



**PROCEDURES FOR ESTABLISHING
AND MAINTAINING THE APLAC MUTUAL
RECOGNITION ARRANGEMENT AMONG
ACCREDITATION BODIES**

PURPOSE

An objective of APLAC is the development and maintenance of mutual recognition arrangements among its members and also among APLAC and recognised accreditation bodies in other economies or other regional groupings of such bodies. Through such arrangements, APLAC aims to establish openly and transparently the equivalence of the operation of accreditation bodies. As a consequence, the equivalent competence of laboratories, inspection bodies and reference material producers (RMPs) accredited by these bodies is demonstrated and hence the market is offered confidence in accepting the certificates and reports issued by accredited laboratories, inspection bodies and RMPs.

This document describes the procedures for APLAC to follow in the evaluation and re-evaluation of an accreditation body that accredits:

- calibration laboratories;
- testing laboratories including to ISO 15189;
- reference material producers; and/or
- inspection bodies

when that accreditation body wishes to become a signatory to the APLAC Mutual Recognition Arrangement (MRA) or wishes to maintain signatory recognition in the APLAC MRA. The accreditation body may be an APLAC member body, or a non-APLAC body from a different region.

AUTHORSHIP

This publication has been written by the APLAC Mutual Recognition Arrangement Council.

OFFICIAL LANGUAGE

The text may be translated into other languages as required. The English language version remains the definitive version.

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PART 1 GENERAL

0 DEFINITIONS

- 0.1 **Accreditation body (AB):** an organisation that operates an accreditation system for calibration laboratories, testing laboratories, reference material producers and/or inspection bodies.
- 0.2 **MRA:** mutual recognition arrangement.
- 0.3 **Non-member accreditation body:** an accreditation body from another region or an unaffiliated accreditation body that is not a member of APLAC.
- 0.4 **Regional group:** a formal group of accreditation bodies from a geographic area of the world whose purpose is to develop and maintain an MRA.
- 0.5 **APLAC MRA group:** the signatory accreditation bodies of the APLAC MRA.
- 0.6 **Accredited organisation:** a calibration laboratory, testing laboratory, inspection body or reference material producer accredited by an accreditation body.
- 0.7 **Applicant body:** APLAC Full Member that applies to become a signatory to the MRA or a non-member body from outside the APLAC region that applies to become a signatory to the APLAC MRA. Associate members are not eligible to apply. For a re-evaluation the phrase “applicant body” applies to a signatory being re-evaluated.
- 0.8 **Proficiency testing activity:** for the purpose of this document, all those activities used by accreditation bodies to assess performance, including proficiency tests (refer to ISO/IEC Guide 43, *Proficiency testing by means of inter-laboratory comparisons and measurement audits*) conducted by cooperations, accreditation bodies, commercial organisations or other providers.
- 0.9 **ISO/IEC Standard:** an ISO/IEC standard or guide related to accreditation and conformity assessment.
- 0.10 **Peer Evaluation:** a structured process of assessment of an Accreditation Body against the specified requirements.
- 0.11 **Evaluation Team Leader (TL):** a person responsible for leading an MRA peer evaluation team.
- 0.12 **Evaluation Team Member (TM):** A person serving on an MRA peer evaluation team.
- 0.13 **Witnessing:** Observing of an AB assessing a CAB’s competence by an evaluation team. (It may also include observing the AB’s staff preparing for an assessment and dealing with assessment reports.)
- 0.14 **Nonconformity:** Finding where the AB does not meet a requirement of the applicable standard(s) (e.g., ISO/IEC 17011), its own management system or the

MRA requirements in a way that discredits its competence or jeopardises the quality of its work.

- 0.15 **Concern:** Finding where the AB's practice may develop into a nonconformity or the team is not fully satisfied.
- 0.16 **Comment:** Finding about documents or the AB's practices with a potential of improvement; but still fulfilling the requirements.

1 SCOPE

- 1.1 This document describes the procedures for APLAC to follow for the evaluation and re-evaluation of member accreditation bodies that apply to become signatories to the APLAC Mutual Recognition Arrangement (MRA). The evaluation and re-evaluation of non-member accreditation bodies from outside the APLAC region that apply to sign the mutual recognition arrangement with the APLAC MRA group is also covered.
- 1.2 This document is also used for evaluating non-APLAC members from outside the APLAC region. Other than clauses 3.4 and 7.5, the same criteria and procedures in this document shall be followed. The result of a successful evaluation in this case will be a contract of bilateral mutual recognition, not the signing of the APLAC MRA.

2 OBJECTIVE

- 2.1 The objective of an evaluation of an applicant body shall be to establish cross-border stakeholder confidence in the endorsed reports and certificates (i.e. reports and certificates containing the accreditation body's accreditation symbol) issued by accredited organisations. The evaluation shall focus on how the applicant body ensures the competence of accredited organisations.
- 2.2 In order to achieve this objective for an applicant body, the evaluation team shall carry out the following:
- 2.2.1 An initial appraisal of the documented policies and procedures of the applicant body as set out in its quality manual and associated documentation; this appraisal shall be done against relevant ISO/IEC standards, ILAC/IAF and ILAC documents (see section 3.1), and APLAC MRA supplementary requirements;
 - 2.2.2 An evaluation, on-site, of the implementation of these policies and procedures; and
 - 2.2.3 An evaluation of the applicant body's ability to accredit organisations, including an appraisal of whether the applicant body obtains sufficient evidence that organisations are technically competent to perform the work for which they have been accredited. Use of peer inspectors as accreditation bodies' technical assessors/experts is particularly important for inspection bodies where proficiency testing and other forms of intercomparison are not practical as a means of establishing the inspection body's competence.
- 2.3 The evaluation process requires the exercise of some judgement and interpretation as it is unlikely that each requirement or activity will be addressed in exactly the same way in different organisations. The evaluation team shall therefore collect sufficient

information on each topic to enable it to appraise the suitability of the practices used by the applicant body. Significant differences in approach must be highlighted in the evaluation report, as they must be made known to all signatories to the MRA.

3 CRITERIA

3.1 Standards

This document refers to ISO and ISO/IEC standards and guides on conformity assessment (hereinafter referred to as ISO(/IEC) standards). Unless otherwise stated, the current edition of each document applies.

- 3.1.1 An applicant body shall, depending upon the type of accreditation offered, fulfil requirements for a single accreditation body stated in Section 2 of ILAC/IAF A2 and Section 5 of ILAC P1, and ILAC/IAF A5.
- 3.1.2 An applicant body shall ensure its accredited organisations fulfil the following criteria:
- For calibration laboratories, ISO/IEC 17025;
 - For testing laboratories, ISO/IEC 17025 (ISO/IEC 17025 or ISO 15189 for medical laboratories);
 - For inspection bodies, ISO/IEC 17020; ILAC/IAF A4;
 - For RMPs, ISO Guide 34 and ISO/IEC 17025 in combination.

3.2 Supplementary Requirements

Additionally, an applicant body shall:

- 3.2.1 Meet the requirements included in ILAC and APLAC documents decided as mandatory by the APLAC General Assembly, the list of which is available from the APLAC Secretariat. At the time of issue of this document, the current issues of the following apply: ILAC P8, ILAC P9, ILAC P10;
- 3.2.2 Be fully operational (i.e., have carried out surveillance and reassessment);
- Note 1. When an applicant body is already a signatory to the APLAC MRA and applies to extend its scope of recognition, this requirement may not necessarily apply to the extended scope. Each case will be considered by the APLAC MRA Council on an individual basis.
- 3.2.3 Demonstrate that its accredited organisations can access an appropriate measurement system that enables them to make measurements traceable to national or international standards of measurement;
- 3.2.4 For re-evaluations, abide by the requirements and obligations of the current issues of APLAC MR 001 and APLAC MR 002.
- 3.2.5 An applicant body for RMP shall either already be a signatory to the MRA for calibration and/or testing, or be applying for testing and/or calibration at the

same time. When the applicant applies to be a signatory for testing and/or calibration and RMP at the same time, signatory status for RMP will be granted only after signatory status has been granted for testing and/or calibration, or at the same time as signatory status for testing and/or calibration is granted.

3.3 Proficiency Testing Activity (Laboratories) and Technical Witnessing (Inspection Bodies)

3.3.1 An applicant body shall satisfy ILAC P9.

APLAC runs proficiency testing programs and inter-laboratory comparisons (ILCs) in some fields of testing and calibration. Each applicant body or signatory to the MRA for calibration and testing shall participate, as far as available and practicable, in order to verify the competence of its accredited laboratories, and to demonstrate the applicant body's ability to take appropriate actions if necessary.

3.3.2 Proficiency testing activities are also applicable to certain types of inspection. An applicant accreditation body to the APLAC MRA for inspection shall have a documented policy on proficiency testing, and encourage its accredited inspection bodies to participate where relevant proficiency testing activities are available.

3.3.3 For RMP accreditation ILAC P9 applies to the relevant calibration, testing and/or measurement activities performed.

3.4 Non-members of APLAC

Accreditation bodies from outside the APLAC region that are not members of APLAC shall enter into a contract of cooperation with APLAC before the evaluation process can be initiated by APLAC.

4 COSTS

4.1 The applicant body shall pay the expenses for each member of the evaluation team engaged in travel related to the evaluation, including lodging and all transportation. Any other costs shall be paid by the organisations providing the evaluators. The applicant body may, however, pay for meals or parts of the meals, within reasonable limitations.

The evaluation team may consist of evaluators and technical experts. When an evaluator or technical expert who comes from outside the region is included on the team, the APLAC Board of Management shall determine whether APLAC itself should pay for inter-country travel costs.

Transportation expenses include airfares, taxi fares, costs for the use of privately owned vehicles, train fares, or the costs associated with other means of conveyance for both inter-country travel and travel within the economy.

The applicant body shall pay expenses for pre-evaluations, evaluations (including multi-part evaluation visits), follow-up evaluations, surveillances and re-evaluations,

and for travel associated with observations of on-site assessments by the applicant body of laboratories, inspection bodies and RMPs.

- 4.2 The evaluators' time is donated at no charge to the applicant body.
- 4.3 An estimate of inter-country travel expenses and details of invoicing procedures should be provided in advance to the applicant body by the individual evaluators.

The applicant body shall pay for economy class airfare unless other arrangements are agreed in advance.

- 4.4 Observers shall pay all their own costs.
- 4.5 Evaluators and the applicant body shall cooperate by timely submission of invoices and timely reimbursement.

5 CONFIDENTIALITY AND IMPARTIALITY

- 5.1 All confidential information received, both in writing and by spoken word, during evaluations and re-evaluations shall be treated as confidential by all parties and persons concerned. This includes information relating to both the applicant body and the accredited or applicant organisations visited.
- 5.2 The applicant body and evaluation team shall agree on the storage or safe disposal of documents that have been provided as part of the evaluation process.
- 5.3 Members and observers of evaluation teams shall sign the declaration of confidentiality and impartiality form in Appendix F . The signed form shall be attached to the final evaluation report.
- 5.4 The Chair of the MRA Council shall ensure that all applications for MRA status are handled in an expeditious and non-discriminatory manner and that the evaluation process is implemented in accordance with Part 3 of this document.

6 CHANGES TO THIS DOCUMENT

- 6.1 This document may be revised by the APLAC MRA Council with the agreement of the APLAC General Assembly.
- 6.2 If a new requirement(s) is added to later versions of this document, an amendment of this document shall be issued immediately or this document shall be revised. If the implementation date is specified, this date shall be stated either in the amendment or in a Note under the relevant clause of the revised document.

PART 2 THE MRA PROCESS

7 APPLICATION

Within the APLAC membership, applications can be lodged only by APLAC Full members. An Associate member is not eligible to apply.

- 7.1 Applications shall be made in accordance with APLAC MR 003. The application form shall be completed in English and provided to the Chair of APLAC with copies to the APLAC Secretariat and the Chair of the MRA Council.
- 7.2 The APLAC Chair shall confirm receipt of the application. The Secretariat shall notify the receipt of the application to members of the MRA Council.
- 7.3 The Secretariat shall inform the applicant body at the time of application of:
- (a) the current issue of this document, i.e. APLAC MR 001; and
 - (b) any imminent changes approved by the General Assembly but not yet included in the current issue of this document.
- 7.4 Applications from APLAC Full Members shall be considered by the MRA Council at its next meeting or by correspondence if the next Council meeting is more than 3 months ahead. Reasons for not continuing with the application shall be discussed by the MRA Council.
- 7.5 (a) Applications from non-member accreditation bodies shall be discussed in the APLAC General Assembly. The APLAC General Assembly shall decide on whether to accept the application and to start the evaluation, and on any payment necessary. The MRA Council shall decide on the actual steps to be followed (see clause 3.4).
- (b) With non-member accreditation bodies (i.e. accreditation bodies from outside the APLAC region), a contract of cooperation shall be signed prior to the start of the evaluation. The contract should include specific topics such as rights and obligations, technical activities, finances, and term of validity of the contract of cooperation (see clause 3.4).
- 7.6 The MRA Council Chair shall ensure that the applicant body is informed by correspondence of the decision of the MRA Council (or General Assembly), and that the evaluation will be conducted in accordance with this document. When an application is not accepted, the applicant body shall be informed of the reason(s). The Secretariat shall ensure that the applicant body is informed of all the necessary relevant documents.
- 7.7 The applicant body shall provide two sets of documents (Set A, Set B) to the team leader and team members at least three months prior to any pre-evaluation or evaluation. In the case that the Set A and Set B documents are not provided three months prior to the planned visit, refer to Clause 11. The contents of the Set A and Set B documents are given in APLAC MR 003, appendix 2.
- 7.8 Special Emphasis in Scope**

The applicant body may request that the evaluation emphasise a certain area(s) of its accreditation activities, such as “EMC to domestic and foreign regulations”. In such a case, organisation of the evaluation team and the mode of the evaluation process may need special consideration so that the request can be met. The applicant body may request that observers (such as regulators of the economy the applicant body is interested in) be invited to participate in the evaluation. The evaluation report should detail the accreditation body’s capabilities in the specific area(s) identified, and the

MRA Council may decide to include reference to this specific area of recognition within the applicant body's scope of recognition listed in APLAC MR 002.

Such service shall only be provided on condition that the normal evaluation activities will not be adversely affected. Where such emphasis on selected areas necessitates extra evaluation activities, the applicant body shall bear all the extra costs associated with the performance of these additional activities. Extra costs would typically include the cost of the extra time of the evaluators for the evaluation, report and follow-up, additional accommodation, subsistence and travelling expenses, and related sundry costs.

8 APPOINTMENT OF TEAM LEADER

8.1 The MRA Council Chair, subject to the approval of the MRA Council, shall appoint a lead evaluator as the team leader for an evaluation or re-evaluation, with his or her consent. The team leader shall be chosen from a list of lead evaluators prepared and kept up-to-date by the MRA Council. The minimum qualifications for team leaders shall be as given in APLAC MR 004. In appointing team leaders for a specific evaluation, the MRA Council Chair:

- shall avoid appointing the same team leader for two successive evaluations of the same applicant body except for pre-evaluations and follow-up evaluations;
- should avoid appointing team leaders nominated from an accreditation body that has been evaluated by a team leader from the applicant body within a relatively short period;
- should ensure that evaluators are nominated from all APLAC MRA signatories (and non-member and cooperation signatories as appropriate) with the objective of evenly distributing the workload.

Note 1. The role and responsibilities of the team leader are given in Appendix B.

Note 2. The APLAC MRA Council requires the team leader for an evaluation to be present at the MRA Council meeting at which the report on the evaluation (s)he led is considered. If the person does not routinely attend MRA Council meetings, APLAC will provide funding for her/his attendance.

8.2 The applicant body shall be informed of the name of the team leader nominated by the MRA Council Chair to carry out the evaluation and the scope of the evaluation, with sufficient notice so that the applicant body has the opportunity to appeal against the appointment of the team leader.

8.3 The MRA Council Chair shall inform the team leader of his/her acceptance by the applicant body, approval of the appointment by the MRA Council, the scope of the evaluation, and, for a re-evaluation, the due date for the on-site evaluation. The Secretariat shall issue a letter of appointment to the team leader.

9 EVALUATION

The evaluation team leader shall organise and conduct the evaluation in accordance with the procedures set out in Part 3 of this document. After completing the process, the team leader shall send the evaluation report, the applicant body's corrective action

and response report, the team's recommendation and a list of the names of the conformity assessment bodies whose assessments were witnessed (four-part package) to the APLAC Secretariat and the APLAC MRA Council Chair, both electronically and as an unbound hard copy. The list of CABs shall be kept on file for future reference, and shall not be sent to the MRA Council with the other information used for decision-making.

10 DECISION MAKING

10.1 The APLAC Secretariat shall copy the final evaluation report and the evaluation team's letter of recommendation to the members of the APLAC MRA Council at least one month before the next meeting of the Council. A copy shall also be sent to the applicant body if it is not already a member of the Council. In exceptional cases where the four-part package cannot be submitted in time, the APLAC MRA Council Chair shall advise the Secretariat on appropriate action.

10.2 The MRA Council shall decide, normally during a meeting, taking into consideration the recommendations by the evaluation team (for voting rules, see APLAC MR 008, clause 2.6):

- (a) whether the applicant body should be accepted as a signatory to the APLAC MRA or whether the signatory status for the re-evaluated signatory should be reaffirmed; and
- (b) the scope of recognition within the APLAC MRA, and the time frame for any follow-up visit or for the next re-evaluation.

Note 1. In most cases, before the MRA Council makes the decision, the team leader will present the evaluation findings to a meeting of the MRA Council. The evaluated applicant body will be invited to respond.

10.3 In the case of an existing signatory to the APLAC MRA, the APLAC MRA Council may decide, if it is not able to accept the corrective action taken by the accreditation body in relation to any significant nonconformity(ies) to suspend MRA signatory recognition temporarily or to withdraw MRA signatory recognition until it is satisfied that the nonconformity(ies) has been addressed.

The date of the suspension of MRA signatory recognition is the date of the decision by the APLAC MRA Council unless the Council decides on a different suspension date, taking into account the recommendation of the evaluation team.

In the case of suspension of MRA signatory recognition, the APLAC MRA Council may decide to appoint a special evaluation team to conduct a follow-up visit. If the outstanding nonconformity(ies) have not been addressed satisfactorily within six months, the Council may resolve to withdraw MRA signatory status.

The accreditation body may appeal the APLAC MRA Council decision in accordance with the APLAC MRA Council's appeals procedure (see section 12).

10.4 The MRA Council may decide to impose other conditions for entry into the MRA on the applicant body, including the conduct of follow-up or surveillance visits or reducing the re-evaluation interval.

11 DELAY IN THE EVALUATION PROCESS

11.1 Caused by the Applicant

- 11.1.1 If the applicant body does not cooperate with the evaluation team within the timeframes specified in this document, the team leader may, at any stage, including before the evaluation team is constituted, propose to the APLAC MRA Council that the evaluation process be suspended.
- 11.1.2 If the applicant body does not provide the two sets of documents, in accordance with clause 7.7, to the team leader and team members at least three months prior to the evaluation visit, the team leader may propose a change in the evaluation schedule to the APLAC MRA Council Chair.
- 11.1.3 For the initial evaluation of an applicant, if the report on the evaluation has not been finalised after two years from the date of application, the team leader shall prepare a report for the APLAC MRA Council setting out the history of the evaluation
- 11.1.4 For a re-evaluation, if the report on the evaluation has not been finalised by the time of the next APLAC MRA Council meeting following the Council meeting where the re-evaluation report is scheduled to be tabled, the team leader shall prepare a report for the APLAC MRA Council, setting out the history of the evaluation.
- 11.1.5 If, in the opinion of the APLAC MRA Council, the delays are caused by the applicant body, and there are no extenuating circumstances, the APLAC MRA Council may resolve to suspend the evaluation process.
- 11.1.6 Once the evaluation process is suspended, the evaluation team shall be dissolved. The APLAC MRA Council may appoint another team leader when the applicant body is ready to resume the evaluation. Any nonconformities and concerns raised by the original evaluation team shall be taken into consideration by the new evaluation team.
- 11.1.7 Once the process for re-evaluation is suspended, the APLAC MRA Council may suspend the signatory status of the accreditation body that is already a signatory to the APLAC MRA.
- 11.1.8 Irrespective of any delays in an evaluation, the subsequent re-evaluations shall be done in accordance with the original schedule, i.e. at a maximum of every four years from the first day of the final full evaluation visit to the accreditation body prior to its being accepted as a signatory to the MRA, unless otherwise determined by the MRA Council.

11.2 Caused by Adverse Travel Advisory

- 11.2.1 If an adverse travel advisory for the applicant's economy occurs before the evaluation date is set, the team leader shall, in consultation with the APLAC MRA Council Chair, postpone setting a date.

- 11.2.2 In the event of an adverse travel advisory for the applicant's economy after the date for the visit has been set, the APLAC MRA Council Chair shall decide, on the basis of advice from the team leader appointed for the evaluation, on the postponement of the evaluation.
- 11.2.3 If the postponed visit is for a re-evaluation, the APLAC MRA Council shall decide, after the postponement, on a case-by-case basis, the impact on the ongoing recognition of the APLAC MRA signatory accreditation body affected.

12 APPEALS

Appeals against any APLAC MRA Council decision, including a decision relating to denial of recognition or to withdrawal of recognition, shall be handled using the appeals procedure detailed in APLAC MR 008, section 2.7..

13 MAINTENANCE OF THE APLAC MUTUAL RECOGNITION ARRANGEMENT

13.1 Notification of Change

- 13.1.1 As required by the APLAC MRA, each signatory shall ensure that all of the other signatories are informed, in writing, of any significant changes in status and/or operating practices. The Chair of the MRA Council and APLAC Secretariat shall also be informed. The following information shall be transmitted as soon as possible:
- (a) details of any change in the name or legal or corporate status of the accreditation body or its parent organisation;
 - (b) details of new mutual recognition arrangements negotiated with other accreditation bodies or other parties, and of the revision, suspension or termination of any existing mutual recognition arrangements;
 - (c) details of any significant changes in key senior staff and the organisational structure of the accreditation body or its parent organisation;
 - (d) significant changes in the mode of operation of the system and in particular in the mechanisms used to assess organisations;
 - (e) details of the use of a sub-contracted organisation(s) to do assessments, either routinely or from time-to-time.
- 13.1.2 When a notification of such changes is received, the APLAC Secretariat shall inform the APLAC MRA Council Chair of the changes, who shall then decide if further information needs to be provided by the accreditation body. Such additional information may include:
- additional details of the change to those provided in the original notification;

- the accreditation body's own analysis of how, and to what extent, the change impacts on its technical competence and APLAC MRA signatory status, etc.

13.1.3 The APLAC MRA Council Chair may appoint an ad hoc review team consisting of one or more experienced evaluators, one of whom is preferably the evaluation team leader for the most recent on-site evaluation of the accreditation body, to review the impact of the changes on conformity of the accreditation body with relevant MRA requirements. If the previous team leader is not able to be part of the review team, at least one member of the previous evaluation team should be included in the review team. The APLAC Secretariat shall provide the notification of changes and any additional information to the review team.

The review team shall review and evaluate the information given and shall have authority to request more information, as necessary, directly from the accreditation body. Any additional information provided shall be copied to the APLAC Secretariat for inclusion in the accreditation body's file. The review team shall also have the authority to recommend to the APLAC MRA Council (via the Chair) that it is necessary to conduct an on-site visit to the accreditation body. All costs shall be met in accordance with section 4 of this document. The review team shall prepare a recommendation to the APLAC MRA Council as to the impact of the change on the MRA status of the accreditation body in question, for discussion and decision, if necessary, at the next APLAC MRA Council meeting.

13.1.4 If the changes notified by the accreditation body are significant or if the review (13.1.3) finds significant nonconformities, the APLAC MRA Council may consider the need to suspend or withdraw the accreditation body's MRA signatory status.

13.2 Monitoring and Re-evaluation of MRA Signatories

13.2.1 Each signatory to the APLAC MRA shall be re-evaluated at a maximum interval of four years from the first day of the final full evaluation visit of the initial evaluation of the accreditation body. If a signatory has not been re-evaluated after four years, the subsequent meeting of the MRA Council may discuss the need for suspension of the MRA signatory status of the accreditation body.

13.2.2 A re-evaluation shall take place at a shorter interval should there be due cause, such as notification of significant changes (see clause 13.1.1). An evaluation for extension of MRA signatory status may be conducted, together with the next re-evaluation if the accreditation body applies for an extension to the scope of recognition.

13.2.3 A re-evaluation visit shall be done by a team chosen in accordance with the procedures described in part 3 of this document, and equivalent evaluation procedures shall be used for a re-evaluation as were used for the initial evaluation. The re-evaluation should concentrate on examining changes, on compliance with the current issues of the relevant ISO(/IEC) standards (especially when a new edition of the standard has been issued since the previous evaluation) and any other

new supplementary MRA requirements adopted by APLAC and ILAC, and on obtaining evidence that accredited organisations continue to operate in compliance with the relevant ISO/(IEC) standards.

14 PROCEDURES FOR EXTENSION OF AN ACCREDITATION BODY'S SCOPE OF RECOGNITION UNDER THE APLAC MRA

If a signatory wishes to extend its scope of recognition (testing, ISO 15189, calibration, inspection and/or RMP) in the MRA, the same procedures described in parts 2 and 3 of this document shall apply, in general. In an evaluation carried out solely for the extension of recognition, only those aspects of the accreditation body relating to its accreditation activities covered by the proposed extension need to be covered. The size of the evaluation team shall correspond to the evaluation activities to be carried out.

15 SUSPENSION OR WITHDRAWAL OF APLAC MRA SIGNATORY STATUS

The procedures to be followed by the APLAC MRA Council for suspension or withdrawal of APLAC MRA signatory status are described in APLAC MR 008.

PART 3 THE EVALUATION PROCESS

16 COOPERATION BY APPLICANT BODY

- 16.1 The evaluation team leader shall endeavour to solicit the cooperation from the applicant body that is necessary for conducting an effective evaluation.
- 16.2 The applicant body shall cooperate with the evaluation team fully and without delay throughout the evaluation process. Any unavoidable situation that could lead to a delay shall be advised to the team leader as soon as possible.

Cooperation shall include but not be limited to:

- (a) provision in a timely manner of all documentation and relevant information necessary for the evaluation (see APLAC MR 003)
- (b) making necessary arrangements for the evaluation visit, that include:
 - (i) ensuring that key personnel, staff members, assessors and committee members of the applicant body are available for interview
 - (ii) providing the evaluation team with a list of assessments that are scheduled to take place from about 6 weeks before the proposed on-site evaluation date
 - (iii) organising for the witnessing of a suitable number of assessments and, if applicable, for other technical visits, in conjunction with the evaluation team, and with the agreement of the laboratories, RMPs and/or inspection bodies to be assessed
 - (iv) arranging accommodation and transportation for the witnessing of assessments and, if necessary, for a visit to the national measurement institute

- (v) providing the opportunity to attend a meeting of the committee concerned with decisions on accreditation, if such a committee exists and is due to meet during the visit
- (vi) providing meeting and working space for the evaluation team, access to a personal computer and to a photocopier, and telecommunication facilities between the team members if they will be separated by long distances during the evaluation and
- (vii) providing interpreters, if necessary.

Note 1. English is the official language for APLAC evaluations and the applicant body is only required to provide translation and/or interpretation from its native language into English. It is not required to provide translation or interpretation into a third language.

- (c) payment of all costs as specified in section 4 of this document
- (d) making an effort to build consensus on the findings given in the evaluation report
- (e) undertaking appropriate cause analysis and/or corrective actions on nonconformities and concerns raised in the evaluation report.

17 PRE-EVALUATION VISIT

17.1 A pre-evaluation visit is optional for the applicant body. Findings from the pre-evaluation visit shall be used to determine whether the applicant body is ready for the full evaluation. A pre-evaluation visit does not pre-empt the evaluation.

17.2 The pre-evaluation visit shall be conducted by the pre-evaluation team leader and a team member chosen by the team leader, in consultation with the Chair of the MRA Council, from the evaluator competencies list maintained by the MRA Council.

Note 1: A team leader should avoid using another lead evaluator as a team member.

17.3 After examination of the documentation by the pre-evaluation team leader and the team member who conduct the pre-evaluation visit, the team leader shall advise the applicant body of the intended agenda for the pre-evaluation visit, and seek an assurance that key personnel will be available during the visit.

17.4 A provisional date for the pre-evaluation visit shall be agreed, subject to supply of the required documentation at least three months prior to the visit.

17.5 In the pre-evaluation stage, the pre-evaluation team leader shall discuss with the head of the applicant body its participation in APLAC and other regional and international accreditation activities.

17.6 (a) After receipt and evaluation of the documentation the pre-evaluation team shall visit the applicant body. During the visit the team shall discuss the quality system, quality documentation and its implementation, and make recommendations, where necessary, on actions to be taken before the full

- evaluation. The pre-evaluation team shall also indicate how many days the full evaluation is likely to take.
- (b) During the visit, the pre-evaluation team shall provide all necessary information related to APLAC MRA requirements and to the full evaluation process.
 - (c) In the case of a calibration laboratory accreditation body, a part of the pre-evaluation shall be an assessment of the existence of laboratories providing traceability to the highest level in the economy or region. This is especially necessary where the traceability schedules are not clear and where participation in CIPM activities by the domestic national measurement institute is not fully known. Participation in international proficiency testing activities should also be covered.
 - (d) During the pre-evaluation visit, the pre-evaluation team may also visit one or two accredited organisations to gain an initial impression of the operation of the accreditation system, and of the technical competence of its accredited organisations. Such a visit should not, however, be considered as witnessing an assessment.
 - (e) A pre-evaluation visit should, in most cases, take 2 to 3 days. The duration may be varied by agreement between the team leader and the applicant body.
- 17.7
- (a) At the end of the pre-evaluation visit, the pre-evaluation team leader shall submit a short written report to the applicant body and to the Chair of the MRA Council with a copy being sent to the APLAC Secretariat.
 - (b) The report shall as a minimum contain the following information:
 - (i) main nonconformities found, referenced to the relevant clauses of ISO/IEC 17011 or other APLAC MRA criteria documents;
 - (ii) the degree to which the applicant body fulfils the relevant criteria;
 - (iii) a recommendation on whether to continue, to suspend or to withdraw the evaluation process;
 - (iv) a recommendation on the type and number of team members necessary, and the estimated duration of any proposed evaluation visit;
 - (v) the conditions to be fulfilled before the evaluation visit is conducted.
 - (c) The applicant body shall be given the opportunity to comment on any factual errors in the report.
 - (d) On the basis of the report, the applicant body shall provide the pre-evaluation team leader with a corrective action report, detailing the actions taken on the nonconformities and providing any supporting documentation. This report shall be provided within three months of the receipt by the applicant of the pre-evaluation report.

Note 1. The pre-evaluation team leader should advise the applicant body, within one month of receiving the response, whether or not the corrective actions are acceptable.

Note 2. The applicant body's response should be able to be inserted as text against each finding that is presented in a table format in the pre-evaluation report.

- (e) Once the pre-evaluation team is satisfied with the response from the applicant body to the nonconformities the pre-evaluation team leader shall, in consultation with the Chair of the APLAC MRA Council (or the APLAC Chair if the team leader is the Chair of the MRA Council), make a decision to proceed with the initial evaluation.
- (f) Neither the applicant body nor any other parties shall use the pre-evaluation report to claim that the applicant body has been evaluated by APLAC.
- (g) The applicant body may appeal in writing to the Chair of the MRA Council a decision to suspend or withdraw the evaluation. The MRA Council during its meeting or by correspondence shall rule on whether to uphold the appeal and to proceed with the full evaluation.

18 COMPOSITION OF EVALUATION TEAM

18.1 For the full evaluation visit, the team leader shall choose the members of the team from the evaluator competencies list, prepared and kept up-to-date by the MRA Council, in consultation with the Chair of the MRA Council and/or a sub-committee, needed to cover the technical fields, size and complexity of the applicant body.

Note 1: A team leader shall avoid using another lead evaluator as a team member.

18.2 No team member shall be associated with any accreditation body that has provided a consultancy service to the body being evaluated during the last four years.

18.3 The team chosen shall consist of representatives from a cross-section of APLAC member accreditation bodies and, if appropriate, representatives of other recognised contract cooperators or ILAC-recognised regional groups. More than one team member from a single economy should be avoided.

18.4 Evaluators designated by the International Laboratory Accreditation Cooperation (ILAC) or from other non-APLAC member bodies or regional groups recognised by ILAC may also be accepted to carry out evaluations.

18.5 The team leader should also take into account of the following when choosing the members of the team.

- (a) The team leader should avoid appointing the same team for two successive evaluations of the same applicant body. For the purposes of team composition, a pre-evaluation visit prior to an evaluation visit and a follow-up evaluation visit after an evaluation visit are treated as part of the same evaluation.

- (b) For calibration and testing laboratory accreditation bodies, at least one team member should be familiar with proficiency testing. For RMP accreditation bodies, at least one member of the team shall have appropriate expertise.
- (c) Technical experts may be specially invited for a specific evaluation or re-evaluation. The team leader is responsible for choosing technical experts, in consultation with the APLAC MRA Council Chair.
- (d) One or two observers may be added to the team with the prior agreement of the applicant body.

Note 1. An observer is normally a provisional evaluator, a representative from another region, a regulator from the applicant's economy or a representative from a third economy.

- (e) Knowledge of the local language should be taken into account when assembling the team.

18.6 Qualification requirements for evaluators and lead evaluators are given in APLAC MR 004.

18.7 The applicant body shall be informed of the names of the team members nominated to carry out the evaluation, with sufficient notice so that the applicant body has the opportunity to appeal against the appointment of any team member. The applicant body shall also be informed of the name of the observers.

Once the team members have been finalised the team leader shall promptly advise the APLAC Secretariat of the names of the team members and their assigned tasks, and shall provide written evidence that the applicant body has accepted the team members. The Secretariat shall then issue letters of appointment to the team members.

18.8 Once the evaluation team has been accepted by the applicant body, all communications between the team and APLAC shall be conducted through the MRA Council Chair. A copy of all correspondence shall be sent to the APLAC Secretariat for inclusion in the official files.

19 PREPARATION FOR EVALUATION

19.1 The team leader shall organize the full evaluation. If a pre-evaluation has taken place, the full evaluation visit shall not be carried out until the applicant body has undertaken all the actions agreed after the pre-evaluation visit.

19.2 The team members shall be allocated specific tasks prior to the evaluation.

19.3 The evaluation team shall conduct the document review. The full evaluation visit shall not be carried out before it appears, from the documentation supplied by the applicant body, to meet the criteria.

19.3.1 The team leader shall ask the Chair of the APLAC Proficiency Testing Committee to provide a brief summary report on the participation and performance in APLAC PT programs by the applicant body's accredited laboratories prior to the evaluation. The evaluation team shall analyse the information provided.

- 19.3.2 The team leader shall ask the APLAC Secretariat to provide details of the applicant body's voting history in APLAC postal ballots. A report on this voting history shall be included in section 5 of the evaluation report (APLAC MR 009).
- 19.3.3 The following aspects shall be taken into account when planning the evaluation of APLAC members and non-members:
- (i) the availability of traceability of measurements to national and international standards of measurement;
 - (ii) the pre-evaluation report (if a pre-evaluation has been done);
 - (iii) any evaluation experience of individual APLAC member bodies with the applicant body;
 - (iv) information from reports from previous evaluations or re-evaluations.
- 19.4 The team leader (in consultation with the team members, when necessary) and the applicant body together shall decide upon the agenda for the evaluation visit, taking into account the scope of the accreditations offered and the time needed to conduct an effective evaluation.
- 19.5 The team leader shall then prepare, in consultation with the applicant body, a detailed agenda of the main activities to be examined during the visit to the applicant body, including the assessments of accredited or applicant organisations to be witnessed. An example of a typical timetable for an evaluation is given in Appendix A. The evaluation shall include the witnessing of an initial assessment, if possible, and of a mix of re-assessment and/or surveillance visits.
- 19.6 The evaluation team shall make provision in the visit agenda for time to prepare a summary report and a draft of the final report (see APLAC MR 009).

Note 1. It is important that a representative sample of the range of accreditation activities under evaluation is witnessed by the team.

The team needs to consider the witnessing of assessments. At present 5 scopes are recognised within the Arrangement:

- Calibration
- Testing
- ISO 15189
- Inspection
- RMP

Note 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.

Note 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.

Note 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.

Note 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.

19.7 The team leader shall obtain confirmation of the arrangements listed in 16.2 (b) from the applicant body.

20 CONDUCT OF THE ON-SITE EVALUATION

20.1 Team Meetings

The team shall hold a meeting in private to consult about the aspects to be evaluated by each team member before commencing the on-site evaluation.

The team shall allow sufficient time to discuss its findings in private at the end of each day or session, and should seek clarification arising from observations of on-site assessment activities before formulating its findings.

20.2 Opening Meeting

An initial meeting shall be held with the senior management of the applicant body to confirm the objectives of the visit, the criteria being used, the visit agenda, and the arrangements for reporting the observations and outcome of the on-site visit. After this meeting, the team will usually split up so that each member proceeds to that part of the evaluation assigned to him or her.

20.3 On-site Evaluation

The evaluation team shall conduct an on-site evaluation of the operational procedures and practices of the applicant body at the offices of the applicant body, and at organisations undergoing assessment/re-assessment and surveillance, placing emphasis on the aspects described in Appendix D.

In addition, the team shall take account of the overall performance of the accreditation body. In this regard, the team shall take into consideration the ILAC/IAF A3 Key Performance Indicators (KPIs) when evaluating the accreditation body's performance and when preparing the evaluation report (see APLAC MR 009). KPIs shall not, however, be used as additional evaluation requirements.

Note 1. Observations of assessment activities should be made after a preliminary meeting with relevant members of the staff of the applicant body, and after any queries

about the operational procedures and technical requirements of the applicant body have been answered.

20.4 Closing meeting

20.4.1 An closing meeting shall be held with the senior management of the applicant body to confirm the findings from the on-site evaluation.

20.4.2 The team shall present the applicant body with a short summary (typically two pages) of the report identifying strengths, weaknesses and conclusions, signed by all team members at the closing meeting. A list of nonconformities, concerns and comments shall be attached to the summary report. The team leader shall give the applicant body an opportunity to comment on and discuss the nonconformities, concerns, comments, and the team's conclusions, and to clear up any misunderstandings that may have arisen.

20.4.3 The evaluation team shall make provision in the visit agenda for time to prepare a draft of the final report (see APLAC MR 009). This draft shall be based on observations made and on other factual information, agreed by the team during the evaluation, including observations made and any clarifications provided by the applicant body.

Note 1. The team leader should also present a more detailed oral summary of the content of the draft final report to the applicant body at the closing meeting at the end of the visit.

20.4.4 The team should also determine the method of follow-up for all nonconformities and concerns identified, including any follow-up visit, if applicable, with the agreement of the applicant body. MRA Council approval is not required for any follow-up activities, including on-site visits before the final report and recommendation of the team are presented to the MRA Council.

20.4.5 If any problems or difficulties are encountered during the course of the evaluation, including for only part of the scope, possible options available to the team leader are to withdraw the team from the visit, to change the visit to a pre-evaluation visit (for an initial evaluation only) or to treat the visit as an incomplete evaluation that requires a further visit. The preferred option is to treat the visit as an incomplete visit. A proposal to withdraw from the visit or to change its purpose shall be discussed by the team leader with the Chair of the MRA Council, unless not practicable, before any such decision is made.

21 EVALUATION REPORT

21.1 After the visit, the team leader shall complete the report and, subject to the approval of the final draft by the team members, provide it to the applicant body, within two months. The report shall be in the format of APLAC MR 009, the evaluation report template.

Note 1. The report should clearly highlight compliance with the requirements of the relevant ISO/(IEC) standard(s), APLAC MRA supplementary requirements, when relevant, and the applicant body's own requirements.

- 21.2 When the team leader is not able to complete the evaluation report and report the findings of the evaluation team within the time prescribed by the MRA Council, (s)he shall advise the MRA Council Chair of the situation. The MRA Council shall re-arrange the schedule or shall appoint a new team leader to complete the task. When a new team leader is appointed, the previous team leader shall send to the new team leader all information gathered to date in relation to the evaluation.
- 21.3 The applicant body shall be given the opportunity to correct any misunderstandings or errors of fact appearing in the report.
- 21.4 Under the conditions detailed in Appendix G, the APLAC MRA Council may permit an evaluated accreditation body to provide copies of its evaluation report to interested parties. Compliance with Appendix G shall be checked by the evaluation team at each evaluation, and details shall be included in the evaluation report.

22 CORRECTIVE ACTION AND EVALUATION TEAM'S RECOMMENDATION TO APLAC MRA COUNCIL

22.1 Corrective Action

The applicant body shall provide to the team leader a corrective action and response report that consists of the corrective actions taken on the nonconformities, and responses to concerns raised in the evaluation report. The report shall include a time schedule to address the nonconformities. For an initial evaluation this report shall be provided within three months of receipt of the evaluation report. For a re-evaluation this report shall be provided within one month of receipt of the evaluation report.

Note 1. The team leader should advise within one month of receiving the response of the applicant body whether the corrective actions are acceptable,

Note 2. Ideally, the accreditation body's response can simply be inserted text under each finding presented in table format in the report, with attachments of supporting evidence of corrective action as appropriate.

22.2 Evaluation Team's Recommendation to APLAC MRA Council

22.2.1 After a satisfactory response by the applicant body to the nonconformities and concerns raised in the report on the evaluation, and following the findings of any follow-up visit (if applicable), the team leader shall discuss with the other members of the evaluation team the recommendations to be made to the APLAC MRA Council. The recommendations for an initial evaluation shall include:

- (a) whether or not the applicant body should be accepted as a signatory to the APLAC MRA;
- (b) the scope of signatory recognition within the APLAC MRA;
- (c) the timeframe for any follow-up visit and full re-evaluation.

For a re-evaluation the recommendations shall include:

- (a) whether or not recognition as a signatory to the APLAC MRA should be continued;
- (b) any variation to the scope of signatory recognition;
- (c) the timeframe for any follow-up visit and full re-evaluation.

If the team recommends that the applicant body not be accepted as a signatory to the APLAC MRA, or that signatory status not be continued after a re-evaluation, the report shall include the reasons for this recommendation.

22.2.2 During the process of 22.1 and 22.2.1, the team leader should consult his/her team members as necessary. If the corrective action is not acceptable, the team leader should discuss it with the applicant body.

22.2.3 The team leader shall send to the APLAC Secretariat:

- (1) the evaluation report using the report format, APLAC MR 009;
- (2) the applicant body's corrective action and response report (including details of corrective actions on nonconformities and responses to concerns) and the team's evaluation of them including findings from any follow-up visits;
- (3) the team's recommendation (consisting of a letter detailing the evaluation team's recommendation to the APLAC MRA Council);
- (4) a list of the names of the conformity assessment bodies whose assessments were witnessed as part of the evaluation.

This four-part package shall be sent electronically (as Word documents) to the APLAC secretariat at least one month prior to the MRA Council meeting. A completed checklist (see Appendix F) shall be sent with the electronic package. Signed originals of the report, etc. shall be sent in hard copy separately to the Secretariat.

22.3 Presentation of Evaluation Report at APLAC MRA Council Meeting

The team leader for the evaluation shall attend the APLAC MRA Council meeting at which the report on the evaluation that s(he) led is considered. If the person does not routinely attend MRA Council meetings, APLAC shall provide funding for her/his attendance.

23 MONITORING THE PERFORMANCE OF EVALUATORS

The team leader and team members shall follow the procedures of APLAC MR 004 to evaluate the performance of the team leader and team members, using Appendix 3 or Appendix 4 as appropriate.

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 report compilation.)

Before visit

Documentation supplied according to clause 7.7 three months before the visit and is 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 preparing 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. For small accreditation bodies and re-evaluations it may be appropriate to leave out one day of visits.

APPENDIX B

ROLE AND RESPONSIBILITIES OF EVALUATION TEAM

The role and responsibilities of the evaluation team are as follows.

- B1. The evaluation team shall evaluate compliance of the applicant body with the APLAC MRA criteria stated in section 3 of this document. The two other key tasks of an MRA evaluation team are to:
- (a) evaluate the effectiveness of the applicant body's assessment team by observing:
 - (i) whether the applicant body's requirements are implemented
 - (ii) whether the applicant body's procedures for assessment are followed
 - (iii) whether the requirements of the relevant ISO(/IEC) standard(s) are implemented satisfactorily by accredited organisations
 - (b) verify whether the technical competence of the accredited organisation is appropriate to the accreditation scope.
- B2. The evaluation team leader is delegated authority by the MRA Council to make final decisions regarding the conduct of the evaluation. (S)he shall have ultimate responsibility for all phases of the evaluation, including:
- (a) composition of the evaluation team
 - (b) document review
 - (c) planning the evaluation visit
 - (d) conducting the evaluation visit
 - (e) planning and conducting any follow-up activities, including an on-site follow-up visit,
 - (f) reporting the results of the evaluation
- B3. The evaluation team leader shall normally, in addition to having the responsibility for managing the evaluation, mentor any "provisional evaluator" assigned to the team. Mentoring includes allocating her/him such tasks as s(he) is capable of performing, supervising, and providing a report to the MRA Council Evaluator Performance Working Group about the performance of the provisional evaluator.
- B4. Evaluation team members shall cooperate with the team leader and other team members and treat one another with mutual respect. The evaluation team should strive to reach consensus, and any disagreement should be resolved amicably.

APPENDIX C

CHECKLIST FOR APLAC LEAD EVALUATORS – RE-EVALUATIONS

C1. No 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 lead 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 PT
 - 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 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, eg 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

C2. No 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
- (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; (NOTE: an observer is either a provisional evaluator or a regulator from the AB's own economy)
 - 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

C3. 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 clause 16.2 above
- (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 accreditation body
- (vi) ensure all team members and any observers sign confidentiality statement (Appendix E below; 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

C4. 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 member; 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 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) during closing meeting ensure any misunderstandings are clarified, disagreements resolved
- (xi) ensure summary report and confidentiality statement are signed by all team members

C5. After evaluation visit

- (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

C6. Documents with which team leader must be familiar

ILAC/IAF A-series

- A1 - ILAC/IAF Multi-Lateral Recognition Arrangements (Arrangements): Requirements for Evaluation of a Regional Group

- 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* - Application of ISO/IEC 17011

ILAC P-series

- P1* - ILAC Multi-Lateral Recognition Arrangement (Arrangement): Requirements for Evaluation of Accreditation Bodies by ILAC-Recognised Regional Cooperations
- P2 - ILAC Multi-Lateral Recognition Arrangement (Arrangement): Procedures for Evaluation of Regional Cooperation Bodies for the Purpose of Recognition
- P3 - ILAC Multi-Lateral Recognition Arrangement (Arrangement): Procedures for Evaluation Unaffiliated Bodies for the Purpose of Recognition
- P4 - ILAC Multi-Lateral Recognition Arrangement (Arrangement): Policy Statement
- P5 - ILAC Multi-Lateral Recognition Arrangement (Arrangement): Text of ILAC Mutual Recognition Arrangement*
- P6 - ILAC Multi-Lateral Recognition Arrangement (Arrangement): Application for Full Member Status
- P8* - ILAC Multi-Lateral 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
- P11 - Monitoring Performance of ILAC Evaluators
- P12 - Harmonisation of ILAC Work with the Regions
- G21 - Cross Frontier Accreditation – Principles for Avoiding Duplication
- S2 - ILAC Rules

APLAC MR-series

- 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) and to Extend Scope of Recognition
- MR 004* - Evaluators – Qualifications, Training and Monitoring Performance
- MR 006 - Procedure for the Conduct of Joint Evaluation with other Regional Cooperations
- MR 007 - APLAC Evaluation Checklist
- MR 008 - APLAC MRA Council – Rules for Operation
- MR 009* - APLAC Evaluation Report Template

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

* key documents

APPENDIX D

IMPORTANT ASPECTS OF EVALUATION

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

D1. Evaluation of the Administration of the System

- D1.1 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.
- D1.2 The evaluation team shall set aside sufficient time for this part of the evaluation (Appendix A above 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, 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. Part of the evaluation is the checking of files, records and archives of the applicant body. The evaluation team shall also appraise the relationship of the applicant body with technical and other organisations in the economy, and the existence and content of any MRAs with other accreditation bodies.
- D1.3 The evaluation team shall check that the applicant body has implemented all of 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.
- D1.4 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.
- D1.5 The evaluation team shall check the availability and content of any documents containing additional requirements or guidance to assessors, and laboratories, RMPs and/or inspection bodies.
- D1.6 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.

D2. Evaluation Concerning Assessors

D2.1 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 organisations.

D2.2 Where accreditation bodies use a staff member as the assessment team leader or as part of the assessment team the same requirements apply.

D3. Evaluation of Performance of Assessors and Competence of Accredited Organisations

D3.1 The evaluation team shall attend at least one initial assessment (if applicable), 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.

D3.2 The assessments witnessed shall involve a range of technical fields representative of the accreditations granted by the applicant body.

D3.3 The evaluation team shall pay particular attention to the procedures adopted by the assessment team and note deviations from the specified requirements by the assessment team when they are observed.

D3.4 The evaluation team members shall maintain the role of observer at all times during the assessment, re-assessment and surveillance visits to avoid influencing the performance or procedures of the assessors and the responses by staff of the organisation under assessment. 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 provided to the applicant body after the assessment.

D4. 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 actions required of organisations assessed 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.

D5. 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.

D6. Evaluation of Proficiency Testing Activities

D6.1 The policies and procedures for proficiency testing of the applicant body shall be evaluated against the requirements of clause 3.3 above.

D6.2 The way in which the results of proficiency testing activities are used by the applicant body shall be examined.

D6.3 The evaluation team shall discuss with the relevant members of the applicant body staff the following matters:

D6.3.1 Identification of areas where proficiency testing activity is available or should be initiated

D6.3.2 Criteria for selection, organisation and use of proficiency testing activities

D6.3.3 Criteria for accepting proficiency testing activities provided by external bodies

D6.3.4 Policies and procedures, including corrective action, for integrating proficiency testing results into the assessment process

D6.3.5 Criteria for the selection of participants when participation in a particular proficiency testing activity is limited

D6.3.6 For accreditors of RMP, criteria for the participation in proficiency testing of collaborators involved in testing associated with production of reference materials.

D7. 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).

D7.1 *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 the latest issue of ILAC P10.

D7.2 Accredited testing laboratories and inspection bodies

The evaluation team shall check whether full and proper use is being made of competent calibration laboratories by the testing laboratories and/or inspection bodies. Where no such 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 the 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 body is party to arrangements recognising the equivalence of calibrations through the APLAC MRA, it will only be necessary to confirm that the quality system requirements of ISO/IEC 17025 are a requirement of the applicant body and are in place in calibration laboratories.

If the calibration laboratories providing measurement support to the testing laboratories and/or inspection bodies 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.

D7.3 Accredited inspection bodies

The tests, calibrations and measurements performed 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.

D7.4 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.

APPENDIX E

DECLARATION OF CONFIDENTIALITY AND IMPARTIALITY

This form shall be signed by all members of an APLAC peer evaluation team and by all observers.

I declare that I will not reveal confidential information gained through peer evaluations or peer evaluation reports to anyone who does not have the right of access to such information and who has not signed an APLAC Confidentiality Declaration Form.

I further declare that I have no conflicts of interest with this accreditation body that would compromise impartiality, and that I have not undertaken consultancies to it during the last four years.

Date:

Names, Affiliations and Role in Evaluation:

Signatures:

APPENDIX F



APLAC MRA EVALUATION – TEAM LEADER REPORT CHECKLIST

The following information for each evaluation and follow-up visit must be sent by the team leader to the APLAC secretariat electronically (as Word documents). Signed originals are to be sent in hard copy. Refer to APLAC MR 001, clause 22.2.3.

1. final report (using the report template MR 009)
2. a letter detailing the evaluation team’s recommendation to the APLAC MRA Council
3. the accreditation body’s corrective action and response report (corrective actions to nonconformities, responses to concerns), including any supporting information provided
4. a list of the names of the CABs whose assessments were witnessed as part of the evaluation

Accreditation Body:					
Team Leader	Eval Date	Final Report *	Letter of Rec. *	AB Response *	List of CABs

* note date sent to secretariat

APPENDIX G

CONDITIONS FOR PROVISION OF EVALUATION REPORT TO INTERESTED PARTIES

A report on the evaluation of an accreditation body, carried out on behalf of the APLAC MRA Council, shall not be published in the public domain. An accreditation body may, however, choose to make the full report available to its interested parties under the conditions detailed in points 1 to 4 below.

Adherence to these conditions for provision of the evaluation report to interested parties will be examined at each evaluation and the evaluation team will report on that adherence in its report.

1. The evaluation report shall not be made available until after it has been formally considered by the APLAC MRA Council.
2. The full evaluation report (including the accreditation body's responses to the findings) and the MRA Council resolution arising from the consideration of the report shall be provided collectively.
3. The report and resolution (point 2 above) shall be provided to individuals or individual organisations with an appropriate statement as to the confidential nature of the information, i.e. the information shall remain confidential to the accreditation body and the recipient.
4. Where there is joint evaluation between regions, the evaluation report shall not be published unless there is agreement by all the relevant regions and the accreditation body.