Guide to the process of accreditation and conduct of assessments

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Bureau of Laboratory Accreditation

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Introduction

This document gives general guidance on the process of accreditation and the conduct of laboratory, proficiency testing provider (PTP), reference material producer (RMP) and assessments. It is applicable to laboratories, PTPs, RMPs and assessors. The varied nature of assessments calls for flexibility of approach from the assessment team, the laboratory, the PTP and the RMP.

The Bureau of Laboratory Accreditation, Department of Science Service (BLA-DSS) assesses and accredits the competence of laboratories, PTPs and RMPs to carry out specified tests or types of test or scopes, and subsequently ensures, by monitoring, that the required standards are maintained. Application for laboratory or PTP or RMP accreditation initially involves a submission of a completed Application form together with a copy of its quality manual and other supporting documentation.

The competence is checked by on-site assessment and/or remote assessment of the laboratory or the PTP or the RMP. The laboratory may be required to participate in proficiency testing or interlaboratory comparison. The purpose of the assessment is to determine whether the laboratory complies with the requirements of ISO/IEC 17025 or the PTP complies with the requirements of ISO/IEC 17043 or the RMP complies with the requirements of ISO 17034 and APAC TEC1-008. In some circumstances, specialised publications provide guidance on the application of these criteria.

All information obtained before, during or after assessment, including the fact that a particular laboratory or PTP or RMP has applied for accreditation, or that an application for accreditation has been deferred or rejected, is treated as strictly confidential by the BLA-DSS and any of its assessors.

Technical Assessors are used to assess the competence of the laboratory or the PTP or the RMP to perform the scopes for which accreditation is sought. Their assessment will be confined to investigating and reporting the findings that result from observation and discussion in the laboratory or the PTP or the RMP and through examination of documentation.

In addition to its own staff, the BLA-DSS uses assessors contracted from external sources to assess laboratories or PTPs or RMPs on its behalf. All BLA-DSS assessors, including BLA-DSS staff acting as assessors, must meet defined criteria in terms of their

technical expertise and experience, must have successfully completed an appropriate assessor training course, be familiar with the assessment procedures of the BLA-DSS and are bound by confidentiality agreements.

The assessment procedures of the BLA-DSS are applicable to all laboratory or PTP or RMP. Assessors take account of the size and complexity of the organisation when assessing the documented quality system of a laboratory or a PTP or a RMP. The quality system must provide assurance that the laboratory or the PTP or the RMP, whatever its size or complexity, meets the requirements of ISO/IEC 17025 or ISO/IEC 17043 or ISO 17034 and APAC TEC1-008.

The procedures described in this publication apply to preassessment and assessment visits, and to visits after accreditation has been granted, for the purposes of surveillance, reassessment, extension of schedule, resolution of complaints or other purposes.

Content

1. Scope

This document is applicable to all laboratories or PTPs or RMPs applying for the laboratory or the PTP or the RMP accreditation from the BLA-DSS.

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 Applicant means the entrepreneur or assignee who requests for accreditation, scope extension or certification extension.

2.3 Accredited laboratory or PTP or RMP means the laboratory or the PTP or the RMP that has already passed assessment, and is approved for accreditation from Laboratory Accreditation Committee.

2.4 The Laboratory Accreditation Committee, hereinafter called “the Committee or LAC” is responsible for making the decisions on accreditation and commit to consideration of 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 that require for the decision making process and service to consultations.

2.5 The BLA-DSS means the Laboratory Accreditation Section, Department of Science Service.

2.6 The BLA-DSS representative means a full-time employee of the accreditation body and someone who works on behalf of the BLA-DSS.

2.7 Case Officer means a full-time employee of the accreditation body who provides advice on the policies and regulations of the accreditation body and may act as a lead assessor or technical assessor if he/she has the relevant assessor qualifications.

2.8 Certificate means Certificate of accreditation.

2.9 Remote assessment means the assessment of the physical location or virtual site of a conformity assessment body, using electronic means.

3. Processing of applications

3.1 All applications for laboratory or PTP or RMP accreditation are reviewed by the BLA-DSS, to ensure that

a) the customer's requirements are understood

b) the proposed scope of accreditation falls within the remit of the BLA-DSS

c) assessment teams with all the necessary expertise and competence are available.

The laboratory or PTP or RMP shall provide all the documents as specified in the LA-F-01 and LA-F-02 or the LA-F-201and LA-F-202 or the LA-F-301 and LA-F-302 to BLA-DSS.

3.2 The BLA-DSS allocates the application to a member of its staff who will be responsible for managing the application and assessment process. Wherever possible the Case Officer will have an understanding of the area of testing concerned, and will be able to discuss with the laboratory's or the PTP's or the RMP's representative any matters that may arise during the processing of the application.

3.3 The relevant Head of LAS is responsible for identifying the assessment team. The assessment team comprises a Lead Assessor and as many Technical Assessors or Technical Experts as are necessary to provide the technical expertise adequately to assess the competence. Laboratories or PTPs or RMPs have the right to object to the appointment of the nominated assessor(s) and, in such cases, the BLA-DSS will endeavor to offer an alternative. In the event that a suitable alternative cannot be identified, or the grounds for objection are considered to be unreasonable, the BLA-DSS reserves the right to appoint the assessor(s) originally selected.

3.4 The Lead Assessor reviews the Quality Manual and any supporting documentation supplied by the laboratory or the PTP or the RMP and advises the BLA-DSS on the apparent compliance with the Standard. At this point, the Lead Assessor recommends whether

a) a preassessment visit should take place

b) exceptionally, plans for assessment of the laboratory or the PTP or the RMP can proceed without any preassessment visit (the Lead Assessor will corporate with the case officer for final decision to omit the preassessment visit)

c) the laboratory or the PTP or the RMP is not in a position to proceed to preassessment.

Note The preassessment visit is not mandatory.

4. Preassessment

4.1 The preassessment visit is normally carried out by the Lead Assessor and Case Officer (where they are different people and sometimes accompanied by a Technical Assessor) and is completed in one day. The preassessment visit allows discussion with the management on the extent to which the quality system, quality manual and operating procedures appear to comply, or not, with the requirements of ISO/ IEC 17025 or ISO/IEC 17043 or ISO 17034 and APAC TEC1- 008.

4.2 The visit should be structured so that the Lead Assessor can ascertain that the essential components of a quality system have been put in place or have been addressed. In particular, the Lead Assessor needs to establish whether the laboratory or the PTP or the RMP has a stated policy for defined responsibilities and a means of meeting each of the requirements of ISO/IEC 17025 or ISO/IEC 17043 or or ISO 17034 and APAC TEC1- 008.

4.3 In addition to examining the documented quality system prepared by the laboratory or the PTP or the RMP, the Lead Assessor will usually take the opportunity to discuss the

proposed scope of accreditation and to carry out a brief examination of the laboratory's or the PTP's or the RMP's facilities.

4.4 Normally, the Lead Assessor will discuss with the laboratory or the PTP or the RMP any documented in-house methods used for testing that form part of the scope of accreditation. This will allow the Lead Assessor to be satisfied that such methods have been validated or have homogeneity and stability test of the proficiency test item or reference material and to permit any necessary changes to be made before the initial assessment. The discussion will cover the laboratory's or the PTP's or the RMP's policy and procedures for estimating uncertainty of measurement.

4.5 During the preassessment visit, the Lead Assessor will advise the laboratory or the PTP or the RMP of any areas that appear to require attention in order to comply with ISO/IEC 17025 or ISO/IEC 17043 or or ISO 17034 and APAC TEC1- 008 and any additional requirements laid down by the BLA-DSS. The Lead Assessor will also remind the laboratory or the PTP or the RMP that the preassessment visit is not a full assessment, and will describe the nature of the full assessment visit.

4.6 A report of the preassessment is prepared by the Lead Assessor, which will indicate

a) if a further preassessment visit is recommended
b) whether plans for initial assessment can proceed
c) specific reasons why plans cannot proceed
d) whether participation in proficiency testing or inter-laboratory comparison is required.

The findings of the pre-assessment visit are passed on to the laboratory or the PTP or the RMP for consideration.

4.7 Immediately after the visit, the Case Officer will finalise the composition of the assessment team, and the effort required for the visit.

4.8 The laboratory or the PTP or the RMP is required to implement any required changes to its quality system and move to an initial assessment within 6 months of the preassessment visit.

5. Preparations for the initial assessment

5.1 When the laboratory or the PTP or the RMP has informed the BLA-DSS that it has carried out any actions resulting from the preassessment (which may involve the laboratory or the PTP or the RMP submitting revised documentation) , the Lead Assessor will prepare a visit program for the initial assessment.

5.2 The detailed visit program will indicate the section/activities to be assessed by each assessor, and specify the tests, or parts of tests, that each assessor wishes to witness during the visit or specify the programs of the proficiency test item or specify the production of the reference material, or the preparation of proficiency test item or reference material and packaging, labeling and distribution of proficiency test item or reference material, that each assessor wishes to witness during the visit.

5.3 Copies of the visit program are sent to the laboratory or the PTP or the RMP and to all the assessment team; all parties will be asked to acknowledge notification of the arrangements.

5.4 In case of remote assessment, selection and management of ICT have been examined and the competence of assessment team and laboratory or the PTP or the RMP staff have been evaluated. The report on the risk assessment are recorded in Remote Assessment Checklist and Risk assessment (LA-F-107). The results of risk assessment must not be at high level.

5.5 All documents have been gathered and supplied to assessment team in advance.

6. The initial assessment

6.1 The visit begins with an Introductory Meeting between the assessment team and representatives of the laboratory or the PTP or the RMP. On some occasions the team may then find it beneficial to make a brief tour of the facilities before starting the assessment. The tour is followed by a discussion, between laboratory or PTP or RMP staff and the Lead Assessor, on the quality documentation, and by detailed observation, by all team members, of the laboratory or the PTP or the RMP at work, to determine whether or not it meets the requirements of ISO/ IEC 17025 or ISO/ IEC 17043 or or ISO 17034 and APAC TEC1- 008. Each assessor should be accompanied by a member of the staff nominated by the management. An assessor may be accompanied by different members of staff in the course of the assessment.

6.2 The visit ends with a Final Meeting involving the assessment team and laboratory or PTP or RMP representatives, at which each assessor presents his or her observations and the Lead Assessor summarises the findings of the team. The team needs to meet in private to prepare for this Final Meeting. For assessments lasting longer than one day, the assessors may also hold a brief, private, review meeting at the end of each day to compare notes and discuss any changes to the assessment plan that may have become necessary. An interim meeting may also be held with the laboratory or the PTP or the RMP management if some members of the assessment team have completed their work.

7. The introductory meeting

7.1 This Meeting is held on arrival to enable the assessment team and the laboratory's or the PTP's or the RMP's representatives to become acquainted, to confirm the purpose of the assessment and to remind the laboratory or the PTP or the RMP of what is expected during the assessment. It sets the scene, and is chaired by the Lead Assessor and will cover, but not necessarily in this order

a) an explanation of the purpose of the assessment, the functions of the assessors and confirmation that the staff understand the procedure

b) discussion of the significance and status of the Quality Manual

c) confirmation of the range of tests covered by the application

d) a confirmation of the assessment program and of the program for witnessing tests

e) confirmation that a representative of the laboratory or the PTP or the RMP has been assigned to accompany each assessor, and an explanation of the role of this representative in the assessment

f) an explanation of what will happen at the Final Meeting and confirmation of the attendees, time and venue

g) an assurance that all findings will be treated in confidence

h) arrangements for providing an office and any services needed by the assessors, e.g. photocopying

i) confirmation of work hours, luncheon breaks etc

j) an opportunity for the laboratory or the PTP or the RMP management and staff to ask relevant questions.

8. The assessment

8.1 On-the-spot observations of the testing/ calibration activities carried out by the laboratory or the PTP or the RMP from the most important part of the assessment. Although the assessment should as far as possible make use of normal on-going work, it maybe necessary for the BLA-DSS to ask the laboratory or the PTP or the RMP to provide a demonstration of some activities that are not on-going, in order to cover the range of tests for which accreditation is sought. This should normally be evident from the visit plan. Assessors need to establish the laboratory's or the PTP's or the RMP's overall competence in all aspects required by ISO/IEC 17025 or ISO/IEC 17043 or ISO 17034 and APAC TEC1- 008.

8.2 Following the dispersal of the assessment team to various sections of the laboratory or the PTP or the RMP, the Lead Assessor will examine the quality system and quality documentation with the Quality Manager and any other appropriate staff, to verify that it meets the requirements of ISO/IEC 17025 or ISO/IEC 17043 or or ISO 17034 and APAC TEC1- 008.

8.3 The technical assessors will proceed according to the agreed program and examine the quality system in operation and the competence of the staff to perform specific tests. All components of the quality system involved will be assessed.

8.4 Assessors will examine the test procedures and their implementation in the laboratory or the PTP or the RMP. They will determine whether the treatment of uncertainties is in accordance with the BLA-DSS and international criteria. It may not always be necessary to examine every procedure in operation because of the similarities between some tests or proficiency testing programs, but assessors will verify the implementation of the procedures for the tests listed in the visit program. The assessors will ask to see the equipment involved, the manufacturer's manuals, and establish the state of calibration of the equipment.

8.5 Assessors will witness tests or proficiency testing programs or reference material production and examine documentation concerning tests in progress, and will trace back results from previously issued certificates or reports to the original entries in the notebooks or work sheets. Aspects requiring evidence from some other area of the laboratory or the PTP or the RMP before they can be settled may be noted down for further investigation, or may be referred to the member of the assessment team dealing with the area concerned.

8.6 During the assessment of the laboratory or the PTP or the RMP, assessors will examine the laboratory's or the PTP's or the RMP's processes for establishing traceability of measurements and the results from participation in appropriate proficiency testing schemes. Assessors will also assess procedures used to establish the validity of methods used.

8.7 The object of assessment is to establish by observation whether the work of the laboratory or the PTP or the RMP meets the requirements of ISO/IEC 17025 or ISO/IEC 17043 or or ISO 17034 and APAC TEC1- 008. Observations made will be based on

objective evidence and will normally be recorded and verified before assessors leave the area under assessment. Detail of observations made are recorded on assessment reports.

9. Recording failures to comply with the requirements of ISO/IEC 17025 or ISO/IEC 17043 or ISO 17034 and APAC TEC1- 008

9.1 Possible failures of the laboratory's or the PTP's or the RMP's arrangements to comply with the requirements of ISO/IEC 17025 or ISO/IEC 17043 or ISO 17034 and APAC TEC1- 008 are recorded on nonconformity forms. Further information is recorded on the Assessment report forms. These records provide the objective evidence on which the Lead Assessor's recommendations on accreditation will be based.

9.2 The nonconformity reports record factual observations relating to possible nonconformities with specific clauses of ISO/IEC 17025 or ISO/IEC 17043 or or ISO 17034 and APAC TEC1- 008.

9.3 Each nonconformity form will include the following information, which will normally be added at the time of observations

a) where each observation was made (location/activity)

b) the system or test under discussion

c) any documents involved

d) a record of the observation.

9.4 At the private meeting of the assessment team each observation will be classified as either a nonconformity or left as an observation for the laboratory or the PTP or the RMP to consider.

10. Summary of findings

10.1 After the assessors have completed their individual assignments, they meet in private to produce a coordinated view of the laboratory's or the PTP's or the RMP's work. Each

assessor, including the Lead Assessor, ensures that his or her Assessment report forms are completed.

10.2 The assessment team will discuss the observations raised throughout the assessment and decide whether they are non conformity, or are to be left as observations.

10.3 In conjunction with the other assessors, the Lead Assessor formulates a summary report based on the findings recorded on the Nonconformity forms and the Assessment Report forms. This summary report summarises the assessors' findings, indicate key areas needing corrective action, and give the Lead Assessor' s recommendations to the laboratory or the PTP or the RMP. The recommendations may be for an unconditional offer of accreditation, for an offer to be deferred until the nonconformities have been cleared, or for refusal. In some cases it may be appropriate to recommend that an offer of accreditation be made for a reduced scope.

11. Factors affecting recommendations on accreditation

11.1 In deciding on the recommendation to be made, the Lead Assessor takes into account the number and severity of the individual nonconformities found during the assessment.

11.2 Where no nonconformities are found, the Lead Assessor normally recommends that accreditation be offered immediately.

11.3 Where nonconformities are found, the recommendation will usually be that accreditation is offered subject to the satisfactory discharge of all the nonconformities. Should there be serious concerns about one particular area of testing or test method, the Lead Assessor may recommend accreditation for an appropriately reduced scope.

11.4 Where the number and seriousness of the nonconformities found is such that the quality system and laboratory's or the PTP's or the RMP's demonstrably fails to meet

the requirements of ISO/IEC 17025 or ISO/IEC 17043 or ISO 17034 and APAC TEC1-008, the Lead Assessor's recommendation will be that accreditation is refused and the laboratory will be advised to discuss future actions with the BLA-DSS.

12. The final meeting

12.1 The Final Meeting is where all assessors present their findings to the management/ staff. The Lead Assessor presents a summary of the results of the assessment and informs the management of the recommendation that will be made to the BLA-DSS.

12.2 The Final Meeting is chaired by the Lead Assessor who will address the following items

a) ask for questions to be deferred until after the findings have been presented, although points of clarification should not be refused

b) the significance of the types of nonconformity

c) the possibility that nonconformities may exist that have not been found

d) invite each assessor to summarise his or her findings, and similarly, will present his or her own findings as an individual assessor

e) present the summary, conclusions and recommendation

f) ensure that summary assessment report is signed and dated by the laboratory or the PTP or the RMP management or representative

g) invite the laboratory or the PTP or the RMP to specify a date by which any required corrective actions will be implemented (a period of up to three months may be allowed at initial assessments)

h) provide the laboratory or the PTP or the RMP with an opportunity to discuss the assessment and to ask any questions

i) obtain copies of all the forms generated during the assessment. If copying facilities are not available, the Case Officer will retain the originals for copying at the BLA-DSS.

13. Post-assessment

13.1 Within 10 working days of the assessment, the Lead Assessor will report his/ her recommendation to the BLA-DSS. After considering by the BLA-DSS, this assessment report will be sent to the laboratory or the PTP or the RMP.

13.2 The laboratory or the PTP or the RMP supplies the BLA-DSS with evidence of the corrective action taken to address any nonconformities found. This evidence is assessed to confirm that the problems raised have been satisfactorily discharged.

13.3 It may be necessary for a follow-up visit to be made to assess the corrective actions taken. Assessment at such a visit will be confined specifically to the clearance of the nonconformities. If an assessor observes a new potential nonconformity, it will be brought to the attention of management and will be reported, in writing, to the BLA-DSS.

13.4 Once all nonconformities have been satisfactorily discharged, the Lead Assessor will send the assessment reports to the BLA-DSS. The BLA-DSS will present the assessment reports to LAC for consideration. Where necessary the LAC may request that the assessment team attend to clarify any issues.

13.5 Once the LAC has agreed with the findings of the assessment team, a decision for accreditation is made by the LAC. The grant letter and the certificate will be sent to the laboratory or the PTP or the RMP.

13.6 If the laboratory or the PTP or the RMP disagrees with the accreditation decision taken by the BLA-DSS, it may appeal. The appeal must be in writing and must be received by the Chairman of the Appeal Committee within 30 days of notification of the decision.

14. Surveillance and reassessment

14.1 Following accreditation, laboratories or PTPs or RMPs are subject to periodic surveillance and reassessment visits. Surveillance visits are normally carried out 18-22 months and reassessment visits every 4 years. However, the BLA-DSS reserves the right to make unannounced visits.

14.2 The purpose of surveillance/ re-assessment visits is to determine whether or not a laboratory or the PTP or the RMP is continuing to comply with the requirements of ISO/ IEC 17025 or ISO/ IEC 17043 or ISO 17034 and APAC TEC1-008. The general approach described in this procedure will apply to all these visits.

However, at the introductory Meeting, the Lead Assessor will establish whether all significant changes in the laboratory or the PTP or the RMP status or operation have been notified to the BLA-DSS and will confirm that there are no outstanding corrective actions from the previous visit.

14.3 If, during a surveillance or reassessment visit, it is found that there have been significant changes, e.g. of staff, equipment or the range of services available, these matters shall be recorded by the Lead Assessor. Assessors shall check that the changes are not such as to diminish the laboratory's or the PTP's or the RMP's capabilities as described in the scope of accreditation, and that they have already been fully notified to the BLA-DSS.

14.4 Normally, during a single surveillance visit, assessors will not be expected to check the whole of the testing work for which a laboratory or a PTP or a RMP is accredited. The complete range of tests for which the laboratory or the PTP or the RMP is accredited will be assessed at least twice between initial assessment/ reassessment visits.

14.5 A reassessment visit will involve a comprehensive reexamination of the quality system and testing activities and will be similar in format and detail to the initial assessment.

14.6 At the conclusion of a surveillance or re-assessment visit, the Lead Assessor will make a recommendations to the BLA-DSS on the continuing accreditation of the laboratory or the PTP or the RMP. Suspension or withdrawal of accreditation will be recommended where the number and seriousness of the nonconformities found is such that the quality system has broken down, and the requirements of ISO/IEC 17025 or ISO/IEC 17043 or ISO 17034 and APAC TEC1- 008 can no longer be met.

15. Extensions to scope of accreditation

When a laboratory or a PTP or a RMP applies for an extension to its scope of accreditation, the BLA-DSS will decide whether accreditation can be granted following the submission, and assessment, of relevant documents without the need for a further assessment visit. Where this approach is not appropriate, the Case Officer may suggest combining this visit with an imminent scheduled visit, or may arrange an extra visit in the normal way.

16. The scope of accreditation

16.1 It is the policy of the BLA-DSS to define closely the scope of a laboratory's or the PTP's or the RMP's accreditation. This ensures that the customers are provided with an accurate and unambiguous description of the range of tests covered by a laboratory's or the PTP's or the RMP's accreditation.

16.2 Scope of accreditation of accredited laboratories or PTPs or RMPs are regarded as being in the public domain.