operations of the CAB.

2. Actions Required By Accreditation Bodies As A Consequence Of Non-conformities

Accreditation bodies are required to issue non-conformity notices with a specified response date.

- Corrective actions for serious non-conformities are required to be resolved before accreditation is granted.
- The AB may require that some non-conformities are corrected more urgently than others, that objective evidence of the CAB's corrective actions are provided and that clients are advised where results are in question. If non-conformities are really serious, accreditation may need to be suspended immediately.
- Corrective actions for less serious non-conformities may not be reviewed by the AB until the next assessment.

3. Grading of Non-Conformities

(a) Where non-conformity is "very serious indeed" the accreditation of the CAB or the affected tests/measurements/inspections is suspended immediately.

(b) Where non-conformity is "quite significant", corrective actions are required within the specified time interval to avoid suspension. Such non-conformities may well need a follow-up on-site assessment to ensure they have been effectively corrected especially if the validity of results or the integrity of the AB is threatened. However, if the assessment team agrees that the CAB understands the issues, written assurance of corrective action and the provision of objective evidence of the measures taken, may be acceptable.

(c) Where the non-conformity is minor or isolated and does not affect test, calibration, or inspection results or certificates, requiring corrective action would not improve the operations of the CAB and could seriously damage the relationship between the CAB and the AB. In such cases the non-conformity may be noted in the assessment report for checking at the next assessment but either no request for corrective action is made or only a corrective action plan is requested.

4. General Comments On Grading Of Non-Conformities And Issuing Of Corrective Action Requests

Technical requirements non-conformities that are threatening the validity of test or measurement results would usually be regarded as at least "quite significant" and possibly "very serious indeed". Similarly, a serious breakdown in the quality management system, such as many complaints being received but none acted upon, may be in the serious category.

Intentional breaching of the rules for the use of AB logo or mark may also be regarded as "very serious indeed". This would be the case particularly if the integrity of the AB had been jeopardized or if an unfair competitive advantage against properly accredited organizations had resulted.

Regardless of the nature of the non-conformities, each one should be evaluated within the circumstances presented so that a fair grading may be established and to ensure the actions taken against the CAB will be appropriate.

It is emphasized that apparently similar situations may result in different gradings. This is because no two circumstances are exactly the same and the consequences of the particular non-conformity may be very different.

Where a grading decision is marginal, the track record of the CAB with its accreditation and the degree to which the AB trusts the body to take prompt and effective corrective action may result in the downgrading of the seriousness of the non-conformity.

Grading of non-conformities should be based only on the findings recorded during the assessment.

Grading decisions should be made by the assessment team who were present on-site. They should be made before the assessment team leaves the site.

A finding should be sufficiently detailed to be able to confirm whether it was a one-time event or a general statement whose corrective action should be implemented throughout the CAB. It is the responsibility of the CAB to determine, through its corrective action procedure, if a one-time event may have wider implications. A corrective action request may ask the CAB to itself determine if the finding indicates a chronic problem.

Minor non-conformities, which are to be checked at the next assessment, may be reported verbally to the CAB, may perhaps be included in the report and should be recorded in the assessment notes, so that the CAB manager understands that they will be checked during the next assessment.

Minor non-conformities have a tendency to grow into significant non-conformities if not addressed appropriately at the time.

Where a non-conformity is found, the assessor(s) should evaluate its effect on the quality of the results of the CAB. For example, an uncorrected error from the calibration of a thermometer used in a testing laboratory may have little effect on the results if that test is not particularly temperature sensitive.

In all cases of non-conformity, assessors need to resist “approving” proposed corrective actions presented on the day of the assessment without a proper corrective action investigation by the CAB. Such approvals may lead to the embarrassment of having to issue another non-conformity at the next assessment because the “approved” corrective action was not adequate.

Findings should be evaluated together with the general picture / history of the CAB (e.g. trust, ongoing improvement, staff competence, repetitive nature (from previous assessments), etc.).

Where urgent suspension of a CAB is indicated after the identification of very serious non-conformities, procedures for immediate suspension are necessary rather than awaiting the next meeting of a committee.