



## **POLICIES AND PROCEDURES FOR A MULTI-LATERAL RECOGNITION ARRANGEMENT AMONG ACCREDITATION BODIES**

### **CLASSIFICATION**

This document is classified as ARAC Mandatory Document.

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## SECTION 1. INTRODUCTION

### 1.1 PURPOSE

To provide the Arab Accreditation Cooperation ARAC with the requirements and procedures of the (ARAC) to establish, maintain and extend a Multilateral Recognition Arrangement (ARAC MLA) among accreditation bodies that are signatories to the Memorandum of Understanding (MoU) of ARAC.

### 1.2 SCOPE

This document identifies general requirements for evaluation of a single accreditation body. Section 3 establishes procedures for the peer evaluation process. The Annexes describe in more detail the major steps of the process.

Note: This document has been based on IAF/ILAC A2.

### 1.3 CONFIDENTIALITY

**1.3.1** All oral and written information received relating to preliminary visits, evaluations, re-evaluations shall be treated confidentially by all parties and persons concerned. This includes information relating to applicants and/or members of the MLA Group. All members and observers of the evaluation teams; all members and observers of the MLA Group, the MLA Secretary, other persons having access to any report on preliminary visits, evaluations and re-evaluations of other applicants and members must have signed a declaration of confidentiality before being given access. (See FM 035 ARAC declaration of confidentiality and commitment).

**1.3.1.1** Form FM 035 shall be signed by evaluators before they are accepted as ARAC evaluators.

**1.3.1.2** Form FM 035 shall be signed by members of MLA Group before they are given access to the first evaluation report.

**Note:** Only one Declaration of Confidentiality will be signed by MLA Group members. It is not necessary to sign form FM 035 for each MLA G meeting.

**1.3.1.3** Observers to the MLA Group meetings shall sign form FM 035 at each meeting, before they are given access to evaluations reports.

**1.3.2** Unless otherwise agreed, the Team Leader (TL), Team Members (TM) and MLA Group members shall destroy all documents they have received, when the final decision has been made by the MLA Group or return all the documents to the AB.

**1.3.3** After conducting the ARAC Peer evaluation, the AB under evaluation and team leader shall agree about how to treat the documents it has provided. This may require the team members to:

- Return all documents to the AB; or
- Destroy the documentation, when it is determined, there is no further need to maintain the documents.

**1.3.4** Ownership and control of evaluation reports: ARAC retains ownership of all peer-evaluation reports and associated evaluation records. Evaluation reports shall be treated as confidential and shall not be publicly disclosed except in accordance with Section 9 of this document or by decision of the ARAC MLA Group. The Accreditation Body under evaluation and the evaluation team shall agree on the handling, retention, return or destruction of documents and records provided during the evaluation after completion of the evaluation and decision-making process.

## 1.4 DEFINITIONS AND ACRONYMS

The following definitions apply for the purpose of this document:

**1.4.1 Accreditation Body (AB):** An organization that operates an accreditation system for one or more types of conformity assessment bodies.

**1.4.2 Accreditation scheme:** Set of criteria specified in a standard or normative document included in the IAF and/or ILAC Arrangements, used for the accreditation of conformity assessment bodies in defined scopes [Level 3].

**1.4.3 Arrangement:** The ARAC Multi-Lateral Arrangement (MLA), which as a consequence of the “recognition” process, will be accepted as a subset of the ILAC or IAF Arrangements.

**1.4.4 ARAC:** Arab Accreditation Cooperation.

**1.4.5 ISO/IEC Standard:** Standard or other normative documents related to accreditation and conformity assessment bodies.

**1.4.6 MLA Committee (MLAC):** The committee responsible for planning and managing the implementation and maintenance of ARAC Multilateral Recognition Arrangement. This committee includes the MLA Group and includes non-signatory members.

**1.4.7 MLA Group (MLAG):** All signatories to the ARAC Arrangement. The MLAG decides on and manages membership in the ARAC Arrangement.

**1.4.8 MLA Secretary:** Secretary for the MLA Committee and MLA Group.

**1.4.9 Peer Evaluation:** A structured process of evaluation of an Accreditation Body by representatives of other peer accreditation bodies.

**Note 1:** *ISO/IEC 17040 defines peer assessment as an evaluation of a body, against specified requirements, by representatives of other bodies in, or candidates for, an agreement group.*

**1.4.10 Proficiency Testing Activity:** All those activities of comparisons of tests, calibrations and inspections between laboratories/inspection bodies used by Accreditation Bodies to assess performance including proficiency tests (refer to ISO/IEC 17043 “Conformity assessment - General requirements for proficiency testing”) inter-laboratory comparisons and measurement audits conducted by competent PT providers (see ILAC P9).

**1.4.11 Signatory:** A Member of ARAC who has signed the ARAC multi-lateral recognition Arrangement for one or more scopes.

**1.4.12 (Peer-evaluation) Team Leader (TL):** A lead evaluator responsible for leading a peer evaluation team.

**1.4.13 (Peer-evaluation) Team Member (TM):** An evaluator or trainee evaluator serving on a peer evaluation team.

**1.4.14 (Peer evaluation) Deputy Team Leader:** An evaluator who is assigned to assist the TL in planning, preparing and managing the evaluation. The Deputy TL can replace the TL in case of illness or unforeseen circumstances.

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

## **SECTION 2: REQUIREMENTS FOR A SINGLE ACCREDITATION BODY**

**2.1** An Accreditation body shall comply with the provisions of ISO/IEC 17011 and future versions thereof.

**2.2** Every applicant or signatory to the ARAC MLA shall operate according to applicable IAF and ILAC mandatory documents, as specified in the IAF/ILAC A series documents, IAF mandatory documents, as specified in the MD series, ILAC procedural and policy documents, as specified in the ILAC P series, and all other requirements of IAF and ILAC, as well as any mandatory documents issued by sector specific schemes that have been endorsed by ARAC, IAF or ILAC. Every applicant or signatory of the ARAC MLA shall comply with any decision made by ARAC, IAF or ILAC regarding the implementation date of these mandatory documents.

**2.3** Every applicant or signatory to the ARAC MLA shall contribute its fair share of personnel resources for carrying out peer evaluations at the regional and/or international level. Each signatory shall contribute to ARAC, within the recognition cycle, at least one peer evaluator for each scope and standard for which it is a signatory.

**2.4** Every applicant Accreditation Body or Signatory to the ARAC MLA for calibration or testing, including medical or clinical laboratories and inspection shall participate in and use, as far as available and practicable, Proficiency Testing Activity offered by ARAC, and when applicable by other Regional Groups, in order to verify the competence of its accredited laboratories and to demonstrate the Accreditation Body's ability to take appropriate actions if necessary.

**2.5** The Accreditation Body shall:

**2.5.1** Demonstrate operational experience and competence in the assessment and accreditation of conformity assessment bodies (CABs) within the scope(s) of the Arrangement for which it applies.

This shall be evidenced by:

- conducting accreditation assessments activities; and
- maintaining a sufficient number of accredited CABs within each applied scope at the time of application, enabling ARAC to evaluate the implementation and effectiveness of the accreditation process.

The Accreditation Body shall have at least one valid accreditation in each applied scope at the time of application.

*Note:* Evidence of operational maturity may be evaluated based on the extent and effectiveness of accreditation activities performed rather than the completion of a full accreditation cycle.

2.5.2 Have demonstrated experience in operating an accreditation body, and have access to technical expertise in all schemes of its accreditation activities. Where the number of accredited Conformity Assessment Bodies is less than 4 at the time of evaluation, the need for a follow-up evaluation before the normal 4 year period shall be considered by the ARAC MLA Group; The MLAG should identify the objective of this follow-up evaluation, including the tasks of the evaluation team.

2.5.3 Specify the acceptable routes for traceability, and assess its implementation by CABs (ILAC applicant and signatory ABs: see ILAC P10);

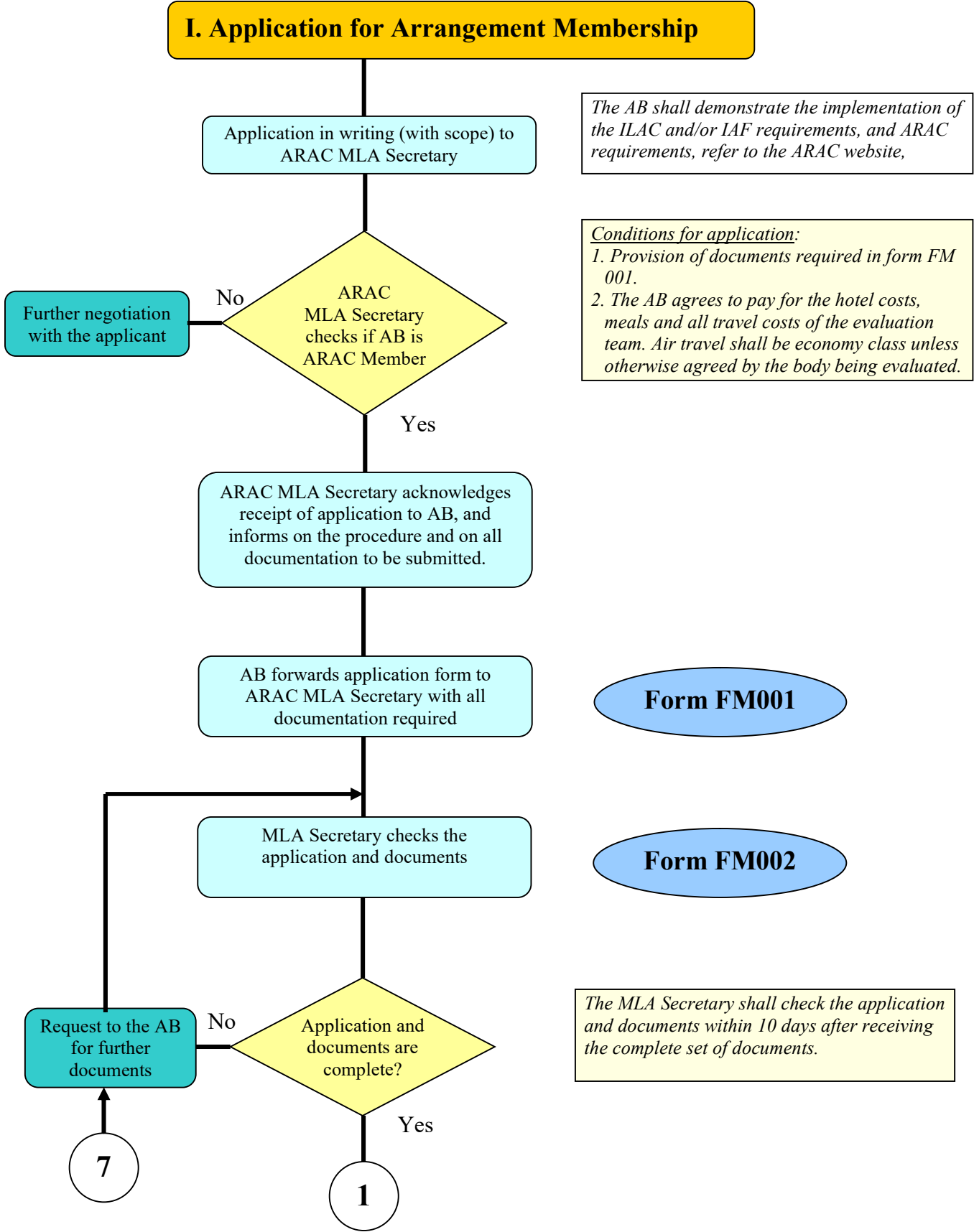
2.5.4 Ensure that it meets the relevant requirements for proficiency testing activity (ILAC applicant and signatory ABs: see ILAC P9);

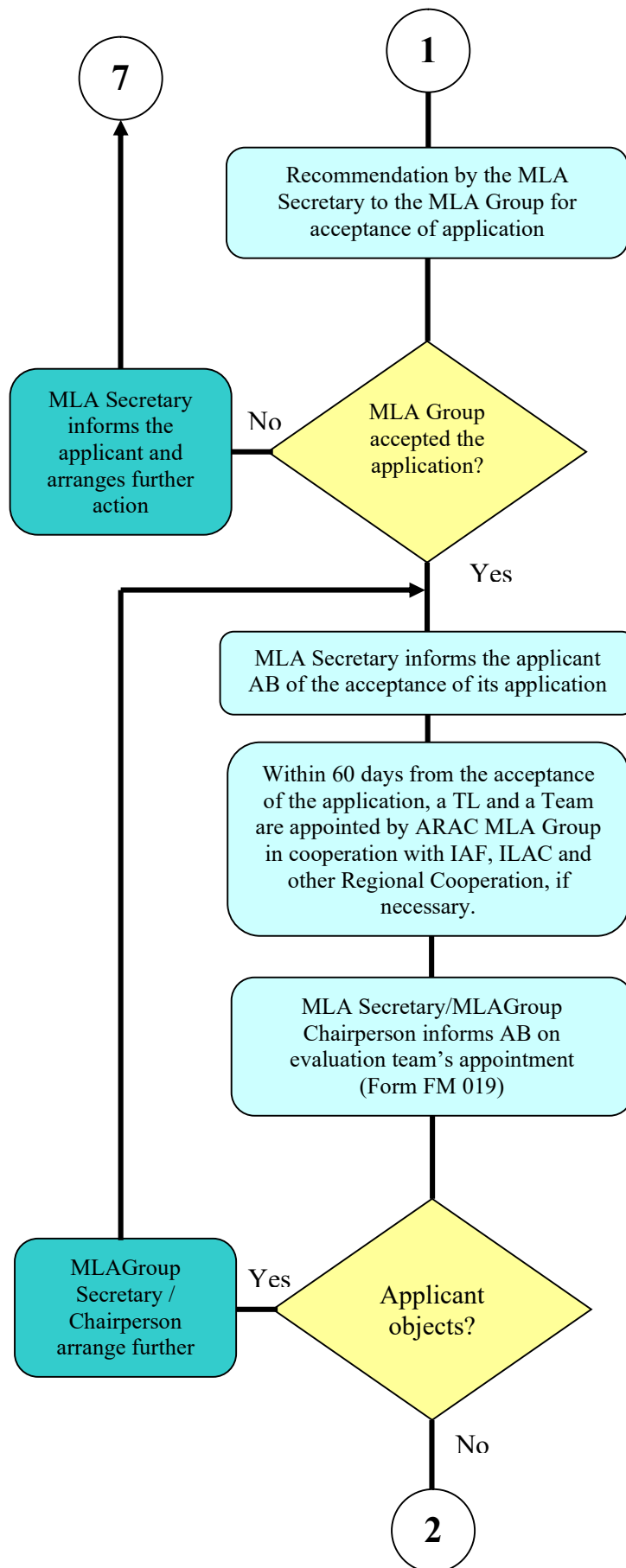
2.5.5 Abide by the requirements and obligations of the ARAC MLA and international Arrangement(s);

2.5.6 Have evidence of promoting the Arrangement with major stakeholders;

2.5.7 Have implemented a cross frontier accreditation policy in accordance with the relevant IAF document(s) (for IAF signatories) or taking into account ILAC Guide 21 (for ILAC signatories).

SECTION 3: Flowchart for Peer Evaluation Procedures of a Single Accreditation Body





*Voting on application has to be done within 30 days from acceptance of application and may be done by email ballot. If MLA Group raises comments during the ballot that may not be resolved by email, the application will be discussed in the next meeting of the MLA Group.*

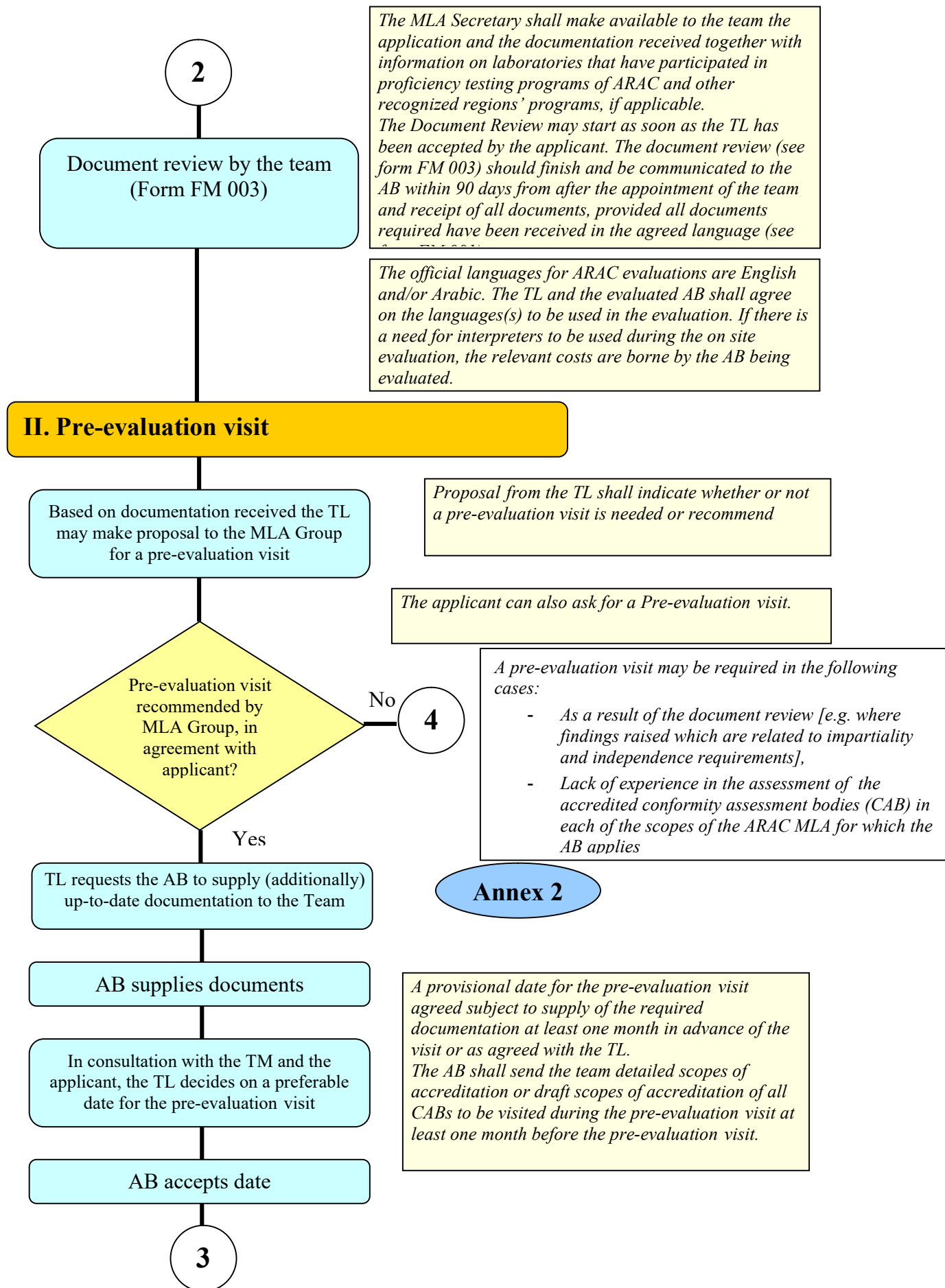
*Note: Members of the team may be appointed on separate occasions.*

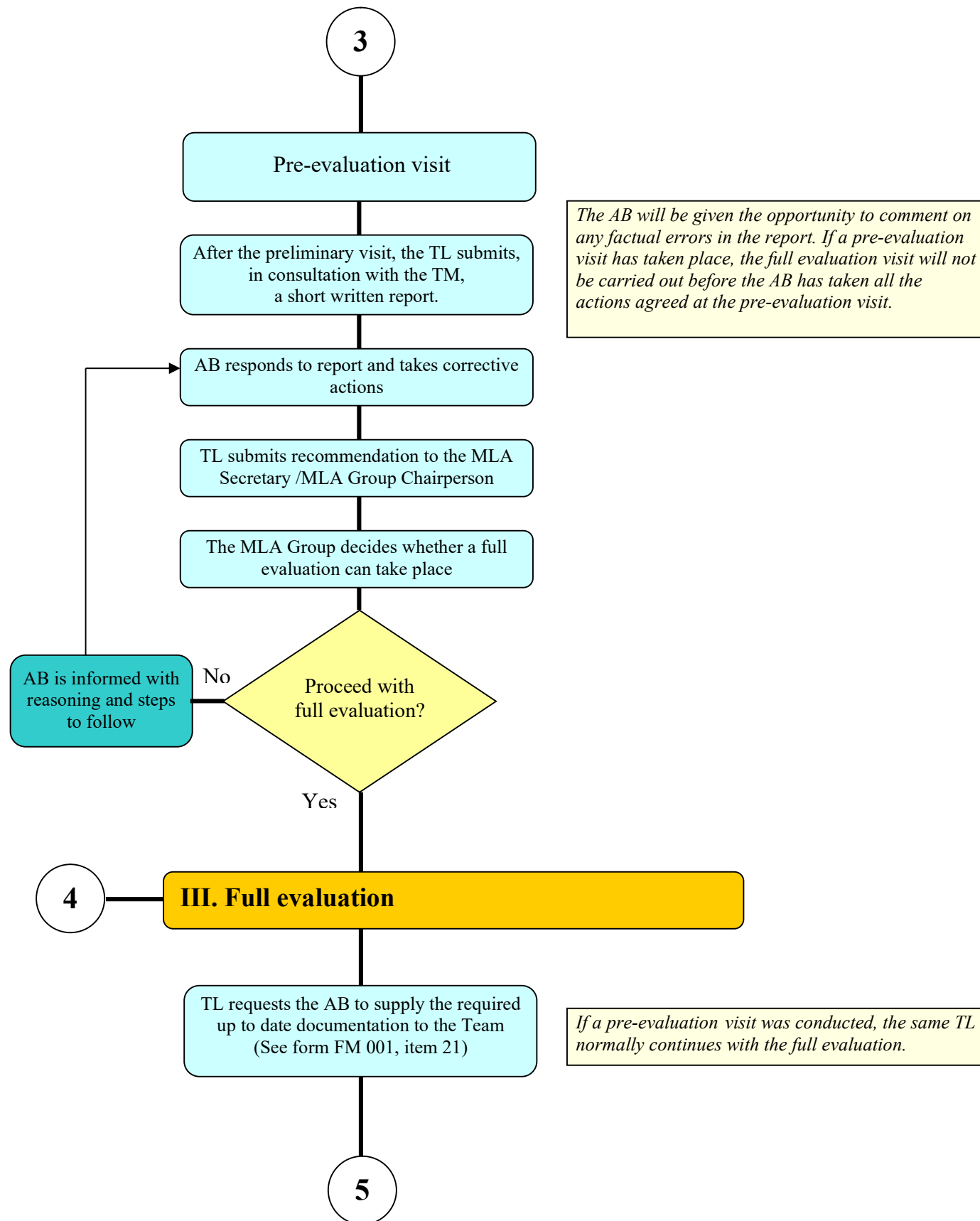
### Annex 1

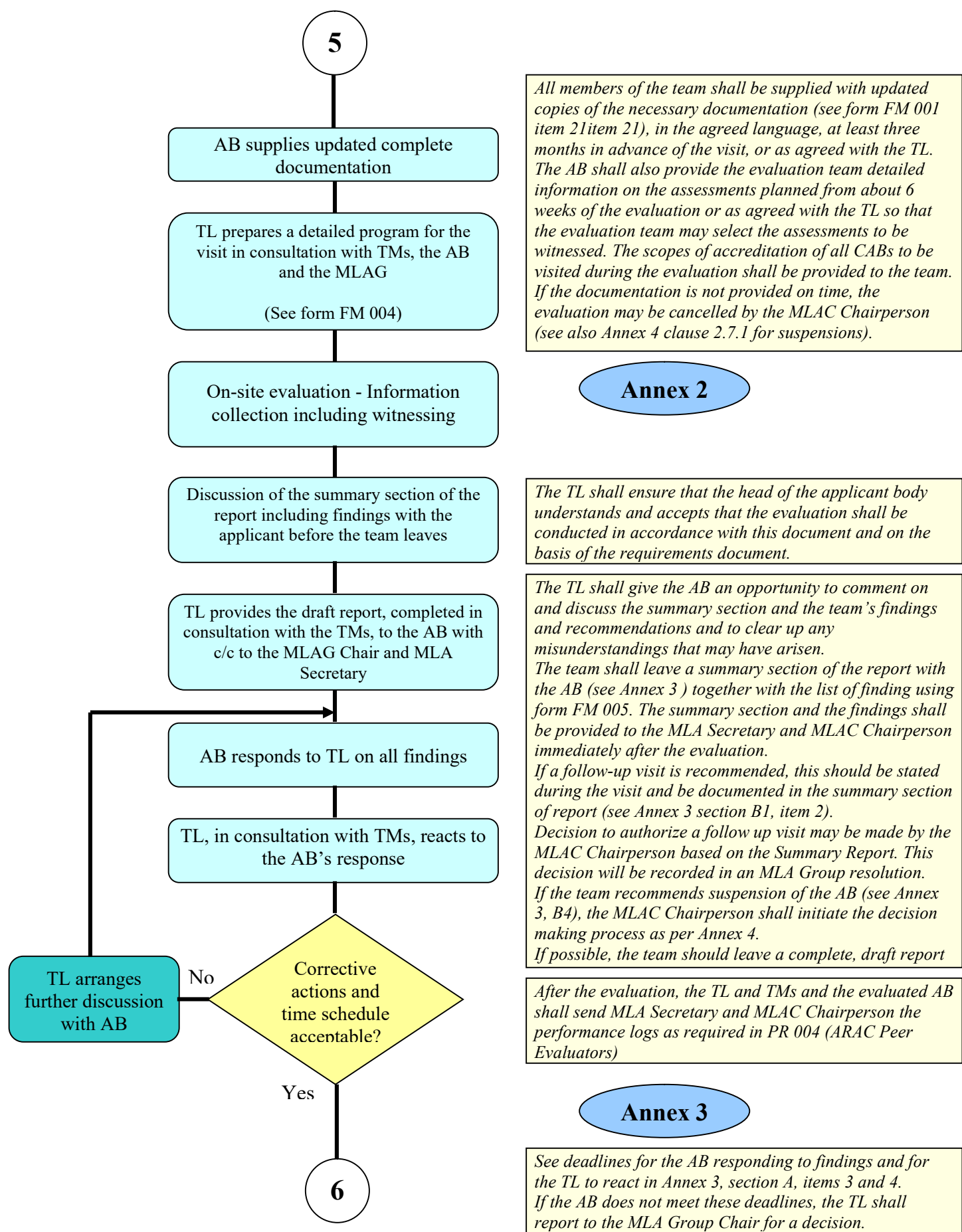
*The MLAGroup Chairperson/ MLA Secretary shall inform the TL and TM of their appointment and mandate, using form FM 019, including any evaluators appointed by IAF, ILAC or other regional cooperation.*

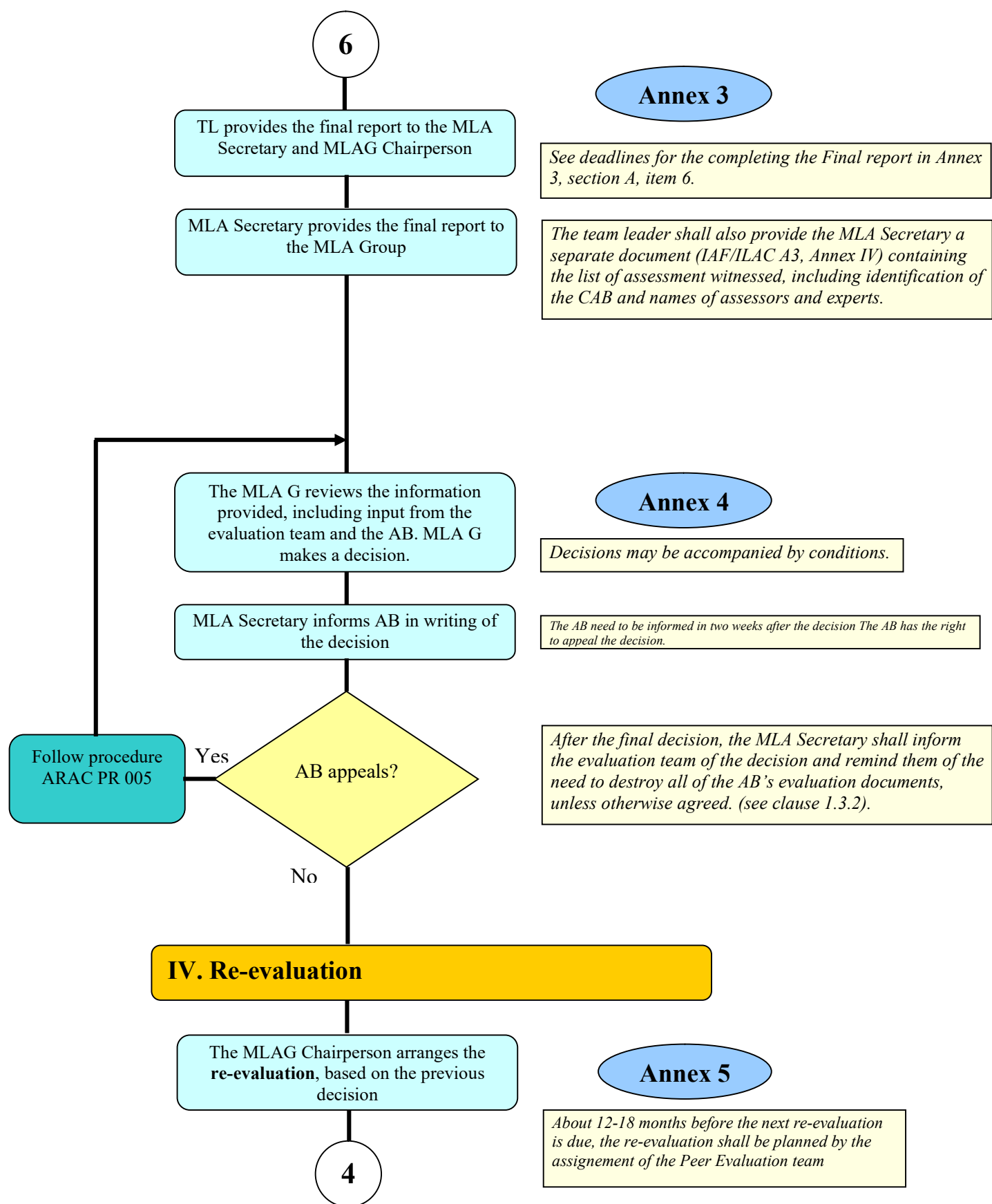
- If the evaluation is done in cooperation with IAF/ILAC or other Regional Cooperation, the team shall take into account the relevant requirements and procedures of ARAC as well as the requirements and procedures of those organizations.*

*The AB may object, based on conflict of interest and impartiality, the appointment of any member of the team. The objection of the AB to any team member shall be within 2 weeks from being informed of the team composition. If the AB exceeds this period then the team is considered accepted by the AB.*









## ANNEX 1

### APPOINTMENT AND COMPOSITION OF THE PEER EVALUATION TEAM

#### 1 APPOINTMENT AND DUTIES OF TEAM LEADER

**1.1** Team leaders shall be chosen from the list of qualified lead evaluators of the ARAC Peer Evaluators List available with the MLA Secretariat and in the member's area on the ARAC Website and kept up to date.

**Note:** See procedure PR 004 for selection, training, qualification and monitoring the performance of ARAC Peer Evaluators.

**1.1.1** In appointing team leaders for a specific evaluation, the MLAC Chairperson should not appoint the same team leader for two successive evaluations of the same accreditation body, and the newly appointed team leader shall not be from the same AB of the previous team leader.

**1.2** The team leader shall have ultimate responsibilities for all phases of evaluation, and shall have the delegation of authority by the MLA Group to make final decisions regarding the conduct of evaluation.

**1.3** The team leader shall normally, in addition to the responsibility for managing the evaluation and preparing the evaluation report, supervise any trainee evaluator assigned to the evaluation team. Supervising Mentoring trainee evaluators includes, assigning a mentoring TM who will mentor the trainee including: allocating him/her such task as he/she is capable of performing, supervising and providing a report to the MLA Secretary about the performance of the trainee evaluator.

#### 2 COMPOSITION OF EVALUATION TEAM

**2.1** For the full evaluation visit, members of the evaluation team shall be chosen as needed to cover the activities and standards of the MLA Scopes, the technical fields, size and complexity of the accreditation system under evaluation.

**Note 1:** A team leader should normally be accompanied by at least one other team member for a pre-evaluation visit to ensure more than one person is involved in establishing an Applicant Body's readiness for a full evaluation visit.

**Note 2:** See procedure PR 004 for information on qualification of ARAC peer evaluators.

**2.2** The evaluation team shall be chosen from the ARAC Peer Evaluators List. Lead evaluators, evaluators and trainee evaluators may be appointed as evaluation team members. The evaluation team chosen shall consist of representatives from a cross-section of accreditation body members of ARAC. The evaluation team shall be chosen to provide a balanced set of skills so as to be able to conduct an effective evaluation of the key components of the system under examination.

**Note 1:** Team members should have working knowledge of the language the team leader and the AB have agreed to use. Knowledge of the local language should be taken into account.

**Note 2:** Some of the team members may have as their only task to perform witnessing at different geographical places or at different times than the rest of the evaluation team.

**Note 3:** *Where an evaluation is conducted jointly by ARAC and ILAC and/ or, IAF or other recognized regional group cooperation, the MLAG will work in cooperation with the other organizations/ groups and the team leader to set up a team that meets the needs of ARAC. Apart from that, all other steps in this procedure apply.*

**Note 4:** *The number of members of the team for each scope of the MLA depend on several factors, such as the variety of fields in which the AB accredits, the number of accredited CAB, the complexity of the AB's management system, the time required for witnessing and office evaluation, the experience of the team members and their scope of qualification, the need for ARAC to involve trainee evaluators so as to increase the number of qualified evaluators.*

**Note 5:** *A team should not have more than two trainee evaluators participating on a team.*

**Note 6:** *Where applicable, There should be no more than one member from each accreditation member body represented in the regional evaluation team*

**2.3** When a person is invited to participate in an evaluation team, he/she or his/her AB shall inform the MLAC Chair person or MLA Secretary of previous involvement with the AB being evaluated. No team member shall be associated with any Accreditation Body that has provided consultancy service to the body being evaluated for the last three years. The following activities performed by the person with the AB being evaluated, in the last two years may be considered a threat to a team member's impartiality:

- Participation in recent internal audits;
  - Provision of training specially tailored for the design and development of the AB's accreditation system;
  - Participation as an assessor in joint assessments of CABs.
- Involvement in any other activities related to the accreditation process of this AB.

Additionally, team members shall commit not to engage in consultancy activities for a period of two years following the evaluation.

**2.4** A re-evaluation visit should be carried out by a team, in which the majority of the members will not have been on the evaluation team that undertook the previous evaluation.

**2.5** The evaluation team shall consist of a lead evaluator and an evaluator for each accreditation standard of the MLA recognition agreement to be evaluated (Level 3), covering the scope within the recognition or as requested for initial evaluation or extensions. A deputy team leader may be appointed as necessary. The decision to assign a DTL may take into account factors such as the size and complexity of the evaluation, the number of team members, the geographic distribution of activities, the scope of recognition being evaluated, and any logistical or coordination challenges foreseen during the evaluation process. A trainee evaluator may be appointed to evaluate one of the activities or programs with the support of the lead evaluator or evaluator who is qualified for the applicable activity or standard.

**Note 1:** *For each accreditation standard that is being evaluated, there should only be one team member from each accreditation body member taking part.*

**Note 2:** *For laboratory accreditation, one member of the evaluation team should be familiar with the use of proficiency testing in accreditation.*

**2.6.** When a trainee evaluator is appointed as a team member, he/she may be assigned evaluation tasks by the team leader and shall be mentored and supervised by the team leader and/or another evaluator so as to ensure those tasks are appropriately carried out. During the evaluation at the AB's facilities, the trainee evaluator shall always be supervised by a lead evaluator or evaluator; during witnessing of assessments the trainee evaluator may work on his/her own.

**2.6.1** The MLA Secretary or MLA Group Chairperson shall provide the team leader with information on

the training and experience of the trainee evaluator and on the task that may be performed by the trainee evaluator.

**Note 1:** *Costs of the participation of a trainee evaluator as a team member in an evaluation are to be covered by the trainee, the AB where the trainee belongs or ARAC..*

**Note 2:** *If a trainee evaluator is appointed to participate in an evaluation only to take advantage of evaluator training opportunities without any responsibility as a team member, the costs of participation shall be covered by the trainee, her/his AB or by the ARAC.*

**2.7** If the team leader or a team member is from another recognized regional cooperation, the MLA Group Chairperson and/or the MLA Secretary shall provide him with instructions about ARAC procedures and requirements for peer evaluations as well as the main differences from the procedures used by IAF/ILAC.

**2.8 Appointment and duties of the Deputy TL:** The role of the Deputy TL is to assist the TL in planning, preparation, and management of the evaluation. The Deputy TL can replace the TL in case of illness or unforeseen circumstances.

A Deputy TL can be identified in one of two ways:

- a) After a minimum of 2 peer evaluations as a TM with positive feedback from the participating TLs and ABs, a TM may be invited to become a Deputy TL if she/he has also demonstrated that she/he fulfils the conditions for a Peer Evaluator Team Leader, as in section 5.1 of ARAC PR 004 "Procedures for Selection, Training, Qualification and Monitoring the performance of ARAC Peer Evaluators".

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

- b) Alternately, a Deputy TL may be an approved team leader but if assigned to a team, the Deputy TL shall have different competences than the TL to cover as much as possible of the accreditation activities of the AB under evaluation

## **ANNEX 2**

### **PLANNING AND MANAGING THE EVALUATION**

#### **RISK-BASED PLANNING OF PEER EVALUATIONS**

Peer evaluations shall be planned using a risk-based approach to ensure effective assessment of the Accreditation Body's competence and operation of its accreditation system.

The evaluation team shall consider, as applicable, factors such as previous evaluation results, complaints, scope complexity, number of accredited conformity assessment bodies, new or expanded scopes, and significant changes since the last evaluation when determining the evaluation programme, duration and witnessing activities.

#### **A PRE-EVALUATION VISIT PROGRAM**

If it is determined by ARAC or the applicant AB that a pre-evaluation visit to the AB is needed before the full evaluation can take place, a pre-evaluation visit program shall be prepared. Based on the results of the document review, the pre-evaluation visit team may consider reviewing the following in the context of the pre-evaluation visit:

- Management system policies and procedures (as part of a document review prior to the pre-evaluation visit);
- Legal identification of the AB;
- Relationships with the regulators and other specifiers (recognition; possible competition);
- Job descriptions and backgrounds of top management, organization chart;
- Impartiality and conflict of interest; related bodies;
- Access to technical expertise;
- Application documents;
- Assessor records and documents;
- Sampling of CAB assessment records, including the decision making process;
- Proficiency testing participation levels (for testing and calibration accreditation);
- Measurement traceability routes (for testing and calibration accreditation and inspection bodies (where applicable). In some cases it may be necessary to visit the NMI;
- Witnessing one or more assessments, if possible.

The witnessing rules for the full evaluation are applied for the Pre-evaluation visit. A short-written report shall be delivered to the AB and MLA Secretariat including the list of findings, brief description of impartiality, traceability, access to technical expertise, and witnessed assessment(s).

#### **B FULL EVALUATION PROGRAM**

##### **1 INTRODUCTION**

In principle it is the task of the TL to create a timetable (see form FM 004) for an evaluation that allows for sufficient time to collect such information that confidence can be obtained in the operation of the AB to such an extent that the signatories to the Arrangement can promote acceptance of results from CABs accredited by the evaluated AB.

It is recommended that the TL start planning the evaluation as soon as the evaluation team is appointed.

Because there exist a large variety of circumstances under which an evaluation will take place, it

should be the prerogative of the TL to deviate from the examples shown under 3.2. The TL should agree with the team members on the duration. Consultation with the AB under evaluation is essential. When the proposed timetable largely differs from the examples of 3.2 or when additional team capacity is required, the MLAC Chairperson should also be consulted at an early stage.

## **2 CONSIDERATIONS**

### **2.1 MAXIMUM DURATION**

The TL is to consider the applicant AB priorities in the fixing of Peer Evaluation dates. The TL should try to arrange the evaluation to take place in the shortest possible time, preferably within one full (7 days) week. If witnessing or any other part of the evaluation is not possible during the week of the formal evaluation the TL should make arrangements to have witnessing activities performed in the weeks preceding/ or following the evaluation. This will allow for a well-founded closing meeting in which all fact finding can be reviewed and discussed. It is additionally advised to use only experienced team members for such parts of the evaluation.

In cases where activities are carried out in the weeks following the evaluation, the TL shall attend the closing meeting.

### **2.2 TYPES OF EVALUATION**

There are different kinds of evaluation: e.g. pre-evaluation, initial evaluation, follow-up evaluation, evaluation for scope extension, re-evaluation.

Given the long interval (approximately 4 years) between evaluations, the duration of a re-evaluation is comparable to that of an initial evaluation. A shorter duration applies for pre-evaluation visits, for follow-up evaluations and for scope extensions that are conducted separately from a re-evaluation. Specific instructions about evaluations for the MLA scope are given in Annex 7

### **2.3 Evaluation of level 3, 4 and 5 activities:**

#### **2.3.1 WITNESSING**

The evaluation team shall consider how to deal with witnessing for the activities and standards of the MLA scopes that are being evaluated. Discussion about number and type of assessments to be witnessed should start as soon as the team has received the AB documentation. The AB should be informed about the evaluation team plans so that they may provide the team with a possible list of assessments to be witnessed and should include both on-site and remote assessment (as applicable)..

For planning of the witnessing, the AB shall provide the evaluation team with a list of assessments that will take place from about 6 weeks before the proposed on-site evaluation date, or as agreed with the team leader. This gives the evaluation team the opportunity to carefully select and plan the witnessing activities taking into consideration:

- standards for accreditation,
- number of accredited CAB,
- size of the fields,
- new fields and complex fields
- initial evaluation/ re-evaluation,
- witnessed assessments from the last evaluation,
- assessment techniques applied by the AB (on-site and/or remote)
- cross frontier accreditation policy and relative arrangements,
- Self declaration of new sub-scopes

It is important to have the opportunity to witness assessments covering all accreditation requirements, particularly in the initial evaluation. It may be necessary to perform more witnessing in initial evaluations than in re-evaluations.

Normally the evaluation team will witness an initial assessment or a reassessment of a CAB or two on-site assessment activities for every level 3 scope. Preferably the evaluation team should witness reassessments instead of initial assessments, as they can demonstrate the AB's ability to verify corrective actions and sustain compliance. In case it is not possible to witness a reassessment or an initial assessment or two other on-site assessment activities, the evaluation team may witness only one on-site assessment activity that covers all accreditation requirements, this shall be clearly stated in the evaluation program (FM 004 and IAF-ILAC A 3 Annex II), the key is that the evaluation team witness the performance of technical activities of the CAB. **Table 1** below provides additional instructions for each scope.

Where the number of accredited CABs is less than 4 at the time of evaluation, the need for a follow-up evaluation before the normal 4 year period shall be considered by the Decision Making Group, the ARAC MLA Group.

Note: For definition of Levels, please refer to ARAC PR 0025, as applicable move to decision making

Since MoUs are being concluded with certain industry sectors, specific attention may be needed to assure the AB's competence to assess in these fields. The evaluation team shall consider the need to witness assessments of CABs accredited for accreditation schemes endorsed by ARAC, IAF and ILAC. Even if witnessing is not considered necessary, the evaluation team shall review records of accreditations granted in those schemes and record this information in the evaluation report.

It must be stressed that despite spending time on witnessing, it is very important to spend ample time to check on how an AB selects its assessors and experts for a particular assessment. Thorough checking of records from assessments is required including matching the assessor's expertise to the scope of the CAB being assessed. It is also important to review assessment records and reports and decision making records other than those of the CAB witnessed.

**TABLE 1: Additional Instructions about witnessing**

| Scope                        | Specific instructions about witnessing                                                                                                                                                                                                                               |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Calibration<br>ISO/IEC 17025 | Witnessing includes witnessing of the assessment by the AB of the CAB performing calibration.<br>Depending on the risk, number of accredited laboratories, the variety of the scopes and the MLA Group decision, it may be necessary to perform more witnessing.     |
| Testing<br>ISO/IEC 17025     | Witnessing includes witnessing of the assessment by the AB of the CAB performing testing.<br>Depending on the risk, number of laboratories and the variety of the scopes and the MLA Group decision it may be necessary to perform more witnessing.                  |
| Testing<br>ISO 15189         | Witnessing includes witnessing of the assessment by the AB of the CAB performing examination.<br>Depending on the risk, the number of accredited laboratories, the variety of the scopes and the MLA Group decision, it may be necessary to perform more witnessing. |

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|-----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Inspection<br>ISO/IEC 17020                                                                                                       | <p>Witnessing includes witnessing of the assessment by the AB of the CAB performing inspection.</p> <p>Depending on the risk, the number of accredited inspection bodies, the variety of the scopes and the MLA Group decision, it may be necessary to perform more witnessing.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <p>Management system certification<br/>ISO/IEC 17021-1<br/>(QMS,EMS, ISMS, OH&amp;SMS, EnMS, MDQMS,FSMS, ABMS, BCMS and EOMS)</p> | <p>Witnessing includes witnessing of an office assessment by the AB of the CAB. It may be a remote assessment, as agreed by the team leader with the AB. The peer evaluation team shall carry out at least one witness of the on-site assessment carried out by the accreditation body to the conformity assessment body in regard to its compliance with the requirements of ISO / IEC 17021-1, regardless of the chosen sub scope. Depending of the number of accredited CB and the variety of the scopes, it may be necessary to perform more witnessing.</p> <p>The witnessing will be selected taking into account:</p> <ul style="list-style-type: none"> <li>- The findings and scopes witnessed in the last evaluation,</li> <li>- The number of accreditations granted for each sub-scope,</li> <li>- The experience of the AB in the sub-scope,</li> <li>- New sub-scope and more complex sub-scopes,</li> <li>- Decision by the ARAC MLA Group.</li> <li>- Risk: the risk assessment should cover and not be limited to the results of previous peer evaluations, complaints received by ARAC, the complexity of the certification scheme, etc</li> </ul> <p>If a particular sub-scope is not witnessed in a re-evaluation, the evaluation team shall review assessment records to confirm the AB's competence in that field.</p> <p>It is not necessary to witness the AB witnessing of the CB perform certification audits. However the evaluation team shall review the AB's procedures for witnessing certification audits as well as assessment records to confirm appropriate implementation.</p> |

|                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product certification<br>ISO/IEC 17065    | <p>Witnessing includes witnessing of an office assessment by the AB of the CAB. It may be a remote assessment, as agreed by the team leader with the AB. The peer evaluation team shall carry out at least one witness of the on-site assessment carried out by the accreditation body to the conformity assessment body in regard to its compliance with the requirements of ISO / IEC 17065. The peer evaluation team shall witness at least one sub-category from each accredited scope.</p> <p>Depending of the number of accredited CB and the variety of the scopes, it may be necessary to perform more witnessing.</p> <p>The witnessing will be selected taking into account:</p> <ul style="list-style-type: none"> <li>- The findings and scopes witnessed in the last evaluation,</li> <li>- The number of accreditations granted for each scope,</li> <li>- The experience of the AB in the scope,</li> <li>- More complex scopes,</li> <li>- Decision by the ARAC MLA Group.</li> <li>- Risk: the risk assessment should cover and not be limited to the results of previous peer evaluations, complaints received by ARAC, the complexity of the certification scheme, product complexity, etc</li> </ul> <p>It is not necessary to witness the AB witnessing the CB perform certification audits. However, the evaluation team shall review the AB's procedures for witnessing certification audits as well as assessment records to confirm appropriate implementation.</p> |
| Certification of persons<br>ISO/IEC 17024 | <p>The evaluation team shall review in detail the AB's procedures for assessing the cases where a CB subcontracts the examination services, as well as assessment records to confirm appropriate implementation.</p> <p>In case where the CB subcontracts the majority of the examination process, the evaluation team may consider appropriate to witness how the AB assesses the competence of the CB for that certification.</p> <p>Depending on the number of accredited CBs, the risk of the scopes, and ARAC MLAG decisions, it may be necessary to perform more witnessing, to be confirmed by the AB's assessment team, when performing assessments to different schemes. The risk assessment should cover and not be limited to the results of previous peer evaluations, complaints received by ARAC, the complexity of the certification scheme, etc</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

### 2.3.2 Additional instructions for Level 4 and 5:

For all level 4 and 5 activities, it must be stressed that despite spending time on witnessing, it is very important to spend ample time to:

- Check how AB selects its assessors and experts for a particular assessment. Through checking of records from assessments is required including matching the assessor's expertise and complete criteria for the scope of the CAB being assessed,
- Review assessment records and reports and decision making records other than those of the CAB witnessed,
- Review of the way an AB expands its accreditation activities for level 4 and 5, according to clauses 4.6.3 and 4.6.4 of ISO/IEC 17011, especially the demonstration of competence by the AB, in new fields and how relevant requirements as defined by IAF, ILAC or ARAC have been

met, when applicable.

## 2.4 SIZE OF THE AB

The influence of the AB's scope on the duration of the on site evaluation relates primarily to the number of witnessing activities. The AB's management system may not differ too much when the AB has one activity or several activities.

When there is a large difference in the number of accreditations in the various fields, the TL may decide to place more emphasis on witnessing in the larger field(s).

## 2.5 Evaluation of Sources of Metrological Traceability and Visit to the NMI

**2.5.1** One of the tasks of the evaluation team is to evaluate the AB's policy on metrological traceability and how the AB ensures traceability of results of their accredited laboratories. *The AB is required to provide the following information (see form FM 001, item 21)*

- information about the available sources of metrological traceability and the calibration and measurement capabilities (CMC) available from these sources (see ILAC P10 and ILAC P14);
- a list of recent international comparisons in which the economy's national metrology institute (NMI) or designated institutes have been involved (e.g., BIPM or regional metrology organization) or, when applicable, reference to the NMI's calibration and measurement capabilities as published on the BIPM website;

This information needs to be evaluated in connection with the AB policy for metrological traceability to confirm its compliance with ILAC P10.

### 2.5.2 Need for a visit to the NMI.

**2.5.2.1** The visit to the NMI will not be necessary in the following cases:

- a) When the NMI is a signatory to the CIPM MRA for all quantities for which traceability is needed under the scopes accredited by the AB.
- b) When the NMI is a signatory to the CIPM MRA for some of quantities for which traceability is needed under the scopes accredited by the AB, and the AB requires traceability for the remaining quantities to acceptable sources of traceability.
- c) When the NMI is accredited by a signatory of the ARAC and/or ILAC Arrangement.

**2.5.2.2** The visit to the NMI is needed in the following cases

- a) When the NMI is not a signatory of the CIPM MRA.
- b) When the NMI is a signatory of the CIPM MRA, but none of its calibration and measurement capabilities (CMC) are listed in Appendix C of the CIPM MRA.
- c) When the NMI is a signatory to the CIPM MRA for some of quantities for which traceability is needed under the scopes accredited by the AB, but is also the source of traceability to quantities which are not yet included in Appendix C of the CIPM MRA.

**Note 1:** *The NMI may be in one or several organizations. The evaluation team needs to take that into account when planning the evaluation.*

**Note 2:** *When deciding whether or not a visit to the NMI is needed, the evaluation team also needs to consider the fact that traceability may be achieved through sources other than the NMI, such as, NMIs from other economies, laboratories accredited by other signatories to the ARAC and/or ILAC Arrangement, in the economy or abroad.*

**Note 3:** *In the situation describe in clause 2.5.2.2 c), the visit to the NMI may not be needed in case the information provided by the AB about sources of traceability in the country is sufficient to confirm compliance with ILAC P10.*

**2.5.2.3** The visit to the NMI, when applicable, aims at:

- a) Confirming the information provided by the AB about the NMI activities, in particular its participation in regional metrology organizations, the BIPM, and regional and international inter-comparisons.
- b) Confirming the calibration and measurement capabilities available from the NMI for quantities which are not included in Appendix C of the CIPM MRA and collecting information the NMI's traceability chain and on how the NMI has validated those CMC.

**Note:** *The evaluation team is not supposed to carry out an assessment of the NMI.*

The information collected in this visit needs to be included in the evaluation report. This information needs to be considered by the evaluation team in connection with the AB's traceability policy and information on its implementation in order to confirm compliance with the requirements in ILAC P10.

### **2.5.3 Use of unaccredited calibration laboratories**

**2.5.3.1** If the AB's policy for metrological traceability allows for the use of non accredited calibration laboratories, the evaluation team needs to evaluate how the AB ensures metrological traceability. The evaluation team needs to provide Information in the evaluation report about the AB's policy for this case and its implementation, in compliance with ILAC P10.

## **2.6 Application from an AB that is a signatory of the MLA of another recognized regional body and/or ILAC and IAF**

**2.6.1** If the AB is applying for recognition for a scope for which it is already a signatory of the MLA of a recognized regional body and/or IAF and ILAC, the MLA Group may decide to admit the applicant as an ARAC MLA signatory without further evaluation, based on document review. The recognition period granted cannot exceed the due date for the re-evaluation by IAF, ILAC or the relevant Regional Group. Otherwise, the team leader shall also take into account the information provided by the AB with the application in planning the peer evaluation, including:

- the previous evaluation report;
- the decision made by the regional body and/or IAF and ILAC;
- the changes that have taken place since the previous evaluation.,

Note: This procedure is also applicable for new MLA scopes that are developed by ARAC. In case the new MLA scope is not yet implemented by ILAC and/or IAF in their own arrangements, any regional cooperation that is recognized by ILAC and/or IAF for other scopes of the MLA are considered recognized cooperation for the new MLA scopes.

**2.6.2** If the AB has been evaluated by an IAF and/or ILAC recognized regional body Group within the past two years and if the findings are closed the team leader may adjust the evaluation program accordingly. Possible adjustments may include:

- a) reduction of the number of assessments to be witnessed;
- b) reduction of the amount of time spent reviewing the AB's management system on site;
- c) elimination of the need to visit the NMI
- d) limitation the evaluation activities to a document review of the current documentation and resolution of any findings observed therein.

**2.6.2.1** If the team leader in consultation with the AB recommends adjustment of the program as described in 2.6.2, he/she shall notify the MLAC Chairperson prior to finalizing the program. The MLAC Chairperson shall review the recommendation approve the evaluation program and shall inform the MLA committee of the decision.

**2.6.2.2** If the evaluation activities are limited to a document review, the next re-evaluation shall be

done 4 years from the previous on site evaluation.

## **2.7 Other factors**

**2.7.1** Factors that may influence the duration of the evaluation include:

- a)** Need for translators and their effect of slowing down the evaluation
- b)** Extensive travel and travel circumstances
- c)** Cultural differences

**2.7.2** This annex cannot provide guidance on all possible cases. It is left to the evaluation team and their experience to judge these effects and to cater for them in such a way that there is no compromise to the principle stated in the introduction to this annex.

## **3 MANAGING THE EVALUATION**

### **3.1 Preparation and planning**

The time that the evaluation team needs to spend on preparation largely depends on the quality of the documents that the AB forwards. The documents that are required for both initial evaluations and re-evaluations are specified in form FM 001 item 21. Accurate translation of the documents into English or Arabic must be done if requested by the TL and /or TMs and agreed with the AB. The self-assessment document as per IAF/ILAC A3 and the checklist (see form FM 003) relating the accreditation standard(s) to the AB's procedures/documents must be detailed and accurate. These two documents will greatly assist the evaluation team in preparation. If the self assessment document does not provide adequate information to the team, the team leader should ask the AB to revise the document with the necessary information. The AB shall send all documents listed in form FM 001, item 21 at least 90 days in advance of a visit to allow for preparation and for requesting additional information.

If documentation is not received on time, the TL shall inform the Chair of the MLAC who may as a result cancel the evaluation (see also Annex 5 for cancelation of a re-evaluation).

The team members must start reviewing the documents directly after receipt. In essence the team leader should be able to prepare a part of the report with background information before the on-site evaluation. This part of the preparation is the same for all types of evaluations. The total time involved in studying of the documentation may take on average 3 to 5 days for the TL and 2 to 4 days for the team members.

When planning the evaluation, the TL shall also consider the need to mentor and supervise trainee evaluators working as team members. Particular care should be taken to ensure that trainee evaluators are supervised by an evaluator or lead evaluator when carrying out evaluation tasks in the AB's office. Trainee evaluators may perform witnessing on their own.

If the applicant AB has applied for accreditation activities for an industry, environment and/or health specific program, then the requirements set by that industry/environment/health group for accreditation bodies shall also be considered.

The TL, in cooperation with the TMs, shall prepare an evaluation plan using form FM 004 and annex II of ILAC/IAF A3 that contains as a minimum:

- Identification of the AB,
- The purpose and date of the evaluation, including the accreditation schemes to be evaluated,
- The names of the TL and TMs and the accreditation schemes that they are qualified for,
- The requirements to be considered,
- Date and time for the opening meeting and date and estimate time for the final meeting,
- General description of activities and/or requirements to be evaluated by each member of the evaluation team each day,
- If necessary, identification of AB personnel that will be involved with particular evaluation activities,
- Private activities of the evaluation team, such as meetings before the evaluation, at night or after the evaluation,
- Identification of the assessments to be witnessed and the evaluators assigned to them (This identification should include the type of CAB, accreditation scheme or specific field of conformity assessment, number of assessor),
- Information on the need for a meeting between the ARAC TM and the AB's assessment team after the end of the assessment witnessed.
- Other organizations to be visited (such as the NMI) or Committee meetings to be witnessed and the TM that has been assigned those tasks.
- Any travel or any other arrangements that may interfere with the performance of the evaluation.

The evaluation plan FM 004 should be sent to the AB 30 days in advance of the evaluation.

### **3.2 On-site evaluation**

The evaluation team should be prepared to make long working days during the on-site evaluation.

An on-site visit typically consists of:

- Opening meeting, presentation by team leader outlining aims, objectives and procedure to be used by evaluation team;
- Evaluation of the AB's offices and management system, review of files and records
- Discussing the results of the self-assessment report as per IAF/ILAC A3: this self assessment is written by the AB using the IAF/ILAC A3 document
- Evaluation of the records of CAB whose assessment is to be witnessed and of the preparation for the assessment; if possible witnessing of the accreditation decision making process
- Splitting the team members in accordance with their experiences for the purpose of witness including the on-site preparation of the draft assessment report with a list of findings;
- Discussing the results of the witnessing with the AB assessment team and AB staff,
- Preparing the report on the witnessed assessments using Annex IV of IAF-ILAC A3 ;
- Preparation of the summary section of the report, and writing and classification of findings; and
- Closing meeting, presentation and discussing of findings.

During the evenings the team members should meet to discuss their findings and possibly adjust the focus of their attention. In case meetings are not possible the evaluation team should arrange means of communication with the team leader. The TL will need to add/modify/enhance the preliminary report that resulted from the studying of the documentation and discuss such changes during the week with the team members.

The evaluation program shall allow the evaluation team sufficient time for all team members to review the findings before presenting them to the AB so as to make sure that all issues raised by all members of the evaluation team have been covered.

Some timetable examples are:

### 3.2.1 Full size scope AB

| Day   | Actions                                                                                                                                     | Evaluators |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Day 1 | >= 4 hours for preparation with the evaluation team (key issues to be addressed + evaluation plan)                                          | TL + 4 TM  |
| Day 2 | Office, opening meeting, records, etc. + preparation for witnessing assessments                                                             | TL + 4 TM  |
| Day 3 | Office + witnessing staff + witnessing assessments (split team)                                                                             | TL + 4 TM  |
| Day 4 | Office + witnessing staff + vertical audits + witnessing assessments (split team)                                                           | TL + 4 TM  |
| Day 5 | Office + witnessing staff + vertical audits (specially directed for confirmation of previous findings + witnessing assessments (split team) | TL + 4 TM  |
| Day 6 | Same + preparation final report + closing meeting                                                                                           | TL + 4 TM  |
| Day 7 | Discussing further actions for TMs + departure                                                                                              | TL + 4 TM  |

### 3.2.2 Single scope AB

| Day           | Actions                                                                                                                                      | Evaluators |
|---------------|----------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Day 1         | 3 hours for preparation with the evaluation team<br>Office, opening meeting, records, etc.<br>(key issues to be addressed + evaluation plan) | TL + 1 TM  |
| Day 2         | Office + witnessing assessments (split team)                                                                                                 | TL + 1 TM  |
| Day 3         | Office + witnessing staff + preparation final report + closing meeting                                                                       | TL + 1 TM  |
| Day 4 morning | Discussing further actions for TMs + departure                                                                                               | TL + 1TM   |

### 3.2.3 ABs with 2 scopes of accreditation

| Day           | Actions                                                                                                                                      | Evaluators |
|---------------|----------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Day 1         | 3 hours for preparation with the evaluation team<br>Office, opening meeting, records, etc.<br>(key issues to be addressed + evaluation plan) | TL + 2 TM  |
| Day 2         | Office, opening meeting + preparation for witnessing assessments                                                                             | TL + 2 TM  |
| Day 3         | Office + witnessing staff + witnessing assessments (split team)                                                                              | TL + 2 TM  |
| Day 4         | Same + preparation final report + closing meeting                                                                                            | TL + 2 TM  |
| Day 5 morning | Discussing further actions for TMs + departure                                                                                               | TL + 2 TM  |

#### 3.2.4 ABs with 3 scopes of accreditation

| Day       | Actions                                                                                                                                     | Evaluators |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Sunday    | >= 4 hours for preparation with the evaluation team (key issues to be addressed + evaluation plan)                                          | TL + 3 TM  |
| Monday    | Office, opening meeting, records, etc. + preparation for witnessing assessments                                                             | TL + 3 TM  |
| Tuesday   | Office + witnessing staff + witnessing assessments (split team)                                                                             | TL + 3 TM  |
| Wednesday | Office + witnessing staff + vertical audits + witnessing assessments (split team)                                                           | TL + 3 TM  |
| Thursday  | Office + witnessing staff + vertical audits (specially directed for confirmation of previous findings + witnessing assessments (split team) | TL + 3 TM  |
| Friday    | Preparation final report + closing meeting + Discussing further actions for TMs + departure                                                 | TL + 3 TM  |

#### 3.3 Activities after the on-site evaluation

Electronic means to communicate with the team members should be sufficient to provide feedback and support as the TL prepares the final report for the AB.

The evaluation team needs to spend time on reviewing the AB's response to the findings and preparing the evaluation team's reaction. The TL shall take the lead in preparing this reaction. Finally the TL shall prepare the evaluation team's recommendation to the ARAC MLA Group. Typically these activities may take 2-3 days for the TL. For TMs, the time involved may be limited to one day.

## ANNEX 3

### EVALUATION REPORTING ON AN ACCREDITATION BODY

#### A STEPS IN EVALUATION REPORTING ON AN ACCREDITATION BODY:

**A1 Preparation of summary section of the report** This summary section has to be completed and be confirmed with the applicant at the end of the on-site evaluation visit. The content of the summary report is described in IAF/ILAC A3. It includes as an appendix the nonconformities and comments presented in table format using IAF/ILAC A3 Annex I (Section B1). This summary report shall also include initial recommendation if possible. (see section B1).

The summary report and the findings shall be provided to the MLA Group Secretary and MLA group Chairperson immediately after the evaluation visit.

In cases where the evaluation activities are conducted at different time intervals (clause 2.1); a summary report shall be completed for the covered activities at the end of each phase. The final summary report shall be consolidated at the end of all evaluation activities.

The evaluation team members should submit to ARAC MLA Group secretariat the completed ARAC Form FM 003 with the summarized data.

**A2 Preparation of the Draft Report of the On-site Evaluation Visit.** (Deadline - within 60 days from the on site evaluation)

This report is the agreed report of the evaluation team and the Accreditation Body and includes all information described in IAF ILAC A3, except the responses to the findings, the reaction from the evaluation team, and the final recommendation.

The report shall include any disagreement within the evaluation team or between the evaluation team and the accreditation body, with opinions of all parties.

For any AB appeals against findings or adverse decision by an evaluation team during the evaluation process, see PR 005, procedure for handling appeals and complaints.

**A3 Formal Response of the Accreditation Body to the Findings.** The accreditation body's response can simply be inserted under each finding in IAF/ILAC A3 Annex I, with attachments of supporting evidence of corrective action as appropriate. (see what is expected of the AB's response and corrective action described in section C of this Annex).

#### **For initial evaluations and extensions of scopes:**

- *Within 3 months from receiving the summary report of the evaluation the AB shall present an action plan and time schedule for implementation of actions for nonconformities. The evaluated AB is encouraged to respond to Comments.*
- *The AB should provide evidence of effective implementation of corrective actions for nonconformities within 5 months from the evaluation or as agreed with the TL.*
- *In case there is a need for a follow up visit to confirm implementation of actions, the AB shall present evidence of implementation of actions at least two months before the follow up visit, or as agreed with the TL. In this case, if there are any actions pending after the follow up visit, the AB should provide evidence of effective implementation of corrective actions for nonconformities within 4 months from the follow up visit.*

#### **For re-evaluations:**

- *Within 1 month from receiving the summary report of the re-evaluation the AB shall present an action plan and time schedule for implementation of corrective actions for nonconformities. The evaluated AB is encouraged to respond to the comments.*
- *The AB shall present evidence of effective implementation of corrective actions for*

*nonconformities within 3 months from the evaluation.*

- *In case there is a need for a follow up visit to confirm implementation of actions, the AB shall present evidence of implementation of actions at least two months before the follow up visit, or as agreed with the TL. In this case, if there are any actions pending after the follow up visit, the AB shall provide evidence of effective implementation of corrective actions for nonconformities within 1 month from the follow up visit.*

**For the Pre-peer evaluations** the AB shall present an action plan and time schedule for implementation of corrective actions for nonconformities followed by the evidences of the implementation of the corrective actions for these nonconformities. The evaluated AB is encouraged to respond to the comments. All the nonconformities shall be closed within one year before proceeding with the full peer evaluation.

**A4 Formal Reaction of the evaluation team to this Response.** The evaluation team's reaction to each response to every finding is submitted in writing to the Accreditation Body for consideration using IAF/ILAC A3 Annex I. (Deadline - within 30 days from step A3)

**A5 Steps A(3 and 4) may be repeated.**

Any problems completing steps A(3 and 4) shall be reported to the Chairperson and Secretary of the ARAC MLAC.

**A6 Preparation of a Final Report to the MLA Group.** (Deadline: 30 days from completion of step A4.)

This report consists of the items identified under steps A(2, 3 and 4) (i.e., formal team report, formal AB response and formal team reaction). In addition, the final recommendation of the evaluation team is stated as a section of the evaluation team's final report (see section B1 in this Annex). Items included in steps A(3 and 4) shall be combined into IAF/ILAC A3 Annex I stating the findings, the formal AB response including corrective actions, and the evaluation team's reaction. The report shall also include information on the follow up visit if relevant (see section B2 in this Annex). This will ease the MLA Group review process.

At this stage of the evaluation, if the evaluation team's recommendation includes a follow-up visit to verify the corrective actions, this decision shall be made by the MLA Group. If a follow up visit is to be conducted, the evaluation team should be composed of one or more members of the evaluation team that conducted the full evaluation.

*For initial evaluations and extensions of scope, the final report shall be provided to the MLA Secretary and MLAC Chairperson 30 days after all findings have been closed.*

*For re-evaluations, the final report shall be provided to the MLA Secretary and the MLAC Chairperson 6 months from the date of the reevaluation even if some findings are still open unless the MLA Group or the MLAC Chairperson has authorized a follow up visit, in which case the final report shall be provided to the MLA Secretary and the MLAC Chairperson 60 days after the follow up visit.*

## **B TYPICAL STRUCTURE AND CONTENT OF A FINAL EVALUATION REPORT ON AN ACCREDITATION BODY**

### **B1 Full evaluation report**

**The report shall be prepared using the IAF/ILAC A3.**

## **B2.1 Follow up visits done before a final decision by the MLA Group.**

- a) The report shall be prepared using the ILAC/IAF A3.

The summary section about the follow up visit and the updated IAF/ILAC A3 Annex I shall be provided to the AB at the end of the visit.

## **B2.2 Follow up visits done after a final decision by the MLA Group.**

If the follow up visit aims at checking implementation of corrective actions **after** ARAC MLA Group makes a decision on granting or maintaining recognition, the information on the activities done in the follow up visit shall be included in a report issued specifically for that follow up visit as follows:

- a) The cover page shall state the type of evaluation, the name of the Accreditation Body that has been evaluated, the dates of the evaluation visit(s), the names of the team leader and team members, specifying the organization to which they belong, and a clear indication that the report is confidential.
- b) The report shall include a section with a summary of the follow up visit, including the reasons for the follow up visit, reference to the decision authorizing the visit, by the MLA Group, the evaluators participating in the visit, dates of the visit, a summary of the activities performed by the evaluation team, confirmation whether or not all findings have been closed and a recommendation to the MLA Group on the next steps of the process.
- c) An annex with the follow up visit program.
- d) An annex with the report on any assessments witnessed using IAF/ILAC A3 Annex V.
- e) IAF/ILAC A3 Annex V includes only the findings and corrective actions of the previous evaluation visit that were checked in the follow up visit, and information about the evidences obtained by the evaluation team for each of the findings, confirmation that the finding is closed or information on the actions that are still pending.

The summary section, the table of findings with information about the actions taken shall be provided to the AB at the end of the visit. The final report shall be sent to the MLA Secretary and MLA Group Chairperson 30 days after the visit.

## **C. CONTENT OF A FINAL EVALUATION REPORT FOR AN ACCREDITATION BODY EXTENDING THE MLA TO LEVEL 4 AND/OR 5.**

C.1 For extensions of scope to include new Level 4 and/or Level 5 normative documents the evaluation report shall include:

- A summary section regarding the application, related documents, the decision to limit the evaluation activities to a document review according to Annex 7 on this document.
- Description of the outcomes of the document review for clauses, 4.6, 6 and, 7 of ISO/IEC 17011 and ARAC, IAF and ILAC mandatory documents applicable to the MLA subscope.

**Note:** Other requirements may be evaluated if the evaluation team finds it necessary.

- Evaluation team recommendation to the MLAG

An annex using IAF-ILAC A3 Annex I, with the nonconformities and comments, and when

applicable, it should include the AB's responses

#### **D. GUIDANCE ON CLASSIFICATION OF FINDINGS**

**Finding:** To be used as a general term

**Nonconformity:** Finding where the AB does not meet a requirement of the applicable standard (ISO/IEC 17011), its own management system or the Arrangement requirements.

The evaluated AB must respond to each non-conformity by undertaking a cause analysis, including the extent of the finding and its impact, and by taking appropriate action (correction and/or corrective action).

The AB must provide the peer evaluation team with evidence of the cause analysis and an action plan and time schedule for implementation of the action. Based on the risk associated with a finding, the AB may also be required to provide evidence of the effective implementation of the action. Wherever possible, the need for the provision of such evidence will be stated in the summary report.

A nonconformity is considered closed when the evaluation team has accepted the evidence of effective implementation of corrective action provided by the AB.

**Comment:** Finding about documents or AB's practices with a potential of improvement; but still fulfilling the requirements.

The evaluated AB is encouraged to respond to comments.

A comment is considered closed when the evaluation team has received the response from the AB.

## DECISION MAKING REGARDING EVALUATIONS

### 1. Decision Making Regarding Evaluations

**1.1** The final evaluation report shall be submitted to the MLA Secretary and MLA Group Chairperson (see deadlines in Annex 3, item A 6).

**Note:** For re-evaluations the report will be submitted to the MLA Group before all findings have been closed if the AB is not able to meet the deadline for closing findings (see Annex 3, item A 6).

**1.2** The MLA Secretary distributes the final report to the MLA Group, which shall decide:

- in the case of an initial evaluation, whether or not the Applicant Body may enter the Cooperation's Arrangement;
- in the case of a re-evaluation, whether or not the Applicant Body will remain a Signatory to the Arrangement. Positive decisions can be accompanied by conditions (see 2.0 Hierarchy of Decisions).

**Note 1** *The MLA Group may decide to carry out a re-evaluation, partly or totally, prior to the normal 4 year period. Normally this would be the case after initial evaluations or fundamental re-organizations.*

**Note 2** *For voting rules see the document AD 023.*

**1.3** The MLA Group shall review the evaluation report findings to confirm that they are correctly classified and that the report contains the necessary information to have full confidence that the applicant complies with ARAC MLA requirements. The MLA Group may request additional information from the evaluation team and the AB, in which case it should duly note it, in order to harmonize peer evaluator criteria.

Regulators or other observers who are allowed to attend the decision making meetings, may also be provided with the evaluation/re-evaluation report for a given AB, with that decision making group's and AB's written permission and they have to sign a declaration of confidentiality before being given access.

Members of the MLA Group who participated in the evaluation team shall not take part in the review and decision of that evaluation report.

**1.3.1** Decision on initial evaluations will normally be made during the MLAG meetings. In case decisions on evaluations or reevaluations are made by email ballot, this process will be carried out in 3 steps:

**Step 1)** Review of the evaluation report by the MLA Group and presentation of comments.

- a)** Reports on evaluations, re-evaluations and interim visits may be copied to the representatives of signatories who have a role to play in decision making.

The MLA Group shall provide written comments to the report within 30 days or as agreed by the MLA Group. All signatories are required to send their comments to the MLA Secretary. If a signatory does not have any comments, the signatory's representative shall state that in writing.

Comments shall clearly identify the section, page of the report and, if relevant, the number of the finding. Comments should include issues that need to be clarified by the evaluation team and/or the evaluated accreditation body.

**Step 2)** Clarification on comments

As soon as the comments for a MLAG member are received, the MLA Secretary will forward them to the evaluation team leader and the evaluated accreditation body for their clarification.

This step should be completed within 30 days from the end of the comment period or as agreed by the MLA Group.

**Step 3) Email ballot**

After getting clarifications on the comments, the MLA Secretary will submit the final report, the comments and the clarifications to the MLAG for a 30 days electronic ballot.

In order to avoid conflict of interests, the person representing the signatory in this email ballot shall not have participated in the evaluation. At the end of the ballot period, any MLAG member who has not submitted their vote will be informed that their silence is considered as agreement with the proposed decision, in accordance with established voting procedures.

- 1.3.2 If an ARAC MLA Group member requests an in-person/virtual discussion for an evaluation/reevaluation instead of an email ballot, they should submit a brief written request to the ARAC MLAG Secretariat before the voting deadline, clearly stating the case and rationale. Upon receipt, the Secretariat will arrange an in-person or virtual meeting. The group will then deliberate, conduct a live vote if required, and formally record the final decision.

**2. Hierarchy of Decisions**

- 2.1 Decisions made as a result of peer evaluations can take many forms. Implicit in these decisions is the possibility of a variety of sanctions. This guidance outlines a hierarchy of the major types of decisions from the most positive decision to the least positive decision (i.e., when conditions or sanctions of increasing severity are imposed).

- 2.2 The ARAC MLA Group makes all decisions on MLA signatories. There are primarily two situations to address: *New MLA Applicant* and Maintenance of a *MLA Signatory*. A third situation that is not addressed below is the possibility of adverse decisions or sanctions imposed on an MLA signatory which fails to abide by its obligations under the Arrangement itself.

**2.3 Decisions on New MLA Applicant and Extensions of Scope.**

- 2.3.1 Approval without conditions (re-evaluation to occur in the normal 4 years period from the date of the evaluation).

- 2.3.2 Approval with conditions (e.g., shortened interval for re-evaluation), a follow up visit by one or more members of the evaluation team.

- 2.3.2.1 Where the number of accredited CAB in the scope the applicant is applying for is less than four at the time of evaluation, the need for a follow-up evaluation before the normal 4 year period shall be considered by the MLA Group.

- 2.3.3 Defer approval pending submittal of required evidence of corrective actions, or of any other information as determined by the MLA Group, and/or a follow-up visit by one or more members of the evaluation team to confirm implementation of corrective actions.

- 2.3.4 Defer re-approval pending submittal of required evidence of corrective actions, or of any other information as determined by the MLA Group, and/or follow up visit by one or more members of the evaluation team. In case the AB is not able to meet the deadlines for responding to and closing findings, the MLA Group may issue warnings and fix a prorogation of the deadline after which a decision will be made.

- 2.3.5 For decisions on new MLA applicants and extensions of scope that are not specified in the situations described above, the MLAG will make a decision considering case by case so as to ensure the reliability of the ARAC MLA.

- 2.3.6 For decisions on MLA signatories that are not specified in the situations described above, the MLAG will make a decision considering case by case so as to ensure the reliability of the ARAC

MLA.

**2.3.7 Disapproval with a new evaluation required.<sup>1</sup>**

Disapproval should rarely happen for New Applicant (Accreditation Bodies) since an evaluation report is normally only submitted for a decision once all findings have been closed.

**2.4 Acceptance into the ARAC MLA Group**

**2.4.1** Once the ARAC MLA Group has approved a new signatory of the MLA, it is accepted immediately into the MLA.

**2.4.2** The MLA Secretary will inform the ARAC General Assembly of new signatories and their scopes of recognition.

**2.5 Decisions on MLA Signatory**

**2.5.1** Approval without conditions (re-evaluation to occur in the normal 4 year period from the date of the evaluation).

**2.5.2** Approval with conditions (e.g., shortened interval for re-evaluation, a follow up visit by one or more members of the evaluation team).

**2.5.3** Defer re-approval pending submittal of required evidence of corrective actions and/or follow up visit by one or more members of the evaluation team. In case the AB is not able to meet the deadlines for responding to and closing findings, the MLA Group may issue warnings and fix a prorogation of the deadline after which a decision will be made.

**2.5.4** Reduction of recognition for one or more scopes of the ARAC MLA.

**2.5.5** Suspension from the MLA (see clause 2.7).

**2.5.6** Withdrawal of Signatory status (see clause 2.7)

**2.5.7** Duration of the evaluation process: the peer-evaluation process, from the first on-site or remote evaluation activity until the decision on MLA status, should normally be completed within 6 months, excluding preparation activities and any witnessing conducted prior to the evaluation

**2.6 Notification of change**

**2.6.1** Each Signatory of the ARAC MLA shall report any significant changes in its status and/or its operating practices (e.g. as listed below) including the impact of these changes without delay to all MLA Group members through the ARAC MLA Secretary.

- Legal status;
- Senior accreditation scheme personnel;
- Contact person or liaison officer for the Arrangement;
- Accreditation criteria and procedures, related to the Arrangement;
- Office address (and postal address, if different), including head office and any offices;
- Relationship with government;
- Sector specific accreditation schemes endorsed by ARAC, IAF and ILAC with which the AB is involved
- Other changes that significantly affect the competence, impartiality or credibility of the accreditation process.

**2.6.2** The MLA Secretary will update the relevant information about the signatory on the ARAC website and inform all ARAC members about the changes. The MLA Group shall review the changes that affect the MLA and decide on the need for any subsequent actions, which may include but are not limited to:

- Request the signatory to provide additional information,
- Perform an extraordinary evaluation,
- Verify the implementation of the changes in the next re-evaluation,
- Update the name of the organization and sign a new Signature Sheet of the ARAC MLA.

## **2.7 Suspension and withdrawal of MLA Group**

**2.7.1** It may be that the ARAC MLA Group cannot accept the significant changes notified by the AB, or the corrective action taken by an AB with regard to nonconformities which have been found, or to substantiated complaints from interested parties. It may also be that the AB does not provide the documentation required to perform the evaluation, delays re-evaluations or follow-up visits, or does not appropriately respond to the nonconformities of a peer evaluation in the timeframe established in this document. The ARAC MLA Group may then take appropriate action. This action can be suspension for a maximum period of 12 months or withdrawal from the ARAC MLA.

**2.7.2** Notwithstanding any other clause in this document, an accreditation body member shall not remain a member of the MLA Group if it is, for any reason, suspended or withdrawn from the MoU. The ARAC Secretary shall immediately notify the MLA Group when any member of the MLA is suspended or withdrawn from the MoU for any reason, and the MLA Group shall immediately suspend or withdraw the membership of the body in the MLA.

**2.7.3** Suspension or withdraw of a signatory shall be decided by the ARAC MLA Group in accordance with the same procedures used for acceptance of MLA signatory. ARAC MLA Secretary shall inform ARAC members, ILAC, IAF, and all recognized Regional Cooperation about any suspension or withdrawal decided by ARAC. That information shall be accompanied by an appropriate explanation stating the reason for suspension or withdrawal to the signatory.

The suspended or withdrawn AB may appeal the decision in accordance with ARAC PR 005.

**2.7.4** Decisions on suspension shall state:

- the reasons for suspension;
- the period of suspension (maximum 12 months) and/or the conditions for reacceptance into the ARAC MLA;
- the consequences of suspension.

**2.7.4.1** The consequences of suspension shall be decided by the ARAC MLA Group on a case by case basis, depending on the reason for suspension. The consequences of suspension may include, for the applicable scope:

- Not actively promote the fact that they are a signatory to the ARAC MLA;
- Not be able to participate in any ballots associated with the ARAC MLA;
- notify all accredited CABs of the suspension and the consequences of the suspension as it relates to them; and
- Notify stakeholders in their economies of the suspension.

**2.7.4.2** The obligations of the accreditation body while suspended are:

- Continue to comply with the obligations of full membership;

- Cooperate fully with the ARAC MLA Group to enable a speedy resolution of the suspension;
- Maintain oversight of their signatories or accredited CABs.

**2.7.4.3** If the appeal is not upheld, amend the list of Arrangement signatories to identify that the AB is suspended or withdraw the signatory

**2.7.4.4** Suspension of MLA signatory status or scope shall not exceed 6 months. If the issues leading to suspension are not satisfactorily resolved within this period, withdrawal of the signatory status or scope shall be considered.

**2.7.5** If the signatory status of the AB is withdrawn, the AB has to inform all applicants and accredited CABs that the accreditation is no longer accepted under the ARAC MLA and the IAF/ILAC Arrangement and the CAB shall no longer make reference to the ARAC MLA and to IAF/ILAC Arrangement.

**2.7.5.1** When a withdrawn AB applies to become an ARAC signatory again, the procedure for new applicants must be followed.

**2.7.6** Where the results of an evaluation, follow-up activity, notification of change, complaint or other relevant information indicate that confidence in a signatory Accreditation Body is no longer assured, ARAC may suspend, reduce or withdraw the MLA signatory status or scope. Reinstatement of status or scope shall be subject to satisfactory resolution of the identified issues and verification by ARAC

**2.8** Information on hazards and local conditions: The Accreditation Body under evaluation shall inform ARAC and the evaluation team, in advance of the evaluation, of any specific hazards, safety conditions, legal restrictions, or local requirements that may affect the planning or conduct of the peer evaluation activities.

## Annex 5

### MONITORING AND RE-EVALUATION OF A SINGLE ACCREDITATION BODY

1. Periodic monitoring and re-evaluation of the Arrangement(s) is necessary. The re-evaluation on-site shall commence before the end of the 4-year peer-evaluation cycle ( $\pm$  3 months), calculated from the date of the initial or previous re-evaluation on-site.

2. All MLA Signatories shall be formally re-evaluated at maximum intervals of four years from the last day when the previous full evaluation was done.

2.1 The procedures for re-evaluation are essentially the same as for an initial evaluation. Although an application as per form FM 001 is not required, the AB shall provide the evaluation team all documents required in form FM 001, item 21, 90 days in advance of the evaluation. For planning of the witnessing, the AB shall also provide the evaluation team with a list of assessments that will take place from about 6 weeks before the proposed on-site evaluation date, or as agreed with the team leader. Failure to meet that deadline may lead to the cancelation of the re-evaluation and other action as found appropriate by the MLA Group (see Annex 4, clause 2.7.1).

2.1.1 In addition, as soon as the evaluation team is appointed, the MLA Secretary shall send the evaluation team:

- a) The final report of the last evaluation or re-evaluation;
- b) Reports on any follow-up visits done after the last evaluation/re-evaluation;
- c) The MLA Profile of the AB which includes all of the MLA Group resolutions regarding the AB, as well as other useful information for the evaluation team;
- d) A list of the names of the CABs and assessors/experts that were witnessed during the previous evaluation, IAF/ILAC Annex IV; and
- e) Information on accredited laboratories that have participated in proficiency testing programs of ARAC and other recognized regions' programs, if applicable.

2.2 Where there are difficulties to agree on a date for the re-evaluation that suits the evaluation team and the accreditation body, the MLA Group Chairperson may authorize the evaluation to be delayed for 30 days. Any delay longer than 30 days, and that is caused by the AB, shall be considered by the ARAC MLA Group and may lead to suspension of the MLA or other actions as found appropriate by the ARAC MLA Group.

3. Partial to total re-evaluation may be conducted at an earlier date as directed by the MLA Group, should there be due cause such as notification of significant changes (see Annex 4, clause 2.6)

**Note:** Re-evaluations may also be conducted earlier than the deadline if that is requested by the accreditation body, for example, in order to carry it out together with an evaluation for extension of the scope of recognition.

4. Monitoring of changes notified by an MLA signatory shall be appropriately examined (see Annex 4, clause 2.6).

5. The MLA Group shall monitor the implementation of new versions of standards applicable to the scope of the ARAC MLA, and if necessary other documents mandatory for the MLA, so as to ensure that implementation dates decided by ARAC, IAF and ILAC are met. The General Assembly shall approve a resolution about the procedures to be used to monitor the implementation. An example of such a resolution is given below:

“Considering that **(ARAC, ILAC or IAF)** has decided that the deadline for transferring accreditation to **(standard and year of publication)** is **(implementation date)** and considering the obligation established in MD 002, Section 2, clause 2.2, in relation to implementation of that deadline, the General Assembly agrees that:

- 1) Certificates of **(standard and year previous version)** shall not be valid after **(implementation date)**.
- 2) Each MLA Group member shall submit a report to the MLAG on the implementation of **(standard and year of publication)** before each MLAG meeting held before the deadline.
- 3) Each MLAG member shall submit a final report to the MLAG on **(first day after the implementation date)**. This report shall state:
  - a) the number of conformity assessment bodies accredited to **(standard and year of publication)**,
  - b) the number of conformity assessment bodies whose accreditations have been suspended or cancelled because they have not been able to implement **(standard and year of publication)**, **(standard and year of publication)**,
  - c) confirmation that there is no valid accreditation to the previous version of **(standard)**.
- 4) In case an MLA signatory maintains any valid accreditation certificates to **(standard and year of previous version)**, after the deadline, the Chair of the MLA Group shall suspend the MLA of that signatory for the scope of **(specify MLA scope)** until evidence that those certificates have been either withdrawn or suspended is submitted to the MLA Group.”

6. Ongoing confidence in signatories: ARAC shall maintain ongoing confidence in signatory Accreditation Bodies between peer evaluations.  
Based on notifications, complaints, significant changes, or other relevant information, ARAC may request additional information, require corrective actions, or initiate additional evaluation activities where necessary.

7. Extraordinary situation: In extraordinary situations beyond the control of the Accreditation Body or ARAC (e.g. natural disasters, public health emergencies, political instability, security restrictions or travel limitations), ARAC may adapt the peer-evaluation process as necessary to maintain confidence in the MLA.  
Such adaptations may include postponement of evaluation activities, remote evaluation techniques, alternative evidence review, or other appropriate measures.  
ARAC shall determine the appropriate actions and any conditions necessary to maintain, suspend or restore MLA signatory status.

## **Annex 6**

### **DISCLOSURE OF EVALUATION REPORTS**

1. A report on the evaluation of an accreditation body carried out on behalf of the ARAC MLA Group shall not be published in the public domain.
2. An accreditation body may, however, choose to disclose the full report to its interested parties with the purpose of promoting the acceptance of the ARAC MLA under the conditions detailed below.
3. The evaluation report shall not be disclosed until after it has been formally considered by the ARAC MLA Group.
4. The ARAC MLA Secretary may provide to the accreditation body the documents that may be collectively disclosed to interested parties. Those documents shall include the full evaluation report, including the responses to the findings and all other Annexes, and the ARAC MLA Group resolution arising from the consideration of the report. All references to any specific conformity assessment body and names of assessors shall be removed by the ARAC MLA Secretary from the documents that may be disclosed. The ARAC MLA Secretary may provide these documents to the accreditation body, if requested, within 30 days from the date of the MLA Group resolution.
5. The documentation provided by the ARAC MLA Secretary to the AB shall be disclosed by the AB collectively; together 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 except where the law requires such information to be disclosed.
6. Where the evaluation is performed jointly with other regional groups or with ILAC or IAF, the evaluation report shall not be disclosed unless there is agreement among the parties involved in the evaluation and the accreditation body.

## **Annex 7**

### **EXTENSION OF THE ACCREDITATION BODY'S MLA SCOPE**

1. A signatory of the ARAC MLA may wish to extend its MLA to include new scopes. This Annex specifies the procedures to be followed for those extensions. The ARAC MLA structure is documented in PR 025 and includes 5 Levels. Those Levels are referred to in this Annex. The term "scope" is used in this Annex a generic term for all MLA Levels; the term "sub-scope" is used for Levels 4 and 5 of the ARAC MLA.
2. Before an AB applies for an extension it shall have a minimum of one accredited CAB under the scope or sub scope applied for. If the AB does not have the minimum of accredited CABs the application shall not be considered by the MLA Group.
3. The AB shall apply for an extension of the ARAC MLA using FM 001. Extensions of MLA scopes are not required for Levels 4 and 5. But for recognition of accreditation of sub-scopes for certification of management systems, the AB shall present to the MLA Secretary a self-declaration using IAF MLA MC 28 "MLA Declaration for sub-scope extensions (ABs)". The MLA Group will decide on the acceptance of the self-declaration by resolution. This decision/resolution will be communicated to IAF by the ARAC Secretary.
4. The additional level 4 and/or 5 scopes will be evaluated at the next peer evaluation. In exceptional cases, the inclusion of a level 4/5 scope may need evaluation as specifically defined by IAF for the particular level 4/5 scope. At the time for the preparation for the evaluation, ARAC MLA secretariat will draw the attention to the AB and the evaluation team to these exceptional cases and where it is defined by IAF.

Note: Instructions on how to evaluate the sub-scopes are described in Annex 2 clause 2.3

5. The review of the received application of scope extension should be performed by the ARAC MLA secretary by completing the ARAC FM 002.
6. Extensions of scope to include a new Level 3 activity will require a full evaluation of all MLA requirements, similar to an evaluation for initial recognition for the ARAC.
7. The evaluation team will need to include at least one evaluator that is qualified for the MLA scope. If an evaluation for scope extension is performed separately from a re-evaluation, depending on the evaluator's experience, it may not be necessary to appoint a team leader to perform the on-site evaluation, however a team leader shall be appointed to supervise the work of the evaluator and to make sure ARAC procedures are followed.

## **Annex 8**

### **GUIDANCE FOR EVALUATION TEAMS**

#### **1 Introduction:**

This Annex is produced as a guide and checklist for ARAC evaluation teams to assist them in the planning and conduct of on- site peer evaluations. It is also a useful resource for ARAC accreditation bodies that are subject to these evaluations.

For initial evaluations and evaluation for extensions of scope, the AB is responsible for submission of the application for arrangement membership to the ARAC MLA Secretary who will carry out a review and if the application is complete, will send it to the MLA Group for a ballot. If the application is accepted, the Team Leader and Team Members will be appointed by the ARAC MLAC Chairperson within 90 days from the acceptance of the application. For a re-evaluation, the evaluation team is usually appointed from 6 to 12 months before the re- evaluation due date. The MLA Secretary informs the AB of the composition of the Team, and the AB may object based on conflict of interest or impartiality.

#### **2 Preparation for the evaluation**

**2.1** The Team Leader must communicate with the AB to, identify any changes occurring since the submittal of the application, and identify potential dates for the evaluation.

**2.2** For an initial evaluation all Team Members will receive the application and documentation from the ARAC MLA Secretary. For extensions of scope, the ARAC MLA Secretary will forward the application to the Team and the AB must provide the documentation specified in FM 001 to the team 15 days after their appointment by ARAC.

**2.3** For a re-evaluation the AB shall provide the evaluation team all documents required in FM 001 90 days in advance of the evaluation. Failure to meet that deadline may lead to the cancelation of the re-evaluation (see Annex 5, clause 2.1 of MD 002). The Team will also receive the previous evaluation report and other documentation from the ARAC MLA Secretary (See Annex 5, clause 2.1.1 of MD 002).

**2.4** The Team will begin the document review as soon as they receive the documentation. For initial evaluations and extensions of scope the document review (FM 003) should be completed and sent to the AB 120 days after the appointment of the Team. FM 003 should also be sent to the AB before a re-evaluation.

**2.5** For initial evaluations, if a Pre Peer evaluation Visit is done a short written report is submitted by the Team Leader and all corrective actions must be completed. The MLAG will receive the recommendation of the Team Leader and decide if a full evaluation can take place.

**2.6** If the evaluation is done jointly with another Regional Body, the Team Leader should liaise

with the Chair of the ARAC MLAC and the other region's MLA Committee Chair to agree on specific arrangements for the evaluation.

**2.7** The AB must provide a list of possible CABs to be visited including detailed scopes of accreditation preferably 3 months prior to the visit. (See Annex 2, section 2.3 for guidance on witnessing)

**2.8** Team Leader must work with AB on agenda of the evaluation visit including:

- Dates of visit, to include any possible need to stay more than 5 days;
- Travel considerations including flight issues to/from the evaluation and travel to CABs for witnessing;
- Assignment of tasks to Team Members; care should be taken to avoid allocating the evaluation of related requirements to different members of the evaluation team, when there is not enough AB personnel available for interviewing, the purpose is to avoid duplication and restricted access to the appropriate AB staff
- Need for interpreters if applicable;
- Ensure sufficient time for team meetings after the evaluation at the AB's office, especially for the evening before the last day of the evaluation. Inform the AB of any dietary requirements and physical limitations of Team Members;
- Ensure that the AB knows the requirement for arranging travel and accommodations, as well as for covering daily expenses incurred by the each Team Member;
- Need for a meeting room at the hotel the day before the evaluation and each evening during the evaluation;
- Need for a private meeting room during the evaluation at the AB's office;
- Need for Internet access at the AB's office and at the hotels;
- Identification of AB Staff Members who will be involved in the evaluation and the requirements they will be involved with;
- It may be important to document in IAF-ILAC A3 Annex II information regarding location, type of assessment and dates of the witnessing activities
- Complete IAF-ILAC A3 Annex II approximately 30 days prior to the visit and submit to the AB.

**2.9** TL should check the AB website to review its accreditation scopes and the dates of accreditations renewals, in order to plan the peer evaluation schedule and to select the assessment activities to be witnessed.

**2.10** Team Leader must communicate with Team Members to :

- Obtain information about their technical background and experience in accreditation and peer evaluations, and language skills;
- Ensure Team Members understand the need to complete document review and submit comments for inclusion in Form FM 003;
- Verify IAF-ILAC A3 Annex II is completed and assignments understood;
- Ensure any special dietary or physical limitations are clearly communicated to the TL;
- Explain how travel and hotel arrangements will be made and how costs of will be managed;
- Explain expectations at the AB's site or witnessing sites including dress codes and /or safety issues.

**2.11** Additional issues to be considered by the Team Leader during preparation:

- Is there a need to visit the NMI? (see Annex 2, section 2.5)
- Is the AB applying for recognition for a scope for which it is already a signatory of the MLA or a recognized regional body and /or IAF or ILAC? (see Annex 2, section 2.6)
- Determine a time for team meeting each day by telephone or some other means

communication.

- Preparation of part of draft report using submitted self-evaluation given in FM 003.
- Consider the need to mentor and supervise trainee evaluators.

## **2.12 Evaluation team meeting before the evaluation**

The Team Leader should conduct a meeting with the Team Members the day before the evaluation in which discussions should focus on:

- Identification of key items arising from the documentation review to follow up on;
- For re-evaluations, identification of any findings from the previous evaluation that need to be reviewed and any special instructions / resolution from the ARAC MLA Group concerning the evaluation;
- What objective evidence to going to be sought to verify conformity requirements;
- Assignment of any specific task to Team Members;
- Any queries to be clarified during the opening meeting;
- Confirmation of means of communication and issues to be reported, particularly when Team Members need to travel for witnessing;
- Review of expectations during witnessing (IAF-ILAC A3 Annex V);
- Confirmation on expectations on reporting from each Team Member (findings, summary report, IAF-ILAC A3);
- Provide any necessary guidance to trainee evaluators and confirm how they will be mentored / supervised;
- Confirmation of evaluation plan (IAF-ILAC A3) and any need for changes, verify that documents not applicable to the evaluations scope are deleted from the program.

## **3 During the evaluation**

### **3.1 The Team Leader should:**

- Lead the opening meeting; ensure any queries from team members have been clarified with AB and remind the AB the classification of findings as describe in MD 002;
- Ensure the evaluation remains on track;
- Ensure team members gather sufficient objective evidence to support their findings;
- Mentor less experienced team members;
- Ensure AB receives feedback, as appropriate, throughout the evaluation;
- Ensure team discussions remain on track;
- Gather information from team members each evening.
- Ensure that meetings and other communications among the team focus on:
  - follow up on issues as decided the day before,
  - findings already confirmed, potential findings and additional evidence to be sought,
  - issues to be followed up and assignment of tasks,
  - confirmation that plans are on track and need for changes of plans,
  - confirmation that reports (IAF-ILAC A3) are being done by each team member as planned;
- Ensure that the meeting the evening before the last day focuses on:
  - confirmation of findings and their classification by all team members
  - drafting the summary report (as far as possible),
  - issues to be finalized the last day,
  - confirmation of the time by which all findings and the summary report will be completed the next day for review by the AB before the final meeting,
  - remind team members that report on witnessing (IAF-ILAC A3 Annex V) should have been completed before that meeting. If that is not possible, all

issues that may result in a finding shall be reported during the meeting and IAF-ILAC A3 Annex V shall be delivered to the Team Leader soon after the evaluation.

- Ensure findings are based on clear and objective evidence, are correctly classified and assigned to clauses of ISO/IEC 17011 and other MLA requirements;
- Prepare summary report and list of non-conformities and comments (IAF-ILAC A3 Annex I) for presentation to AB at closing meeting;
- IAF-ILAC A3 Annex I should be reviewed for comment by the AB prior to the closing meeting;
- Recommendations for follow up visits should be made based on:
  - the need of confirming implementation of actions,
  - AB has not demonstrated enough experience due to a limited number of accredited CABs or limited number of evaluators,
  - Or the peer evaluation team may indicate that the recommendation for follow up will be made after they received the AB's response for the findings. The summary report should highlight any findings that are recurrences of findings from the previous evaluations;
- Ensure, during closing meeting, that any misunderstandings are clarified, disagreements resolved;

### **3.2 Team Members should:**

- Follow the evaluation plan and instructions given by the Team Leader;
- Make sure enough evidence is collected to confirm compliance and competence, or sufficient evidence for any finding;
- Keep notes of evidence collected for reference (document number, forms, identification and dates of records, details observed in records, persons interviewed, etc.);
- Make sure the AB understands any finding and is given opportunity to clarify the issue;
- Make sure the person that provides information is the appropriate responsible person in the AB and, if necessary double check and reconfirm the information given;
- Not interfere with the work of AB assessors during witnessing;
- Provide feedback after the conclusion of the witnessing and clarify any outstanding issues with the AB assessors
- Make notes of discussion, records and documents during witnessing so that information may be recollected and confirmed with assessors after the end of the witnessing;
- Confirm facts with assessors and AB representative after the end of witnessing;
- Report to the Team Leader any issues that may need to be confirmed by other team members;
- Complete the reports on time.

## **4 After the evaluation**

### **4.1 The Team Leader should:**

- Provide the draft report, agreed among the team members, to the AB for comment and correction of factual errors (if necessary) within 60 days of the evaluation visit (see Annex 3, section A2);
- Review the AB's corrective action and response report (IAF-ILAC A3 Annex I), assigning parts to team members, as applicable;
- Ensure AB provides evidence of identification of and correction of the root cause(s) of non-conformities as well as a response to comments (see Annex 3, section E);
- Advise the AB if the response is acceptable within 30 days of receipt;

- Ensure the deadlines for responses from the AB and the team for delivering the report to the MLAC Chairperson is met (see Annex 3, section A3, A4 and A6);
- Once the team is satisfied that the AB 's response is satisfactory and all necessary corrective action has been taken, prepare a recommendation to the ARAC MLA Group and include it in the Final Report (IAF-ILAC A3);
- Send the Final Report (IAF-ILAC A3), findings, AB 's response, evaluation team 's reaction to that response), and any relevant annexes to the MLA Secretary and the MLAG Chairperson, together with Lists of Witnessed Assessment (IAF-ILAC A3 Annex IV);
- complete evaluator performance log for each team member (FM 007) and send it to the ARAC MLA Secretary;
- In case the Final Report is distributed to the MLA Group for written comments, respond to comments as requested and amend the Final Report, if necessary (see Annex 4); within 30 days
- Inform the MLA Secretary whether you will be present in the next MLA Group meeting or whether you may be available via Internet. In case attendance of the meeting is not possible, inform the MLA Secretary who may represent the evaluation team during the meeting.

#### **4.2 Team Members should:**

- Provide the Team Leader their complete report on assessments witnessed (IAF-ILAC A3 Annex V) immediately after the evaluation (if not complete during the evaluation);
- Provide the Team Leader their assigned part of the Final Report (IAF-ILAC A3) immediately after the evaluation;
- Review AB 's response for the findings assigned to him/her as soon as they are received;
- Complete evaluator performance log for the Team Leader (FM 008) and send it to the ARAC MLA Secretary.