



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

PURPOSE

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;
- medical testing laboratories;
- inspection bodies;
- reference material producers (RMPs); and/or
- proficiency testing providers (PTPs).

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 Full member or an accreditation body from outside of the APLAC region.

This document should be read in conjunction with the following APLAC MR documents:

- APLAC MR 008: APLAC MRA Council – Rules for Operation
- APLAC MR 011: A Guide for APLAC Evaluation Teams for the Planning and Conduct of Evaluations

AUTHORSHIP

This document is produced by the APLAC Mutual Recognition Arrangement Council.

OFFICIAL LANGUAGE

The text may be translated into other languages as required. The English language version is the official version.

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PART 1: GENERAL

0 DEFINITIONS

- 0.1 **Accreditation body (AB):** an authoritative body that operates an accreditation system for one or more types of conformity assessment 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, representing different economies, whose purpose is to develop and maintain an MRA.
- 0.5 **APLAC MRA group:** the accreditation bodies that are signatories to the APLAC MRA.
- 0.6 **Accredited organisation:** a calibration laboratory, testing laboratory, inspection body, reference material producer or proficiency testing provider accredited by an accreditation body.
- 0.7 **Applicant body:** APLAC Full Member that applies to become a signatory to the APLAC 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 of comparisons of tests, calibrations & inspections between laboratories/inspection bodies and used by accreditation bodies to assess performance, including proficiency tests (refer to ISO/IEC 17043 *Conformity assessment – General requirements for proficiency testing*), inter-laboratory comparisons and measurement audits conducted by Regional Groups, accreditation bodies, commercial organisations or other providers (see ILAC P9).
- 0.9 **ISO/IEC Standard:** an ISO/IEC standard, guide or technical report related to accreditation and conformity assessment.
- 0.10 **Peer evaluation:** a structured process of evaluation of an accreditation body against the specified requirements by representatives of other accreditation bodies.
- 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:** observation by an evaluation team of an accreditation body’s assessment of a conformity assessment body’s competence. (It may also include observing the accreditation body’s staff preparing for an assessment and dealing with assessment reports.)

- 0.14 **Nonconformity:** a 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.
- 0.15 **Concern:** a finding where the accreditation body's practice may develop into a Nonconformity.
- 0.16 **Comment:** a finding about documents or the accreditation body's practices with a potential for 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).
- 1.2 When used to evaluate non-APLAC members from outside the APLAC region, the same criteria and procedures in this document, other than section 3.4 of this document and section 3.5 of APLAC MR 008, 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 is to establish confidence in the endorsed reports and certificates (i.e. reports and certificates containing the accreditation body's accreditation symbol) issued by its accredited conformity assessment bodies. The evaluation focuses on how the applicant body ensures the technical competence of its accredited conformity assessment bodies.
- 2.2 In order to achieve this objective, the evaluation team does the following:
 - 2.2.1 An initial appraisal of the applicant body's documented policies and procedures as set out in its quality manual (by whatever name) and associated documentation. This appraisal is done against the relevant ISO/IEC standards, IAF/ILAC and ILAC documents (see section 3.1), and APLAC MRA supplementary requirements.
 - 2.2.2 An on-site evaluation of the implementation of the policies and procedures.
- 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 accreditation bodies. 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 are to 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 accreditation and 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 fulfil the requirements for a single accreditation body as stated in Section 2 of IAF/ILAC A2 and in IAF/ILAC A5.

3.1.2 An applicant body shall ensure its accredited conformity assessment bodies fulfil the following criteria:

- For calibration laboratories: ISO/IEC 17025;
- For testing laboratories: ISO/IEC 17025;
- For medical testing laboratories: ISO 15189;
- For inspection bodies: ISO/IEC 17020;
- For reference material producers (RMP): ISO Guide 34 (until November 2019), ISO 17034;
- For proficiency testing providers (PTP): ISO/IEC 17043.

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 as indicated:

- All CAB accreditation: ILAC P5, ILAC P8, ILAC P9, ILAC P10
- PTP accreditation: ILAC P13
- Calibration laboratory accreditation: ILAC P14
- Inspection body accreditation: ILAC P15

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, the requirement to have completed a full cycle through to reassessment may not necessarily be applied to the requested scope extension. Each case will be considered by the APLAC MRA Council on an individual basis.

3.2.3 Demonstrate that its accredited conformity assessment bodies 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 (the APLAC MRA text);
- 3.2.5 For RMP applicants and PTP applicants, either already be a signatory to the APLAC MRA for testing or calibration, or be applying for testing or calibration at the same time. When the applicant applies to be a signatory for testing or calibration and RMP or PTP at the same time, signatory status for RMP or PTP will be granted only after signatory status has been granted for testing or calibration, or at the same time as signatory status for testing or calibration is granted.

3.3 Proficiency Testing Activity

- 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 technical competence of its accredited laboratories, and to demonstrate the applicant body's ability to take corrective action when 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

- 3.4.1 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.

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 accommodation and all transportation directly related to the evaluation.
 - 4.1.1 Accommodation costs are for those days directly related to the on-site evaluation activities. Transportation costs are those from the team members' home city to the applicant body's home city and return. Should members of the evaluation team wish to lengthen their stay for other business or personal reasons, or to travel to other destinations en-route to or from the evaluation for reasons not related to the evaluation, the additional costs are to be met by the team member.

- 4.1.2 The applicant body shall pay for meals or parts of the meals, within reasonable limitations.
- 4.1.3 Transportation expenses include airfares, taxi fares, costs for the use of privately owned vehicles(including parking), train fares, or the costs associated with other means of travel for both inter-country travel and travel within the economy.
- 4.1.4 Any other costs shall be paid by the organisations providing the evaluators.
- 4.2 Prior to any incurred expenses, the evaluation team leader shall contact the applicant body to discuss expense expectations, considerations and reimbursement protocol.
- 4.3 The evaluation team may consist of evaluators and technical experts. When an evaluator or technical expert from outside the APLAC region is included on the team, the APLAC Board of Management shall determine whether APLAC itself should pay for inter-country travel costs.
- 4.4 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 witnessing of on-site assessments done by the applicant body.
- 4.5 If the applicant body requests that the evaluation emphasise certain areas of its accreditation activities (see section 15.2), and such emphasis requires extra evaluation activities, the applicant body shall bear all the extra costs involved. Extra costs would typically include the cost of the extra time of the evaluators for the evaluation, report and follow-up, and additional accommodation, subsistence and travelling expenses, and related sundry costs.
- 4.6 The evaluators' time is donated at no charge to the applicant body.
- 4.7 An estimate of inter-country travel expenses and details of invoicing procedures should be agreed in advance between the applicant body and the individual evaluators.
- 4.8 The applicant body shall pay for economy class airfare unless other arrangements are agreed in advance.
- 4.9 Observers shall pay all their own costs.
- 4.10 Evaluators and the applicant body shall cooperate by timely submission of invoices and timely reimbursement.

5 CONFIDENTIALITY AND IMPARTIALITY

- 5.1 All 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 conformity assessment bodies visited.

- 5.2 The evaluation team members and observers shall securely dispose of all documents that have been provided to them by the applicant body when it is determined there is no further need to maintain the documents.
- 5.3 Members of evaluation teams shall sign the MR 001.1 Declaration of Confidentiality and Impartiality form. Those observers who observe all of the evaluation activities including the closed sessions (or parts thereof) of the evaluation team, shall also sign this form. The signed form shall be attached to the final evaluation report.

The applicant body is responsible for the confidentiality requirements placed upon any observers who observe only the open sessions of the evaluation i.e. those where the team is interacting with the accreditation body.

- 5.4 The Chair of the MRA Council shall ensure that all applications for MRA signatory status are handled in an expeditious and non-discriminatory manner, and that the evaluation process is implemented in accordance with Sections 3, 4 and 5 of APLAC MR 008, and 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 Unless otherwise stated, any changes to this document apply from the date of issue. If a different implementation date applies, this date shall be stated in the amended document.

PART 2: THE MRA PROCESS

7 APPLICATION

Within the APLAC membership, applications can be lodged only by APLAC Full members, using APLAC MR 003. An Associate member is not eligible to apply.

8 EVALUATION TEAM LEADER ROLE & RESPONSIBILITIES

An evaluation team leader shall be appointed in accordance with MR008, Section 4.

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.

The evaluation team leader shall organise and conduct the evaluation in accordance with the procedures set out in Part 3 of this document. The team leader, in conjunction with the MRA Council and APLAC Secretariat, shall use the Evaluation Control Record (ECR) to record key decisions and authorisation throughout the process. After completing the process, the team leader shall send the evaluation report, the applicant body's corrective action and response report (accompanied by all supporting documentation), the team's recommendation, a list of the names of the conformity assessment bodies whose assessments were witnessed, completed Evaluator and Technical Expert Performance Logs, and the completed Evaluation Control Record (ECR) (six-part package) to the APLAC Secretariat in accordance with the MR 001.2 Evaluation Control Record (ECR). The list of CABs whose assessments were witnessed 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. The supporting documentation shall not be sent to the MRA Council but a copy shall be available at the MRA Council meeting for review if necessary.

9 DELAY IN THE EVALUATION PROCESS

Please see APLAC MR 008, Section 5.

10 MAINTENANCE OF THE APLAC MUTUAL RECOGNITION ARRANGEMENT

10.1 Notification of Change

See also Section 14 of the APLAC Quality Manual.

- 10.1.1 As required by the APLAC MRA, each signatory shall ensure that all of the other signatories are informed (via the APLAC Secretariat), in writing, of any significant changes in status and/or operating practices. The following information shall be provided to the APLAC Secretariat as soon as possible after the change(s), together with 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:
- (a) Details of any change in the name or legal or corporate status of the accreditation body or its parent organisation; details of any changes in the accreditation body's relationship with government;
 - (b) Details of any changes to contact details including changes to designated representatives (or Alternates in the case of the MRA Council) to the APLAC General Assembly and APLAC MRA Council; changes of address and contact details;
 - (c) 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;
 - (d) Details of any significant changes in key senior staff and the organisational structure of the accreditation body or its parent organisation;

- (e) Significant changes in the mode of operation of the system and in particular in the accreditation criteria and procedures used to assess organisations (except where such changes result from new ISO, ILAC and/or APLAC requirements and would otherwise be known to all signatories);
- (f) Details of the use of a sub-contracted organisation(s) to do assessments, either routinely or from time-to-time;
- (g) Any other changes that significantly affect the competence or credibility of the accreditation process.

10.1.2 When a notification of such changes is received, the APLAC Secretariat shall inform the APLAC MRA Council Chair of the changes, who shall review the changes and decide if further information needs to be provided by the accreditation body.

10.1.3 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 the 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.

10.1.4 After the completion of 10.1.2 and, if necessary, 10.1.3, the APLAC MRA Council Chair shall decide whether the changes need to be circulated to all signatories along with the decision of the Chair (i.e. no further action required, consideration at the next MRA Council meeting) and if appropriate, a copy of the report from the review team. Significant changes are forwarded to all signatories.

10.1.5 If the changes notified by the accreditation body are significant or if the review (10.1.3) finds significant nonconformities, the APLAC MRA Council may consider the need to suspend or withdraw the accreditation body's MRA signatory status.

10.2 Monitoring and Re-evaluation of MRA Signatories

- 10.2.1 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.
- 10.2.2 A re-evaluation shall take place at a shorter interval should there be due cause, such as notification of significant changes (see section 10.1.1). 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.
- 10.2.3 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 at the applicant body and in its documentation, 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 conformity assessment bodies continue to operate in compliance with the relevant ISO/(IEC) standards.

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

If a signatory to the APLAC MRA wishes to extend its scope of recognition (testing, ISO 15189, calibration, inspection, RMP and/or PTP) in the MRA, the same procedures described in Parts 2 and 3 of this document shall apply, in general. For 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.

PART 3: THE EVALUATION PROCESS

12 COOPERATION BY APPLICANT BODY

- 12.1 The evaluation team leader shall endeavour to solicit that cooperation from the applicant body that is necessary for the conduct of an effective evaluation.
- 12.2 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 by the applicant body 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, appendix 2);

- (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 conformity assessment 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;
 - vii. Providing individual evaluation team members with information on visa requirements and appropriate letters of invitation, as necessary, and 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) Timely payment of all costs as specified in section 4 of this document;
- (d) Making an effort to build consensus with the evaluation team 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.

13 DOCUMENT REVIEW

- 13.1 The evaluation team leader shall review the information and documentation provided by the applicant body (referenced in section 12.2(a)) within 90 days of receipt. For re-evaluations, document reviews shall be conducted as soon as practicable following receipt of the information and documentation from the accreditation body.

- 13.2 MR 007 may be used by the team leader to record the findings of the review. APLAC MR 001.2 shall be used to record completion of this review and to document any significant departures from the requirements.
- 13.3 Where the document review on an applicant body indicates significant departures from the criteria for MRA signatory status, the team leader shall advise the MRA Council Chair who shall determine whether a pre-evaluation visit is required. Where the document review on a signatory body indicates significant departures from the criteria, the team leader shall advise the MRA Council Chair who shall determine whether or not the evaluation should proceed as scheduled.

14 PRE-EVALUATION VISIT

- 14.1 A pre-evaluation visit may be required as a result of the document review or may be requested by an applicant body. Findings from the pre-evaluation visit shall be used to determine whether the applicant body is ready for a full evaluation. A pre-evaluation visit shall not pre-empt the evaluation.
- 14.2 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 APLAC Secretariat on behalf of the MRA Council.

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

- 14.3 A provisional date for the pre-evaluation visit shall be agreed upon by the applicant and the team leader, subject to supply of the required documentation at least three months prior to the visit. A pre-evaluation visit should, in most cases, take 2 to 3 days. The duration may be varied by agreement between the pre-evaluation team leader and the applicant body.
- 14.4 After examination of the documentation by the pre-evaluation team, 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. A typical program for a pre-evaluation visit is given in IAF/ILAC-A2 Annex 2, and should include the following:
- (a) The pre-evaluation team leader should discuss with the head of the applicant body its participation in APLAC and other regional and international accreditation activities. The pre-evaluation team should review the application documentation with the applicant and provide all necessary information about APLAC MRA requirements and about the full evaluation process.
 - (b) The team should discuss the management system's documented policies and procedures (as reviewed prior to the pre-evaluation visit) and their implementation, and make recommendations, where necessary, on actions to be taken before a full evaluation could be done. The pre-evaluation team shall also indicate the recommended team composition and duration expected for the full evaluation.

- (c) The team should discuss the structure of the applicant accreditation body; its legal identification, any related bodies and how it addresses potential issues of impartiality and conflicts of interest. This may include discussion on the applicant's relationships with regulators and other specifiers (e.g. recognition, possible competition).
- (d) The applicant's access to technical expertise should also be discussed and may include:
- Job descriptions and backgrounds of top management, organisation charts;
 - Assessor records and documents;
 - Sampling of CAB assessment records, including the decision-making process.
- (e) Access to and participation levels in proficiency testing programmes should also be established.
- (f) A part of the pre-evaluation shall be an assessment of the existence of laboratories providing measurement traceability to the highest level in the economy or region. This is especially necessary where the measurement traceability schedules are not clear and where participation in CIPM activities by the domestic national measurement institute (NMI) is not fully known. In some cases it may be necessary to visit the NMI.
- (g) During the pre-evaluation visit, the pre-evaluation team may also visit one or two accredited conformity assessment bodies to gain an initial impression of the operation of the accreditation system and of the technical competence of the accredited conformity assessment bodies. These visits may be during the applicant's assessment of the CAB, but visits should not, however, be represented as the formal witnessing of an assessment.
- 14.5 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.
- The report shall, as a minimum, contain the following information:
- (a) Main nonconformities found, referenced to the relevant clauses of ISO/IEC 17011 and/or other APLAC MRA criteria documents;
 - (b) The degree to which the applicant body fulfils the relevant criteria;
 - (c) A recommendation on whether to continue, to suspend or to withdraw the evaluation process;
 - (d) A recommendation on the type and number of team members necessary, and the estimated duration of any proposed evaluation visit;
 - (e) The conditions to be fulfilled before the evaluation visit is conducted.
- 14.6 The applicant body shall be given an opportunity to comment on any factual errors in the report.

- 14.7 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 body 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.

- 14.8 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 his/her delegate if the team leader is the Chair of the MRA Council), make a decision to proceed with the initial evaluation.
- 14.9 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.
- 14.10 The applicant body may appeal in writing to the Chair of the MRA Council against any decision to suspend or withdraw the evaluation. The MRA Council, during a meeting or by correspondence, shall rule on whether to uphold the appeal and to thus proceed with the full evaluation.

15 COMPOSITION OF EVALUATION TEAM

- 15.1 For a 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 APLAC Secretariat on behalf of 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. In accordance with the Evaluation Control Record (ECR), the MRA Council Chair shall record the approval of the team composition and the APLAC Secretariat shall be informed.

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

Note 2: Except where an evaluation is solely for the purpose of an application for extension of scope to the MRA, at least one provisional evaluator is expected to be included as a team member.

- 15.2 No team member shall be associated with any accreditation body that has provided a consultancy service to the body being evaluated during the last three years.
- 15.3 The team chosen shall consist of representatives from a cross-section of APLAC member accreditation bodies and, if appropriate, representatives of other recognised contract of cooperation partners or ILAC-recognised regional groups. The inclusion of more than one team member from a single economy should be avoided.
- 15.4 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.

- 15.5 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 shall be familiar with the application of proficiency testing as an assessment tool. For RMP and PTP 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 usually a provisional evaluator, a representative from another region, a regulator from the applicant's economy or a regulator from a third economy.
 - (e) Knowledge of the local language should be taken into account when assembling the team.

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

15.7 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 any observers (see MR 011).

Once the team members have been finalised the team leader shall, using the Evaluation Control Record (ECR), promptly advise the APLAC Secretariat of the names of the team members and their specific 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.

15.8 Once the evaluation team has been accepted by the applicant body, all significant communication (other than about logistical arrangements) between the evaluation 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.

16 PREPARATION FOR EVALUATION

16.1 The team leader shall organise 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.

- 16.2 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 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.

- 16.3 The team members shall be allocated specific tasks by the team leader prior to the evaluation.

- 16.4 The team leader shall ask the APLAC Secretariat to provide:

- (i) 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);
- (ii) Where relevant, a copy of the final 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.

The team leader shall ensure that this information and the documentation provided by the accreditation body (refer APLAC MR003, Appendix 2) is provided to the evaluation team members to allow sufficient time for team members to prepare for the evaluation. Ideally, team members should receive these documents three months prior to the evaluation.

- 16.5 The following aspects shall be taken into account when planning the evaluation:

- (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.

- 16.6 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. Careful consideration shall be given to the selection of accreditation assessments of CABs to be witnessed. Ideally, for each of the scopes of recognition in the MRA (testing, calibration, ISO 15189, inspection, RMP and/or PTP accreditation) being sought by the applicant body, the evaluation team shall witness at least one initial assessment, or reassessment, or on-site assessment involving a significant component of technical assessment by a technical assessor or technical expert. The key objective is that the evaluation team witness the performance of technical assessors as much as possible. The remainder of the witnessing schedule can be filled with assessments of other types.

Other factors that may impact on the number and selection of witnessed assessments include:

- The relative number of accreditations within each conformity assessment type or sub-fields of conformity assessment type;
 - Witnessed CAB assessment from the last evaluation;
 - Geographical distribution of accredited CABs;
 - Cross frontier accreditation policies and procedures.
- 16.7 The evaluation team shall make provision in the visit agenda for time to prepare a summary report and a list of findings (Section 1 and Annex I of MR 009 respectively).
- 16.8 The team leader shall obtain confirmation of the arrangements listed in 12.2 (b) from the applicant body.

17 CONDUCT OF THE ON-SITE EVALUATION

17.1 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.

17.2 Opening Meeting

An opening meeting shall be held with the senior management of the applicant body to confirm the objectives of the visit, the criteria to be used, the visit agenda, and the arrangements for reporting the observations arising from the on-site visit. After this meeting, the team will usually split up so that each member can do those evaluation tasks assigned to her/him.

17.3 On-site Evaluation

The evaluation team shall do an evaluation of the operational procedures and practices of the applicant body at its offices, and at conformity assessment bodies undergoing assessment/re-assessment and surveillance, placing emphasis on the issues described in Section 2 of APLAC MR 011.

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 self-narrative provided by the accreditation body (IAF/ILAC A3) when evaluating the accreditation body's performance and when preparing the evaluation report (see APLAC MR 009).

Note 1: Witnessing of assessment activities (see APLAC MR009, Annex V) should normally 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.

17.4 Closing Meeting

- 17.4.1 A closing meeting shall be held with the senior management of the applicant body to present the findings from the on-site evaluation.
- 17.4.2 The team shall present the applicant body with a short summary (see Section 1 of APLAC MR 009) identifying strengths, weaknesses and conclusions, and 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.
- 17.4.3 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. Approval by the MRA Council 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.
- 17.4.4 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 impracticable, before any such decision is made.
- 17.4.5 If, for a re-evaluation of a current signatory, the findings of the evaluation are considered of a nature that the on-going competence of the accreditation body and/or its accredited CABs are in doubt and the accreditation body's ability to implement and maintain MRA signatory requirements cannot be assured, the team leader shall inform the Chair of the MRA Council within two weeks after the on-site evaluation. In consultation with the team leader the Chair of the MRA Council shall decide whether any additional action needs to be undertaken in addition to that otherwise specified in this document. For example, the evaluation report (Sections 17.1 and 17.3 below) may be required to be presented to the next MRA Council meeting irrespective of whether Section 18 below has been fully completed.

18 EVALUATION REPORT

18.1 After the visit, the team leader shall draft the final 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 and ILAC MRA supplementary requirements, when relevant, and the applicant body's own requirements.

18.2 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 the new team leader all information gathered to date in relation to the evaluation.

18.3 The applicant body shall be given the opportunity to correct any misunderstandings or errors of fact appearing in the report.

18.4 Under the conditions detailed in Appendix B, the APLAC MRA Council may permit an evaluated accreditation body to provide copies of its evaluation report to interested parties. Compliance with Appendix B shall be checked by the evaluation team at each evaluation, and details shall be included in the evaluation report.

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

19.1 Corrective Action and Response Report

The applicant body shall provide the team leader with a response to the findings that consists of:

- For Nonconformities – taking appropriate corrective action and providing the evaluation team with evidence of effective implementation. (Where the time constraints arising from the need to provide the Corrective Action and Response Report within a specified time (see paragraph below) prevent the applicant body from fully implementing the corrective action, evidence that implementation has commenced shall be provided along with a time schedule to complete full implementation.);
- For Concerns – providing the evaluation team with an appropriate action plan and time schedule for implementation;
- For Comments – the accreditation body is encouraged to respond to comments.

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 the applicant body within one month of receiving the response whether the corrective actions are acceptable.

Note 2: Preferably, the accreditation body's response should be inserted as text against each finding presented in table format in the report, with attachments of supporting evidence of corrective action as appropriate.

19.2 Evaluation Team's Recommendation to APLAC MRA Council

19.2.1 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/or 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/or 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, or that a follow-up visit is recommended, the report shall include the reasons for this recommendation.

19.2.2 During the process of 18.1 and 18.2.1, the team leader shall consult her/his team members as necessary. If there is a disagreement within the evaluation team or between the evaluation team and the applicant body, all parties should describe their opinions in the report.

19.2.3 In accordance with the MR 001.2 Evaluation Control Record (ECR) , the team leader shall send the following documents to the APLAC Secretariat as soon as practicable after the satisfactory close-out of findings but at least one month prior to the next MRA Council meeting:

- (i) The evaluation report using the report format, APLAC MR 009. This shall be as both:
 - A hard copy and include the signed originals of the relevant signature pages (Section 1: Summary of Findings and Appendix VIII: Declaration of Confidentiality and Impartiality);
 - An electronic copy (MS Word), which may include scanned copies of the signed original signature pages;

- (ii) The applicant body's corrective action and response report (accompanied by all supporting documentation) and the team's evaluation of corrective action and response report, including findings from any follow-up visits (electronic copies only);
- (iii) The evaluation team's letter of recommendation to the APLAC MRA Council. This shall be provided as both:
 - A hard copy signed original;
 - An scanned electronic copy of the signed original;
- (iv) A list of the names of the conformity assessment bodies whose assessments were witnessed as part of the evaluation (electronic copy only);
- (v) The completed Evaluator and Technical Expert Performance Logs (electronic copies only);
- (vi) The completed Evaluation Control Record (ECR) (electronic copy only).

19.3 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.

The applicant body should also be represented at the APLAC MRA Council meeting at which the (re)-evaluation report is considered.

20 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 MR 004.2 MRA Evaluator and Technical Expert Performance Log or MR 004.3 MRA Evaluation Team Leader Performance Log as appropriate.

APPENDIX A

ROLE AND RESPONSIBILITIES OF EVALUATION TEAM

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

- A1. 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 conformity assessment bodies.
 - (b) Verify whether the technical competence of the accredited conformity assessment body is appropriate to its scope of accreditation.
- A2. The evaluation team leader shall, in addition to being responsible 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.
- A3. 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 B

**CONDITIONS FOR PROVISION OF AN 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.

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 a joint evaluation between regions, the evaluation report shall not be provided to any interested party unless there is agreement by all the relevant regions and the accreditation body.