



Policies and procedures for a multi-lateral recognition arrangement among accreditation bodies

CLASSIFICATION

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AVAILABILITY

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SECTION 1. INTRODUCTION

1.1 PURPOSE

This document defines the policies and procedures of the Arab Accreditation Cooperation (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 011 Declaration of Confidentiality and Impartiality).

1.3.1.1 Form FM 011 shall be signed by evaluators before they are accepted as ARAC evaluators.

1.3.1.2 Form FM 011 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 011 for each MLA G meeting.

During each MLA Group and MLA Committee meetings, the MLA Group and MLA Committee members must sign the attendance sheet ARAC FM 031 which contains declaration of confidentiality.

1.3.1.3 Observers to the MLA Group meetings shall sign form FM 011 at each meeting, before they are given access to evaluations reports.

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

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.

1.4 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 program: Accreditation of bodies according to a standard or normative document included in the ARAC MLA, used for the accreditation of conformity assessment bodies.

1.4.3 Arrangement: The Multi-Lateral Arrangement (MLA), 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: An ISO/IEC standard, guide or technical report related to accreditation and conformity assessment.

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.

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 ARAC and/or other Regional or International Groups, Accreditation Bodies, commercial organizations, or other 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 Witnessing: Observing of an AB assessing the CABs premises, management system and records by an evaluation team. (It may also include observing the AB’s staff preparing for an assessment and dealing with assessment reports, and observing committee meetings). If there is not enough witnessing to establish the assessor competence of the AB, the team leader may require an interview with a representative sample of the AB’s assessors.

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. Every signatory shall provide ARAC with 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, 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 Have demonstrated experience in operating an accreditation body, and have access to technical expertise in all aspects of its accreditation activities. Where the number of accredited testing or calibration laboratories 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;

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

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

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

2.5.5 Have evidence of promoting the Arrangement with major stakeholders;

2.5.6 Contribute its fair share of personnel resources for carrying out peer evaluations at ARAC and/or global level; and

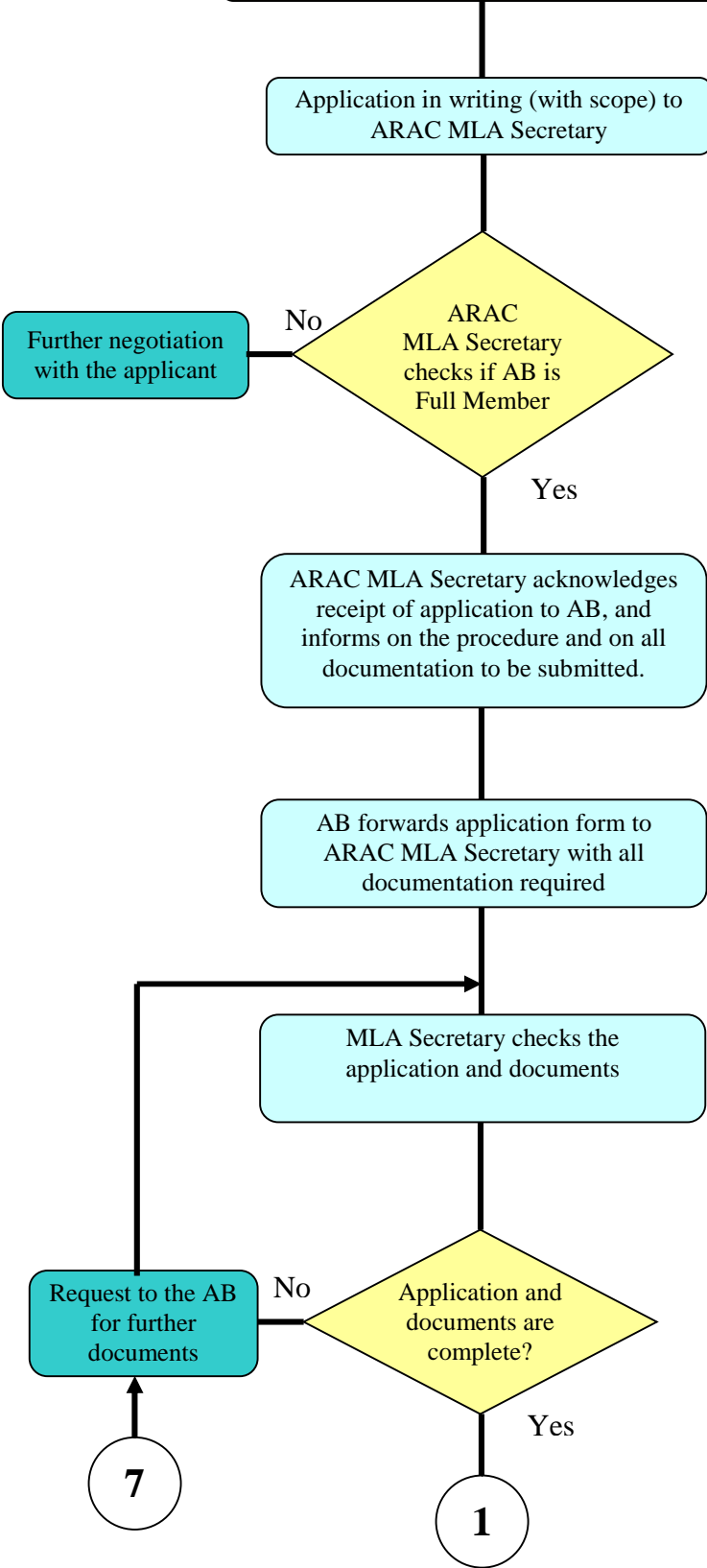
2.5.7 Have implemented a cross frontier accreditation policy in accordance with the relevant IAF document(s) (for IAF signatories) or taking into account ILAC Guide 21 (for ILAC signatories).

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

I. Application for Arrangement Membership

The AB shall demonstrate the implementation of the ILAC and/or IAF requirements, and ARAC requirements, refer to the ARAC website,

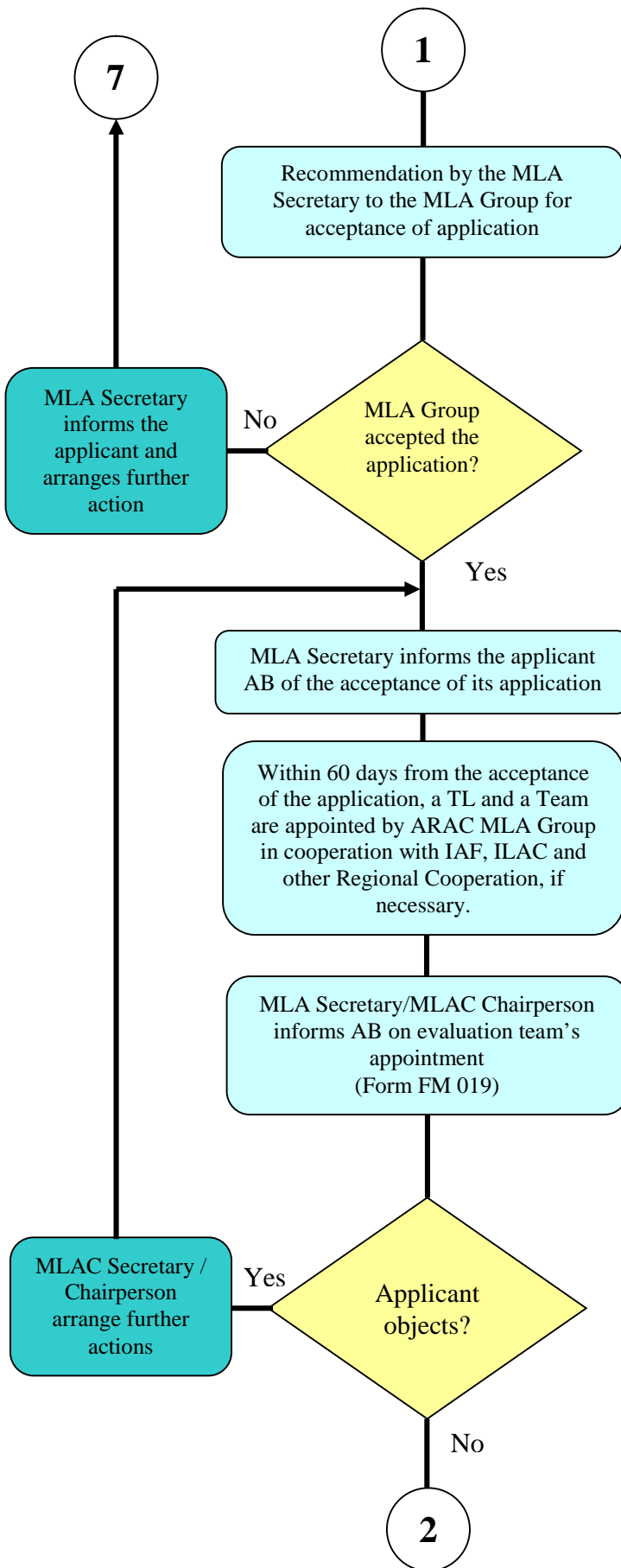
Conditions for application:
 1. Provision of documents required in form FM 001.
 2. The AB agrees to pay for the hotel costs, meals and all travel costs of the evaluation team. Air travel shall be economy class unless otherwise agreed by the body being evaluated.



Form FM001

Form FM002

The MLA Secretary shall check the application and documents within 10 days after receiving the complete set of documents.



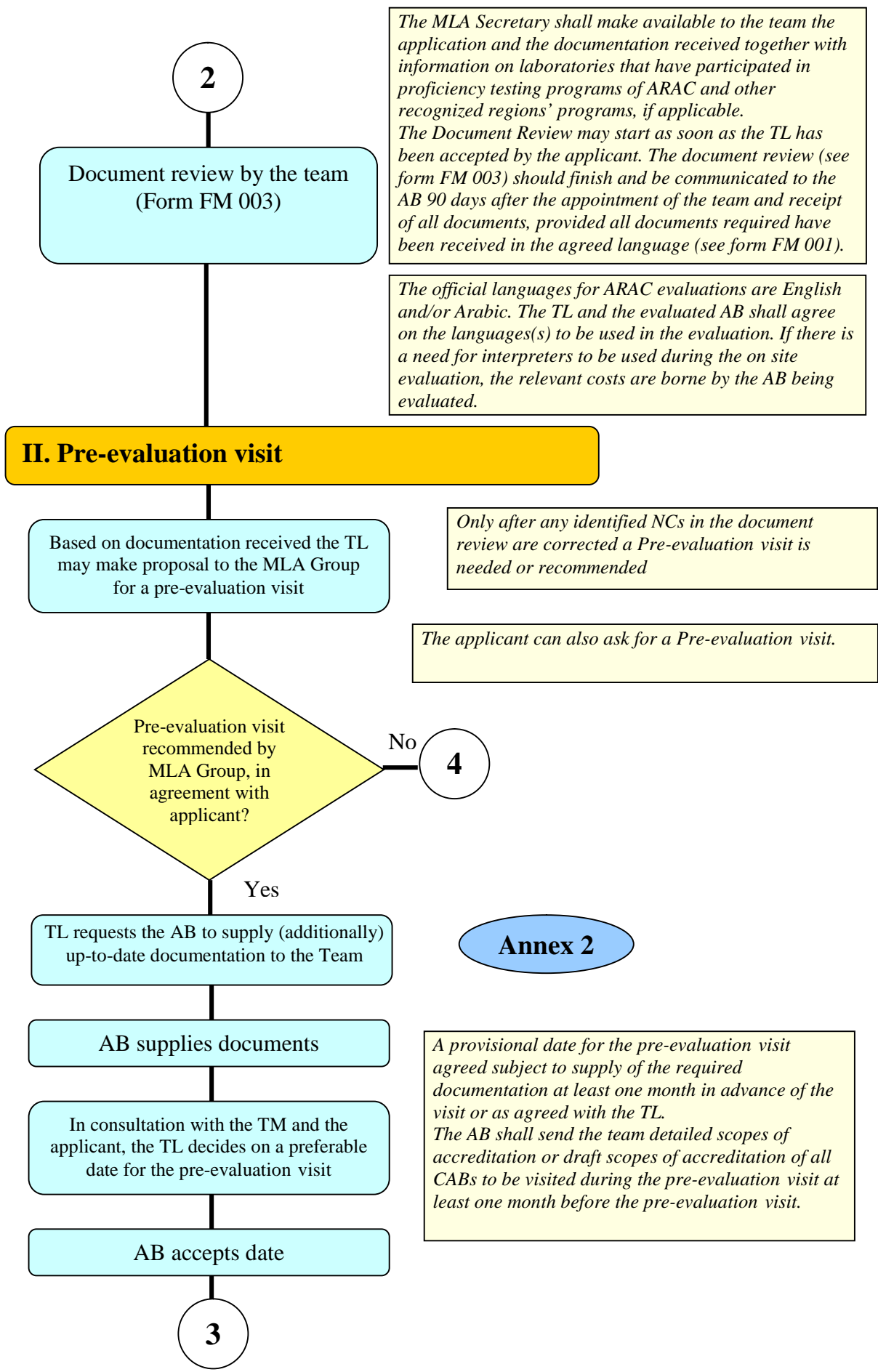
Voting on application has to be done within 30 days from acceptance of application and may be done by email ballot. If MLA Group raises comments during the ballot that may not be resolved by email, the application will be discussed in the next meeting of the MLA Group.

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

Annex 1

The MLAC 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.



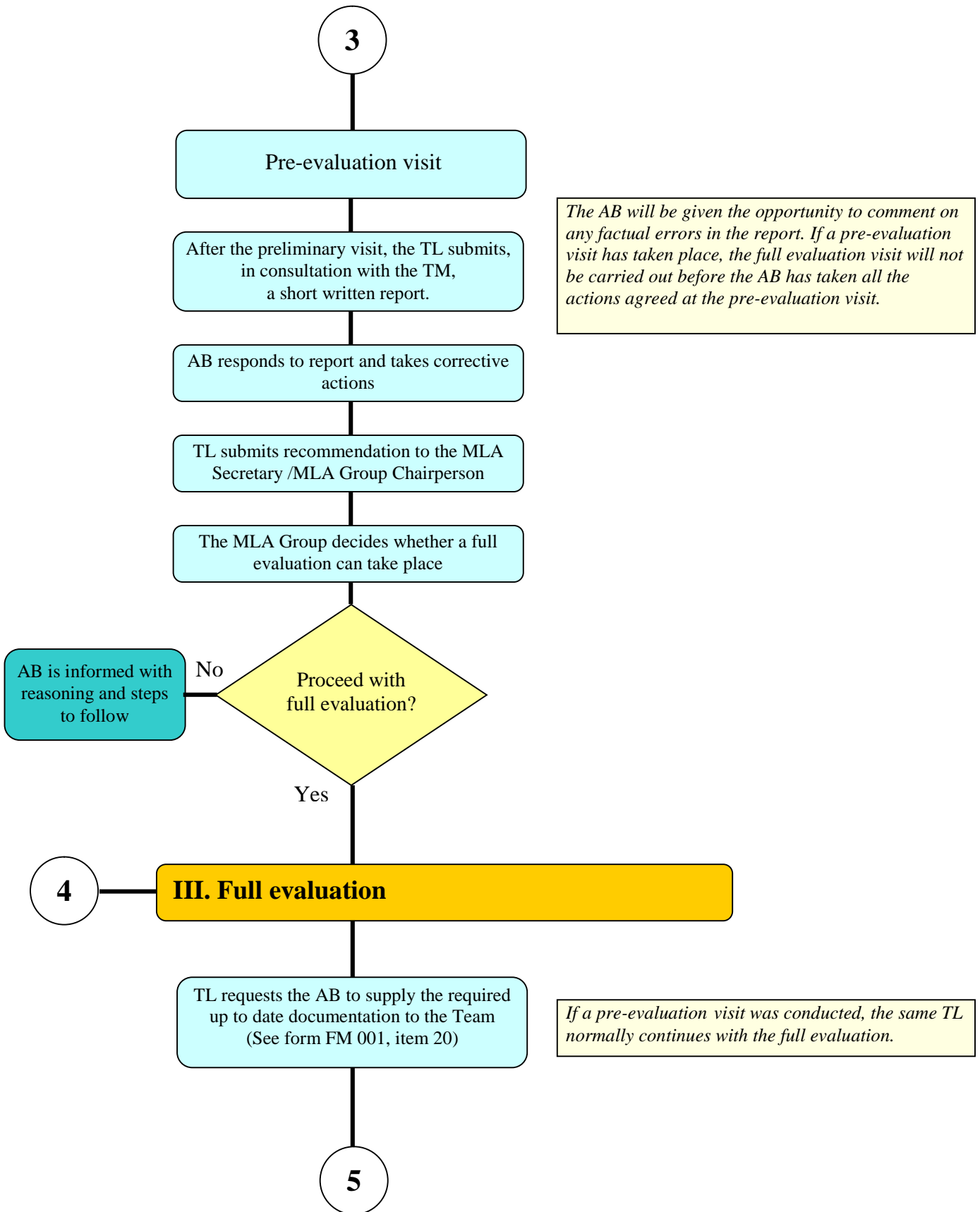
The MLA Secretary shall make available to the team the application and the documentation received together with information on laboratories that have participated in proficiency testing programs of ARAC and other recognized regions' programs, if applicable. The Document Review may start as soon as the TL has been accepted by the applicant. The document review (see form FM 003) should finish and be communicated to the AB 90 days after the appointment of the team and receipt of all documents, provided all documents required have been received in the agreed language (see form FM 001).

The official languages for ARAC evaluations are English and/or Arabic. The TL and the evaluated AB shall agree on the languages(s) to be used in the evaluation. If there is a need for interpreters to be used during the on site evaluation, the relevant costs are borne by the AB being evaluated.

Only after any identified NCs in the document review are corrected a Pre-evaluation visit is needed or recommended

The applicant can also ask for a Pre-evaluation visit.

A provisional date for the pre-evaluation visit agreed subject to supply of the required documentation at least one month in advance of the visit or as agreed with the TL. The AB shall send the team detailed scopes of accreditation or draft scopes of accreditation of all CABs to be visited during the pre-evaluation visit at least one month before the pre-evaluation visit.



5

AB supplies updated complete documentation

TL prepares a detailed program for the visit in consultation with TMs, the AB and the MLAG Chairperson
(See form FM 004)

On-site evaluation - Information collection including witnessing

Discussion of the summary section of the report including findings with the applicant before the team leaves

TL provides the draft report, completed in consultation with the TMs, to the AB with c/c to the MLAG Chair and MLA Secretary

AB responds to TL on all findings

TL, in consultation with TMs, reacts to the AB's response

Corrective actions and time schedule acceptable?

No

TL arranges further discussion with AB

Yes

6

All members of the team shall be supplied with updated copies of the necessary documentation (see form FM 001 item 20), in the agreed language, at least three months in advance of the visit, or as agreed with the TL. The AB shall also provide the evaluation team detailed information on the assessments planned from about 6 weeks of the evaluation or as agreed with the TL so that the evaluation team may select the assessments to be witnessed. The scopes of accreditation of all CABs to be visited during the evaluation shall be provided to the team. If the documentation is not provided on time, the evaluation may be cancelled by the MLAC Chairperson (see also Annex 4 clause 2.7.1 for suspensions).

Annex 2

The TL shall ensure that the head of the applicant body understands and accepts that the evaluation shall be conducted in accordance with this document and on the basis of the requirements document.

The TL shall give the AB an opportunity to comment on and discuss the summary section and the team's findings and recommendations and to clear up any misunderstandings that may have arisen. The team shall leave a summary section of the report with the AB (see Annex 3) together with the list of finding using form FM 005. The summary section and the findings shall be provided to the MLA Secretary and MLAC Chairperson immediately after the evaluation. If a follow-up visit is recommended, this should be stated during the visit and be documented in the summary section of report (see Annex 3 section B1, item 2). Decision to authorize a follow up visit may be made by the MLAC Chairperson based on the Summary Report. This decision will be recorded in an MLAC resolution. If the team recommends suspension of the AB (see Annex 3, B4), the MLAC Chairperson shall initiate the decision making process as per Annex 4. If possible, the team should leave a complete, draft report

After the evaluation, the TL and TMs and the evaluated AB shall send MLA Secretary and MLAC Chairperson the performance logs as required in PR 004 (ARAC Peer Evaluators)

Annex 3

See deadlines for the AB responding to findings and for the TL to react in Annex 3, section A, items 3 and 4. If the AB does not meet these deadlines, the TL shall report to the MLA Group Chair for a decision.

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 in the member's area on the ARAC Website.

Note: See procedure PR 004 for information on training and qualification of ARAC 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. The team leader appointed for an evaluation should not be from the same AB as the team leader from the previous evaluation.

1.2 The team leader shall have ultimate responsibilities for all phases of evaluation and is delegated 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, mentor any trainee evaluator assigned to the evaluation team. Mentoring trainee evaluators includes, 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, IAF or other recognized regional cooperation, the MLAC will work in cooperation with the other organization 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: 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 in the last two years may be considered a threat to a team member's impartiality:

-) Participation in recent internal audits (last 2 years);
-) Provision of training specially tailored for the design and development of the AB's accreditation system;
-) Participation as an assessor in joint assessments of more than 5 CABs.

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 There shall be at least one lead evaluator or evaluator qualified for each accreditation standard, except where there are two standards for the same activity (e.g. testing - ISO/IEC 17025 and ISO 15189). Where more than one accreditation activity or program is covered by the same accreditation standard (e.g. ISO/IEC 17025, for testing and calibration; ISO/IEC 17021 for QMS, EMS, FSMS, etc.), or more than one standard for the same accreditation activity (e.g. for testing, ISO/IEC 17025 and ISO 15189), 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 AB being evaluated.*

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, the AB where the trainee belongs 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.

ANNEX 2

PLANNING AND MANAGING THE EVALUATION

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:

Issues to be considered:

-) 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);
-) Traceability routes (for testing and calibration accreditation). 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.

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 is not possible during the week of the formal evaluation the TL should make arrangements to have witnessing performed in the weeks preceding 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.

2.2 TYPES OF 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.

2.3 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.

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,
- initial evaluation/ re-evaluation,
- witnessed assessments from the last evaluation,
- cross frontier accreditation policy and relative arrangements.

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 surveillances for every accreditation program. Preferably the evaluation team should witness reassessments instead of initial assessments.; this shall be clearly stated in the evaluation program (FM 004). **Table 1** below provides additional instructions for each scope.

Where the number of accredited testing or calibration laboratories 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.

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 CAB accredited for accreditation programs 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.

If there is not enough witnessing to establish the assessor competence of the AB, the team leader may require an interview with a representative sample of the AB's assessors.

TABLE 1: Additional Instructions about witnessing

Scope	Specific instructions about witnessing
Calibration ISO/IEC 17025	Witnessing includes witnessing of the assessment by the AB of the CAB performing calibration. Depending on the number of accredited laboratories and the variety of the scopes, it may be necessary to perform more witnessing.
Testing ISO/IEC 17025	Witnessing includes witnessing of the assessment by the AB of the CAB performing testing. Depending on the number of laboratories and the variety of the scopes, it may be necessary to perform more witnessing.
Testing ISO 15189	Witnessing includes witnessing of the assessment by the AB of the CAB performing examination. Depending on the number of accredited laboratories and the variety of the scopes, it may be necessary to perform more witnessing. If the team witness an initial assessment of testing laboratory to ISO/IEC 17025 it may not be necessary to witness the assessment of the management system requirements of ISO 15189 which are essentially the same as those in ISO/IEC 17025. In any case witnessing needs to cover the assessment of the technical requirements of ISO 15189 as well as those management requirements of ISO 15189 which are not addressed in ISO/IEC 17025.
Inspection ISO/IEC 17020	Witnessing includes witnessing of the assessment by the AB of the CAB performing inspection. Depending on the number of accredited inspection bodies and the variety of the scopes, it may be necessary to perform more witnessing.
Management system certification ISO/IEC 17021 (QMS and EMS)	It is also appropriate to witness a reassessment for one of the programs and a surveillance visit for the other one. 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.
Product certification ISO/IEC 17065	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.
Certification of persons ISO/IEC 17024	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. 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.

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 20)*

-) 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 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, 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.,

2.6.2 If the AB has been evaluated by an IAF and/or ILAC recognized regional body 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) limit 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 reevaluation 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 20. 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. The AB shall send all documents listed in form FM 001, item 20 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 reevaluation).

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 has applied for accreditation activities for an industry specific program, then the requirements set by that industry group for accreditation bodies shall also be considered.

The TL, in cooperation with the TMs, shall prepare an evaluation plan using form FM 004 that contains as a minimum:

- Identification of the AB,
- The purpose and date of the evaluation, including the accreditation programs to be evaluated,
- The names of the TL and TMs and the accreditation programs 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 program 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;
- Evaluation of the records of CAB whose assessment is to be witnessed and of the preparation for the assessment;
- 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 form FM 012;
- 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 Office, opening meeting, records, etc. (key issues to be addressed + evaluation plan)	TL + 2 TM
Day 2	Office + witnessing assessments (split team)	TL + 2 TM
Day 3	Office + witnessing staff + preparation final report + closing meeting	TL + 2 TM
Day 4 morning	Discussing further actions for TMs + departure	TL + 2 TM

3.2.3 ABs with 2 scopes of accreditation

Day	Actions	Evaluators
Day 1	3 hours for preparation with the evaluation team Office, opening meeting, records, etc. (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 report This summary section has to be completed and be confirmed by the applicant at the end of the on-site evaluation visit: It includes as an appendix the nonconformities, concerns and comments presented in table format using form FM 005. This summary report shall also include initial recommendation if possible. (see section B1).

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

The evaluation team members should submit to ARAC MLA Committee 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 section B of this Annex, except the responses to the findings, the reaction from the evaluation team, and the final recommendation.

A3 Formal Response of the Accreditation Body to the Findings. The accreditation body's response can simply be inserted under each finding in form FM 005, 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 and concerns as well as responses to the 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.*

Note: For initial evaluations and extensions of scopes, it is acceptable that the AB may need more time to implement corrective actions.

For reevaluations:

- *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 and concerns, as well as responses 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.*

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 form FM 005. (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 form FM 005 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.

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

0 Cover page

The cover page states 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.

1 Contents

For a full evaluation, this page should list the contents of the report, including the Annexes.

2 Summary section

For a full evaluation the summary section shall include:

- a) the name of the accreditation body, the type of evaluation, date of evaluation,
- b) scope of the MLA considered in the evaluation and evaluators for each scope,
- c) criteria against which the evaluation was performed,
- d) activities undertaken during the evaluation, types of assessments witnessed and other institutions visited. If the team witnesses a surveillance visit where all requirements of the accreditation standard are assessed, this shall be informed in the summary section,
- e) strengths of the AB's accreditation system, with reference to relevant sections / topics of ISO/IEC 17011 and other MLA requirements,
- f) number and type of findings,
- g) If a follow up visit is recommended by the evaluation team, the evaluation team shall inform in

the summary section the reasons for the visit including the MLA scopes that are affected, preferably with reference to the findings to be checked, and propose a composition of the evaluation team,

- h) In the case where during an on-site the evaluation team finds nonconformities that clearly show that the AB is not able to ensure confidence in the accreditations granted and the competence of the accredited CAB is questioned, the evaluation team shall make a recommendation for suspension of the AB. The recommendation shall indicate the reason for the suspension including the MLA scopes that are affected, with reference to the relevant findings.
- i) The report shall include, if possible, initial recommendation by the team according to their opinion of the severity of the findings and the ability of the AB to solve it.
- j) Information that the summary section was delivered to the AB at end of the visit.

3 Introduction

The introduction should give the reason for the evaluation, the participants, a summary of the content of the evaluation, criteria against which the evaluation was performed, provisions of documentation and translation, activities undertaken during the evaluation, types of assessments witnessed and other institutions visited, and follow up from previous evaluation findings.

4 Recommendation to the ARAC MLA Group

For initial evaluation and for extensions of the MLA scope the recommendation shall indicate whether or not the AB should be accepted into the MLA and the scope of recognition.

For re-evaluations this recommendation shall indicate whether or not the AB should be maintained in the MLA and the scope of recognition.

The recommendation shall also indicate when the next re-evaluation should be done. Normally the next re-evaluation will be done within 4 years from the last evaluation; if a shorter interval is recommended the evaluation team shall provide the reasons for that and the proposed scope of the evaluation.

In the case where the team recommends suspension of the AB from the MLA, the recommendation shall indicate the reason for the suspension including the MLA scopes that are affected, with reference to the relevant findings.

The recommendation to the MLA Group should reflect the consensus of the evaluation team. If the evaluation team cannot reach consensus, the recommendation shall reflect the different views of the team members and include the reasons for the difference.

5 Performance of the System

The subsections of this section are based upon IAF/ILAC A3 parts 2.1 and 2.2.

6 Arrangement Obligation

For re-evaluations, the steps taken by the signatory to implement the obligations stated in the Arrangement document(s). See Part 2, section 2.3 of IAF/ILAC A3.

7 Annexes

Annex 1 - Nonconformities, concerns and comments to be left at the end of the on-site evaluation visit. Note: The list of findings is to be prepared using form FM 005. The response and actions by the evaluated AB and the reaction by the evaluation team shall be included in form FM 005. Form FM 005 is to be filled out in such a way that it will allow the MLA Committee to understand the proposal made and actions taken by the AB as well as the reactions of the evaluation team.

Annex 2 Evaluation program and agenda using form FM 004.

Annex 3 Reports on the assessments witnessed using form FM 012.

Note: The evaluation team should avoid referring to names of CABs, assessors, experts and AB staff in findings and in the report about the performance of the AB's system.

The team leader shall also provide the MLA Secretary and MLA Chair a separate document (FM 022) containing the list of assessment witnessed, including identification of the CAB and names of assessors and experts. This document will not form part of the evaluation report due to the fact that the AB may disclose it to interested parties (see Annex 6). This information will be used by the ARAC MLA Committee to help plan future reevaluations of the AB.

B2 Follow up Visit Report

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

If the follow up visit aims at checking implementation of corrective actions **before** ARAC MLA Committee makes a decision on granting or maintaining recognition, the information on the activities done in the follow up visit shall be included in the summary section of the Final Report of that evaluation as follows:

- a) 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, either by the MLA Committee or the Chairperson of the MLA Committee; the evaluators participating in the visit and dates of the visit; a summary of the activities performed by the evaluation team: confirmation whether or not all findings have been closed; and the next steps of the process.
- b) An annex with the follow up visit program.
- c) An annex with the report on any assessments witnessed using form FM 012.
- d) In form FM 005, information about the evidence obtained by the evaluation team for each of the findings that was checked, if relevant confirmation that the finding is closed or information on the actions that are still pending.

The summary section about the follow up visit and the updated form FM 005 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 form FM 012.
- e) Form FM 005 including 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 MLAC Chairperson 30 days after the visit.

C 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 is required to respond to nonconformity by taking appropriate corrective action and providing the evaluation team with evidence of effective implementation.

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

Concern: Finding where the AB's practice may develop into non-conformity.

The evaluated AB is required to respond to a concern by providing the evaluation team with an appropriate action plan and a time schedule for implementation.

A concern is considered closed when the evaluation team has accepted the plan and the time schedule proposed 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.

Annex 4

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 reevaluations 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 021.*

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 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.

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.
- b) 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.

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.

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.¹

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)

2.6 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) without delay to all MLA Group members through the ARAC MLA Secretary.

- Legal status;
- Senior accreditation program 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 programs/schemes endorsed by ARAC, IAF and ILAC with which the AB is involved
- Other changes that significantly affect the competence 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 corrective action taken by an AB with regard to significant changes notified by the AB, or 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 and concerns 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 withdrawal 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

2.7.5 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.

Annex 5

MONITORING AND RE-EVALUATION OF A SINGLE ACCREDITATION BODY

1. Periodic monitoring and re-evaluation of the Arrangement(s) is necessary.
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 reevaluation 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 20, 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 reevaluation;
 - b) Reports on any follow up visits done after the last evaluation/reevaluation;
 - 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, form FM 022; 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 MLAC Chairperson may authorize the evaluation to be delayed for 30 days. Any delay longer than 30 days shall be considered by the ARAC MLA Group and may lead to suspension from 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.”

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.