Guide to the conduct of assessments for assessors (LA-G-02)

Bureau of Laboratory Accreditation

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Introduction

The Bureau of Laboratory Accreditation, Department of Science Service (BLA-DSS) recognises that confidence in the accreditation process is dependent on the competence of the personnel conducting the assessment. A competent assessor is one who has the necessary combination of education, experience and personal attributes and, when acting as a Technical Assessor, possesses relevant technical knowledge. This document gives general guidance to trained and authorised assessors on

a) assessor responsibilities within the process of accreditation

b) assessment techniques.

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1. Scope

This document is applicable to qualified assessors.

2. Definitions

2.1 Accreditation means the formal recognition that a laboratory or a proficiency testing provider or reference material producer is technically competent to carry out specific tests and scopes.

2.2 The BLA-DSS means the Bureau of Laboratory Accreditation, Department of Science Service.

2.3 The Technical Sub Committee, hereinafter called “the Sub Committee or TSC” is responsible for considering the competence of laboratory accreditation according to ISO/IEC 17025 or PTP accreditation according to ISO/IEC 17043 or RMP accreditation according to ISO 17034 and APAC TEC1- 008 for the decision making process.

2.4 The Laboratory Accreditation Committee, hereinafter called “the Committee or LAC” is responsible for making the decisions on accreditation and consulting and advising the accreditation activities.

3. Responsibilities and commitments of assessors

3.1 Conflict of interest

Assessors are required to complete the conflict of interest form (LA-F-13 or LA-F-213 or LA-F-313) on first appointment to a case. Assessors should ensure that they declare any changes to their situation that may change their conflicts of interest. Examples of conflict may include

a) company alliances and commercial interests in the facility
b) commercial arrangements, e.g. customer/supplier relations
c) intellectual property considerations
d) consultant arrangements (current and/or past)
e) close personal associations (family and/or friends).

3.2 Time availability

By accepting a case, assessors are confirming they have the appropriate resources (time availability and technical knowledge) to undertake the assessment(s) in the timescales outlined by the BLA-DSS. It is the responsibility of the assessor to notify the relevant Case Officer of any changes to such resources.

3.3 Confidentiality

3.3.1 Assessment team members are in a position of privilege with respect to information about the facility under assessment. Confidentiality is essential part of the assessment.

Information to be kept confidential includes

a) all assessment arrangements including the name of the facility to be assessed and other assessors involved

b) paperwork about the assessment, including briefing notes and report

c) any recommendations or discussions arising out of the assessment

d) any information about the facility and its operation obtained during the course of an assessment that would otherwise not normally be available to assessor.

3.3.2 Breaches of confidentiality are viewed very seriously and as a minimum will jeopardize an assessor's participation in any future assessment activity.

3.4 Gifts and inducements

3.4.1 The acceptance of dining invitations and gifts can be an area of concern for assessors. The following guidance may assist with situations that might arise in the course of participating in assessment visits for the BLA-DSS.

3.4.2 Most companies will provide lunch and other refreshments (e.g. tea/coffee) during the assessment. Additionally, companies may present individuals

within the assessment team with company souvenirs such as corporate mugs, pens, ties etc. Dining invitations or gifts of this nature may be viewed as hospitality tokens, unless the value of the gift is excessive.

Assessors should however, remember that the provision of lunch and refreshments are not an obligation of the accreditation assessment process and under no circumstance should gifts and meals ever be suggested to, or expected of, an organisation.

3.4.3 Where the offer of lunch/dinner and or/any small company gifts is made to the assessment team, it is the responsibility of the Lead Assessor (in conjunction with the Case Officer) to decide whether to accept of decline the offer. Where an offer for lunch/dinner is made to an individual assessor, the assessor should discuss this issue with the Lead Assessor. Where a small gift is offered to an individual assessor the individual is responsible for making a judgment as to whether to accept or gracefully decline the gift.

4. Assessment arrangements

4.1 It is the responsibility of the laboratory or the PTP or the RMP to pay for all reasonable costs associated with the conduct of assessment activities including accommodation, meals and travel.

4.2 The laboratory or the PTP or the RMP should provides, reserve and pay for or arranges, all transport and appropriate accommodation. If, in order to perform an assessment, an overnight stay away from home is required.

4.3 All assessors are required to minimize expenses where possible and to check the accuracy of any bills before authorisation. Where expenses are to be claimed these should be recorded accurately on the appropriate forms and submitted, together with supporting information, as soon as possible after the completion of the assessment activity.

5. The assessment process

5.1 Types of visit

5.1.1 There is a number of types of visit which can be categorised as

a) preassessment

b) initial assessment

c) reassessment

d) assessment for the extension of its scope of accreditation

e) surveillance

f) follow-up as a result of the outcome of b) - e) above.

5.1.2 In addition to routine surveillance and reassessment visits, the BLA-DSS reserves the right to visit laboratories or PTPs or RMPs to establish continuing compliance at any time but particularly in cases where there are significant changes in the circumstances of the laboratory or the PTP or the RMP.

5.2 Arranging the assessment

The Case Officer is responsible for arranging any visit. The Case Officer is the first point of contact for assessors contracted to act on a visit.

5.3 Review of documents

5.3.1 The Lead Assessor is responsible for reviewing the Quality Manual, and related documents, and for preparing a report to be used during the preassessment visit to confirm that all sections of ISO/IEC 17025 or ISO/IEC 17043 or ISO 17034 and APAC TEC1- 008 have been addressed and for additional comments where necessary. These comments typically refer to inconsistencies and ambiguities identified within the document.

5.3.2 It is the responsibility of the Technical Assessors to review documents relating to the technical assessment of the laboratory or the PTP or the RMP e.g. test methods, internal calibration methods, QC data, homogeneity

testing, stability testing and evaluation performance etc if necessary. Assessors should examine the test methods or proficiency testing scheme or reference material production prior to the assessment of the laboratory or the PTP or the RMP and prepare any specific technical questions in advance of the visit. Review of documents also allows the assessor to highlight to the Case Officer

a) any significant areas of concern e.g. validity of the proposed method or homogeneity testing, stability testing and evaluation performance, that must be communicated to the laboratory or the PTP or the RMP in advance of the visit
b) a list of methods, or parts of methods or proficiency testing scheme or reference material production to be witnessed during the visit.

5.4 The Preassessment visit

5.4.1 The preassessment visit is generally conducted by the Lead Assessor and Case Officer (these roles may be performed by one person).

5.4.2 The preassessment visit aims to provide

a) feedback to the laboratory or the PTP or the RMP on the compliance of the supplied quality manual and related documents with the requirements of ISO/IEC 17025 or ISO/IEC 17043 or ISO 17034 and APAC TEC1- 008
b) an opportunity for the BLA-DSS to establish the implementation of the quality system and the laboratory or the PTP or the RMP commitment to accreditation
c) an opportunity for the laboratory or the PTP or the RMP to clarify points of concern.

5.4.3 Following the preassessment visit the Lead Assessor is responsible for providing a written report to the BLA-DSS on the findings and outcome of

the visit. A copy of this report is forwarded to the laboratory or the PTP or the RMP.

5.5 The assessment visit

5.5.1 It is the responsibility of the Case Officer to liase with the assessors and establish a visit program. This visit program outlines

a) date(s) for the assessment

b) persons for the assessment (and on which days if not all are present all the time)

c) activities to be assessed, including an indication of the methods or parts of methods or proficiency testing program or reference material process to be witnessed and, where appropriate, specified members of the laboratory who the assessor wishes to observe performing the test.

All participants in the assessment visit are required to confirm receipt of the visit program.

5.5.2 Assessors are encouraged to travel to the laboratory's or the PTP's or the RMP's premises together. This enables the team to plan its approach and to confirm the part that each member will play in the assessment process. If it is not possible for the team to travel together, the Lead Assessor should allocate a few minutes prior to the start of the assessment to discuss the assessment plan with the assessment team.

5.5.3 Although each assessment will be different the overall flow of assessment follows a consistent pattern involving five sequential phases

a) team briefing

b) opening meeting by Lead Assessor

c) assessing of the quality system and the technical competence of the laboratory or the PTP or the RMP

d) private meeting of assessors

e) closing meeting.

5.5.4 It is the responsibility of the Lead Assessor to manage the conduct of the assessment including

a) ensuring all activities are co-ordinated and monitored

b) providing advice and guidance to the assessor(s)

c) ensuring all operations relating to the tests within the scope of accreditation to be assessed are adequately covered.

5.5.5 The Lead Assessor is responsible for conducting the opening meeting with management and will

a) introduce the assessment team to the facility staff

b) completion of attendance register

c) explain the purpose and scope of the assessment and accreditation criteria

d) outline the sequence and timetable for the assessment including lunch and tea breaks

e) outline the assessment approach

f) reconfirm the visit program and proposed scope of accreditation

g) clarify variations requested

h) confirm appropriate arrangements gave been made for witnessing of test or proficiency testing scheme or reference material production

i) confirm the availability of people nominated for signatory approval and any time constraints on them

j) explain the classification of assessment findings

k) explain how any conditions for accreditation will be handled

l) assure those present of the confidentiality of the assessment

m) ensure that suitable guides for the assessment team have been arranged

n) ensure that a room or area has been set aside for the assessment team's use throughout the visit; and

o) answer any questions from the organization's representatives about the assessment.

5.5.6 The Lead Assessor should use this meeting to present a positive approach to the assessment and to attempt to put the organisation at their ease. Where necessary a familiarisation tour of the facility may be useful if any members of the team have not visited the organisation previously. However, the tour should be kept short.

5.5.7 Assessment of the quality system is normally the responsibility of the Lead Assessor. However, the Lead Assessor may allocate the assessment of specific parts of the quality system to other team members subject to them having the competence and time to do so. Technical Assessors will be responsible for confirming the implementation of the quality system in the area that they are assessing.

5.5.8 Technical Assessors are required to examine the technical aspects of the laboratory's or the PTP's or the RMP's operation including assessment of

a) technical competence of testing staff; including their theoretical knowledge and practical techniques

b) all aspects of testing or proficiency testing scheme or reference material production including sample preparation, equipment and methods used, environmental conditions under which the tests are conducted, method validation, reference standards, calibration, reference materials, data recording and analysis, and reporting procedures

c) performance in proficiency testing

d) proposed approved signatories (in conjunction with the Lead Assessor if necessary).

5.5.9 Both Lead and Technical Assessors are encouraged to make use of preprepared notes to ensure that all key aspects are covered during the visit.

5.5.10 Where an assessor believes the requirements of ISO/IEC 17025 or ISO/IEC 17043 or ISO 17034 and APAC TEC1- 008 have not been met, a nonconformity shall be recorded. Assessors should record the observations on the standard forms at the time that they are observed, scribbling notes and filling out the forms later wastes a lot of time at the end of the day.

5.5.11 Lead Assessors are encouraged to hold interim private meetings with the assessor team at convenient times through out the assessment (e.g. lunchtime). The purpose of these team discussions is to allow the Lead Assessor to review the progress of the assessment, resolve any differences and discover whether any aspect of the laboratory's or the PTP's or the RMP's operation has been overlooked or not investigated sufficiently.

5.5.12 At the close of the assessment the team of assessors meet, in private, to discuss the findings of the assessment, to confirm observations as nonconformities and to prepare the summary report and recommendation.

5.5.13 The closing meeting is chaired by the Lead Assessor and involves the assessment team and representatives of the laboratory or the PTP or the RMP. It follows a structured approach to include

a) introductions (if required)
b) completion of attendance register
c) reiteration of the purpose and accreditation criteria of the visit
d) confirmation of the confidentiality nature of assessments
e) indication that nonconformities may exist that have not been found during the assessment

f) deferral of questions

g) thanks for assistance and hospitality

h) reports from individual Assessors and Lead Assessor

i) questions from the organisation

j) discussion of corrective action

k) presentation of the summary report and recommendations

l) agreement of timescale for submission of corrective action (maximum of three months for initial assessment) and the timescale for submission the specific action plan for corrective action (within 15 working days for initial assessment)

m) provision of copies of forms to laboratory or PTP or RMP

n) close of meeting.

The efficient conduct of the final meeting will leave a lasting impression of the professionalism of the assessment team and the value of the assessment process. The meeting should not therefore be conducted hastily and a suitable provision for the meeting in the assessment timetable should be included.

5.6 Post assessment activities

5.6.1 Following completion of the visit all original copies of visit report forms are returned to the BLA-DSS.

5.6.2 The Case Officer in conjunction with the Lead Assessor prepare the assessment report including the recommendation (LA-F-26 or LA-F-226 or LA-F-326) and send to the laboratory or the PTP or the RMP. The Case Officer prepares a draft scope of accreditation for the laboratory or the PTP or the RMP.

5.6.3 The laboratory or the PTP or the RMP supplies the BLA-DSS with evidence of the corrective action taken to clear the nonconformities found.

5.6.4 The Case Officer reviews the corrective for completeness and distributes the relevant information to the appropriate members of the assessment team.

5.6.5 Individual assessment team members are required to review the corrective documents received and confirm whether the nonconformities raised have been satisfactorily discharged using form LA-F-24 or LA-F-224 or LA-F-324.

5.6.6 Where assessment team members identify that nonconformities have not been discharged it is the responsibility of the Case Officer to contact the laboratory or the PTP or the RMP, in writing, and request additional information.

5.6.7 On occasions it may be necessary for a follow-up visit to be made to assess the corrective action taken. Such visits are confined to clearing the specific nonconformities raised. Where the assessor performing the follow-up visit observes new nonconformities, these are communicated to the BLA-DSS in writing.

5.6.8 Once all nonconformities have been cleared the Case Officer prepares summary assessment report (LA-F-29 or LA-F-229 or LA-F-329) and a draft scope of accreditation to be submitted to the relevant Head of LAS who is required to produce a report for submission to the Technical Sub Committee.

5.6.9 The TSC considers the documentation supplied to ensure that

a) all nonconformities have been discharged
b) an appropriate assessment has taken place
c) the recommendation of the assessment team was consistent with the findings of the assessment.

5.6.10 Where the TSC has concerns about the assessment of the laboratory or the PTP or the RMP, it may request additional information/clarification from the Case Officer, Lead Assessor or Technical Assessors as appropriate.

5.6.11 The Secretariat of the TSC is responsible for producing a report and submitting it for approval and ratification to the LAC.

5.6.12 It is the responsibility of the LAC to make the decision on whether accreditation is to be granted. It will notify the laboratory or the PTP or the RMP, in writing, of its decision.

5.6.13 Where the LAC refuses accreditation it will notify the laboratory or the PTP or the RMP, in writing, of its decision.

5.7 Surveillance, reassessment and extensions to scope

5.7.1 Laboratories or PTPs or RMPs are subject to regular surveillance visits to confirm continued compliance with the requirements of ISO/IEC 17025 or ISO/IEC 17043 or ISO 17034 and APAC TEC1- 008. The process for conducting surveillance visits is similar to that for initial assessments with the exception that laboratories or PTPs or RMPs are usually only allowed one month to submit corrective action for nonconformities raised and the timescale for submission the specific action plan for corrective action (within 10 working days). Additionally, for surveillance visits it is the responsibility of the Head of LAS to recommend maintenance of accreditation.

5.7.2 Reassessment and extensions to scope are treated in a similar manner to initial assessments in that the laboratory or the PTP or the RMP may have up to one month to clear nonconformities, the timescale for submission the specific action plan for corrective action (within 10 working days) and the accreditation must be ratified by the LAC.

6. Assessment techniques and tactics

6.1 Professional Image

6.1.1 It is vitally important that all assessors and technical experts behave in a professional manner as the image that they project reflects on both themselves and the BLA-DSS. A professional approach will be facilitated if assessors

a) are well prepared

b) ask clear and concise questions

c) remain calm and courteous

d) keep a sense of proportion and focus on critical issues. Every assessment will reveal examples of human error and trivial discrepancies but pursuing every minor problem wastes time and alienates the laboratory or the PTP or the RMP personnel. Critical comment on minor issues dilutes the effectiveness of critical comment on the major nonconformities identified

e) distinguish between systematic and isolated incidences. A large number of nonconformities may indicate the absence of an effective system. If only a few minor nonconformities are identified then the system may be in a development phase or staff may not be fully familiar with the system

f) make allowances for nerves

g) be sensitive

Assessors should try to put staff at their ease and should not openly criticise staff

h) be determined and decisive

Assessors should persist with a line of questioning until compliance with specific criteria has been established. However, once sufficient information has been gathered to form the basis of a sound judgement, there is no point in going over the same ground again

i) manage time effectively. Efforts should be made not to be side-tracked into irrelevant conversations.

6.2 Information Gathering Techniques

6.2.1 Observation of the laboratory's or the PTP's or the RMP's practices

Observation of the activities in the laboratory or the PTP or the RMP will provide an insight into the level of competence of staff and the manner in which the laboratory or the PTP or the RMP functions. The assessors must witness sufficient tests, or parts of tests or proficiency testing scheme or reference material production, to establish the competence of the laboratory or the PTP or the RMP to perform the tests on the proposed scope of accreditation.

Even if a particular test or proficiency testing scheme or reference material production is too lengthy to be performed in its entirety during the visit, it should be possible for at least the most critical phases of the test to be performed in the presence of the assessment team. This may involve setting up aspects of the test in advance of the assessment in the work is not conducted on a day-to-day basis.

6.2.2 Inspection of the laboratory's or the PTP's or the RMP's facilities and documentation

Thorough examination of facilities and records is essential to the success of any assessment. Depending upon the volume and variety of work being undertaken in the laboratory or the PTP or the RMP, the assessment team should select several examples of the types of samples or tests being performed and trace these through the testing process or PT process or RMP process from start to finish. The records should be examined for clarity, completeness and consistency.

6.2.3 Review of proficiency testing results

Proficiency testing is used in many laboratories as part of the overall quality control program. In some cases accreditation may be conditional on

participation and satisfactory performance in a particular scheme. The details of any participation by the laboratory in external proficiency testing programs should be included in the briefing documents for consideration during the assessment. In the course of the assessment the results obtained in these proficiency testing programs should be reviewed with the appropriate person. Aspects to be covered include:

a) the adherence to the program instructions
b) the acceptability of the results obtained in relation to the assigned value or consensus mean
c) the appropriateness of action taken by the laboratory to determine the causes of and rectify outlying results
d) the use of the results of the program to improve the general standard of undertaken by the laboratory.

6.2.4 Questioning of staff

Effective questioning of the laboratory's or the PTP's or the RMP's staff is vital to the success of any assessment. Questioning should not be aggressive but must be thorough, and on occasions persistent, if the real facts are to be established.

The assessment team should try to put the staff at ease at the start of any questioning or interview session. Knowing that they are under investigation, the staff may react in a variety of ways, for example, by becoming withdrawn or defensive or at the other extreme by responding aggressively. While this reaction may be due to nothing more than nervousness, it may result in evasive answers which make it more difficult for the assessment team to establish the facts.

In general terms, indirect questions requiring a substantial response are more useful than direct questions which permit yes/no answers. For example, it is better to ask

"*What interferences have you encountered in analysis by this method?*"

and continue this line of questioning rather than simply ask
"*Do you correct for the interference from ……?*"

Direct questions have a role in the questioning process, but they tend to evoke a defensive reaction in the recipient and may be interpreted as being critical or aggressive. They are best used to clarify particular points during the discussion.

The art of questioning also involves listening for what is not said as much as what is being said. Assessors should be alert to answers which appear to be superficial or evasive and be prepared to continue the line of questioning if they sense that any response is incomplete.

Hypothetical questions of the "what if" variety often help in understanding the laboratory's or the PTP's or the RMP's systems and in determining whether they can cover all reasonable eventualities.

Assessors should not be afraid to admit that they do not understand if the laboratory's or the PTP's or the RMP's explanation or response is unclear or unsatisfactory. They should keep questioning, rephrasing the question if necessary, until the answer is clear.

When junior staff are being interviewed there is sometimes a tendency for senior staff to answer on the junior's behalf. This practice must be politely, but firmly, discouraged.

When interviewing the staff the assessors should never talk down to the staff member. Such an attitude of superiority is unlikely to elicit co-operation. It is important to speak clearly and carefully, phrasing questions using terminology likely to be understood by the staff member in question.

Credit should be given where it is due. An occasional compliment and the use of 'please' and 'thank you' are effective in developing communication.

Finally, assessors should be alert to differences in information presented to them from different sources, for example, conflicting answers from different staff members, or differences between what is said and what is observed. Any such differences should be probed until the true situation is established.

6.3 Diversionary tactics used by laboratories or the PTPs or the RMP's

The following tactics are occasionally adopted by staff, sometimes deliberately, but often unwittingly under stress.

6.3.1 Time wasting techniques

a) The waffler

Person may speak at length but says nothing. Questions are never answered directly

b) The long lunch break

The staff may arrange to take the assessment team to lunch. If this is at a restaurant some distance away, over two hours can be wasted. A light working lunch at the laboratory or the PTP or the RMP premises is preferable

c) Interruptions

The staff may be constantly interrupted during the assessment to take telephone calls, etc. In such circumstances, a request to have these calls held until the assessment is finished should be made politely

d) Unavailability of key personnel

The laboratory or the PTP or the RMP has plenty of notice of the assessment so there should be no excuse, other than sickness, for the absence or lateness of key staff members. If they are absent, the

assessors may need to consider stopping the assessment and rescheduling it

e) Sidetrack tours

Some laboratories or PTPs or RMPs may present the assessment team with their version of the assessment program, which may include a lengthy tour of the laboratory or the PTP or the RMP and other areas. Such tours should be politely declined until the assessment is finalised.

6.3.2 Preselected documents

The assessment team may be presented with sets of test records or test reports or proficiency test report or certification reference material. The Assessors/Lead Assessors should not spend too much time looking at these. Instead they should tactfully select more records and reports of their own choice from the laboratory's or the PTP's or the RMP's filing system.