

A Guide for the Planning and Conduct of Evaluations

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**AUTHORSHIP**

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1. INTRODUCTION

The purpose of this document is to provide guidance for APAC evaluation teams for the planning and conduct of key aspects of APAC evaluations in accordance with APAC MRA-001 and APAC MRA-009 (in the case of remote evaluations).

It is also a useful resource for APAC accreditation bodies who are subject to these evaluations. Throughout the document (especially in Section 2) frequent use is made of “shall” statements. While these are not requirements under the APAC MRA, these statements reflect actions that are considered best peer evaluation practices and, indeed, are necessary to evaluate accreditation bodies effectively against the APAC MRA requirements for acceptance as a signatory to the APAC MRA.

1. 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.

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 must be carefully planned. When necessary additional 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. Such witnessing should take place within weeks, rather than months, of the visit to the applicant body’s office.

2.1.5 As MoUs may be concluded by APAC 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 and checking that on-site assessment time is adequate to cover the scope of accreditation being assessed.

**2.2 Evaluation of the Administration of the Applicant Body’s 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. management system manual or associated documentation, 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 agreements or 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 APAC MRA 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 and, as appropriate, technical experts 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, sampling assessment visits. The template report on witnessed assessments in Annex V of IAF/ILAC- shall be used to record observations. The details of assessed conformity assessment bodies witnessed shall also be recorded in APAC FMRA-012.

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 ILAC P9. Access to and participation levels in proficiency testing programme should be established.

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 Reference Material Producers, criteria for the participation in proficiency testing by collaborators involved in testing associated with the production of reference materials.

2.7.4 The applicant body’s ability to accredit conformity assessment bodies, including an appraisal of whether the applicant body obtains sufficient evidence that the conformity assessment bodies are technically competent to perform the work for which they are seeking accreditation or have been accredited, shall be evaluated. Use of peer inspectors as an accreditation body’s technical assessors/experts is particularly important for the assessment of inspection bodies where proficiency testing and other forms of inter-comparisons are not practical as a means of establishing the inspection body’s technical competence.

**2.8 Evaluation Concerning Metrological Traceability and Measurement Uncertainty**

2.8.1 General

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 APAC documents and ISO (/IEC) standard(s).

2.8.2 Accredited calibration laboratories

The evaluation team shall establish whether or not Clause 6.5 of ISO/IEC 17025 and ILAC P14 is being satisfied, that the uncertainty of the measurements performed is properly evaluated and reported, and that appropriate calibration and measurement capabilities are properly calculated. For further guidance on traceability, see also ILAC P10 and ILAC P14.

2.8.3 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 APAC MRA or to the ILAC Arrangement for calibration.

2.8.4 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 are fulfilled.

2.8.5 Accredited Reference Material Producers

The evaluation team shall establish whether or not clauses 7.9, 7.11 and 7.12 of ISO 17034 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.

2.8.6 Accredited Proficiency Testing Providers

The evaluation team shall establish whether or not Clauses 4.4.5.1 to 4.4.5.3 of ISO/IEC 17043 are being met; that the assigned values of PT schemes in the area of calibration are metrologically traceable with properly assigned uncertainties of measurement, and that in the area of testing the assigned values are determined taking account metrological traceability and uncertainty of measurement estimations.

2.8.7 Accredited Biobanking Organizations

The evaluation team shall establish whether or not clause 6.5.10 of ISO 20387 is being met. The tests, calibrations and measurements done by an accredited biobank, or on behalf of such a body, shall be traceable to national or international standards. The evaluation team shall evaluate whether calibration and testing included in biobanking activities fulfil the requirements of the appropriate ISO/IEC standards for laboratories. For further guidance on traceability, see ILAC P10.

1. CHECKLIST FOR APAC TEAM LEADERS – RE-EVALUATIONS

**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 any 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 APAC MRA MC 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 APAC and carried out in accordance with APAC MRA-001 and APAC MRA-009 in the case of remote evaluations;

(v) In consultation with APAC MRA MC Chair, select evaluation team members and seek endorsement of team by AB:

- use current edition of Evaluator Competency Spreadsheet (APAC FMRA-015);

- check that team members’ ABs have not provided consultancy to AB in last 3 years;

- ask potential team members to provide fuller biographical details, if needed;

- no more than 1 evaluator from any one economy;

- sufficient evaluators to cover all scopes of the AB’s activities;

- one evaluator knowledgeable also in the application of proficiency testing as an assessment tool;

- balance of experienced and less experienced evaluators, and the inclusion of at least one Provisional Evaluator;

- language skills, including knowledge of AB’s native language;

- cost of travel considerations;

(vi) Immediately advise APAC Secretariat of Team Members (and their assigned tasks) and the exact dates 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, or Team Members book tickets and invoice AB for the costs. Ensure all Team Members are aware of travel visa requirements to the AB’s economy and that the necessary letters of invitation are provided by the AB;

(viii) Obtain from the APAC Secretariat a copy of the full report from the previous evaluation, 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 (see APAC FMRA-002) by a 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 (see APAC FMRA-002) 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 to ensure confidentiality of the information;

 (ii) Obtain a report on AB’s voting ballot history from the APAC Secretariat;

(iii) Obtain list of possible assessments for witnessing from AB;

(iv) Agree the agenda for the visit with the AB including:

* 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 intervening sampling assessments (if appropriate);
* assigned 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;

- determine any dietary requirements for team members and ensure the AB is informed of these.

**3.3 Prior to the Evaluation**

(i) Prepare a detailed timetable for the visit and have it endorsed by the 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 APAC MRA-001, Clause 15;

(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 (IAF/ILAC-A3), building upon the partially completed evaluation report template provided by the applicant AB;

(vi) Ensure all Team Members and any observers sign confidentiality statements (APAC FGOV-007);

(vii) Prepare Team Leader Performance Log (APAC FMRA-007) 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’ findings are based on clear and objective evidence, are correctly classified and correctly assigned to clauses of ISO/IEC 17011;

(ix) Prepare summary report and list of nonconformities and comments for presentation to AB at closing meeting;

- this should be reviewed for comment by the AB prior to the closing meeting;

- the 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;

(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 APAC 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 APAC MRA MC and to APAC Secretariat (electronically);

(vii) Complete evaluator performance log for each team member (APAC FMRA-008) and send to the Secretariat for APAC MRA MC approval;

(viii) If required, present a verbal report to a meeting of the APAC MRA Council, summarising the team’s findings and supporting the team’s recommendations.

**3.6 Documents with which the Team Leader must be Familiar**

The Team Leader must be familiar with the documents giving the requirements for signatory status in the APAC MRA that are described in APAC FMRA-001 *List of APAC Endorsed Normative Documents*.

1. AMENDMENT TABLE

This table provides a summary of the changes to the document with this issue.

|  |  |
| --- | --- |
| **Section(s)** | **Amendment(s)** |
| All | Updated to include reference to APAC MRA-009 for remote evaluations and removal of reference to Recommendation Letter as this is now already include in the IAF/ILAC A3 template. |
| 3.4 ix), 3.5 iii) | Minor editorial amendment to remove refence to ‘concerns’ as no longer included in IAF/ILAC A3 evaluation report template. |
| All | New issue on establishment of APAC. Based upon APLAC MR 011 Issue 3. |
| End |  |

APPENDIX A - TYPICAL TIMETABLE FOR AN INITIAL EVALUATION VISIT

*The following timetable is given for reference only. Further guidance and examples can be found in IAF/ILAC-A2 Annex 2.*

*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 sampling assessment visits, other technical visits, private discussion among team members and preparation of the report.*

**Before visit**

Documentation supplied in accordance with Clause 16.2 of APAC MRA-001 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, sampling assessments 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.*