

Procedures for Establishing and Maintaining Mutual Recognition Amongst APAC Accreditation Bodies

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1. INTRODUCTION

1.1 The Asia Pacific Accreditation Cooperation (APAC) is an Association of accreditation bodies that accredit the following types of conformity assessment bodies (CABs):

* Calibration laboratories;
* Greenhouse gas validation and verification bodies;
* Inspection bodies;
* Management system certification bodies;
* Medical/clinical testing laboratories;
* Persons certification bodies;
* Product certification bodies;
* Proficiency testing providers;
* Reference material producers;
* Testing laboratories

1.2 APAC has established a Mutual Recognition Arrangement (APAC MRA) based on the demonstrated conformance by accreditation bodies to ISO/IEC 17011 and internationally agreed normative documents for the competence of accreditation bodies.

1.3 The aim of the APAC MRA is to provide formal recognition of accreditation bodies from the Asia Pacific region, thereby helping facilitate international trade by enabling acceptance of endorsed reports and certificates issued by CABs accredited by signatories to the APAC MRA.

REFERENCES

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

IAF/ILAC-A2 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): - Requirements and Procedures for Evaluation of a Single Accreditation Body

IAF/ILAC-A3 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Template report for the peer evaluation of an Accreditation Body based on ISO/IEC 17011:2017



IAF ML 2 IAF General Principles on the Use of the IAF Mark

IAF ML 4 Policies and Procedures for an MLA on the level of Single Accreditation Bodies and on the Level of Regional Accreditation Groups

ILAC P 8 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies

ILAC P 9 ILAC Policy for Participation in Proficiency Testing Activities

1. DEFINITIONS AND ABBREVIATIONS

Further to the terms and definitions given in ISO/IEC 17000 *Conformity Assessment – Vocabulary and general principles,* ISO/IEC 17011 *Conformity Assessment – Requirements for accreditation bodies accrediting conformity assessment bodies, IAF/ILAC-A1, and IAF/ILAC-A2,* the following definitions and abbreviations apply:

**APAC:** Asia Pacific Accreditation Cooperation;

**APAC MRA**: APAC Mutual Recognition Arrangement;

**APAC MRA Council:** the standing committee established in accordance with the APAC Constitution (APAC GOV-001) to coordinate APAC’s activities with respect to the mutual recognition arrangement amongst APAC Members;

**APAC MRA Council Management Committee (APAC MRA MC):** The APAC MRA MC is a standing sub-committee of the MRA Council appointed to manage and oversee the conduct of APAC MRA peer evaluations;

**Applicant body:** In the context of this document, an applicant body is either an APAC Associate Member seeking APAC MRA signatory status (APAC Full Membership) or an APAC Full Member undergoing APAC re-evaluation and/or scope extension;

**Deputy Team Leader (DTL):** a member of the APAC MRA peer evaluation team nominated to assist the Team Leader to plan, prepare and manage an evaluation;

**Evaluation Finding:** Results of a Peer Evaluation in one of the following forms in accordance with IAF/ILAC-A3:

* **Non-conformity:**  a finding where the accreditation body does not meet a requirement of the applicable standard(s) (e.g., ISO/IEC 17011), its own management system or the APAC MRA requirements.
* **Concern:**  a finding where the accreditation body’s practice may develop into a Non-conformity.
* **Comment:** a finding about documents or the accreditation body’s practices with a potential for improvement, but still fulfilling the requirements.

**Evaluation Review Panel (ERP):** an ad-hoc sub-group of the APAC MRA MC established to review a specified evaluation report;

**Evaluator:** a person accepted by the APAC MRA MC as meeting the requirements given in APAC MRA-004 and the criteria for Peer Evaluator Team Members as detailed in IAF/ILAC-A2, Annex 1;

**IAF:** International Accreditation Forum, Inc;

**ILAC:** International Laboratory Accreditation Cooperation;

**Lead Evaluator:** a person accepted by the APAC MRA MC as meeting the requirements given in APAC MRA-004 and the criteria for Peer Evaluator Team Leader as detailed in IAF/ILAC-A2 Annex 1;

**MLA:** Multilateral Agreement;

**MRA:** Multilateral Recognition Arrangement;

**Peer evaluation:** a structured process of evaluation of an accreditation body against the specified requirements by representatives of other accreditation bodies;

**Proficiency testing activity:** for the purpose of this document, all those activities or 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*), and inter-laboratory comparisons conducted by Regional Groups, accreditation bodies, commercial organisations or other providers (see ILAC P9)*;*

**Provisional Evaluator:** a person accepted by the APAC MRA MC as meeting the requirements given in APAC MRA-004 and the criteria for Candidate Peer Evaluation Team Member as detailed in IAF/ILAC-A2 Annex 1;

**Team Leader (TL):** a person responsible for leading an APAC MRA peer evaluation team;

**Team Member (TM):**  a person serving on an APAC MRA peer evaluation team;

**Witnessing:** Observation of an AB carrying out assessment at the premises of the conformity assessment body (CAB), and evaluating the AB’s management system and records by an evaluation team. (It may also include observing the AB's staff preparing for an assessment and dealing with assessment reports.)

PART 1: GENERAL

1. SCOPE OF THIS DOCUMENT

3.1 This document describes the policies and procedures for establishing and maintaining mutual recognition amongst APAC accreditation bodies. This document is aligned with IAF/ILAC-A2 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): - Requirements and Procedures for Evaluation of a Single Accreditation Body.

1. OBJECTIVE OF A PEER EVALUATION

4.1 The objective of an evaluation is to establish confidence in the competence of an accreditation body, thereby establishing confidence in the reports and certificates issued by CABs it has accredited. The evaluation therefore focuses on how the accreditation body assesses the competence of its accredited CABs.

1. CRITERIA FOR APAC MRA SIGNATORY STATUS (APAC FULL MEMBERSHIP)

5.1 Standards and other normative documents

5.1.1 The requirements for signatory status in the APAC MRA are described in APAC FMRA-001 *List of APAC Endorsed Normative Documents*. These requirements include those applicable to accreditation bodies and the requirements that accreditation bodies must ensure are fulfilled by their accredited CABs. APAC MRA signatories (Full Members) shall consistently satisfy these requirements and the requirements in clause 5.2, as applicable, at all times.

5.2 Supplementary Requirements

5.2.1 Accreditation bodies, if applicable, must demonstrate that their accredited conformity assessment bodies can access an appropriate measurement system that enables them to make measurements that are traceable to national or international standards of measurement.

5.2.2 Accreditation bodies shall ensure that their accredited calibration and testing laboratories participate in APAC proficiency testing programs where relevant and practicable.

1. COSTS

6.1 The applicant body shall pay the expenses for each member of the evaluation team (including provisional evaluators and technical experts) engaged in travel directly related to the evaluation, as shown below.

6.1.1 Peer evaluation team members and host accreditation bodies are to ensure that they provide sufficient time for team members to travel and recover prior to an evaluation. This should include allowing for additional accommodation to provide for a recovery day if appropriate. The accreditation body and evaluation team members shall consider these issues and seek to reach consensus as part of the planning process.

6.1.2 Peer evaluation team members shall be provided with flexible economy class airline tickets for itineraries requiring up to seven hours cumulative flying time, and premium economy class airline tickets for more than seven hours cumulative flying time. Any alternative arrangement should be by consensus between the accreditation body and the affected team member(s).

NOTE Cumulative flying time is the amount of time in an aircraft from the point of original departure to the point of final arrival, regardless of the how many flight segments are included.

Example: If a direct flight from the airport of original departure to the airport of final arrival is more than 7 hours then it is eligible for premium economy class.

Example: For non-direct flights, if the flight durations of various segments add up to more than 7 hours, then the entire trip it is eligible for premium economy class. For example, the indirect flight itinerary is 2 segments – the first segment is from the airport of original departure to a transit location and is 2 hours flying time, then 2 hours waiting in transit, then the next flight segment is 5.5 hours flying time to the airport of final arrival. The calculation of flying time is 2 hours (first segment) + 5.5 hours (second segment) = cumulative flying time of 7.5 hours, and thus the entire trip (both first and second segments) are eligible for premium economy.

 When a premium economy class seat is not available, the AB and the affected peer evaluator(s) shall reach an alternative arrangement by consensus (for example, including a 24 hour stop-over during the trip if flying economy class or flying business class without a stop-over).

6.1.3 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, any additional travel costs are to be met by the team member.

6.1.4 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.

6.1.5 Transportation between the applicant body’s offices and the locations of any conformity assessment activities to be witnessed as part of the evaluation shall be arranged by the applicant body at their own cost.

6.1.6 Accommodation costs of evaluation team members are for those days directly related to the on-site evaluation activities. 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 accommodation costs are to be met by the team member.

6.1.7 The applicant body shall pay for meals or parts of the meals, within reasonable limitations.

6.1.8 The applicant body is not required to pay other non-evaluation related costs. Non-evaluation related costs shall be paid by the evaluators or by agreement with the organisations providing the evaluators.

6.2 Prior to any incurred expenses, the evaluation team leader shall contact the applicant body to discuss expense expectations, considerations and reimbursement protocol.

6.3 When an evaluator or technical expert from outside the APAC region is included on the team, the applicant should pay for inter-country travel costs.

6.4 The applicant body shall pay expenses for pre-evaluations, evaluations (including multi-part evaluation visits), follow-up evaluations, and re-evaluations, and for travel associated with witnessing of on-site assessments done by the applicant body.

6.5 The evaluators’ time is donated at no charge to APAC for use in the evaluation of other APAC Members.

6.6 An estimate of any inter-country travel expenses and details of invoicing procedures should be agreed in advance between the applicant body and the individual evaluators.

6.7 If the applicant body requests that the evaluation emphasises certain areas of its accreditation activities (see section 19.2) 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 additional accommodation, subsistence and travelling expenses, and related sundry costs.

6.8 Observers shall pay all their own costs.

6.9 Evaluators and the applicant body shall cooperate by timely submission of invoices and timely reimbursement.

1. CONFIDENTIALITY

7.1 All information received, both in writing and orally, 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 CABs visited.

7.2 The evaluation team members and any 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.

7.3 All members of the evaluation team, including any observers, shall provide a signed confidentiality declarations to the Secretariat using document APAC FGOV-007. Confidentiality declarations need only be signed once, and cover all activities within APAC.

7.4 The applicant body is responsible for any confidentiality requirements placed upon any observers who observe the open and/or closed sessions of the evaluation.

1. CHANGES TO THIS DOCUMENT

8.1 This document may be revised by APAC MRA MC with the agreement of the APAC MRA Council.

8.2 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 APAC MRA PROCESS

1. APPLICATION FOR SIGNATORY STATUS

9.1 An applicant accreditation body shall submit its written application in English to the APAC Secretariat using the form APAC FMRA-002 together with the required documentation specified in Annex F of this document.

9.2 Accreditation bodies shall be fully operational (i.e. have carried out surveillance and reassessment for each program under their scope of recognition and/or for which they have applied for recognition).

*Note 1: When an applicant body is already a signatory to the APAC 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 APAC MRA MC on an individual basis.*

9.3 Applications shall be submitted at least 6 months prior to the requested date for the peer evaluation.

9.4 The APAC Secretariat shall confirm receipt of the application on behalf of the APAC Chair and inform the applicant body at the time of application of:

(a) The current issue of APAC MRA-001; and

(b) Any imminent changes approved by the MRA Council but not yet included in the current issue of APAC MRA-001.

9.5 Upon receipt of an application, the APAC Secretariat shall complete the APAC MRA Application Checklist (APAC FMRA-003).

9.6 The application shall be processed as follows:

9.6.1 If the application is from an APAC Associate Member for an initial evaluation, the completed APAC FMRA-002 shall be forwarded to the APAC MRA MC for review and endorsement. It, together with the completed APAC FMRA-003, shall then be forwarded to the APAC MRA Council for ballot to proceed with the initial evaluation. The APAC Secretariat shall inform the applicant of the subsequent decision.

9.6.2 If the application is from an existing APAC Full Member for extension of a main scope or a sub-scope, the APAC MRA MC shall review the application and inform the applicant whether the application has been accepted.

9.6.3 For re-evaluation, no application is needed.

9.6.5 If the applicant accreditation body wishes to have a joint or concurrent evaluation with another Regional Group, the accreditation body should advise the APAC MRA Council Chair of the request. The APAC MRA Council Chair will inform the appointed peer evaluation team leader.

9.7 Application from an IAF MLA or ILAC MRA Signatory that is not an APAC Member, or from an APAC Member for a scope already recognised under the IAF MLA or ILAC MRA:

9.7.1 The applicant must first obtain APAC Associate Member status in accordance with APAC’s process for membership application. Once Associate Membership has been granted, an application for APAC MRA signatory status (APAC Full Membership) can be made.

9.7.2 The application is reviewed by the MRA MC and provided that the requested scope of recognition is aligned with the IAF/ILAC scope of recognition, the recognition is not suspended, and the relevant fees have been paid, the MRA Council may determine to admit the applicant as a Full Member without further evaluation. The recognition period cannot exceed the due date for the re-evaluation by IAF/ILAC.

1. APPOINTMENT OF THE EVALUATION TEAM LEADER

10.1 The evaluation Team Leader shall be appointed by the APAC MRA MC.

10.1.1 For an evaluation, the Team Leader is assigned within 60 days of the approval of the application. For a re-evaluation, the Team Leader is assigned approximately 18-24 months prior to the evaluation date specified in the relevant MRA Council resolution.

10.1.2 The APAC MRA MC selects the Team Leader from the list of lead evaluators prepared and kept up-to-date by the APAC Secretariat on behalf of the MRA Council. In appointing a Team Leader for a specific evaluation, the APAC MRA MC:

(a) Shall avoid appointing the same Team Leader for two successive evaluations of the same applicant body, except for pre-evaluations and follow-up evaluations;

(b) Should avoid appointing a Team Leader nominated from an accreditation body that has been evaluated by a Team Leader from the applicant body within a relatively short period;

(c) Should ensure that Team Leaders are selected from all APAC MRA signatories with the objective of evenly distributing the workload.

10.1.3 A Deputy Team Leader may also be appointed as appropriate to assist with the management of the evaluation, and in the coverage of a large scope of recognition or one that is also covered by IAF and ILAC recognition. For example, a Team Leader may be selected to ensure adequate coverage of one of the ILAC or IAF areas of recognition and the Deputy Team Leader can assist with coverage of the other.

10.2 The applicant body is informed by the MRA MC Chair of the name of the nominated Team Leader 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.

10.3 Once the APAC MRA MC has selected the Team Leader and Deputy Team Leader (where applicable), the Team Leader in consultation with the Deputy Team Leader then selects the evaluation Team Members. The APAC MRA MC approves the selection of the Team Members.

*Note: Where the Team Leader/Deputy Team Leader is unable to compose the evaluation team, the MRA MC shall select the Team Members. The APAC MRA MC has the overall approval authority.*

10.4 The evaluation Team Leader is delegated authority by the APAC MRA Council to make final decisions regarding the conduct of the evaluation. Team Leaders shall have ultimate responsibility for all phases of the evaluation, including:

* Selecting the evaluation team;
* Document review;
* Planning the evaluation visit;
* Conducting the evaluation visit;
* Planning and conducting any follow-up activities, including an on-site follow-up visit;
* Reporting the results of the evaluation.

10.5 The evaluation Team Leader shall organise and conduct the evaluation in accordance with the procedures set out in Part 3 of this document.

10.6 The Team Leader, in conjunction with the APAC MRA MC Chair and APAC Secretariat, shall use the Evaluation Control Record (ECR) (APAC FMRA-005) to record key decisions and authorisations throughout the process.

1. APPOINTMENT OF AN EVALUATION REVIEW PANEL

11.1 Once the evaluation team is confirmed, the APAC MRA MC shall appoint an ad-hoc Evaluation Review Panel (ERP) for the particular evaluation.

11.2 The ERP shall be at least three members drawn from APAC MRA Council Members (Delegates or Alternates) and Evaluators. The ERP shall consist of at least one APAC MRA MC member and one Lead Evaluator. The APAC MRA Council Chair shall appoint one of the ERP members as the Moderator.

11.3 The composition of the ERP shall have competence in the program(s) covered by the evaluation. For example: if the evaluation covers more than one APAC MRA recognition, the ERP members should together be experienced to cover all areas of the evaluation. The ERP may request the use of technical support from a peer evaluator or technical expert to cover a specific program.

11.4 The APAC Secretariat shall inform the Team Leader and the members of the ERP of the appointment and composition of the ERP.

11.5 At their own discretion, the APAC MRA MC Chair may participate in the deliberations of the ERP.

11.6 Further guidance on ERP competencies is given in Annex D to this document.

1. PROCEDURE FOR DELAYS IN THE EVALUATION PROCESS

12.1 Caused by the Applicant

(a) 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 APAC MRA MC that the evaluation process be suspended.

(b) If the applicant body does not provide the documents in accordance with the requirements set out in this document and the Application Form (APAC FMRA-002) 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 APAC MRA MC.

(c) 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 APAC MRA MC setting out the history of the evaluation.

(d) For a re-evaluation, if the report on the evaluation has not been finalised within a year of the date of the on-site evaluation, the Team Leader shall prepare a report for the APAC MRA MC, setting out the history of the evaluation.

(e) If, in the opinion of the APAC MRA MC, the delays are caused by the applicant body and there are no extenuating circumstances, it may request the APAC MRA Council to suspend the evaluation process.

(f) If the evaluation process is suspended, the evaluation team shall be dissolved. The APAC MRA MC may appoint another Team Leader when the applicant body is ready to resume the evaluation. A new application form (APAC FMRA-002) shall be completed by the applicant body. Any nonconformities and concerns raised by the original evaluation team shall be taken into consideration by the new evaluation team and a full evaluation conducted.

(g) If a re-evaluation process is suspended, the APAC MRA Council may also suspend the signatory status of the accreditation body that is already a signatory to the APAC MRA.

(h) 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 date of the closing meeting of the 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.

12.2 Caused by Adverse Travel Advisory

(a) 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 APAC MRA MC, postpone setting a date or change the proposed evaluation team.

(b) In the event of an adverse travel advisory for the applicant’s economy after the date for the visit has been set, the APAC MRA MC shall decide, on the basis of advice from the Team Leader appointed for the evaluation, on the postponement of the evaluation.

(c) If the postponed visit is for a re-evaluation, the APAC MRA Council may be requested by the APAC MRA MC to decide, after the postponement, on a case-by-case basis, the impact on the ongoing recognition of the APAC MRA signatory accreditation body affected.

1. MAINTENANCE OF MUTUAL RECOGNITION

13.1 Notification of Changes

13.1.1 As required by the APAC MRA (APAC MRA-002), each signatory shall ensure that the APAC Secretariat is informed, in writing, of any significant changes in status and/or operating practices. The following information shall be provided to the APAC 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 APAC MRA signatory status:

(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 APAC MRA Council) to the APAC General Assembly and APAC MRA Council; changes of address and contact details. The APAC MRA MC Chair shall review the competence of the newly advised MRA Council Delegate or Alternate;

(c) Details of new MRAs or MLAs or bilateral agreements/arrangements with other accreditation bodies, and details of the revision, suspension or termination of any existing arrangements/agreements;

(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, IAF, ILAC and/or APAC 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.

13.1.2 When a notification of substantive changes is received, the APAC Secretariat shall inform the APAC MRA MC Chair of the changes, who shall, in conjunction with the APAC MRA MC, review the changes and decide whether further information needs to be provided by the accreditation body.

13.1.3 The APAC MRA MC Chair may appoint a member or members of the APAC MRA MC, to review the impact of the changes on conformity of the accreditation body with the relevant APAC MRA requirements. The APAC Secretariat shall provide the notification of changes and any additional information to the review team.

 The appointed APAC MRA MC member(s) 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 APAC Secretariat for inclusion in the accreditation body’s file.

 The appointed APAC MRA MC member(s) shall also have the authority to recommend to the APAC MRA MC Chair that it is necessary to conduct an on-site visit to the accreditation body. All costs shall be met in accordance with Section 6 of this document.

The review team shall prepare a recommendation to the APAC MRA Council on the impact of the change on the APAC MRA status of the accreditation body in question, for discussion and decision, if necessary, at the next APAC MRA Council meeting.

13.1.4 After the completion of 13.1.2 and, if necessary, 13.1.3, the APAC MRA MC Chair shall decide whether the changes need to be circulated to all signatories along with the decision of the Chair (for example, no further action required, or consideration at the next APAC MRA Council meeting) and if appropriate, a copy of the report from the review team. Significant changes are usually forwarded to all signatories.

13.1.5 If the changes notified by the accreditation body are significant or if the review finds significant nonconformities, the APAC MRA Council may consider the need to conduct a visit to verify the changes in the accreditation body, suspend or withdraw the accreditation body’s APAC MRA signatory status.

13.2 Re-evaluation of APAC MRA Signatories

13.2.1 Each signatory to the APAC MRA shall be re-evaluated at a maximum interval of four years from the date of the closing meeting of the last full evaluation. If a signatory has not been re-evaluated after four years, the subsequent meeting of the APAC MRA Council may discuss the need for suspension of the APAC MRA signatory status of the accreditation body.

13.2.2 A re-evaluation shall take place at a shorter interval should there be due cause, such as notification of significant changes (see section 12.1.1).

13.2.3 An evaluation for extension of APAC MRA signatory status may be conducted, together with the next re-evaluation if the accreditation body applies for an extension to the scope of recognition.

13.2.4 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 APAC MRA requirements adopted by APAC, IAF or ILAC, and on obtaining evidence that accredited CABs continue to operate in compliance with the relevant ISO/(IEC) standards.

13.3 Suspension/Withdrawal of Recognition

13.3.1 Suspension or withdrawal of recognition shall be handled consistently with the procedures given in IAF/ILAC-A2.

13.3.2 If the accreditation body’s signatory status is suspended, it shall implement any resolutions of the APAC MRA Council, which may include advising its accredited conformity assessment bodies of any consequences. Any new accreditation by the accreditation body during the suspension period is not covered by the APAC MRA and not recognized by IAF/ILAC.

13.3.3 If the signatory status of the accreditation body is withdrawn, the accreditation body shall inform all applicant and accredited CABs that the accreditation is no longer recognised under the APAC MRA, ILAC MRA, or IAF MLA and that the CABs shall no longer make reference to the APAC MRA, ILAC MRA or IAF MLA.

13.3.4 During the course of any appeal by the accreditation body against suspension or withdrawal of its signatory status, the signatory status shall remain in effect.

1. PROCEDURES FOR EXTENSION OF AN ACCREDITATION BODY’S SCOPE OF RECOGNITION UNDER THE APAC MRA

14.1 If an APAC Full Member wishes to extend its MRA scope at main-scope (level 3), the same procedures described in Parts 2 and 3 of this document shall in general apply. For an evaluation carried out solely for the extension of recognition, at least those aspects relating to its accreditation activities covered by the proposed extension need to be covered. The composition of the evaluation team shall correspond to the evaluation activities to be carried out.

14.2 Some main-scope MRA programmes have sub-scopes (level 4 and 5) within them and scope extensions to add additional such sub-scopes under an already-recognised main-scope of accreditations may be granted by the APAC MRA Council on the basis of the member’s self-declaration that:

* The level 4/5 scope has been introduced and,
* Relevant requirements as defined in APAC FMRA-001 have been met.

14.3 Members shall complete and submit IAF MLA MC 28 *MLA Declaration for Sub-Scope Extensions (AB)* to the APAC Secretariat, if applicable. The self-declaration shall be forwarded to the APAC MRA MC for review and endorsement.

14.4 The additional sub-scope to the scope of recognition will be fully evaluated at the next re-evaluation of the member.

PART 3: THE EVALUATION PROCESS

COOPERATION of the APPLICANT BODY

15.1 The evaluation team leader shall endeavour to solicit that cooperation from the applicant body that is necessary for the conduct of an effective evaluation.

15.2 The applicant body shall cooperate with the evaluation team fully and without delay throughout the evaluation process and shall promptly advise the Team Leader of any unavoidable situation that could lead to a delay.

15.3 Cooperation shall include but not be limited to:

* Provision in a timely manner of all documentation and relevant information necessary for the evaluation (see the Application Form APAC FMRA-002);
* Making necessary arrangements for the evaluation visit, that include:

(a) Ensuring that key personnel, staff members, assessors and committee members of the applicant body are available for interview;

(b) Providing the evaluation team with a list of assessments that are scheduled to take place from at least 6 weeks before the proposed on-site evaluation date;

(c) 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;

(d) Arranging accommodation and transportation for the witnessing of assessments and, if necessary, for a visit to the national measurement institute;

(e) 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;

(f) 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;

(g) Providing individual evaluation Team Members with information on visa requirements and appropriate letters of invitation, as necessary;

(h) Providing interpreters, if necessary. The applicant shall provide the team with a resume of any proposed translator, detailing qualifications and experience, if requested.

*Note 1: English is the official language for APAC 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.*

* Timely payment of all costs as specified in Section 6 of this document;
* Making an effort to build consensus with the evaluation team on the findings given in the evaluation report;
* Providing a comprehensive and timely response to the evaluation report including, as necessary, appropriate corrective actions and/or cause analysis on the non-conformities and concerns.

DOCUMENT REVIEW

16.1 The document review shall be conducted in accordance with IAF/ILAC-A2 and this document.

16.2 The applicant body shall prepare a narrative report for the document review using IAF/ILAC-A3 and submit it and supporting documentation to the Team Leader prior to any determination of an evaluation date. Normally, this should be at least three months before any proposed on-site evaluation.

16.3 The evaluation Team Leader, and if required in order to cover the necessary scopes and sub-scopes, Team Members, shall review the information and documentation provided by the applicant body. For re-evaluations, document reviews shall be conducted as soon as practicable following receipt of the information and documentation from the accreditation body.

16.4 After the examination of all relevant documentation, the Team Leader shall return the updated IAF/ILAC-A3 to the applicant identifying any findings or areas requiring further clarification. This review process should be completed normally at least 30 days prior to on-site evaluation but should be continued to establish compliance with requirements prior to the evaluation.

16.5 Where the document review on an applicant body indicates significant departures from the criteria for APAC MRA signatory status, the Team Leader shall advise the APAC MRA MC Chair who shall determine the necessary course of action. This could include a pre-evaluation visit, deferral of the application or other action as deemed appropriate.

16.6 Where the document review on a signatory body indicates significant departures from the criteria, the Team Leader shall advise the APAC MRA MC Chair who shall determine whether or not the evaluation should proceed as scheduled.

16.7 The Team Leader shall prepare the evaluation plan and submit it to the applicant.

PRE-EVALUATION VISIT

17.1 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.

17.2 The pre-evaluation visit shall be conducted by the pre-evaluation Team Leader and a team member chosen by the Team Leader, in consultation with the Chair of the APAC MRA MC, from the evaluator competencies spreadsheet (APAC FMRA-015) maintained by the APAC Secretariat on behalf of the APAC MRA Council.

17.3 A provisional date for the pre-evaluation visit shall be mutually agreed 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.

17.4 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:

17.4.1 The pre-evaluation Team Leader should discuss with the head of the applicant body its participation in APAC 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 APAC MRA requirements and about the full evaluation process.

17.4.2 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.

17.4.3 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, etc).

17.4.4 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;
* Familiarity with IAF, ILAC and APAC requirements.

17.4.5 Access to and participation levels in proficiency testing programmes should also be established.

17.4.6 A part of the pre-evaluation shall be an assessment of the existence or access to 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.

17.4.7 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. Only formal witnessing completed as part of initial evaluation will be considered as relevant for APAC MRA Council decision making.

17.5 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 APAC MRA MC with a copy being sent to the APAC Secretariat.

17.6 The report shall, as a minimum, contain the following information:

* Main comment(s) found, referenced to the relevant clauses of ISO/IEC 17011 and/or other APAC MRA criteria documents;
* The degree to which the applicant body fulfils the relevant criteria;
* A recommendation on whether to continue to full evaluation;
* A recommendation on the type and number of team members necessary, and the estimated duration of any proposed evaluation visit;
* The conditions to be fulfilled if the accreditation body decides to have an initial onsite evaluation conducted.

17.7 The applicant body should be given an opportunity to comment on any factual errors in the report.

17.8 On the basis of the pre-evaluation report, the applicant body can strive towards improving their processes to address any deficiencies. The applicant body can provide the pre-evaluation Team Leader with a response, detailing the actions taken on the comments. 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. No further action is required by the evaluation team beyond this response.

17.9 Once the pre-evaluation is completed, the applicant can then make a decision to proceed with the initial evaluation, if the recommendation of the evaluation team was positive.

17.10 Neither the applicant body nor any other parties shall use the pre-evaluation report to claim that the applicant body has been evaluated by APAC.

17.11 Where possible, the same Team Leader or Team Member who participated in the pre-evaluation could be requested by the APAC MRA Council Chair to participate in the initial evaluation of the applicant.

COMPOSITION OF EVALUATION TEAM

18.1 The competence of an evaluation team (including where necessary, Technical Experts) shall always collectively satisfy Levels 1 to 4 of APAC FMRA-001 for specific programs within the scope of the evaluation.

18.2 Selection and Appointment of an Evaluation Team

18.2.1 The Team Leader with the assistance of the Deputy Team Leader (where applicable) shall select individuals to participate in each evaluation (initial, extension of scope, or re-evaluation) at least twelve months prior to the due date of re-evaluation or the requested date in the case of initial or extension of scope. Where the Team Leader and Deputy Team Leader, where applicable, are unable to compose the evaluation team, the MRA MC shall appoint the Team Members.

18.2.2 The Team Leader and Deputy Team Leader (where applicable) shall take into account the following when selecting members of the team:

(a) The selection 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) Technical Experts may be specially invited for a specific evaluation or re-evaluation. The Team Leader is responsible for proposing Technical Experts, in consultation with the APAC MRA MC;

*Note 1: A Technical Expert should not be expected to function as a peer evaluator, but only to provide specific knowledge or expertise to the evaluation team. A Technical Expert shall be closely supervised by the Team Leader or other qualified Team Member both during the applicant body office and witness visits.*

(c) One or two observers may be added to the team with the prior agreement of the applicant body;

*Note 2: Examples of observers are a representative from another region, a regulator from the applicant’s economy, or a regulator from a third economy, etc.*

(d) Knowledge of the local language;

(e) The potential appointment of a Deputy Team Leader;

*Note 1: A Deputy Team Leader can replace the Team Leader in case of illness or unforeseen circumstances.*

*Note 2: A Deputy Team Leader should preferably have a minimum of 2 peer evaluations (pre-evaluations can be considered) as a Team Member with positive feedback from the participating Team Leaders and ABs.*

*Note 3: The role of Deputy Team Leader may be used as training for a future Team Leader.*

*Note 4: A Deputy Team Leader may be a lead evaluator but if assigned to a team, the Deputy Team Leader shall have different competencies to the Team Leader to cover as much as possible of the accreditation activities of the accreditation body under evaluation.*

(f) The inclusion of Provisional Evaluators, for which a qualified mentor (an evaluator with experience in more than two evaluations) will be appointed.

*Note 1: At least one Provisional Evaluator, and no more than two Provisional Evaluators, is expected to be included as a Team Member, except where an evaluation is solely for the purpose of an application for extension of scope to the APAC MRA.*

(g) A team member may, in addition to his/her evaluation tasks, mentor any Provisional Evaluator (those performing their first evaluation) assigned to the evaluation team. Mentoring Provisional Evaluators includes allocating him/her such task as he/she is capable of performing, supervising and providing a report to the MRAMC about the performance of the trainee.

 (h) The team chosen shall consist of representatives from a cross-section of APAC member accreditation bodies. The inclusion of more than one Team Member from a single economy should be avoided as far as practicable.

(i) 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. Providing public training courses is not considered to be consultancy.

18.2.3 The Team Leader shall conclude the team composition and agree to the week of the peer evaluation with the applicant body six to nine months prior to the due date or requested date. Once agreed, the Team Leader shall advise the APAC Secretariat and APAC MRA MC Chair. The ECR form (APAC FMRA-005) must be updated and approved by the APAC MRA MC Chair.

18.2.4 The Team Leader shall inform the applicant body 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 proposed observers.

18.2.5 Once the Team Members have been finalised, the Team Leader shall, using the ECR form (APAC FMRA-005), promptly advise the APAC 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.

18.2.6 Once the evaluation team has been accepted by the applicant body, all significant communication (other than about logistical arrangements) between the evaluation team and APAC shall be conducted through the Team Leader, copied to the APAC MRA MC Chair. A copy of all correspondence shall be sent to the APAC Secretariat for inclusion in the evaluation records.

18.2.7 The APAC Secretariat shall prepare and distribute the letters of appointment (mandate letters) to the team and the AB.

18.2.8 Upon receipt of the letters of appointment (mandate letters), all members of the evaluation team shall confirm to the APAC Secretariat that they have no conflict of interest with the applicant.

18.2.9 Evaluators qualified/recognized by IAF, ILAC or other Regional Groups are deemed competent by APAC for the equivalent scopes and may be used for APAC MRA evaluations.

18.3 Competence requirements for Provisional Evaluators, Evaluators and Lead Evaluators are given in APAC MRA-004 and IAF/ILAC-A2.

18.4 The role and the responsibilities of the evaluation team are outlined in Annex B to this document.

PREPARATION FOR EVALUATION

19.1 The Team Leader (with the assistance of a Deputy TL as necessary) shall organise the evaluation. If a pre-evaluation has taken place, the evaluation visit shall not be carried out until the applicant body has submitted an application for the full evaluation after the pre-evaluation visit.

19.2 The applicant body may request that the evaluation emphasises a certain area(s) of its accreditation activities, such as “EMC to domestic and foreign regulations” or “Medical Device certification.” 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 APAC MRA Council may decide to include reference to this specific area of recognition within the applicant body’s scope of recognition listed in the APAC Register of Members and Affiliates (APAC FGOV-011). Such service shall only be provided on condition that the normal evaluation activities will not be adversely affected.

19.3 The Team Members shall be allocated specific tasks by the Team Leader prior to the evaluation.

19.4 The APAC Secretariat shall provide:

* Details of the applicant body’s voting history in APAC ballots;
* Where relevant, a copy of the final report from the previous evaluation, a copy of the APAC MRA Council’s resolution decision on the previous evaluation, and a list of CABs whose assessments were witnessed at the previous evaluation.

19.5 The Team Leader shall ensure that this information and the documentation provided by the accreditation body 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.

19.6 When planning the evaluation, information in the pre-evaluation report, where relevant, or information in reports on previous evaluations shall be taken into account.

19.7 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. For each of the scopes of recognition in the APAC MRA being sought by the applicant body, the evaluation team shall witness at least one initial assessment, or reassessment, or two other on-site assessments involving a significant component of technical assessment by the applicant body. The key objective is that the evaluation team witness the performance of the accreditation body’s technical assessors to determine the level of competency and adherence to the applicant accreditation body and APAC MRA requirements.

19.8 The above witnessing requirements are deemed to be a minimum. More witnessing may be required at the discretion of the Team Leader. The objectives of the witness shall be achieved by evaluating the applicant body’s assessment which covers a substantial majority of the accreditation criteria.

19.9 Other factors that may impact 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;
* Domestic and regulatory requirements, policies and/or procedures.

19.10 The evaluation team shall make provision in the visit agenda for time to prepare a summary of findings in accordance with IAF/ILAC-A3.

CONDUCT OF THE ON-SITE EVALUATION

20.1 Team Meetings

20.1.1 Before commencing the on-site evaluation, the team shall hold a meeting in private to consult about the aspects to be evaluated by each Team Member.

20.1.2 The team shall allow sufficient time to discuss its findings in a closed meeting at the end of each day or session and should seek clarification arising from observations of on-site assessment activities before formulating its findings. The team should consider whether information arising from observing on-site assessments is sufficient to confirm that the objectives of the witnessing have been fully achieved or if additional witnessing is required.

 20.2 Opening Meeting

20.2.1 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.

20.3 On-site Evaluation

20.3.1 The on-site evaluation shall be conducted in accordance with IAF/ILAC A-2 and this document.

20.3.2 The evaluation team shall evaluate the operational procedures and practices of the applicant body at its offices, and at conformity assessment bodies undergoing assessment/re-assessment.

*Note: Additional guidance on the conduct of evaluations can be found in APAC MRA-006.*

20.3.3 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.

20.3.4 An on-site visit consists of, as a minimum, a visit to the office of the accreditation body and witnessing the assessment(s) of a CAB(s) in order to evaluate the operational processes of the accreditation body and verify that these processes ensure the competence of its accredited CABs.

20.3.5 The duration of an on-site evaluation depends on the number of scopes and sub-scopes being assessed and the length and number of the assessments to be witnessed. In accordance with IAF/ILAC A2 other factors influencing duration can include the need for translators; extensive travel and travel circumstances; and cultural differences.

*Note 1: Witnessing of assessment activities 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.*

20.6 Closing Meeting

20.6.1 A closing meeting shall be held with the senior management of the applicant body to present the findings from the on-site evaluation.

20.6.2 The team shall present the applicant body with a Summary of Findings (in accordance with IAF/ILAC-A3) 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. The Team Leader shall give the applicant body an opportunity to comment on and discuss the nonconformities, concerns, comments, and the team’s conclusions, and to clear up any misunderstandings that may have arisen.

20.6.3 The applicant may also add its own observations. If it is obvious to the team that a follow-up visit is required, then this should also be included in the Summary. The summary shall be signed by all the team members

20.6.4 The team should also determine the method of follow-up for all nonconformities and concerns identified, including any follow-up visit, if applicable, with the agreement of the applicant body. Approval by the APAC 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 APAC MRA Council.

20.6.5 If any problems or difficulties are encountered during the course of the evaluation, including for only part of the scope, possible options available to the Team Leader are to withdraw the team from the visit, 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 APAC MRA MC, unless impracticable, before any such decision is made.

20.6.6 If the applicant does not accept any of the findings or refuses to take any actions as requested by the Team Leader, the Team Leader shall seek the advice of the Chair of APAC MRA MC. If the evaluation team, the applicant, and the Chair of APAC MRA MC cannot reach an agreement, the matter shall be referred to the APAC MRA Council for a decision. The Chair of the APAC MRA Council may choose to appoint a three-member group independent of the APAC MRA MC to deal with any disagreements, or to refer the matter to the appropriate APAC or ILAC/IAF committee, as appropriate.

20.6.7 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 APAC MRA signatory requirements cannot be assured, the Team Leader shall inform the Chair of the APAC MRA MC within two weeks after the on-site evaluation. In consultation with the Team Leader, the APAC MRA MC Chair shall decide whether any additional action needs to be undertaken in addition to that otherwise specified in this document.

EVALUATION REPORT

21.1 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 IAF/ILAC-A3, the evaluation report template and the findings and their classification shall be consistent with IAF/ILAC A-3 Part 3 B.

*Note 1: The report should clearly highlight compliance with the requirements of the relevant ISO(/IEC) standard(s), APAC and IAF/ILAC MLA/MRA supplementary requirements, when relevant, and the applicant body’s own requirements.*

21.2 The report’s Summary of Findings shall be updated based on the evidence from any follow up visit.

21.3 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 APAC MRA Council, the evaluation Team Leader shall advise the APAC MRA MC Chair of the situation. The APAC MRA MC shall re-arrange the schedule or shall appoint a new Team Leader (or assign the Deputy 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.

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

21.5 Under the conditions detailed in Appendix C, the APAC MRA Council permits an evaluated accreditation body to provide copies of its evaluation report to interested parties, as decided by the applicant body.

CORRECTIVE ACTIONS AND RESPONSES TO EVALUATION FINDINGS

22.1 Corrective Action and Response Report

The applicant body shall provide the Team Leader with a response to the findings that consists of:

22.1.1 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);

22.1.2 For Concerns – providing the evaluation team with an appropriate action plan and time schedule for implementation;

22.1.3 For Comments – the accreditation body is encouraged to respond to comments.

22.2 For an initial evaluation, the accreditation body’s response shall be provided within three months of receipt of the evaluation report. For a re-evaluation, the accreditation body’s response shall be provided within one month of receipt of the evaluation report.

*Note 1: The accreditation body’s response shall be inserted as text against each finding presented in the report, with attachments of supporting evidence of corrective action as appropriate.*

22.3 Evidence of implementation of any corrective action shall be provided by the evaluated body. The level of verification required to assess the effectiveness of the corrective action taken may vary depending on the significance of the findings. For example, in certain circumstances the Team Leader may consider it appropriate to accept remote evaluation of the corrective action taken. In other circumstances, depending on the severity of the nonconformity, the Team Leader may consider it appropriate to conduct a follow-up visit for on-site verification of the corrective action taken.

22.4 The Team Leader, in consultation with the other members of the team, shall review the applicant’s response to the report including all proposed corrections and corrective actions. Where possible, the Team Leader shall notify the applicant within 30 days after receiving the response whether or not the team finds the corrections and corrective actions and the time schedule acceptable.

22.5 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.

22.6 Where the team finds the applicant’s response unsatisfactory, the applicant must provide a further response within two weeks after having communications with the team.

22.7 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 APAC MRA MC.

22.8 The Team Leader shall draft and submit the draft final evaluation report within 30 days after all nonconformities, concerns and comments have been closed.

1. DOCUMENTS FOR REVIEW BY THE EVALUATION REVIEW PANEL

23.1 In accordance with the Evaluation Control Record, the Team Leader shall send the following documents to the APAC Secretariat as soon as practicable after the satisfactory close-out of findings for consideration by the APAC ERP:

* The evaluation report as an electronic copy (MS Word), which may include scanned copies of the signed original signature pages, including the applicant body’s Corrective Action and Response Report (accompanied by all supporting documentation) and the team’s reply;
* The evaluation team’s recommendation to the APAC ERP;
* A list of the names of the conformity assessment bodies whose assessments were witnessed as part of the evaluation (see template APAC FMRA-012);
* The completed Peer Evaluator and Technical Expert Performance Forms (APAC FMRA-008);
* The completed Evaluation Control Record (ECR) (APAC FMRA-005).

23.2 The recommendations for an initial evaluation shall include:

* Whether or not the applicant body should be accepted as a signatory to the APAC MRA;
* The scope of signatory recognition within the APAC MRA;
* The timeframe for any follow-up visit and/or full re-evaluation.

23.3 For a re-evaluation the recommendations shall include:

* Whether or not recognition as a signatory to the APAC MRA should be continued;
* Any variation to the scope of signatory recognition;
* The timeframe for any follow-up visit and/or full re-evaluation.

23.4 If the team recommends that the applicant body not be accepted as a signatory to the APAC 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.

REVIEW BY THE EVALUATION REVIEW PANEL

24.1 The task of the APAC ERP is to review the evaluation, planning and execution and to consider the scope, breadth and depth of the evaluation. The ERP shall review all reports and shall decide and formally record its decision on two aspects of the report and any recommendations made by the Evaluation Team:

1. Does the report satisfactorily close the findings?
2. Is the report and its recommendations considered acceptable for presentation to APAC MRA Council in either electronic ballot or at a face-to-face meeting?

24.2 Upon receipt of the draft final report the members of the APAC ERP shall study the report to ensure that it complies with the requirements of APAC peer evaluation process and make recommendations to the ERP Moderator. The date for responses is to be 30 days from the date of receipt of the draft final report.

24.3 The draft final evaluation report may be returned to the evaluation team leader for clarification if required. If the report is changed from that provided to the applicant body, the amended report shall be provided to the applicant body for comment. The applicant shall have a period of 15 days to review the amended report and provide a response.

24.4 If the evaluation team has recommended a follow up visit after acceptance of the applicant body as a signatory of the APAC MRA, the APAC ERP will judge this on a case-by-case basis. The follow up visit should address, as a minimum, all findings identified as requiring verification by a visit, and can include other observations on actions taken by the applicant.

24.5 The Moderator of the ERP shall generate and provide an Evaluation Review Panel Summary Report.

24.6 If the ERP determines that the report or the recommendations of the Evaluation Team will not result in clear consensus in the APAC MRA Council to agree with the recommendations of the Evaluation Team, the Moderator of the ERP is to discuss action to address the relevant issues with the Team Leader and arrange for resubmission of a revised report within a specified timeframe not longer than one month.

24.7 Any decision to delay and modify the team’s report and recommendations is to be communicated to:

* Chair, APAC MRA MC
* APAC Secretariat
* Evaluated body.

24.8 The Team Leader shall amend the report as appropriate and send the amended report and recommendations to the ERP for agreement and / or clarification.

24.9 If the Team Leader does not agree with the ERP comments, the comments shall be forwarded to the APAC Secretariat for a determination by the APAC MRA Council.

24.10 Once the draft evaluation report has been agreed by the evaluation Team Leader and the ERP, the evaluation Team Leader shall forward the final draft of the report to the applicant body.

24.11 Further guidance on the operation of the APAC evaluation report review procedure is given in Annex E to this document.

REVIEW AND DECISION-MAKING BY THE MRA COUNCIL

25.1 The APAC Secretariat shall submit the final evaluation report together with the ERP Summary Report to the APAC MRA Council for a 14 day comment period.

25.2 At the end of the comment period any comments received shall be forwarded to the ERP Moderator and Team Leader for consideration. Within seven days of receiving the comments the Final Evaluation Report and/or Evaluation Review Summary Report shall be sent to the Secretary for MRA Council ballot. A copy shall also be sent to the applicant body if it is not already a member of the Council.

25.3 The MRA Council ballot shall close 30 days after issue by the APAC Secretariat. The APAC MRA Council Delegates or Alternate Delegates shall be competent for any decision-making processes of the APAC MRA Council for which they are involved. The competence shall be reviewed by the APAC MRA MC Chair.

25.4 Evaluation team members shall not vote on ballots that relate to their own evaluation reports. APAC MRA Council Members shall vote abstention on ballots where they are the evaluatee.

25.5 The APAC MRA Council shall not approve any member body for admission or continuance to the APAC MRA before all nonconformities are closed out and that action plans provided in response to Concerns are to the satisfaction of the evaluation team and APAC ERP.

25.6 The APAC Secretariat informs the applicant body of the result of balloting.

25.7 The APAC Secretariat informs the Chair of the APAC MRA MC to allow the latter to forward a copy of the form APAC FMRA-006 *Peer Evaluation Feedback* to the applicant for completion and return within 30 days after the close of ballot. The feedback received is discussed by the APAC MRA MC, if required.

25.8 Requirement for Team Leader to Appear before APAC MRA Council

25.8.1 The Team Leader (and where required the Deputy Team Leader) for the evaluation shall attend the APAC MRA Council meeting at which the report on the evaluation is considered, in all instances when the APAC MRA Council reviews the Evaluation Report during a regularly scheduled meeting. Attendance via teleconference may be considered as an option.

25.8.2 If the person(s) does not routinely attend APAC MRA Council meetings, APAC shall provide funding for her/his attendance based on: return economy airfare; 3 night’s 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).

25.8.3 If a report is considered at a meeting, the applicant body shall also be represented at any APAC MRA Council meeting at which their (re)-evaluation report is considered.

APPEALS

26.1 Appeals shall be handled in accordance with IAF/ILAC-A2 and APAC MRA-003.

AMENDMENT TABLE

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

|  |  |  |
| --- | --- | --- |
| **Date** | **Section** | **Description** |
| 16/06/2019 | Definition of witnessing, 16.3,18.2.2,20.3.5, 20.6.6, 25.1 and 25.2, Annex F 11 | Minor changes to address IAF/ILAC Regional Evaluation findings, and introduce a MRA Council opportunity. |
| 07/05/2019 | Part 1 and 2 | Minor modifications in response to APAC MRAMC Action 1901-01, including removal of reference to provisional lead evaluator, allowing for extensions on the basis of reports from other regions, clarity that evaluation team members cannot vote on their own evaluation reports, and amendment of the evaluator performance form. |
| 01/01/2019 | All | New issue on establishment of APAC.  |

ANNEX A – PROCESS FLOW FOR PEER EVALUATIONS

| **Function** | **APAC MRA MC** | **Secretariat** | **TL** | **AB** | **ERP** | **Timeframe** |
| --- | --- | --- | --- | --- | --- | --- |
| Appoint TL, and where applicable, DTL | X |  |  |  |  | 18 – 24 months prior to the evaluation due date |
| Inform TL and DTL of the appointment  |  | X |  |  |  |
| Select TMs |  |  | X |  |  |  9-12 months prior to the due date |
| Confirm the evaluation week with TMs and AB (\*) |  |  | X |  |  |
| Approve TM selection (MRA MC Chair) | X |  |  |  |  |
| Appoint Evaluation Review Panel (ERP) | X |  |  |  |  |
| Inform TL of the composition of the ERP |  | X |  |  |  |
| Distribute the Mandate letters to the team and AB |  | X |  |  |  |
| Distribute copies of the preceding evaluation report to the TL |  | X |  |  |  |
| TL to receive draft IAF/ILAC-A3 report from AB |  |  |  | X |  | 3 months before any proposed on-site evaluation |
| Complete the document review  |  |  | X |  |  | Normally at least 30-90 days before on-site evaluation |
| Submit the evaluation plan to the AB  |  |  | X |  |  |
| Submit Summary Report and Findings to the AB at the closing meeting |  |  | X |  |  | Evaluation Closing Meeting |
| Complete responses to findings and submit to TL |  |  |  | X |  | 30 or 60 days after receipt the report depending on areas covered |
| Review AB responses to findings with Evaluation Team |  |  | X |  |  |  |
| Verify the corrective actions |  |  | X |  |  | 30 days plus 2 weeks for further response post receipt of responses |
| Submit the draft final report to Moderator ERP  |  |  | X |  |  |
| Review the draft final evaluation report |  |  |  |  | X | 30 days after receipt of the report |
| Agree the draft final evaluation report |  |  | X |  | X  |  |
| If changes are made, resubmit the draft final evaluation report to the AB (\*) |  |  | X |  |  |  |
| Agree the draft final evaluation report |  |  | X | X | X | 30 days after receipt of the draft final report |
| Prepare ERP Summary report and agree with TL on content (\*) |  |  |  |  | X  |
| Submit the final evaluation report to the AB and Secretariat |  |  | X |  |  |
| Submit the final evaluation report and the ERP recommendations to the APAC MRA Council |  | X |  |  |  |
| Complete ECR |  | X | X |  | X | 7 days after ERP endorsement |
| Inform the AB of the result of balloting |  | X |  |  |  | 7 days after the close of ballot |
| Send letter to AB to solicit comments on conduct of Evaluation Team | X |  |  |  |  | 7 days after the close of ballot |

(\*) The APAC Secretariat must be informed.

ANNEX B – ROLE AND RESPONSIBILITIES OF EVALUATION TEAM

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

1. The evaluation team shall evaluate conformity of the applicant body with the APAC MRA criteria stated in Section 5 of this document. The two other key tasks of an APAC 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.

1. Verify whether the technical competence of the accredited conformity assessment body is appropriate to its scope of accreditation.

2. 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 she/he is capable of performing, supervising, and providing a report to the APAC MRA MC about the performance of the Provisional Evaluator (APAC FMRA-008).

3. Evaluation Team Members shall cooperate with the Team Leader and other Team Members and treat one another with multilateral or mutual respect. The evaluation team should strive to reach consensus, and any disagreement should be resolved amicably.

ANNEX C – 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 APAC 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 APAC MRA Council.

2. The full evaluation report (including the accreditation body’s responses to the findings) and the APAC 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.

ANNEX D – EVALUATION REVIEW PANEL COMPETENCIES

1. The Evaluation Review Panel (ERP) will need to have an understanding of what should be in an APAC evaluation report from a generic and specific perspective. The ERP shall have collective expertise at levels 1, 2 and 3 of the IAF MLA, the ILAC MRA, and the APAC MRA.
2. The ERP needs to understand the planning and conduct of the evaluation, its breadth and depth, the findings and their classification, and the adequacy of the conclusions, and recommendations. The competencies required would be consistent with that of an individual with experience as an accreditation body assessor, and exposure to the APAC documents, Joint-A series documents, IAF MLA P&P documents, ILAC P-series documents as well as practical experience in the peer evaluation process.
3. To be able to effectively correspond with the evaluation Team Leader, the ERP requires good communication skills and an understanding of the criteria and process. The competencies would be similar to those listed in point 2 above.
4. There should be a balance of members with competencies on the IAF MLA and on the ILAC MRA.

ANNEX E – APAC EVALUATION REPORT REVIEW PROCEDURE

**1. INTRODUCTION**

The MRA Council begins an evaluation by assigning a Team Leader (and where applicable, a Deputy Team Leader) and appointing an Evaluation Review Panel. The Team Leader then forms the evaluation team with the approval of the APAC MRA MC. When the evaluation has been completed, the team will provide its report on the evaluation to the Secretariat and the Evaluation Review Panel. The report will be reviewed by the Evaluation Review Panel to ensure its consistency of application and distributed to all MRA Council members for review before a decision is made on the team’s recommendations.

The work of the Evaluation Review Panel is fundamental to the success of the APAC MRA. Review of an evaluation report and approval by the MRA Council delegates is an essential element of the APAC Mutual Recognition Arrangement process. These two processes ensure 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 APAC MRA signatories. During the review process, ambiguity in the recognition criteria can also be raised for discussion to achieve harmonisation. The checklist in APAC FMRA-013 is designed to aid the review process through a series of questions that Review Panel members 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.

ERP Members should ensure the evaluation report is ready for full MRA Council examination before asking the MRA Council to consider and discuss it. Consideration should be given to any precedents (passed as MRA Council resolutions) set by the MRA Council in similar cases.

MRA Council delegates should study the evaluation report carefully before making their decision.

Should any ambiguities in interpreting the MRA criteria be brought to light through the evaluation or the review process, they should be addressed through discussion between the ERP and the evaluation team and may include the evaluated body before such issues are raised for discussion 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, the ERP Members should seek clarification from the evaluation team and the AB before recommending acceptance of the evaluation report by MRA Council Members. When raising issues to the evaluated body and the evaluation team, care should be taken to ensure that the issue is well understood in the sense that the information requested is clearly expressed.

As the role of the ERP reviewer is to ensure that the evaluation has been properly conducted and that the conclusions and recommendations are well substantiated by the findings, she/he should form her/his own judgement based on the preponderance of the evidence given in the evaluation report. Where the findings, conclusions and recommendations are properly made based on sufficient evidence and justification, ERP Members should respect the judgement made by the evaluation team and should not amend the findings or the recommendations because of an individual preference.

**3. ERP REVIEW PROCEDURE**

The review procedure used by the ERP consists of four sequential steps. The questions included in the corresponding sections of APAC FMRA-013 are designed to provide assistance in carrying out these steps.

Step 1: Establishing whether the findings are reliable

The ERP Member 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 APAC MRA-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 ERP Member 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 APAC MRA criteria are given in Section 1 (Summary of Findings) of the evaluation report, and in the letter of recommendation to the ERP Moderator written by the Team Leader. Based on the analysis in Step 2, the ERP Member 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 ERP Member should establish whether such recommendations are supported by the conclusions of the evaluation team, as reviewed in Step 3.

**4. RESOLUTION OF ISSUES**

Issues identified by the ERP during review must be addressed through discussion between the ERP and the evaluation team (and may include the evaluated body) before such issues are raised for discussion in the MRA Council. Such resolution is required before the ERP can make a recommendation to the MRA Council.

Identified inadequacy in the evidence and rationale supporting the team’s recommendations require clarification from the evaluation team and the AB before recommending acceptance of the evaluation report by MRA Council Members.

**5. ERP RECOMMENDATION TO MRA COUNCIL**

When ERP is satisfied that all issues have been addressed appropriately, they may make a suitable recommendation to MRA Council.

The Team Leader formally presents the report that has been through this entire process to the MRA Council during the next available meeting or provides an appropriate recommendation for the Secretariat to include in any electronic balloting process.

ANNEX F – REQUIRED DOCUMENTATION – SET A AND SET B DOCUMENTS

**SET A:**

General

1. Self-evaluation report against ISO/IEC 17011 and other APAC requirements by completing the template given in IAF/ILAC-A3;

2. The applicant body’s quality documentation in which its policies and procedures, and the responsibility for implementation of the quality system are clearly described;

3. Accreditation criteria and associated generally applicable technical criteria that the applicant body publishes;

4. All other general criteria published which include formal rules or regulations affecting the applicant body’s operation and the responsibilities and obligations of its accredited organisations;

5. A checklist or other cross-reference showing the applicant body’s compliance with the requirements of the relevant ISO(/IEC) standard(s);

6. Details of any organisations to which assessment activities are sub-contracted, either routinely or from time-to-time (if not included in 1. above);

7. Detailed scopes of accreditation (or draft scopes of accreditation) of all CABs to be visited during the evaluation visit.

Specific

8. The written guidance, if any, provided for the calculation of measurement uncertainty for calibration laboratories, testing laboratories and RMPs;

9. If applicable, the policy statement on the use of peer inspectors for inspection body assessments (if not included in 1. above);

10. Operational procedures covering proficiency testing, including criteria for statistical evaluation and corrective action procedures;

11. Summary listing of all proficiency testing activity undertaken in the last two years by accredited (and applicant) organisations, e.g.

(i) APAC and/or international (other regional) proficiency testing programs (where a final or interim report has been issued), including details of any associated corrective actions. Participation in APAC (and other regional co-operations e.g. IAAC) PT programs for the last 4 years shall be listed;

 (ii) External programs (national or international) that have been mandated by the accreditation body;

(iii) Where it is practical to collate the information, measurement audits and/or any other on-site practical tests;

12. The policy for measurement traceability routes (if not included in 1. above);

13. List of international comparisons in which the economy’s national metrology institute (NMI) has been involved (e.g. comparisons run by Comité Internationale des Poids et des Mésures (CIPM), Asia Pacific Metrology Programme (APMP) or other Regional Metrology Organisations (RMOs)).

*Note: The list of CIPM and RMO key comparisons is available on the BIPM (Bureau Internationale des Poids et des Mésures) website (http://kcdb.bipm.org/).*

**SET B:**

1. Any other documentation that describes the mechanics of operation of the accreditation system, including annual reports, questionnaires, newsletters, guidance documents, summary reports of proficiency testing programs (where applicable), etc;

2. A copy of the applicant body’s directory or other listings providing the name and scope of accreditation of each accredited organisation. If the directory is published through the Internet, the web site address of the directory should be given;

3. Descriptions of any separate functions or affiliations of the applicant body to activities other than accreditation (such as standards writing, etc);

4. Description of the economy’s metrological infrastructure (e.g. national measurement institute or links to any other national measurement institutes);

5. Details of any formal agreement or recognition to which the applicant body is party either nationally or internationally, including with government authorities, private sector organisations, other accreditation systems, etc, and;

6. Reports of any recent evaluations carried out by other relevant organisations, if applicable.