



**A GUIDE FOR APLAC EVALUATION TEAMS
FOR THE PLANNING AND CONDUCT OF
EVALUATIONS**

PURPOSE

This document provides guidance for APLAC evaluation teams for the planning and conduct of key aspects of APLAC evaluations.

AUTHORSHIP

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1. INTRODUCTION

This document is produced as a guide for APLAC evaluation teams to assist them in the planning and conduct of on-site peer evaluations in accordance with the requirements of APLAC MR 001. It is also a useful resource for APLAC accreditation bodies who are subject of these evaluations. Throughout the document (especially in Section 2) frequent use is made of “shall” statements. While these are not requirements under the APLAC MRA, these statements reflect actions that are considered best peer evaluation practices and, indeed, are necessary to evaluate accreditation bodies effectively against the APLAC MRA requirements for acceptance as a signatory to the APLAC MRA.

2. IMPORTANT ASPECTS OF THE EVALUATION

The evaluation team shall place emphasis on the following aspects prior to and during an evaluation.

2.1 Selection of Assessments for Witnessing

2.1.1 It is important that a representative sample of the range of accreditation activities under evaluation is witnessed by the team.

Currently 5 scopes are recognised within the APLAC MRA:

- calibration
- testing
- ISO 15189
- inspection
- RMP

2.1.2 The time schedule and its time span will depend on the scope of the applicant body’s activities and the geographical area it covers. In geographically widespread economies, travelling time and logistics are critical and have to be carefully planned. Where necessary, extra time may have to be allocated.

2.1.3 Given the long interval (approximately 4 years) between evaluations, the duration of a re-evaluation is comparable to that of an initial evaluation. A shorter duration applies for pre-evaluations, for follow-up evaluations and for scope extensions that are conducted separately from a re-evaluation.

2.1.4 If it is difficult to identify suitable assessments to witness during the evaluation visit, witnessing may have to be arranged for before or after the visit to the applicant body’s office has taken place.

2.1.5 As MOUs may be concluded by APLAC with certain industry sectors, specific attention may be needed to give an assurance of the applicant body’s competence to assess in these sectors. It must be stressed that, despite spending time on witnessing, it is very important to spend ample time to check on how the applicant body selects its assessors and experts for a particular assessment. Thorough checking of records from assessments is required, including matching the assessor’s expertise to the scope of the conformity assessment body being assessed.

2.2 Evaluation of the Administration of the System

- 2.2.1 Part of the evaluation visit shall be devoted to establishing confidence in the applicant body's permanent secretariat and the administrative and organisational arrangements for overall operation of the system.
- 2.2.2 The evaluation team shall set aside sufficient time for this part of the evaluation (Appendix A of this document gives guidance on the amount of time typically needed). During this time the team shall hold discussions with a cross-section of the staff operating at all levels in the organisation and shall discuss the documentation used by the applicant body, i.e. quality manual, accreditation criteria, specific procedures, etc, and shall make an appraisal of the effectiveness of the implementation of the documented policies and procedures of the applicant body, as set out in its quality manual and associated documents. Files, records and archives of the applicant body shall be checked. The evaluation team shall also evaluate the relationship of the applicant body with technical and other organisations in its economy, and the existence and content of any MRAs with other accreditation bodies.
- 2.2.3 The evaluation team shall check that the applicant body has implemented all the requirements of the relevant ISO(/IEC) standard(s). After examination of the quality system documentation (or at the same time) the team shall check the extent to which the applicant body's accreditation criteria incorporate the requirements of the appropriate ISO(/IEC) standard(s) and APLAC MRA supplementary requirements. A record shall be made of any requirements not covered and of any alternative or additional requirements used.
- 2.2.4 The evaluation team shall examine the guidance documents provided to the staff of the applicant body and to external assessors, detailing the use and implementation of the accreditation criteria, and any rules or regulations issued by the applicant body.
- 2.2.5 The evaluation team shall check the availability and content of any documents containing additional requirements or guidance to assessors, and conformity assessment bodies.
- 2.2.6 The evaluation team shall check the applicant body's procedures for issuing accreditation documents, defining the scope for which accreditation has been granted, identifying approved signatories or key personnel, as appropriate, and maintaining such information up-to-date.

2.3. Evaluation Concerning Assessors

- 2.3.1 The applicant body's policies and procedures for selecting, training, contracting and appointing internal and external assessors shall be examined. Checks shall be made to ensure that up-to-date records detailing the qualifications, experience, expertise, training and performance monitoring of assessors are maintained. The evaluation team shall ensure that each assessment is conducted by personnel familiar with the requirements of the accreditation system, trained in the techniques of assessment, and possessing appropriate technical expertise for their assignment. The evaluation team shall check that the assessment team leader or a member of each assessment team has

sufficient knowledge in the evaluation of quality systems appropriate for the accredited or applicant conformity assessment bodies.

- 2.3.2 Where accreditation bodies use a staff member as the assessment team leader or as part of the assessment team the same requirements apply.

2.4 Evaluation of Performance of Assessors and Competence of Accredited Conformity Assessment Bodies

- 2.4.1 The evaluation team shall witness at least one initial assessment (if available), reassessments and, where applicable, surveillance visits. The template for recording the findings in relation to witnessed assessments (annex VI of the evaluation report template, MR 009) shall be used to record observations.
- 2.4.2 The assessments witnessed shall involve a range of technical fields representative of the accreditations granted by the applicant body.
- 2.4.3 The evaluation team shall pay particular attention to the procedures used by the assessment team and shall note deviations by the assessment team from the specified requirements when they are observed.
- 2.4.4 The evaluation team members shall maintain the role of observer at all times during the witnessing to avoid influencing the performance or procedures of the assessors and the responses by staff of the conformity assessment body being assessed. Any observations made by the evaluation team regarding the organisations under assessment, the assessors, the applicant body's staff or the applicant body's procedures shall be made to the applicant body after the assessment.

2.5 Evaluation Concerning Assessment Reports

The evaluation team shall examine the procedure for reporting the findings of assessment teams. In particular, the evaluation team shall check that any corrective actions required of assessed conformity assessment bodies are carried out within the required time frame. If the assessment findings are subject to endorsement by a committee before a decision on accreditation is made, records of the decisions of such committees shall be examined. The evaluation team shall review the applicant body's records of the accreditation process to ensure these are sufficient to justify the decision to accredit or to deny accreditation.

2.6 Evaluation of Committees

Where committees are used to review the reports of assessments, to assist in the decision-making process or to provide technical advice on criteria, assessors, etc, their terms of reference and the procedures for appointment of committee members shall be examined.

2.7 Evaluation of Proficiency Testing Activities

- 2.7.1 The policies and procedures of the applicant body for proficiency testing shall be evaluated against the requirements of APLAC MR 001, clause 3.3.

- 2.7.2 The way in which the results of proficiency testing activities are used by the applicant body shall be examined.
- 2.7.3 The evaluation team shall discuss with the relevant members of the applicant body staff the following matters:
- (i) Identification of areas where proficiency testing activities are available or should be initiated
 - (ii) Criteria for selection, organisation and use of proficiency testing activities
 - (iii) Criteria for accepting proficiency testing activities provided by external bodies
 - (iv) Policies and procedures, including in relation to corrective action, for integrating proficiency testing results into the assessment process
 - (v) Criteria for the selection of participants when participation in a particular proficiency testing activity is limited
 - (vi) For accreditors of RMPs, criteria for the participation in proficiency testing by collaborators involved in testing associated with the production of reference materials.

2.8 Evaluation Concerning Traceability and Measurement Uncertainty

The evaluation team shall evaluate how traceability of measurement and associated estimates of measurement uncertainty are established, wherever applicable, in accordance with the provisions of applicable ILAC and/or APLAC documents and ISO (/IEC) standard(s).

2.8.1 Accredited calibration laboratories

The evaluation team shall establish whether or not clause 5.6.2.1.1 of ISO/IEC 17025 is being satisfied, that the uncertainty of the measurements performed is properly evaluated and reported, and that appropriate best measurement capabilities are properly calculated. For further guidance on traceability, see also ILAC P10.

2.8.2 Accredited testing laboratories

The evaluation team shall check whether full and proper use is being made of competent calibration laboratories by the testing laboratories. Where no such calibration laboratories exist, the arrangements in use must be examined in detail to ensure that there is compliance with the appropriate requirements. When traceability to national or international standards of measurement is not relevant, practicable or technically possible, the team shall check that laboratories are required to provide satisfactory evidence of correlation or accuracy of test results (for example, by participation in a suitable program of

inter-laboratory comparisons or by the use of reference materials that are traceable to national or international standard reference materials). For further guidelines on traceability see ILAC P10.

The evaluation team shall also confirm that competence in estimating measurement uncertainty for testing, where applicable, is adequately assessed.

If the applicant body offers accreditation to calibration laboratories as well as to testing laboratories and/or inspection bodies, the evaluation team shall check the relationship between the accreditation system and the national or regional measurement system, and the arrangements made to ensure traceability of measurement.

If the calibration laboratories providing measurement support to the testing laboratories are accredited by a separate accreditation body, it may be necessary to hold discussions with the secretariat of that accreditation body as part of the overall agenda for the evaluation, particularly if that accreditation body is not a signatory to the APLAC MRA or to the ILAC Arrangement for calibration.

2.8.3 Accredited inspection bodies

The tests, calibrations and measurements done by an accredited inspection body or on behalf of such a body shall be traceable to national or international standards where available. The evaluation team shall evaluate whether calibration and testing included in inspection activities fulfil the requirements of the appropriate ISO/(IEC) standard(s) for laboratories. The evaluation team shall establish whether the applicant body has adequate policies and procedures to ensure this requirement for accredited inspection bodies is fulfilled.

2.8.4 Accredited RMPs

The evaluation team shall establish whether or not clauses 5.12, 5.14 and 5.15 of ISO Guide 34 are being met, that uncertainty of measurement assignments are properly evaluated and reported, characterisation of the reference materials complies with ISO Guide 35, and that traceability of measurement is properly achieved. For further guidance on traceability, see ILAC P10.

3. CHECKLIST FOR APLAC LEAD EVALUATORS – RE-EVALUATION

3.1 Not Less Than 6 Months Prior to Scheduled Date of Evaluation

- (i) check if AB wishes to expand its scope of recognition
- (ii) check if AB wants the evaluation visit to place emphasis on specific areas within scope (e.g. to meet regulatory requirements)
- (iii) check with AB whether any weekly/monthly/annual religious or national holidays will be observed during the proposed time frame for the evaluation, i.e. Monday to Friday may not be appropriate in some economies
- (iv) check if AB is part of another regional cooperation or has a contract of cooperation with another region, and whether a joint evaluation is expected; if so, in consultation with the APLAC MRA Council Chair,

- liaise with the MRA/MLA Council Chair of the other region(s) on the appointment of evaluators from the region(s)
- advise all parties from the other region(s) that the evaluation will be led by APLAC and carried out in accordance with APLAC MR 001
- (v) in consultation with APLAC MRA Council Chair, select evaluation team members and seek endorsement of team by AB
 - use current edition of evaluator competencies table
 - check that team members' ABs have not provided consultancy to AB in last 4 years
 - ask potential team members to provide fuller biographical details, if needed
 - no more than 1 evaluator from any one economy
 - sufficient testing evaluators to cover the scope for testing, and at least 1 evaluator for each of calibration, inspection, ISO 15189, RMP, when applicable
 - one evaluator knowledgeable also in the application of PT as an assessment tool
 - ensure adequate coverage of scope of AB activities
 - balance of experienced and less experienced evaluators (unless unavoidable, e.g. because of limited evaluator resources, no more than one "provisional" evaluator; use of more than one "provisional" evaluator requires specific approval by the Chair of the APLAC MRA Council)
 - language skills, including knowledge of AB's native language
 - cost of travel considerations
- (vi) immediately advise APLAC Secretariat of team members (and their assigned tasks) and of exact date of visit; provide written evidence to the Secretariat of the applicant's acceptance of the team members
- (vii) agree with AB on arrangements for booking and paying for travel between countries, e.g. AB books tickets and sends to team; team members book tickets and invoice AB for the costs
- (viii) obtain from the APLAC Secretariat a copy of full report from previous evaluation, including evidence of corrective actions, a copy of the MRA Council's resolution decision on the previous evaluation, and a list of CABs whose assessments were witnessed at the previous evaluation
- (ix) remind AB of obligation to provide set A and set B documents by set date and to arrange witnessing of assessments according to a provisional timetable

3.2 Not Less Than 3 Months Prior to Scheduled Date of Evaluation

- (i) obtain copies of set A and set B documents (APLAC MR 003, Appendix 2) from AB; obtain written confirmation from the AB as to how these and other documents and records obtained during the evaluation are to be disposed of at the end of the evaluation so as to ensure confidentiality of the information
- (ii) obtain summary report on AB's participation and performance in APLAC PT programs from Chair of APLAC PT Committee
- (iii) obtain a report on AB's postal ballot history from the APLAC Secretariat
- (iv) obtain list of possible assessments for witnessing from AB
- (v) agree with AB on agenda for the visit
 - may need to do some witnessing before or after week of evaluation visit
 - may need to consider spending more than 5 days on the evaluation visit
 - geographical and inter-country flight considerations (for witnessing)
 - witnessing should include mix of initial assessments, reassessments and surveillance visits (if these are different from reassessments)
 - assign tasks to team members

- if necessary, ascertain if AB will accept an observer on the team
- ensure AB has made arrangements for a meeting room at team's hotel for team meetings prior to the evaluation and each evening
- consider the need for interpreters

3.3 Prior to the Evaluation

- (i) prepare a detailed timetable for the visit and have it endorsed by AB
 - match team member assignments to AB staff to be interviewed and/or to act as escorts
 - include a half-day team meeting prior to start of evaluation
 - allow for team meetings (including by telephone) each evening, if necessary
 - allow extra time for team leader in AB office, usually first or last day of assessment witnessing, i.e. day 2 or penultimate day
 - advise AB of days that are not convenient for any formal hospitality function, e.g. evening of day 1, evening prior to last day
- (ii) obtain confirmation from AB to cooperate on matters listed in APLAC MR 001, clause 16.2
- (iii) ensure team members have all necessary AB documents and other briefing documents, as well as evaluation timetable
- (iv) do document review
- (v) draft body of final report (APLAC MR 009), building upon the partially completed evaluation report template provided by the applicant AB
- (vi) ensure all team members and any observers sign confidentiality statement (Appendix B in APLAC MR 001; available as Word document from "members only" area of APLAC web site)
- (vii) prepare Lead Evaluator Performance Log (APLAC MR 004, Appendix 4) for distribution to team members at conclusion of evaluation

3.4 During the Evaluation

- (i) lead the opening meeting; ensure any queries from team members have been clarified with AB
- (ii) ensure the evaluation remains on track
- (iii) ensure team members gather sufficient objective evidence to support their findings
- (iv) mentor less experienced team members
- (v) ensure AB receives feedback, as appropriate, throughout the evaluation
- (vi) gather information from team members each evening (if geography and channels of communication allow)
 - main meeting on evening of day 1 to allow areas for follow-up to be identified and assigned to team members; evening prior to last day when findings should be finalised as much as possible
- (vii) ensure team discussions remain on track
- (viii) ensure team members correctly assign findings to clauses of ISO/IEC 17011
- (ix) prepare summary report and list of nonconformities, concerns and comments for presentation to AB at closing meeting
 - this should be reviewed for comment by the AB prior to the closing meeting
 - summary report should highlight any findings that are recurrences of findings from the previous evaluations
- (x) ensure, during closing meeting, that any misunderstandings are clarified, disagreements resolved

- (xi) ensure summary report and confidentiality statement are signed by all team members

3.5 After the Evaluation

- (i) provide full report, agreed among the team members, to the AB for comment and correction of factual errors (if necessary) within two months of the evaluation visit
- (ii) review the AB's corrective action and response report, assigning parts to team members, as applicable
- (iii) ensure AB provides evidence of identification of and correction of the root cause(s) of nonconformities and concerns
- (iv) advise the AB if the response is acceptable within one month of its receipt
- (v) once the team is satisfied that the AB's response is satisfactory and all necessary corrective action has been taken, prepare a recommendation to the APLAC MRA Council
- (vi) send full report, AB's response and evidence of corrective actions, evidence of team consideration of that response, team recommendation (continued status in the MRA; change of scope of recognition, if applicable; recommended re-evaluation period), and a list of the CABs whose assessments were witnessed during the evaluation to the Chair of APLAC MRA Council and to APLAC Secretariat (electronically)
- (vii) complete evaluator performance log for each team member (APLAC MR 004, Appendix 3; available in Word format from "members only" area of APLAC web site) and send to Chair of Evaluator Performance Working Group
- (viii) present a verbal report to the APLAC MRA Council, summarising the team's findings and supporting the team's recommendations

3.6 Documents With Which the Team Leader Must Be Familiar

ILAC/IAF A-series

- A2* - ILAC/IAF Multi-Lateral Recognition Arrangements (Arrangements): Requirements for Evaluation of a Single Accreditation Body
- A3* - ILAC/IAF Multi-Lateral Recognition Arrangements (Arrangements): Key Performance Indicators – A Tool for the Evaluation Process
- A4* - Guidance on the Application of ISO/IEC 17020 (for ABs whose (proposed) scope includes inspection)
- A5* - ILAC/IAF Multi-Lateral Mutual Recognition Arrangements (Arrangements) Application of ISO/IEC 17011

ILAC P-series and other

- P1* - ILAC Mutual Recognition Arrangement (Arrangement): Requirements for Evaluation of Accreditation Bodies by ILAC-Recognised Regional Cooperations
- P5* - ILAC Multi-Lateral Recognition Arrangement (Arrangement), i.e. Text of ILAC Mutual Recognition Arrangement
- P8* - ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories
- P9* - ILAC Policy for Participation in National and International Proficiency Testing Activities

- P10* - ILAC Policy on Traceability of Measurement Results
- G21 - Cross Frontier Accreditation – Principles for Avoiding Duplication

APLAC MR-series and other

- MR 001* - Procedures for Establishing and Maintaining the APLAC Mutual Recognition Arrangement Among Accreditation Bodies
- MR 002* - APLAC Mutual Recognition Arrangement Text
- MR 003 - Application for Signatory Status in the APLAC Mutual Recognition Arrangement (MRA) or to Extend Scope of Recognition
- MR 004* - Evaluators – Qualifications, Training and Monitoring of Performance
- MR 006 - Procedure for the Conduct of Joint Evaluation with Another Regional Cooperation
- MR 007 - APLAC Evaluation Checklist
- MR 008 - APLAC MRA Council – Rules for Operation
- MR 009* - APLAC Evaluation Report Template
- MR 010 - Guidelines....When Requested to Accredit...CAB Within Another..

- SEC 042* - APLAC Code of Ethics for Laboratory, Inspection Body and RMP Accreditation Bodies
- SEC 052* - APLAC Constitution

* key documents

APPENDIX A

TYPICAL TIMETABLE FOR AN INITIAL EVALUATION VISIT

(The following timetable is given for reference only. The evaluation team and the applicant body should agree on a plan to suit the evaluation to be conducted, the logistics for transportation; whether a pre-evaluation visit has been conducted, and other relevant factors should be taken into consideration. Sufficient time should be allowed for examination of the office operations, discussion with staff members of the applicant body, witnessing assessments, reassessments and surveillance visits, other technical visits, private discussion among team members and preparation of the report.)

Before visit

Documentation supplied according to clause 3.7 of APLAC MR 008 three months before the visit and examined by team members (and questions prepared).

Sunday

Arrival at hotel – discussion amongst team members.

Monday

At offices of the applicant body:

Opening meeting:

- presentation by team leader outlining aims, objectives and procedure to be adopted by evaluation team;
- presentation by head of applicant body;

Specific checking (the team usually splits up):

- discussions with staff of accreditation body on quality system and its implementation;
- demonstration by the staff of the accreditation body of its administrative and operational procedures.

Tuesday

Attendance as observers at initial assessments, surveillance visits or re-assessments.

Wednesday

Same as Tuesday.

Thursday

Same as Monday or Tuesday and then analysis of findings and preparation of the draft of the final report.

Friday

Completion of summary of report;

Completion of the first draft of the report;

Presentation and discussion of findings to applicant body at its offices (modify report as required).

Note 1. It is now common practice, especially for larger accreditation bodies to conduct the visit over 6 days, thus providing for an extra day to be spent in applicant body's office prior to any witnessing.