



Asia Pacific Laboratory Accreditation Cooperation

APLAC MRA COUNCIL – RULES FOR ITS OPERATION

PURPOSE

This procedure sets out the rules for the operation of the APLAC MRA Council. It should be read in conjunction with Part 2 of APLAC MR 001.

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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FURTHER INFORMATION

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1. MEMBERSHIP

- 1.1 Each Full Member of APLAC shall appoint a Delegate to the APLAC Mutual Recognition Arrangement Council (hereinafter referred to as “the MRA Council”) with full voting rights. Each Full Member may also appoint a permanent Alternate delegate who may automatically assume the full voting rights of the Delegate in his/her absence. Additional Alternate delegates (intended to be temporary appointments to cover specific MRA Council meetings when neither the Delegate nor Alternate are able to attend) may be nominated by the Delegate in writing (see also Section 8).

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 Secretariat 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, particularly those items related to evaluation reports. Any declared potential conflict of interest shall be recorded in the minutes of the meeting.

2. GENERAL

- 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 MRA Council, any sub-committee shall operate under APLAC’s rules for such committees. The 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 on the application form APLAC MR 003.
- 2.3 The APLAC MRA Council shall arrange for an evaluation of the activities of the accreditation body by an appropriate evaluation team.
- 2.4 The activities of an accreditation body that is a signatory to the APLAC MRA shall be re-evaluated at regular intervals.
- 2.5 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, Section 18.2.3 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 MR 008.1 Evaluation Report Review Checklist, to assist in their review of the report. Use is, however, optional.

- 2.6 When the MRA Council Chair was the team leader or team member for the evaluation under consideration or when the evaluation of the MRA Council Chair's organisation is being considered, the Vice Chair of the APLAC MRA Council shall chair that part of the MRA Council meeting. In cases where both the MRA Council Chair and Vice Chair were both involved in the evaluation process, or when the Vice Chair is not available to chair the meeting, the APLAC Board of Management shall appoint an acting Chair to chair that part of the meeting.
- 2.7 The Chair of the MRA Council may invite appropriate observers to attend meetings of the Council.
- 2.8 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 Secretariat informed about its activities by providing the Secretariat with agendas and records of meetings, including summaries of conclusions of meetings conducted using electronic media.
- 2.9 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

3. APPLICATION FOR APLAC MRA

- 3.1 Applications shall be made in accordance with APLAC MR 003. The application form shall be completed in English and sent to the APLAC Secretariat at secretariat@aplac.org (who shall forward copies to the APLAC Chair and the Chair of the MRA Council).
- 3.2 The APLAC Secretariat shall confirm receipt of the application on behalf of the APLAC Chair. The Secretariat shall notify members of the MRA Council of the receipt of the application.
- 3.3 The Secretariat shall inform the applicant body at the time of application of:
- (a) The current issue of APLAC MR 001; and
 - (b) Any imminent changes approved by the General Assembly but not yet included in the current issue of MR 001.

- 3.4 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. Acceptance or non-acceptance (including reasons for the latter) of the application shall be recorded in the minutes of the meeting (or in the applicant file if considered by correspondence).
- 3.5 Applications from accreditation bodies outside the APLAC region
- (a) Applications from accreditation bodies outside the APLAC region who are not APLAC Full Members shall be discussed in the APLAC General Assembly. The APLAC General Assembly shall decide 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 APLAC MR 001, Section 3.4);
 - (b) Applicant accreditation bodies who are not Full Members of APLAC shall sign a contract of cooperation with APLAC prior to the start of the evaluation process. The contract should include specific topics such as rights and obligations, technical activities, finances, and term of validity of the contract of cooperation (see APLAC MR 001, Section 3.4).
- 3.6 The APLAC Secretariat shall ensure that the applicant body is informed by correspondence of the decision of the MRA Council (or General Assembly), and, if accepted, that the evaluation will be conducted in accordance with APLAC MR 001 and the applicable sections of this document. When an application is not accepted, the applicant body shall be informed of the reason(s).
- 3.7 The applicant body shall provide two sets of documents (Set A and Set B; see APLAC MR 003, Appendix 2) to the team leader and team members at least three months prior to any planned pre-evaluation or evaluation visit. If the Set A and Set B documents are not provided three months prior to the planned visit, refer to Section 5.1.2.
- 3.8 **Emphasis to Specific Areas of AB's Scope**
- For initial evaluations and re-evaluations, the applicant body may request that the evaluation pay particular attention to 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 of the evaluation process may need special consideration so that the request can be met. The applicant body may request that stakeholders or other interested parties (such as regulators of the economy of interest) be invited to observe 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.
- This special emphasis 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 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.

4. APPOINTMENT OF THE TEAM LEADER

- 4.1 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 her/his consent. For an evaluation, the team leader shall be assigned within 60 days of the approval of the application. For a re-evaluation, the team leader shall be assigned approximately 18-24 months prior to the evaluation date specified in the relevant MRA council resolution.

The team leader shall be chosen from the list of lead evaluators prepared and kept up-to-date by the APLAC Secretariat on behalf of the MRA Council. The minimum qualifications for team leaders are 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 Section 4.4 of this document and Section 8 of APLAC MR 001.

- 4.2 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.
- 4.3 The MRA Council Chair shall inform the team leader of her/his 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 and for the provision of the finalised evaluation report to the MRA Council. The Secretariat shall issue a letter of appointment to the team leader.
- 4.4 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 of any follow-up activities, including an on-site follow-up visit;
- (f) Reporting the results of the evaluation.

5. DELAY IN THE EVALUATION PROCESS

5.1 Caused by the Applicant

- 5.1.1 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.
- 5.1.2 If the applicant body does not provide the two sets of documents, in accordance with Section 3.7, 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 date of the evaluation to the APLAC MRA Council Chair.
- 5.1.3 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.
- 5.1.4 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.
- 5.1.5 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.
- 5.1.6 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.
- 5.1.7 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.
- 5.1.8 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.

5.2 Caused by Adverse Travel Advisory

- 5.2.1 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 or change the proposed evaluation team.
- 5.2.2 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.
- 5.2.3 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.

6. EVALUATION REPORT AND EVALUATION TEAM'S RECOMMENDATION TO THE APLAC MRA COUNCIL

- 6.1 As stated in Section 17.2 of APLAC MR 001, 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.
- 6.2 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 meetings where a payment of a registration fee is required, e.g. those alongside the General Assembly).

7. DECISION MAKING

- 7.1 The APLAC Secretariat shall provide, when available from the evaluation team leader, 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 final evaluation report, letter of recommendation, and information supporting the clearance of findings (see MR 001) cannot be submitted in time to the Secretariat, the APLAC MRA Council Chair shall advise the Secretariat on appropriate action to ensure that Council members receive the final report and letter of recommendation.

- 7.2 The team leader shall present the evaluation findings to the MRA Council, and the evaluated applicant body will be invited to respond. The MRA Council delegates may then seek any clarification from either the team leader or the applicant body's delegate. Once any clarification has been given all those present from the applicant body shall be asked to leave the room. They may enter the room again once the ballot on the applicant body has been completed. After seeking any further clarification from the team leader, the MRA Council shall decide, taking into consideration the recommendations by the evaluation team:
- (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,
 - (c) The time frame for any follow-up visit and/or for the next re-evaluation; and,
 - (d) Decide on the meeting of the APLAC MRA Council to which the report on the follow-up visit and/or next evaluation shall be presented.

The team's recommendation shall be projected on screen for consideration by the MRA Council as a proposed resolution (MRA RES), and edited as appropriate during the MRA Council deliberations. The agreed edited text will be framed as a MRA Council resolution which will be voted upon by the Council in accordance with the voting rules in Section 8 below.

The MRA Council may decide to impose additional conditions for entry into or continuation in the MRA on the applicant / re-evaluated body, including the provision of additional information to be provided to the MRA Council at future meeting(s); the conduct of follow-up or surveillance visits; reducing the re-evaluation interval; and/or other conditions the MRA Council considers appropriate. Such conditions will be clearly detailed in the text of the MRA Council resolution. Reasons for the additional conditions imposed shall be part of the resolution projected on screen, communicated to the applicant body representative at the meeting and recorded in the minutes of the meeting.

- 7.3 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 actions taken by the accreditation body in relation to any significant nonconformity(ies) to suspend MRA signatory recognition (all or in part) temporarily until it is satisfied that the nonconformity(ies) has been addressed, or to withdraw MRA signatory recognition (all or in part).

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 shall 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 date of withdrawal of APLAC MRA signatory recognition is the date of the decision by the APLAC MRA Council.

The accreditation body may appeal the APLAC MRA Council decision in accordance with the APLAC MRA Council's appeals procedure (see Section 10).

8. VOTING RULES

See also Section 1.1 above.

- 8.1 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.
- 8.2 All signatories to the APLAC MRA are entitled to a single vote in ballots on decisions described in 8.1 above. The following signatory appointees are entitled to cast this vote:
- (a) The official MRA Council Delegate or MRA Council Alternate as appointed by the signatory member and listed on the MRA Council list (APLAC SEC 020);
 - (b) An alternate, nominated in writing by the official MRA Council Delegate using the MR 008.2 Nomination of Additional MRA Council Alternate form .

Proxy votes by the Delegate of a different signatory accreditation body on behalf of an absent Delegate are not permitted except when the evaluation team leader or evaluation team member is the only representative from a signatory accreditation body present at the MRA Council meeting. Refer to APLAC MR 012 MRA Council Proxy Procedure.

- 8.3 Once an applicant body has been accepted as a signatory to the APLAC MRA, it is permitted to vote on any subsequent MRA decision made during the meeting.

9. SUSPENSION OR WITHDRAWAL OF APLAC MRA SIGNATORY STATUS

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 this document.

10. APPEALS AGAINST DECISIONS OF THE APLAC MRA COUNCIL

10.1 Introduction

An accreditation body may appeal an APLAC MRA Council decision, including not to grant signatory status in the MRA (all or in part), or to suspend or withdraw signatory status (all or in part). In such cases, the APLAC MRA Council appeals process applies. The Council must consider appeals within the boundaries of the APLAC Constitution (APLAC SEC 052) and the APLAC Mutual Recognition Arrangement (APLAC MR 002). In the case of an existing signatory, during the course of the signatory's appeal against suspension or withdrawal of its signatory status, the signatory status shall remain in effect.

As defined in the APLAC Constitution (SEC 052, Section 8), the APLAC MRA Council is the sole body within APLAC that makes decisions with regard to signatory status within the APLAC MRA. Furthermore, the Rules for Operation of the Council (this document) defines the membership of the Council and the eligibility and rights to vote, and specifies that it is the Council who decides on entry or continuation in the MRA and that these decisions are made by voting. It is, therefore, the MRA Council that also considers appeals on MRA signatory status decisions.

Entry of an accreditation body into (or continuation in) the APLAC MRA places obligations on all other signatories to the MRA to accept the accreditations of the applicant accreditation body as being equivalent to their own. Therefore, there is a fundamental right for all signatory accreditation bodies to participate in the decisions on other potential or existing signatories to the MRA. While it is acknowledged it is unusual to have appeals considered by the same people who made the original decision, it would equally be inappropriate for MRA obligations to be "imposed" following an appeal (by independent persons who would necessarily not be MRA signatories) upon signatories who have not had the opportunity to exercise their right to vote on such appeal decisions.

Decisions (by voting) on MRA signatory status are formally acknowledged and recorded by the Council as MRA Council Resolutions (whether or not to grant or continue signatory status and under what conditions). An appeal, by its very nature, is seeking to change the decision (Resolution) and to make another one. Procedurally, this is managed by revoking (or otherwise) the original Resolution (decision) and to formulate another one, otherwise there would exist two conflicting resolutions.

The following procedures set out two mechanisms by which an appellant can have the appeal considered by the Council, depending upon the time at which the appeal is submitted. If a potential appellant is in anyway unclear as to the processes described they should seek additional briefing from the Chair of the APLAC MRA Council.

10.2 Lodging an Appeal

10.2.1 In all cases, the appeal shall be made in writing and be sent to the APLAC Secretariat within 30 days of the notification of the decision of the MRA Council. The appeal shall include:

- (a) the decision (or part thereof) of the MRA Council being appealed (as described in the MRA Council Resolution);
- (b) details of the basis of the accreditation body's appeal;
- (c) the remedy sought, including actions requested of the MRA Council and requested time frames in which such actions should be done;
- (d) 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.

10.2.2 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.

10.3 Appeals Lodged Between MRA Council Meetings

10.3.1 When an appeal is lodged between meetings of the MRA Council, the MRA Council Chair shall appoint within 30 days an ad-hoc sub-committee of the Council to investigate the appeal. The sub-committee shall consist of at least 3 MRA Council delegates who are preferably lead evaluators or experienced evaluators and who were not part of the last evaluation team to the appellant accreditation body. The sub-committee shall provide a written report to the MRA Council, including a recommendation on a decision. This would normally be at the next scheduled meeting of the MRA Council, but if the sub-committee has clear evidence to either uphold or rebut the appeal they can recommend to the MRA Council Chair that the MRA Council's decision be decided by postal ballot.

- 10.3.2 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 the process described in 10.5 below.

10.4 Appeals Lodged at MRA Council Meetings

When an appeal is lodged during the meeting of the MRA Council in which the decision in dispute was made, the appellant may request the appeal be considered at that meeting (or may choose that the procedures in 10.3 above be followed). This request shall be reviewed by the Chair of the MRA Council according to 10.2.2 above. The Chair shall also inform the appellant of the procedures the Council will use to consider the appeal and seek the appellant's agreement or otherwise clarify any queries the appellant may have. Should the request to consider the appeal at this meeting be practical and achievable, the consideration of the appeal shall be by the full MRA Council in attendance at the meeting.

10.5 Consideration of appeals by the MRA Council

- 10.5.1 The MRA Council shall decide within 6 months whether to uphold the appeal or otherwise, by means of a vote in accordance with Section 8.1 above. Such votes shall be confined to decisions "on the entry of an accreditation body into the APLAC MRA (all or in part) or whether or not it may remain in the APLAC MRA (all or in part)". The wording of a resolution for voting shall be confined to such decisions.
- 10.5.2 In general, the following process will be applied but may be adjusted by the Chair of the MRA Council (with the agreement of the Council) to suit the particular circumstance.
- (a) The appellant accreditation body shall present the appeal (Section 10.2.1 above) to the Council along with any additional information they wish to provide in support of the appeal.
 - (b) The Council will consider the report and recommendation from the ad-hoc sub-committee (where relevant).
 - (c) The MRA Council delegates may then seek any clarification from the appellant, the ad-hoc sub-committee, and/or the evaluation team leader (if present).
 - (d) Once any clarification has been given, the Council should review in a stepwise manner all the issues under consideration and the remedies sought by the appellant (to ensure there are no misunderstandings). When completed, all those present from the appellant accreditation body shall be asked to leave the room. They may enter the room again once the ballot on the appeal has been completed.

- (e) Following any additional discussion within the Council, a Resolution to revoke the original decision (Resolution) should be voted upon. If such a Resolution is not passed (i.e. that the original decision is not to be revoked) this essentially means that the appeal is not upheld and the Council will inform the appellant at the meeting.
- (f) If the Resolution passes (i.e. the Council revokes the original decision), a new decision (Resolution) shall be formulated and balloted. Such new decisions could be formulated taking into consideration the original recommendation from the evaluation team, the remedy sought by the appellant in the lodged appeal and the recommendation of the ad-hoc subcommittee (where relevant), but the Council may choose to modify these at its discretion until a new decision is agreed.

10.5.3 The MRA Council's decision on the appeal shall be final.

10.6 The APLAC Secretariat shall advise the appellant in writing within 5 days of the outcome of the APLAC MRA Council resolution.

10.7 Records as listed in the APLAC Management System Manual, section 13.3 shall be retained.

11. NOTIFICATION OF SUSPENSION OR WITHDRAWAL OF APLAC MRA SIGNATORY STATUS

11.1 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 conformity assessment bodies accredited by the suspended accreditation body, including prior to addressing any appeals procedure (see Section 10.1 above). Any such suspension of recognition shall not be considered as a breach of APLAC MRA obligations (APLAC MR 002, Section 1(b) of Arrangement Text).

11.2 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.

11.3 The APLAC Secretariat shall promptly advise other signatories to the APLAC MRA and the ILAC Secretariat of the change in MRA signatory status of the accreditation body. The accreditation body's scope of recognition shall be amended (or removed in the case of full suspension) on 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.

- 11.4 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.
- 11.5 The accreditation body itself should 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.

12 PROCEDURES FOR THE EXTENSION OF THE APLAC MRA

12.1 Proposals to Expand the APLAC MRA

- 12.1.1 Proposals to expand the APLAC MRA into other areas of accreditation can originate from a variety of sources:

(a) Individual APLAC Members

Accreditation bodies themselves may need confirmation of competence in accreditation activities not currently covered by the APLAC MRA – either entirely new areas of accreditation, or in areas which are complementary to areas already accredited by them (e.g. historically, laboratory accreditation bodies needed confidence in calibration laboratories in support of accreditation of testing laboratories). Likewise, confidence in reference material (RM) producers and proficiency testing (PT) providers was needed to support the accreditation of all laboratory types and prompted inclusion of the recognition of accreditation bodies that accredit RM Producers and PT Providers in the APLAC MRA.

(b) Other Regional and/or Global Co-operations

Expansion of the MLAs/MRAs in other regional or global co-operations may prompt APLAC to follow suit or to expand its MRA in support of these other developments. This may include IAF and its affiliated Regional Groups.

(c) Conformity Assessment Bodies (or groups thereof)

These groups may need independent recognition of their competence (especially outside of their own economy) for activities not currently addressed by APLAC (or ILAC, IAF or other parties).

(d) Other Stakeholders such as Regulators, Trade Bodies, Industry or Professional Associations

Such groups may be seeking reassurance of the technical competence of organisations against commonly agreed criteria not currently addressed by APLAC (or ILAC, IAF or other parties).

- 12.1.2 Proposals to expand the APLAC MRA will initially be taken up at a meeting of the APLAC MRA Council.

12.2 Review of Proposals to Expand the APLAC MRA

- 12.2.1 The initial high-level review of a proposal will be conducted by the MRA Council and will focus on the appropriateness of expanding the APLAC MRA into the new area.

- 12.2.2 The MRA Council shall consider, as appropriate and relevant, the following questions:

(a) The Accreditation Standard(s)

- (i) Is there an established accreditation standard or normative document covering the conformity assessment activity, or for the attestation of competence of the bodies subject to accreditation? Is the standard or document credible and robust e.g. has it been produced by an international consensus process involving relevant interested parties?
- (ii) If not, is APLAC prepared to develop and publish such a document?

(b) The Accreditation Activity

- (i) With reference to ILAC-R6 *Structure of the ILAC Mutual Recognition Arrangement and Procedure for Expansion of the Scope of the ILAC Arrangement*, at what level in the structure of the APLAC MRA does the standard or normative document (and associated accreditation activity) reside?

- Documents and activities in Level 4 (which would typically be of a sectorial specific nature) would not usually require a formal expansion of, and recognition under, the APLAC MRA and are not explicitly covered under these procedures. However, the general principles could be applied on a case-by-case basis as appropriate should a sector's stakeholders seek a formal mechanism for the recognition of APLAC MRA signatory accreditation bodies operating within the sector.
- Documents and activities in Levels 2 and 3 would normally require formal expansion of the APLAC MRA.

- (ii) For Level 2 accreditation activities:

- Is the activity consistent with APLAC's core objectives, as set out in the APLAC Constitution (SEC 052, Section 2.1)?
 - Is the activity more consistent with the accreditation activity covered by complementary Regional and Global Co-operations (e.g. PAC at a regional level, IAF at the global level)?
 - Is it of sufficient substance to enhance recognition of competence?
 - Does it dilute the substance of any existing standard under the APLAC MRA?
- (iii) For Level 3 accreditation activities:
- Does the activity have significant relevance to the accreditation of laboratories, inspection bodies and/or bodies involved in related activities? Is it complementary to or supportive of other standards being used (particularly Level 2 standards)?
 - Is it of sufficient substance to enhance recognition of competence?
 - Does it dilute the substance of any existing standard under the APLAC MRA?
- (iv) Can the operation (by a member accreditation body) of an accreditation programme for the new activity be conducted in accordance with the general principles of ISO/IEC 17011? Is ISO/IEC 17011 an appropriate base standard for the operation of such a programme?
- (c) APLAC's Internal Considerations
- (i) Does the lack of inclusion of the accreditation activity in the APLAC MRA pose a threat to APLAC's leadership in accreditation?
- (ii) Will APLAC be able to effectively evaluate an accreditation body using the existing general principles and procedures for peer evaluations? What form of evaluation will be necessary for existing signatories to expand their scope into the new area? For example, Level 2 activities would be expected to have a full on-site evaluation with witnessing; Level 3 activities may not require as comprehensive of an evaluation depending on stakeholder expectations, technical complexity, technical similarity with (or difference from) existing standards, or other risk factors.

- (iii) Is there sufficient interest from the APLAC membership to participate in and be recognised under an expanded MRA?
- (iv) Will the expanded area under the APLAC MRA be 'owned' (in full or in part) by (an) external stakeholder(s)?
 - Does the APLAC membership wish to operate the APLAC MRA under such arrangements?
 - Do the requirements of the stakeholder(s) threaten the impartiality and independence of APLAC MRA signatories, i.e. conformity with ISO/IEC 17011 and other existing MRA requirements?
 - Do the requirements of the stakeholder(s) threaten the impartiality and independence of APLAC, i.e. as set out in the APLAC Constitution, and conformity with IAF/ILAC-A1 and other existing ILAC MRA requirements?
- (v) How many applicant accreditation bodies would need to successfully complete evaluation activities in the expanded area before an expanded MRA can be signed (e.g. historically this has been a minimum of 4 signatories)?

12.3 Approval to Expand the APLAC MRA

12.3.1 On completion of the initial high-level review, the MRA Council will decide whether to take the proposal to expand the APLAC MRA to the APLAC General Assembly for a decision to proceed. The initial high level review by the MRA Council may take several meetings to come to a decision as information is gathered and considered. The APLAC General Assembly makes the final decision as to whether to proceed with expanding the APLAC MRA.

12.3.2 In accordance with APLAC's obligations under ILAC-P12 *Harmonisation of ILAC Work with the Regions*, once a decision to expand the APLAC MRA has been made, APLAC shall inform ILAC, the other Regional Co-operations affiliated to ILAC, and the ILAC unaffiliated bodies (via the ILAC Executive Committee) of the new work item and invite participation in the work from outside the APLAC region.

12.4 Development of an Expanded MRA

12.4.1 Prior to acceptance of any applications for member bodies to enter the expanded MRA, the MRA Council shall ensure it has the appropriate infrastructure to effectively administer an expanded MRA. It shall establish an ad-hoc Working Group to oversee, coordinate and/or conduct the following activities to this end:

- (a) Review any related activities in other regions (including ILAC) and include any learning in the development work to be undertaken by the MRA Council to avoid duplication of effort and ensure consistency.
- (b) Analyse the potential for problems in the new area associated with the application of existing requirements documents on accreditation body signatories under the APLAC MRA, e.g. but not necessarily limited to:
 - (i) ISO/IEC 17011 and IAF/ILAC-A5
 - (ii) IAF/ILAC-A2 (Section 2) and MR 001 (Section 3)
 - (iii) ILAC-P8, ILAC-P9, ILAC-P10, ILAC-P13, ILAC-P14, ILAC-P15 (as appropriate)
 - (iv) Expressions of scopes of accreditation (for any accreditation bodies already accrediting in the new area), which are a common source of inconsistency and should also be considered.

Anticipated problems shall be brought to the MRA Council for resolution.

- (c) Analyse the potential for problems in the new area associated with the interpretation and application of the accreditation standard(s) or normative document(s) by accreditation bodies in the assessment and accreditation of applicant organisations. Anticipated problems shall be brought to the MRA Council, who typically will request resolution through the APLAC Technical Committee. Additional criteria and/or guidance documents may be required before the expanded MRA can be implemented.
- (d) In association with the MRA Council Evaluator Performance Working Group, identify what evaluator resources will be required to evaluate accreditation bodies in the new area. In particular, what additional competencies will be required (if any; from those currently held by APLAC evaluators in the evaluator pool), and how these competencies will need to be demonstrated and recorded. If necessary, evaluator training may need to be undertaken in association with the MRA Council Evaluator Training Working Group.
- (e) In association with the MRA Council's Documentation Working Group, review the APLAC MR-series of documents to identify and implement changes needed to administer the new scope of the MRA. Generally it will be expected that significant amendments will need to be made to MR 001, MR 002, MR 003, MR 004, MR 007, MR 009 and MR 011. The General Assembly will approve the criteria for recognition under the expanded APLAC MRA and the APLAC procedures for evaluating conformity.

- (f) Once the key documentation allowing effective administration of the expanded MRA is in place, in association with the MRA Council Evaluator Performance Working Group, recruit, train if necessary, and qualify sufficient evaluators to evaluate possible future applicant accreditation bodies.
 - (g) In association with the APLAC committees, the APLAC Secretariat and/or the Board of Management arrange for other APLAC documents to be reviewed to identify and implement changes needed to reflect the expanded MRA, i.e.
 - (i) SEC-series documents and the APLAC Quality Manual (the APLAC Secretariat)
 - (ii) PR-series documents (the Public Information Committee)
 - (iii) TR-series documents (the Training Committee)
 - (iv) TC-series documents (the Technical Committee)
 - (v) PT-series documents (the Proficiency Testing Committee).
- 12.4.2 The ad-hoc Working Group shall report regularly to the MRA Council, including any items requiring decision/resolution. Once developments are sufficiently advanced (typically up to and including 12.4.1(f) above) the MRA Council will decide when applications to enter the expanded MRA can be accepted. Applications would be open to any APLAC Full Member and processed according to the established (or as revised under 12.2.2(c)(ii) and/or 12.4.1(e) above) APLAC MRA Council procedures.
- 12.4.3 The MRA Council shall dissolve the ad-hoc Working Group upon completion of its set tasks in Section 12.4.1, or otherwise maintain it under revised terms of reference.

APPENDIX 1: APLAC EVALUATION REPORT REVIEW PROCEDURE**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 the 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 are made and also provides information to substantiate the surveillance measures adopted by the 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 accreditation body (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 be 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.