



Asia Pacific Laboratory Accreditation Cooperation

APLAC MRA COUNCIL – RULES FOR OPERATION

PURPOSE

When APLAC was established, section 4 of the APLAC Memorandum of Understanding mandated the establishment of a standing committee to coordinate APLAC's activities in respect of mutual recognition arrangements among Members. This standing committee is known as the APLAC MRA Council. This procedure sets out the rules for the operation of the MRA Council. It should be read in conjunction with part 2 of APLAC MR 001.

This document replaces section 9 of APLAC SEC 004 (*APLAC Rules of Procedure*) that has been superseded by the APLAC Constitution (APLAC SEC 052).

AUTHORSHIP

This publication has been written by the APLAC MRA 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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1. MEMBERSHIP

- 1.1 Each Full Member of APLAC shall appoint a delegate to the APLAC Mutual Recognition Council (herein after referred to as “the MRA Council”) with full voting rights. Each Full Member may also appoint an alternate delegate.

While each Full Member has full voting rights for general deliberations of the MRA Council, only those Full Members that are also signatories to the APLAC Mutual Recognition Arrangement (MRA) are eligible to vote on the acceptance of new signatories and the continuation of signatory status for current signatories, other than for themselves.

- 1.2 The General Assembly shall elect the designated representative of one of its Full Members to act as the Chair of the MRA Council. A Secretary shall be appointed by the Chair with the approval of a majority of Council members. The APLAC Secretary may also be the Secretary for the MRA Council.
- 1.3 All attendees at each MRA Council meeting shall sign a declaration of confidentiality. This shall form an attachment to the Minutes of the meeting.
- 1.4 At the start of each meeting the Chair shall ask delegates to declare any potential conflict of interest with any agenda item. Any declared potential conflict of interest shall be recorded in the Minutes of the meeting.

2. OPERATIONS

- 2.1 The MRA Council may appoint a sub-committee to coordinate the evaluation of accreditation bodies wishing to join the APLAC MRA. While appointed by the Council, any sub-committee shall operate under APLAC’s rules for such committees. The APLAC MRA Council shall also operate under these rules.
- 2.2 An accreditation body participating in APLAC as a Full Member and wishing to become a signatory to the APLAC MRA shall submit an application, in accordance with APLAC MR 001, clause 7.1, on the application form APLAC MR 003. The APLAC MRA Council shall arrange for an evaluation of the activities of the accreditation body by an appropriate evaluation team.
- 2.3 The activities of an accreditation body that is a signatory to the APLAC MRA shall be re-evaluated at regular intervals.
- 2.4 The report of the evaluation or re-evaluation team, and the team’s recommendation to the MRA Council are provided to the Council delegates by the Secretariat for review prior to the MRA Council meeting at which the report is to be considered. .

NOTE 1: APLAC MR 001, clause 22.2.3 details the information to be provided to the APLAC Secretariat by the evaluation team leader on completion of the evaluation. It includes information in support of the report, typically that provided by the evaluated accreditation body in support of its response to the findings. This supporting information is not routinely provided to MRA Council delegates but can be requested from the Secretariat.

NOTE 2: MRA Council delegates may choose to use the evaluation report review checklist, given in Appendix 1, to assist in their review of the report. Use is, however, optional.

- 2.5 The team leader for an initial evaluation shall attend the APLAC MRA Council meeting to present the evaluation report and participate in the discussions on the report. Under normal circumstances the team leader shall also attend the APLAC MRA Council meeting to present the report on a re-evaluation, although attendance via teleconference may be considered as an option.

For those team leaders who do not normally attend APLAC MRA Council meetings, APLAC will provide the following funding for their attendance at an MRA Council meeting that considers a report on an evaluation for which they were the team leader: return (discount) economy airfare; 3 nights accommodation; half of the registration fee (applicable for end of year meetings only).

- 2.6 The APLAC MRA Council shall decide on the entry of an accreditation body into the APLAC MRA or whether or not it may remain in the APLAC MRA, subject to the appeal provisions referred to below. Three-fourths of the signatories to the MRA must cast a vote for the ballot to be valid. Abstention votes are counted as valid votes. A positive vote by three-fourths of the sum of those voting “yes” and “no” is required for the ballot to be accepted.

If the MRA Council resolves to suspend MRA signatory recognition of an accreditation body it shall decide also on the continued recognition of accredited conformity assessment bodies taking into account the reasons for the suspension.

A suspension of APLAC MRA signatory status shall only be lifted after a follow-up visit, to establish that appropriate and effective corrective action has been taken, and subsequent report and recommendation from the evaluation team to the MRA Council.

An accreditation body whose APLAC MRA signatory status has been withdrawn and wishes to regain that signatory status shall follow the same process as an applicant, as described in APLAC MR 001.

When the MRA Council Chair was the team leader for the evaluation under consideration or when the evaluation of the MRA Council Chair’s organisation is being considered, a deputy shall be appointed to chair that part of the MRA Council meeting, usually the APLAC Chair.

- 2.7 An accreditation body may appeal an APLAC MRA Council decision not to grant signatory status in the MRA, or to withdraw signatory status. In such cases, the APLAC MRA Council appeals process applies.

The APLAC MRA Council is the sole body within APLAC that makes decisions with regard to signatory status within the APLAC MRA. It is, therefore, the MRA Council that handles appeals on MRA signatory status, generally through revocation of previous resolutions and voting upon new resolutions.

The appeal shall be sent to the APLAC Secretary, in writing, within 30 days of the notification of the decision of the MRA Council. The appeal shall include:

- (i) the decision (or part thereof) of the MRA Council being appealed;
- (ii) details of the basis of the accreditation body's appeal;
- (iii) the remedy sought, including actions requested of the MRA Council and requested time frames in which such actions should be done;
- (iv) the name and title of the executive or official who will represent the accreditation body and any other person(s) who will accompany the executive or official at the appeals process.

The Chair of the MRA Council shall review the written appeal to establish its validity in accordance with the above, and whether the requested actions and timeframes are practical and achievable. The Chair of the MRA Council may negotiate with the appellant to define a mutually satisfactory process to consider the remedy sought.

When an appeal is lodged between meetings of the MRA Council, the MRA Council Chair shall generally appoint an ad-hoc sub-committee of the Council to consider the appeal and report to the next MRA Council meeting with a recommendation on a decision. The sub-committee shall consist of at least 3 MRA Council delegates who are lead evaluators or experienced evaluators and who were not part of the last evaluation team to the appellant accreditation body.

When an appeal is lodged during the meeting of the MRA Council in which the decision in dispute was made, and the appellant requests the appeal be considered at that meeting, this request shall be considered in the above review by the Chair of the MRA Council. Should such an arrangement be practical and achievable, the consideration of the appeal shall be by the full MRA Council in attendance at the meeting.

Upon receiving the report and recommendation from the ad-hoc sub-committee, the MRA Council shall decide whether to uphold the appeal or otherwise, by means of a vote in accordance with section 2.6 above. Such votes shall be confined to decisions "on the entry of an accreditation body into the APLAC MRA or whether or not it may remain in the APLAC MRA". The wording of a resolution for voting shall be confined to such decisions.

The APLAC Secretary shall promptly advise the appellant in writing of the outcome of the APLAC MRA Council resolution.

Records as listed in the APLAC Quality Manual, section 10.2.3 shall be retained.

- 2.8 In the event that the APLAC MRA Council suspends or withdraws the MRA signatory recognition of an accreditation body, the MRA Council Chair shall promptly advise the accreditation body of this, and provide a detailed explanation of the reasons for the decision. The MRA Council Chair shall also advise whether or not the Council has also resolved to suspend recognition by the other signatories to the MRA of the equivalence of endorsed reports and certificates issued by accredited conformity assessment bodies, including prior to addressing any appeals procedure (see 2.7 above). Any such suspension of recognition shall not be considered as a breach of APLAC MRA obligations (APLAC MR 002, clause 1(ii) of Arrangement Text).

The change in signatory status shall apply from the date of the APLAC MRA Council resolution on the matter, unless otherwise decided as part of the MRA Council resolution.

The APLAC Secretary shall promptly advise other signatories to the APLAC MRA and the ILAC Secretary of the change in MRA signatory status of the accreditation body. The accreditation body's name shall be removed from the list of APLAC MRA signatories, including on the APLAC web site. An announcement on the change in signatory status shall also be placed on the web site.

The other signatories to the APLAC MRA should advise all relevant organisations in their own economy of the change in APLAC MRA signatory status of the accreditation body.

The accreditation body itself shall advise its applicant and accredited conformity assessment bodies, and all relevant organisations in its own economy of its change in APLAC MRA signatory status, and of the subsequent impact on the acceptance of its accreditations by APLAC MRA signatories.

- 2.9 The chair of the MRA Council may invite appropriate observers to attend meetings of the Council.
- 2.10 The APLAC MRA Council shall report to each meeting of the APLAC General Assembly and the APLAC Board of Management on its evaluation and re-evaluation activities. The MRA Council shall keep the APLAC Secretary informed about its activities by providing the Secretary with agendas and records of meetings, including summaries of conclusions of meetings conducted using electronic media.
- 2.11 In the event of a dispute between signatories or with applicants to the APLAC MRA, the provisions of the MRA apply. The General Assembly may, however, discuss such matters and offer advice to the MRA Council.

APPENDIX 1: APLAC EVALUATION REPORT REVIEW CHECKLIST

1. INTRODUCTION

The MRA Council begins an evaluation by assigning a team leader. The team leader then forms the evaluation team in consultation with the MRA Council Chair. When the evaluation has been completed, the team will provide its report on the evaluation to the MRA Council Chair and Secretariat. The report will be distributed to all MRA Council members for review and discussion during the MRA Council meeting before a decision is made on the team's recommendations.

Review of an evaluation report by MRA Council delegates is an essential element of the APLAC Mutual Recognition Arrangement process. It ensures the reliability of the evaluation results on which decisions on admitting and affirming signatories and also provides information to substantiate the surveillance measures adopted by the APLAC MRA Council to monitor the performance of MRA signatories. The review also contributes to harmonisation of evaluations conducted by different teams and therefore, indirectly, to harmonisation of the standards of accreditations granted by the APLAC MRA signatories. During the review process, ambiguity in the recognition criteria can also be raised for discussion to achieve harmonisation. The checklist in this Appendix is designed to aid the review process through a series of questions that MRA Council delegates should ask when reviewing an evaluation report. Use of the checklist for the review process is, however, not mandatory.

2. ROLE OF THE REVIEW

The objectives of the review are to establish that

- a. the findings are reliable;
- b. the actions taken by the AB to address the findings are effective;
- c. the conclusions of the evaluation team are well substantiated by the findings; and
- d. the recommendations of the team are appropriate to the conclusions.

MRA Council delegates should study the evaluation report carefully before attending the MRA Council meeting in which the evaluation report is to be discussed. Consideration should also be given to any precedents (passed as MRA Council resolutions) set by the MRA Council in similar cases.

Should any ambiguities in interpreting the MRA criteria are brought to light through the evaluation or the review process, they should be raised for discussion and resolution in the MRA Council. In most cases, such ambiguities should not count against the accreditation body being evaluated.

If any potential inadequacy in the evidence and rationale supporting the team's recommendations is identified, a reviewer should seek clarification from the evaluation team and the AB during the MRA Council meeting. When raising questions, care should be taken to ensure that the question is well constructed in the sense that the information requested is clearly expressed. Discussions outside of a MRA Council meeting among a reviewer, the evaluation team and the evaluated AB are not permitted. As the role of an MRA Council delegate as a reviewer is to ensure that the evaluation has been properly conducted and that the conclusions and recommendations are well substantiated by the findings, (s)he should not form her/his own judgement based on the findings given in the evaluation report. Where the findings, conclusions and recommendations are properly made based on sufficient evidence

and justification, MRA Council delegates should respect the judgement made by the evaluation team and should not amend the findings or the recommendations because of an individual preference.

3. REVIEW PROCEDURE

The review procedure consists of four sequential steps. The questions included in the corresponding sections of the table in the Appendix are designed to provide assistance in carrying out these steps.

Step 1: Establishing whether the findings are reliable

The MRA Council delegate should start by reading the evaluation report to confirm that it contains sufficient evidence that the evaluation had been conducted in accordance with the principles laid out in APLAC MR 001 and that the findings are reliable.

Step 2: Establishing whether the actions taken by the AB to address the findings are effective

Once the MRA Council delegate is satisfied with the reliability of the findings, the actions taken by the AB (where required) should be analysed to confirm their effectiveness in addressing the issues identified.

Step 3: Establishing whether the conclusions are substantiated by the findings

The overall conclusions made by the evaluation team on whether or not the AB meets (fully or otherwise) the APLAC MRA criteria are given in section 1 (Summary of Findings) of the evaluation report, and in the letter of recommendation to the MRA Council Chair written by the team leader. Based on the analysis in Step 2, the MRA Council delegate should confirm that the conclusions are supported by the evidence.

Step 4: Establishing whether the team's recommendations are supported by the conclusions

The evaluation team makes recommendations to the MRA Council on whether signatory status of the AB in the MRA should be granted or continued, the interval before the next evaluation, and any other follow-up actions. The MRA Council delegate should establish whether such recommendations are supported by the conclusions of the evaluation team, as reviewed in Step 3.

Evaluation Report Review Checklist

Activities	Yes/No	Remark
<i>Step 1. Establishing whether the findings are reliable</i>		
With reference to the evaluation schedule, was sufficient time allocated to different evaluation activities (team meetings, AB office evaluation, assessment witnessing, exit briefings)?		
Was the number and type of assessments witnessed appropriate to the range of accreditation activities covered by the AB's (proposed) MRA recognition?		
Were the major and/or critical fields of activity subject to appropriate witnessing?		
Does the evaluation report (primarily Sections 4 and 5) contain sufficient evidence that the evaluation team has conducted an evaluation of the AB against the criteria to sufficient depth?		
Were the findings (Non-conformities and Concerns) detailed in Appendix 1 of the evaluation report supported by objective evidence (detailed either with the finding or in the main body of the report)?		
Based on the evidence, <ol style="list-style-type: none"> 1. Were the findings correctly classified in accordance with the definitions in APLAC MR 001? 2. Were they correctly referenced against the MRA criteria? 3. Were these references valid? 4. Where necessary, was the interpretation of criteria adequately explained? 		

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Activities	Yes/No	Remark
<i>Step 2. Establishing whether the actions taken by the AB to address the findings are effective</i>		
Has the AB accepted the findings?		
In the case of nonconformities, Has the AB identified the root cause? Has the AB fully addressed the nonconformity, or as fully as is possible?		
In cases where time is required to fully address the root causes of nonconformities: Has sufficient progress been made? Has a reasonable timeframe for completion been defined?.		
In the case of concerns Has the AB identified the root cause? Has the AB defined a reasonable action plan to address the identified issue?		
Has the evaluation team evaluated the corrective actions and response from the AB in sufficient detail?.		
Is the outcome of this examination (as conveyed to the AB) acceptable? When drawing conclusions on the acceptability of the outcome, the MRA Council delegate should recognise that (s)he may not have full knowledge of the supporting evidence provided by the AB. The MRA Council delegate should therefore seek clarification during the Council meeting before drawing a conclusion.		
<i>Step 3. Establishing whether the conclusions are substantiated by the findings</i>		
Has the report in its entirety provided sufficient evidence to support the conclusions and recommendations of the team? The scope and nature of any or all of the findings and the corrective actions taken by the AB should be taken into consideration.		
Has the evaluation provided adequate evidence that the CABs accredited by the AB are technically competent and capable of being recognised under the MRA?		

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Activities	Yes/No	Remark
<i>Step 4. Establishing whether the team's recommendations are substantiated by the conclusions</i>		
Is the recommendation of the team with regard to entry/continuation in the MRA consistent with the conclusions made by the team and acceptable to the MRA Council?		
<p>Does the recommendation of the team with regard to the re-evaluation time frame reflect the current status of the AB? Issues to consider include:</p> <ul style="list-style-type: none"> • The nature of the findings from the evaluation and the status of their closure. • The maturity of the AB's accreditation programs (proposed to be) covered by the MRA. • The relative stability of the AB • Whether the AB and its accredited CABs pose a risk to the MRA. • The precedents established by the Council when deliberating similar cases in the past. 		