



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

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PREAMBLE

The international accreditation community comprising Regional Groups, recognized accreditation bodies, and their stakeholders cooperates through the International Accreditation Forum, Inc. (IAF) and the International Laboratory Accreditation Cooperation (ILAC). A principal objective of IAF and ILAC is to put in place world-wide, Multilateral Arrangements/Mutual Recognition Arrangements (Arrangements). Both IAF and ILAC aim to demonstrate the equivalence of the outcomes of their Member Accreditation Bodies through these Arrangements. As a consequence, the equivalent competence of conformity assessment bodies (CABs) accredited by these accreditation bodies is demonstrated. The market can then be more confident in accepting certificates and reports issued by the accredited conformity assessment bodies.

IAF and ILAC are linking the existing Arrangements of the Regional Groups (also called: regional accreditation cooperations or regional cooperations) and are encouraging the development of new Regional Groups to complete world-wide coverage. For the purposes of their Arrangements, both IAF and ILAC recognize Regional Groups for the evaluation, surveillance and re-evaluation of Full Member Accreditation Bodies within their defined territory and associated decision making relating to the membership of the IAF and ILAC Arrangements in that territory. Formal “Recognition” of a Regional Group with respect to the IAF and ILAC Arrangements is based on an external evaluation of the Regional Group’s competence in Arrangement management, practice and procedures by an evaluation team composed of evaluators from other IAF and ILAC Member Regional Groups and accreditation bodies.

Evaluations relating to the development and maintenance of the IAF and ILAC Arrangements operate at two levels:

- ◆ the evaluation of the competence of single accreditation bodies to perform accreditation of CABs;
- ◆ the evaluation of a Regional Group’s competence in managing the operations of regional Arrangements (see IAF/ILAC A1).

The general requirements to be used by IAF and ILAC and their recognized Regional Groups, when evaluating the competence of a single accreditation body for the purpose of qualifying to sign the applicable Arrangement(s) are set out in this document.

The requirements to be used by IAF and/or ILAC when evaluating the competence of a Regional Group in managing, maintaining, and extending a regional Arrangement for the purposes of IAF and ILAC Recognition are set out in IAF/ILAC A1.

The effective date for mandatory adoption of this document is two years from the date of publication. IAF, ILAC and the Regional Groups are encouraged to adopt this document at their earliest convenience.

Date of publication: 21 March 2017

Date of mandatory application: 21 March 2019

PURPOSE

To provide IAF and/or ILAC with general requirements and procedures for evaluating single accreditation bodies for the purpose of qualifying them to sign applicable Arrangement(s). Regional Groups shall follow these requirements and their procedures shall be consistent with those specified in this document.

AUTHORSHIP

This publication was prepared by a joint IAF/ILAC working group on Harmonization of Peer Evaluation Processes and endorsed for publication by the respective General Assemblies of IAF and ILAC in 2004. It was reviewed by the joint IAF/ILAC working group on maintenance of A-series documents in 2006, 2009, 2013, 2015 and in 2016.

This latest version was endorsed by letter ballot in IAF and ILAC in 2017.

SECTION 1: Introduction

1.1 Scope

This document identifies requirements and procedures for evaluation of a single accreditation body. It shall be used by IAF and/or ILAC for the evaluation of single ABs (also called: unaffiliated accreditation bodies). IAF/ILAC A1 requires the Arrangement Groups to adopt the requirements of Section 2 of this document and develop procedures consistent with those described in Section 3 and the relevant annexes of this document. Section 3 includes a flowchart with harmonized procedures. There are seven annexes to describe in more detail the major steps of the process.

1.2 Definitions

For the purpose of this document the following definitions apply:

- 1.2.1 *Accreditation Body (single or multi economy AB)*: An organization that operates an accreditation system for one or more types of conformity assessment bodies.
- 1.2.2 *Accreditation scheme*: rules and procedures specified in a standard or normative document included in IAF and/or ILAC Arrangements that address the process for the accreditation of conformity assessment bodies (Level 3).
- 1.2.3 *Arrangement*: The IAF Multilateral Recognition Arrangement (MLA) or ILAC Mutual Recognition Arrangement (MRA). The term can also refer to the Arrangements of recognized Regional Groups which pre-date the establishment of the IAF and ILAC Arrangements and which, as a consequence of the recognition process, will be accepted as a subset of the IAF and ILAC Arrangements.
- 1.2.4 *Arrangement Group*: All signatories to an Arrangement (In IAF: MLA Group; In ILAC: Arrangement Signatories; see also 1.2.13).
- 1.2.5 *Decision Making Group*: A body that decides on the status of membership of an Arrangement (In IAF: MLA Group; In ILAC: Arrangement Council).
- 1.2.6 *Evaluation Team Leader (TL)*: A person responsible for leading a team in the evaluation of an accreditation body.
- 1.2.7 *Evaluation Team Member (TM)*: A person serving on a team in the evaluation of an accreditation body.
- 1.2.8 *Standard*: A standard or other normative documents related to accreditation and conformity assessment bodies.
- 1.2.9 *Management Committee (MC)*: A small member group responsible for the everyday management of the Arrangement process (In IAF: IAF MLA MC; In ILAC: ILAC Arrangement Management Committee (AMC)).

1.2.10 *MC Secretariat*: Secretariat for the Management Committee (In IAF: IAF MLA MC Secretariat; in ILAC: ILAC Secretariat).

1.2.11 *Peer Evaluation*: A structured process of evaluation of a Regional Group or accreditation body by representatives of accreditation bodies.

NOTE: In ISO/IEC 17040, instead of peer evaluation the term peer assessment is used and is defined slightly differently.

1.2.12 *Proficiency Testing Activity*: All those activities of comparisons of tests, calibrations & inspections between laboratories/inspection bodies and used by accreditation bodies to assess performance, including proficiency tests (refer to ISO/IEC 17043) interlaboratory comparisons and measurement audits conducted by Regional Groups, accreditation bodies, commercial organizations, or other providers (see ILAC P9).

1.2.13 *Regional Arrangement Group*: All signatories to an Arrangement of a Regional Group.

1.2.14 *Regional Group*: A regional cooperation body member of IAF and/or ILAC. This term can also refer to a group of accreditation bodies (possibly involving other stakeholders) whose purpose is to develop and maintain an Arrangement and is a group of different accreditation bodies representing different economies.

1.2.15 *Signatory*: A Member of IAF and/or ILAC who has signed one or more of the Arrangements of a Regional Group or has signed the IAF and/or ILAC Arrangement.

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

SECTION 2: Requirements for a Single Accreditation Body

2.1 Requirements

- 2.1.1 An accreditation body shall comply with the provisions of ISO/IEC 17011 requirements and mandatory documents in IAF and ILAC where applicable.
- 2.1.2 An accreditation body shall also comply with relevant supplementary requirements (see Clause 2.2) and any applicable requirements of the Regional Group to which it belongs as a member or through a contract of cooperation.

2.2 Supplementary requirements

- 2.2.1 An accreditation body shall:
 - 2.2.1.1 Have demonstrated experience in the assessment of its accredited conformity assessment bodies (CAB) and have carried out and granted at least one accreditation that is valid at the time of the evaluation in each of the scopes of the Arrangement for which it applies;

NOTE: This experience may be obtained by having accredited at least one CAB in a particular scope (Level 3) and having carried out an on-site assessment activity and reassessment of the CAB.

For IAF additional level 4 and/or 5 extensions under the same level 3 scope will be granted on the basis of AB self-declaration that the level 4/5 scope has been introduced and relevant requirements as defined by IAF have been met. The additional level 4 and/or 5 scope will be evaluated at the next peer evaluation. In exceptional cases, inclusion of a level 4/5 scope may need evaluation as specifically defined by IAF for the particular level 4/5 scope.

Note: For definitions of Levels, please refer to IAF PR 4 or ILAC R6, as applicable.

- 2.2.1.2 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 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.
- 2.2.1.3 Specify the acceptable routes for traceability, and assess its implementation by CABs (ILAC applicant and signatory ABs: see ILAC P10);
- 2.2.1.4 Ensure that it meets the relevant requirements for proficiency testing activity (ILAC applicant and signatory ABs: see ILAC P9);

2.2.1.5 Abide by the requirements and obligations of the applicable regional and international Arrangement(s);

2.2.1.6 Have evidence of promoting the Arrangement with major stakeholders;

2.2.1.7 Contribute its fair share of personnel resources for carrying out peer evaluations at the regional and/or global level; and

2.2.1.8 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).

2.2.2 Notification of change

Each accreditation body signatory to an Arrangement 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 the relevant Arrangement Group(s). For possible consequences associated with changes see Annex 7.

- Legal status;
- Senior accreditation program personnel;
- Contact person or liaison officer for the Arrangement;
- Accreditation criteria and procedures for its accreditation programs, related to the Arrangement;
- Office address (and postal address, if different), including head office and any offices;
- Relationship with Government;
- Other changes that significantly affect the competence or credibility of the accreditation process.

2.2.3 Confidentiality

2.2.3.1 All oral and written information received about the AB through the operation of the arrangement group relating to evaluations, re-evaluations, appeals and complaints (except that information which is already publicly accessible) shall be treated confidentially by all parties and persons concerned. This includes information relating to applicants and/or signatories of the Arrangement. All individuals having access to confidential information shall provide a signed declaration of confidentiality to the relevant secretariat(s) before being given access.

2.2.3.2 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.

2.3 Conditions for application

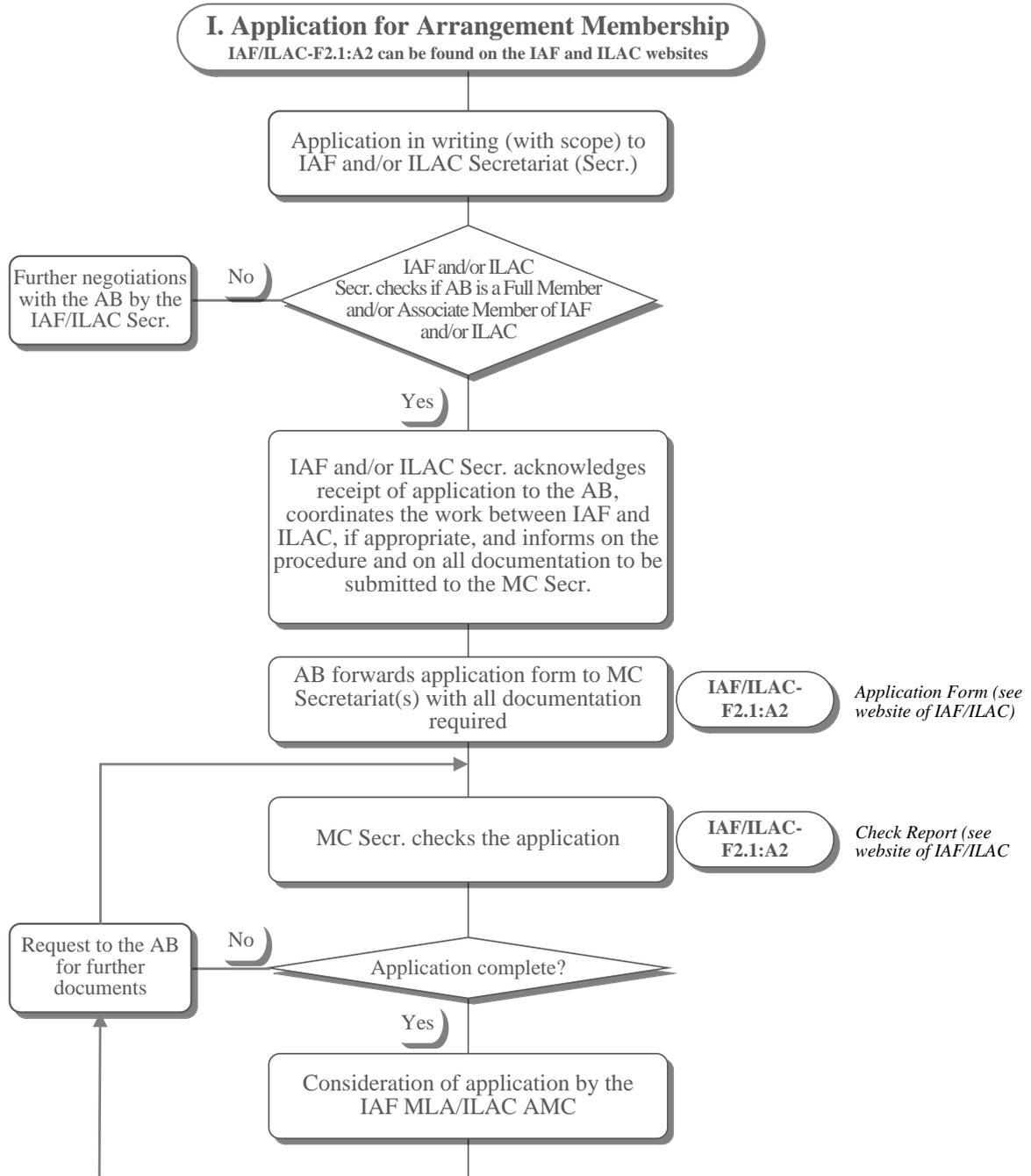
2.3.1 The AB agrees to pay for the hotel costs, meals and all travel costs of the evaluation team.

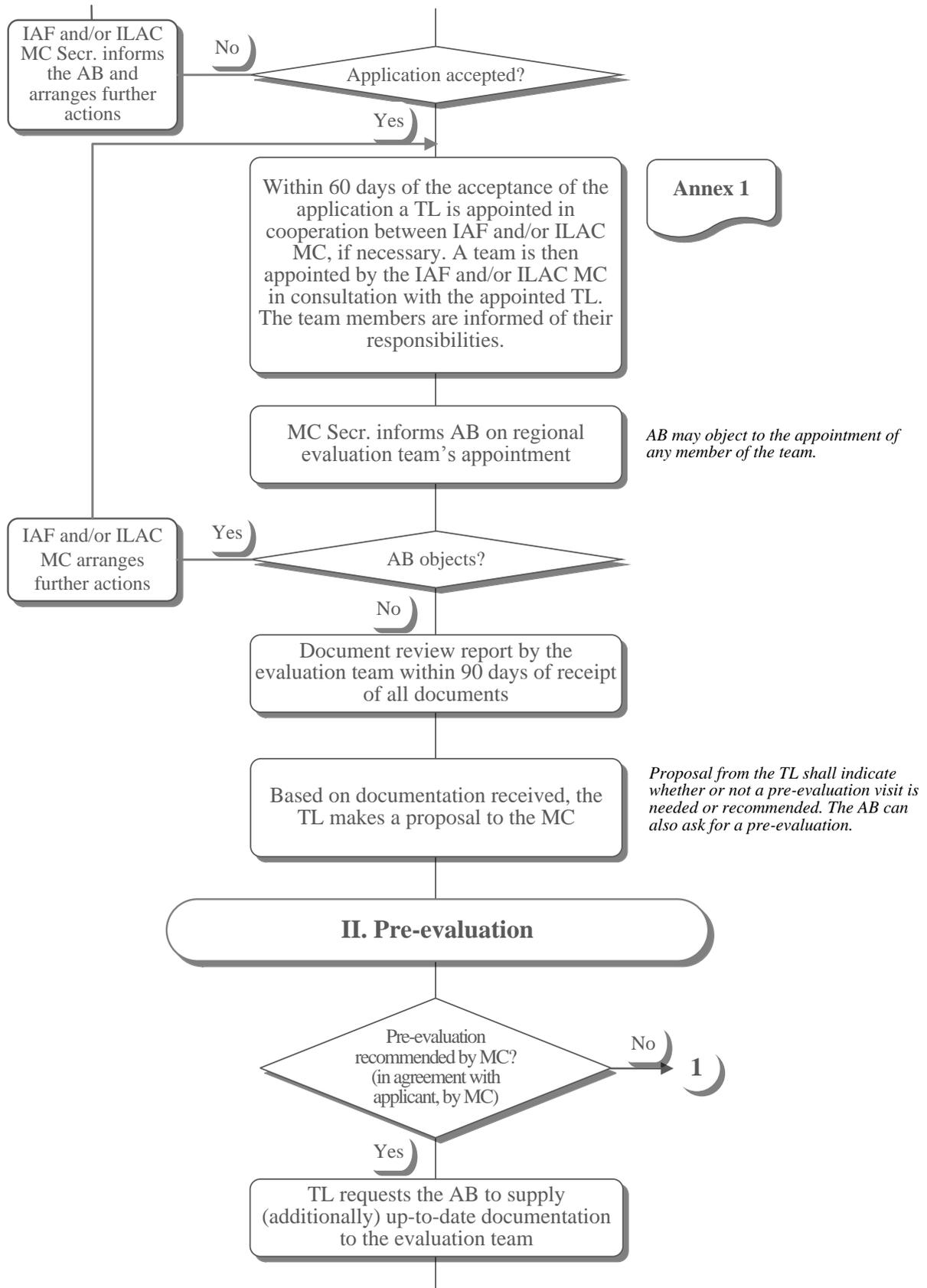
2.3.2 Travel shall be done in economy class unless the applicant agrees to pay business class. If the AB does not agree, then economy travel is mandated unless the evaluators wish to pay for their own airlines upgrades.

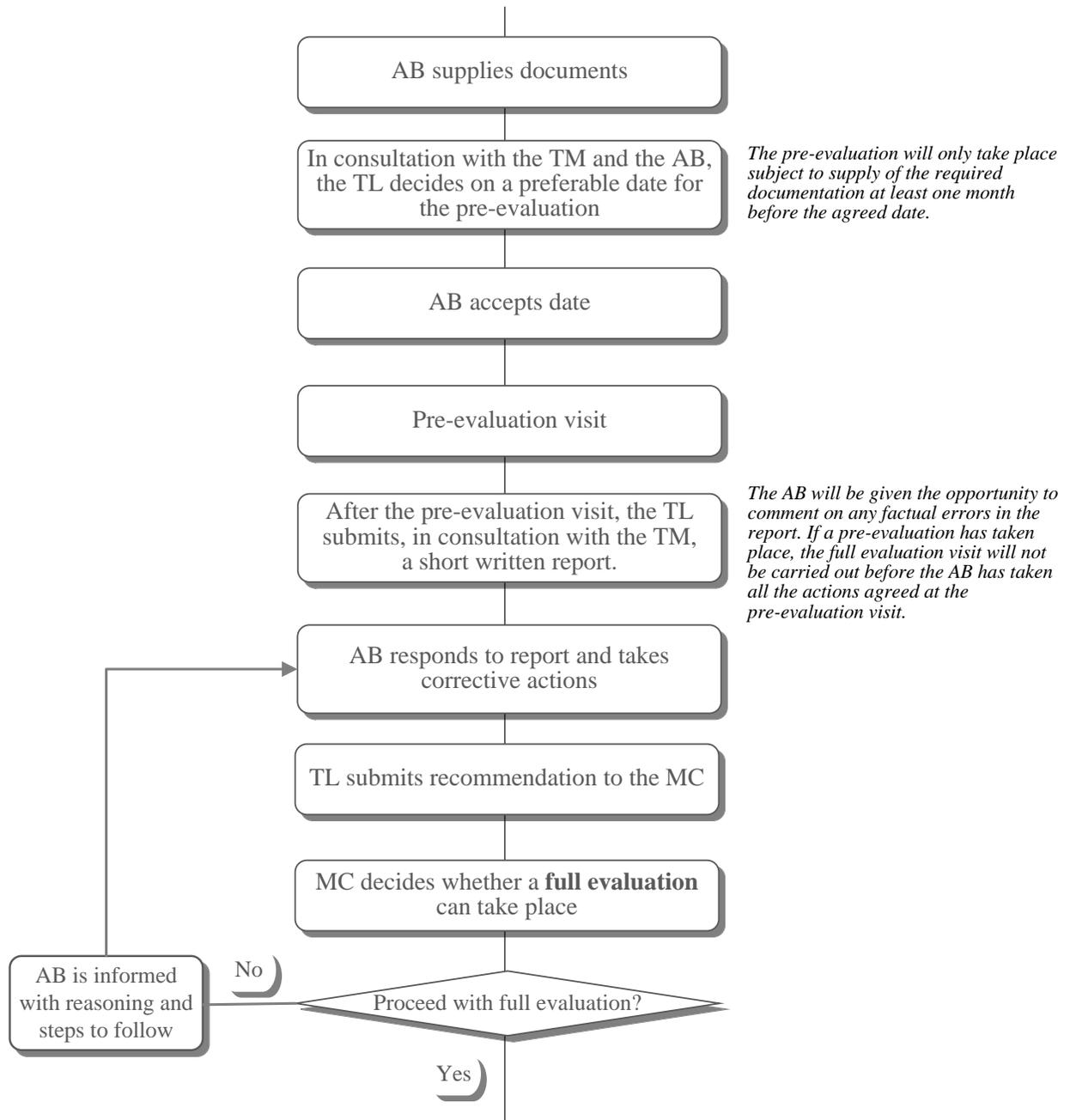
2.3.3 Observers/trainees pay all of their own costs.

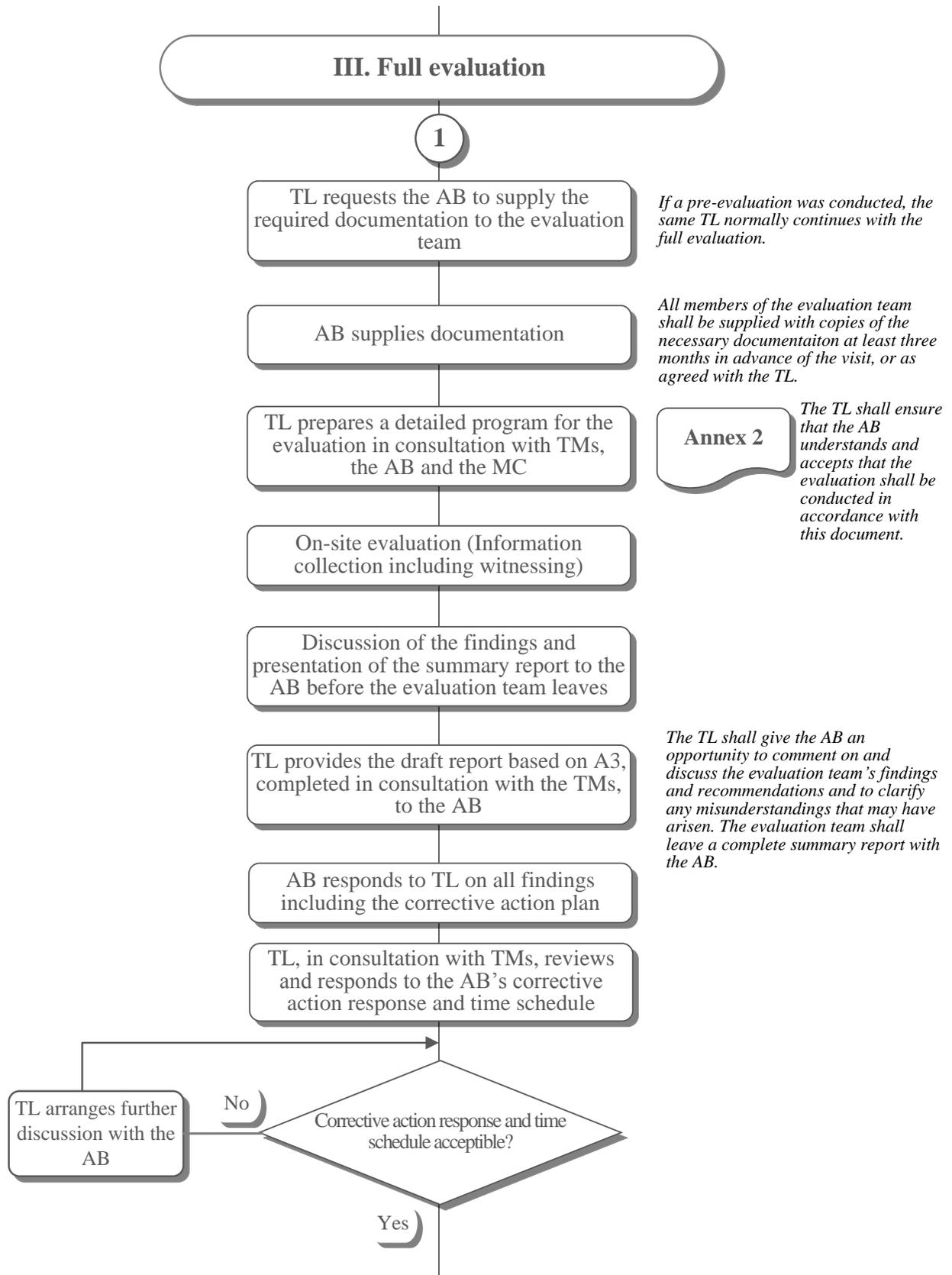
SECTION 3: Flow Chart for the Evaluation Process

The following procedures shall be used by IAF and/or ILAC for the evaluation of single ABs (also called unaffiliated accreditation bodies). Regional Groups are required in IAF/ILAC-A1 to develop procedures consistent with these harmonized procedures and those described in the Annexes.

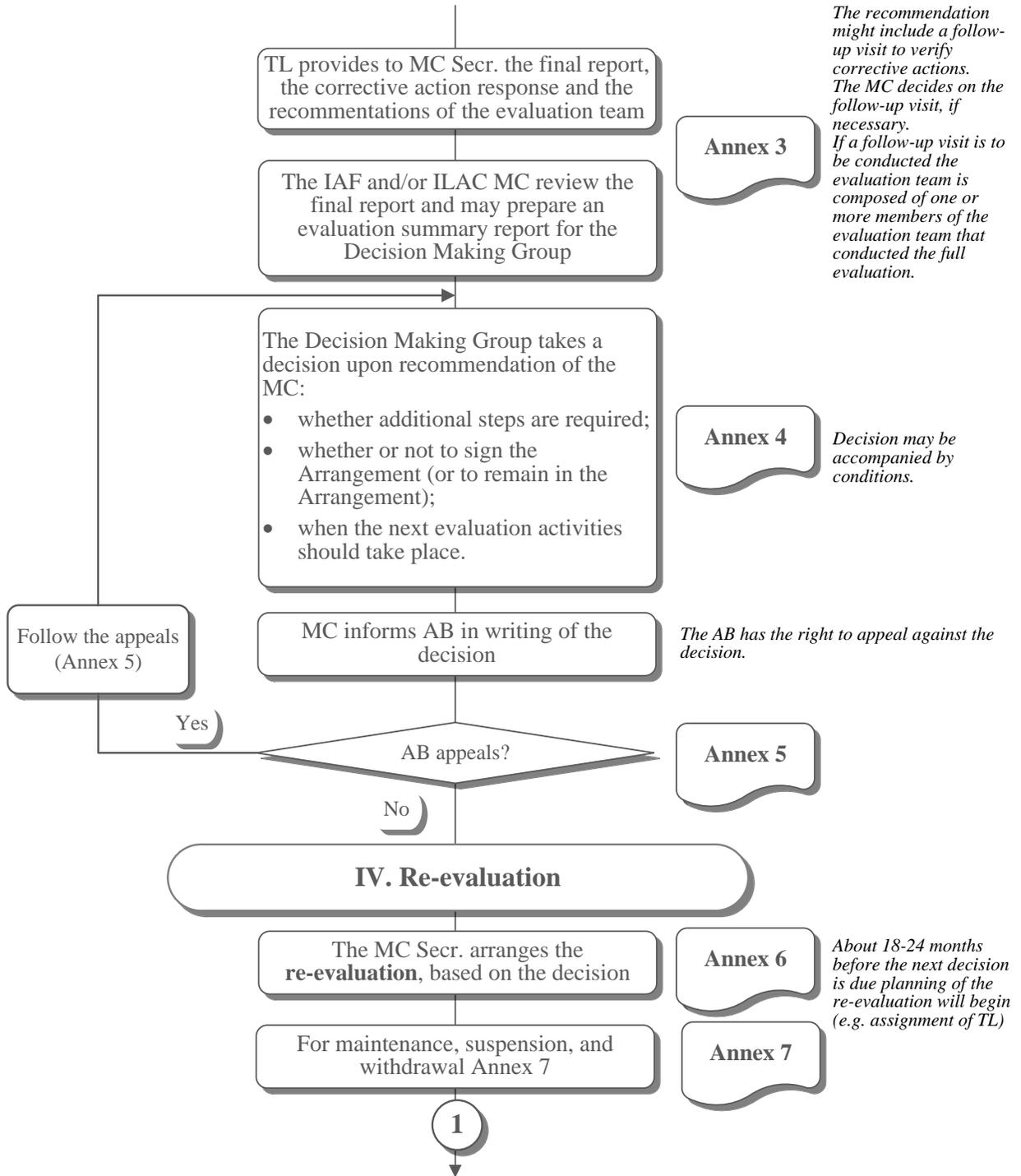








IAF-ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Single Accreditation Body



ANNEX 1: Process and Procedures for Selection, Qualification and Monitoring of Evaluators

1.1 Process for selection and qualification of evaluators

- 1.1.1 Initial selection and training of Evaluators:
- 1.1.2 When proposing a candidate peer evaluator the AB shall provide the relevant committee (e.g. MC) with information about the person's competence to confirm that the criteria stated in 1.5 are met.
- 1.1.3 The relevant committee shall review the information either denying the application or inviting the person for the training for new team members.
- 1.1.4 Training for new TMs shall be designed to ensure and confirm that the evaluators meet the competence criteria stated in 1.5.
- 1.1.5 An evaluator, trained in accordance with Clause 1.1.4, shall be observed and evaluated on the job by appointing the evaluator as a trainee team member in his/her first evaluator assignment (see Clause 1.6.1.6 for the tasks of a trainee).
- 1.1.6 After positive feedback from the team leader and the AB the trainee team member will be qualified as a team member peer evaluator.
- 1.1.7 For each team member the regional group or unaffiliated body shall state the main scopes, and sub-scopes if relevant for which the person is considered competent.

1.2 Selection of team leaders

- 1.2.1 After a defined minimum number of evaluations as TM and positive feedback from the participating team leaders and ABs, the relevant committee in IAF/ILAC may invite a TM to become a team leader.
- 1.2.2 To demonstrate fulfilment of the competence criteria as stated in Clause 1.5.3, a TM may first act as a deputy TL (assisting the TL in planning, preparing, managing the evaluation) or as a TL supervised by a qualified TL.

1.3 Monitoring and evaluation of performance

- 1.3.1 The relevant committee shall monitor the performance of evaluators in accordance with the criteria in the following sections on an on-going basis.
- 1.3.2 Monitoring of team leaders and team members shall consist of collecting and evaluating feedback from the evaluated AB, using ILAC/IAF form IAF/ILAC F1.9-A1/A2 *for Evaluation Team Performance Review by the Evaluated AB*.
- 1.3.3 Monitoring of evaluation team members shall also include evaluation by each team leader of the teams in which a team member is participating, completing IAF/ILAC form IAF/ILAC F1.8-A1/A2 *Performance Log for an IAF/ILAC Evaluator (TM) or IAF/ILAC Technical Expert (TE)*.

1.3.4 Monitoring of evaluation team leaders shall include feedback from the team members in IAF/ILAC form IAF/ILAC F1.7-A1/A2 *Performance Log for an ILAC/IAF Team Leader*.

1.3.5 At least once every three years the performance shall be re-evaluated and the qualification (see Clause 1.5) of an evaluator shall be re-confirmed.

1.4 Improving and harmonisation

1.4.1 There shall be implemented procedures for improving the performance of evaluators (team leaders and team members) and to harmonise the evaluations by:

- a) Exchange of experience by regular meetings of evaluators, or by other means.
- b) Informing the evaluators about new requirements and changes in peer evaluation procedures.
- c) Feedback to evaluators on their performance as received from the AB and/or team leader/member(s) and/or decision makers.
- d) Informing the evaluators of areas for improvement

1.5 Competence criteria

1.5.1 Candidate peer evaluator team member

1.5.1.1 A candidate team member shall possess the qualities to enable him/her to evaluate or assess organisations. In particular a candidate team member shall have the following personal attributes and skills:

- ◆ Be open-minded and mature;
- ◆ Have sound judgment and analytical skills;
- ◆ Be able to perceive situations in a realistic way, to understand complex operations from a broad perspective, and to understand the role of individual units within an organization;
- ◆ Be decisive and diplomatic;
- ◆ Be versatile and culture sensitive;
- ◆ Be persistent and able to focus;
- ◆ Be a team player;
- ◆ Have interviewing, presentation, note-taking and report writing skills;
- ◆ Have appropriate language skills to enable effective communication (orally and in writing).

- 1.5.1.2 A candidate team member shall be able to determine whether the bodies accredited by the AB under evaluation comply with the requirements of the appropriate ISO/IEC standard(s) and corresponding IAF/ILAC documents, by having:
- ◆ knowledge of the relevant standards for accreditation of conformity assessment bodies and other documents; and
 - ◆ understanding of the applicable sector/scheme.
- 1.5.1.2.1 A candidate team member shall be able to understand the management practices and processes of accreditation bodies based on his/her knowledge and experience in accreditation.
- 1.5.1.3 A candidate team member shall have knowledge of ISO/IEC 17011 and the regional MLA/MRA requirements.
- 1.5.2 Peer evaluator team member
- 1.5.2.1 In addition to the attributes and competencies described above for candidate evaluators the team member in particular shall be able to evaluate whether an AB complies with the requirements of ISO/IEC 17011, IAF/ILAC A5 and other relevant requirements, based on:
- ◆ Understanding of the application of ISO/IEC 17011 in a peer evaluation context;
 - ◆ knowledge of IAF/ILAC A5 and other relevant requirements;
 - ◆ knowledge of evaluation principles, procedures, practices and techniques; and
 - ◆ skills to effectively plan and organize the assigned evaluator tasks.
- 1.5.2.2 A team member shall be able to:
- ◆ decide from the submitted documentation any features requiring special study during the evaluation;
 - ◆ decide on sampling of activities and files to be selected and persons to be interviewed based on the analysis of risks and related to the scope of work and the scope of the MLA/MRA;
 - ◆ evaluate constantly the effects of evaluation observations and personal interactions during an evaluation;
 - ◆ treat concerned personnel in a way that will best achieve the evaluation objective;
 - ◆ react with sensitivity to the local conventions of the area in which the evaluation is performed;
 - ◆ perform the evaluation process without deviating due to distractions;
 - ◆ react effectively in stressful situations;
 - ◆ commit full attention and support to the evaluation process.
- 1.5.2.3 A team member shall be able to obtain and evaluate objective evidence fairly and to report on his/her findings according to the applicable reporting procedures.

- 1.5.2.4 A team member shall be able to understand quickly and easily cultural differences, as far as essential in the evaluation process.
- 1.5.2.5 A team member shall be able to:
- ◆ determine the criticality of the findings and to evaluate whether the corrective actions decided by the AB are likely to be effective and to evaluate the corrective actions carried out;
 - ◆ arrive at generally acceptable conclusions based on evaluation observations;
 - ◆ remain true to a conclusion that is based on objective evidence, despite pressure to change.
- 1.5.2.6 Be able to act impartially and remain true to the purpose of the evaluation without fear or favour also based on the absence of any conflicting interests.
- 1.5.3 Peer evaluator team leader
- 1.5.3.1 In addition to the attributes and competencies described above for evaluator team members the team leader shall be able to manage an evaluation, lead an evaluation team in an efficient and effective way, plan and control the contribution of the individual team members and report clearly and succinctly the results of the evaluation.
- 1.5.3.2 A team leader shall be able to discuss the objectives and impact of accreditation services with the management and staff of an AB, based on his/her knowledge of the accreditation body's services, the (business and regulatory) context thereof and the associated risks.
- 1.5.3.3 The team leader shall be able to understand issues raised by the other members in the team on the accreditation fields which are outside his/her area of expertise.
- 1.5.3.4 Based on his/her interpersonal skills a team leader shall be able to optimize the performance of an evaluation team taking into account the strengths and weaknesses of the individual team members.
- 1.5.3.5 The team leader shall be able to take decisions on the classification of findings and on the closing of findings based on the recommendation of the team members.
- 1.5.3.6 The team leader shall be able to chair meetings and to reach consensus on delicate points.
- 1.5.3.7 The team leader shall be able to report to the decision making committee, and to present a recommendation, taking into account the findings of all team members, in conformity with the Arrangement requirements.

1.6 Procedure for the Appointment and Composition of the Evaluation Team

1.6.1 Composition of the evaluation team

- 1.6.1.1 For the full evaluation visit, members of the evaluation team shall be chosen as needed to cover the types of accreditation, the technical scopes, and the size and complexity of the accreditation system under evaluation.
- 1.6.1.2 Team members shall be chosen, in consultation with the TL, from a list of team members qualified according to the process described in 1.1 and kept up-to-date by the MC. This list should record the scopes and sub-scopes for which the evaluator is considered competent and experienced in evaluations.
- 1.6.1.3 The evaluation team chosen shall consist of representatives from a cross-section of Member Accreditation Bodies. 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.
- 1.6.1.4 No team member shall be associated with any accreditation body that has provided consultancy service to the accreditation body being evaluated within three years prior to the evaluation.
- 1.6.1.5 A team should not have more than two evaluators participating in their first evaluation (trainees). For the trainee evaluators on the team, a qualified mentor (an evaluator with experience in more than two evaluations) will be appointed.
- 1.6.1.6 A team member may, in addition to his/her evaluation tasks, mentor any "trainee peer evaluator" (those performing their first evaluation) assigned to the evaluation team. Mentoring trainees includes allocating him/her such task as he/she is capable of performing, supervising and providing a report to the Arrangement MC about the performance of the trainee.

NOTE 1: It is normal practice that evaluators from as many members as possible are appointed in a team.

NOTE 2: 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's readiness for a full evaluation visit.

NOTE 3: There should be no more than one team member from each economy.

NOTE 4: Some of the evaluation 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.

1.6.2 Appointment and duties of the evaluation team leader:

- 1.6.2.1 In appointing an evaluation team leader for a specific evaluation, the MC should not appoint the same team leader for two successive evaluations of the same applicant.
- 1.6.2.2 Team leaders shall be chosen from a list of team leaders prepared based on the process described in 1.2 and kept up-to-date by the MC. This list should record the scopes and sub-scopes for which the team leader is considered competent and experienced in evaluations.
- 1.6.2.3 The team leader shall have ultimate responsibilities for all phases of evaluation and is delegated authority by the MC to make final decisions regarding the conduct of evaluation.

1.6.3 Appointment and duties of the evaluation deputy team leader:

- 1.6.3.1 A Deputy Team Leader (Deputy TL) may be assigned. 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.

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

- a) After a minimum of 2 peer evaluations (pre evaluations can be considered) as a TM with positive feedback from the participating TLs and ABs, a TM may be invited to become a Deputy TL if he/she has also demonstrated that he/she fulfils the conditions referred to in section 1.5.3 above.

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

- b) Alternately, a deputy team leader 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: Typical Evaluation Program of a Single Accreditation Body

A. Pre-evaluation program

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

- ◆ 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 (e.g. 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, and inspection bodies where relevant);
- ◆ Measurement traceability routes (for testing and calibration accreditation, and inspection bodies where relevant). In some cases it may be necessary to visit the NMI;
- ◆ Witnessing one or more assessments, if possible.

B. Full evaluation program

1. Introduction

The task of an evaluation of an AB is to collect sufficient information about the assessments and decision making process of the AB to have confidence in the conformity assessment results from CABs accredited by the AB such that the signatories to the Arrangement can promote acceptance of these results.

It is the task of the TL to create a timetable in a timely manner prior to the evaluation of the AB that allows sufficient time to collect information for obtaining such confidence.

Because there exists a large variety of circumstances under which an evaluation will take place, it is the prerogative of the TL to deviate from the examples shown in 3.2 of this annex. The TL

should agree with the team members on the duration. Consultation with the accreditation body under evaluation is essential. When the proposed timetable largely differs from the examples of 3.2.2 of this annex or when additional evaluation team capacity is required, the Chair of the MC should also be consulted at an early stage.

2. Considerations

2.1 Maximum Duration

The TL should 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 and if no alternatives are possible, the TL should schedule witnessing to be 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

There are different kinds of evaluation: e.g. initial evaluation, pre-evaluations, follow-up evaluations, evaluation for scope extensions, 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-evaluations, 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 every level 3 there shall be:

- One witness of an initial assessment or reassessment of a CAB.
 - While full assessments are preferred, other on-site assessment activities may be considered. When the witnessing of other on-site assessment activities takes the place of the witnessing of a full assessment or re-assessment, then those activities must include all of the accreditation requirements and assessment of a portion of the scope of accreditation. The key is that the evaluation team witness the performance of technical activities of the CAB as much as possible;
- or two other on-site assessment activities, including a portion of the scope of accreditation which may each only include parts of the accreditation requirements.

The evaluation team shall also witness other reassessments and assessments activities as determined by the team leader or the MC.

For certification and validation/ verification, the evaluation team should witness the AB assessment team performing the assessment of the body only at the office location.

Note: For definitions of Level 2 and Level 3, please refer to IAF PR 4 or ILAC R6, as applicable.

2.4 Size of the Accreditation Body

The influence of the AB's scope on the duration of the evaluation (on-site part) relates primarily to the number of witnessing activities. The AB's management system may not differ (see ISO/IEC 17011) 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).

Since Memoranda of Understanding (e.g. with regulators or specifiers of the AB's economy) are being concluded with certain industry sectors, specific attention may be needed to assure the AB's competence to assess in these fields.

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.

2.5 Other Factors

Factors that may influence the duration of the evaluation include:

- Need for translators;
- Extensive travel and travel circumstance; and
- Cultural differences.

This annex cannot provide guidance on all these items. It is left to the team members and their experience to judge these effects and to cater to 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

3.1.1 The time for the evaluators to spend on preparation largely depends on the quality of the documents that the AB forwards. The documents that are required are specified in the *Application from a Single Accreditation Body to join the Arrangement* (IAF/ILAC-F2.1:A2). Accurate translation of the documents into English by the AB is essential.

3.1.2 The self-assessment document (IAF/ILAC A3) shall be detailed and accurate. This document will greatly assist the evaluation team in preparation. If the self assessment document (IAF/ILAC A3) does not provide adequate information to the team, the team leader can ask the AB to revise the document with the necessary information.

3.1.3 The AB shall send all documents to the evaluation team, at least 3 months in advance of a visit to allow for preparation and for requesting additional information.

3.1.4 The team members should 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 the documentation may take an average of 3 to 5 days for the TL and 2 to 4 days for the team members.

3.1.5 For planning of the witnessing, the AB shall provide the assessment planning. This gives the evaluation team the opportunity to carefully select and plan the witnessing activities taking into consideration the following:

- 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 procedures.

If the applicant or signatory is active in the framework of-an industry or regulator specific scheme, then the fulfilling of the requirements set by that industry group or by regulators for accreditation bodies shall also be considered on a sampling basis.

3.2 On-site Evaluation

3.2.1 The evaluation team should be prepared to undertake 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 of the results of the self-assessment document (IAF/ILAC A3)
- Evaluation of the assessment reports, including preparation of the assessment and decision making records (and possible witnessing of the accreditation decision making process.)
- Splitting of the team in accordance with their experiences for the purpose of witness including the on-site preparation of the draft evaluation report with a list of findings
- Witness of a CAB for every scope (see Clause B 2.3 of this annex)
- Discussion of the results of the witnessing with the evaluation team and AB
- Closing meeting, presentation and discussion of findings.

Some timetable examples are shown on the following page.

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

3.2.2 ABs with single scope

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 evaluation 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

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 + preparation for witnessing assessments	TL + 2 TM
Day 3	Office + witnessing staff + witnessing assessments (split evaluation 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

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 evaluation team)	TL + 3 TM
Wednesday	Office + witnessing staff + vertical audits + witnessing assessments (split evaluation team)	TL + 3 TM
Thursday	Office + witnessing staff + vertical audits (specially directed for confirmation of previous findings) + witnessing assessments (split evaluation team)	TL + 3 TM
Friday	Preparation final Report + closing meeting + Discussing further actions for TMs + departure	TL + 3 TM

3.2.5 ABs with full scope

Day	Actions	Evaluators
Sunday	>= 4 hours for preparation with the evaluation team (key issues to be addressed + evaluation plan)	TL + 4 TM
Monday	Office, opening meeting, records etc + preparation for	TL + 4 TM

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

Day	Actions	Evaluators
	witnessing assessments	
Tuesday	Office + witnessing staff + witnessing assessments (split evaluation team)	TL + 4 TM
Wednesday	Office + witnessing staff + vertical audits + witnessing assessments (split evaluation team)	TL + 4 TM
Thursday	Office + witnessing staff + vertical audits (specially directed for confirmation of previous findings) + witnessing assessments (split evaluation team)	TL + 4 TM
Friday	Same + preparation final report + closing meeting	TL + 4 TM
Saturday	Discussing further actions for TMs + departure	TL + 4 TM

NOTE: This is guidance only. In some regions it is common for a four person (laboratory accreditation evaluation) team to witness up to 10 different laboratories, during a five day evaluation. Where the NMI is not a signatory to the CIPM MRA or where the NMI's CMCs are not listed in the BIPM database, the evaluation team should consider the need to visit the NMI and any designated institute so as to evaluate the traceability routes available to accredited laboratories. The emphasis should be on witnessing enough to have confidence in the accreditation process, and a high level of confidence in the competence of the accredited bodies.

- 3.2.6 The team members should meet to discuss their findings and possibly adjust the focus of their attention. 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 TL may also require the AB to provide a general description of the AB to be used in the report.

3.3 Activities after the On-site Evaluation

- 3.3.1 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.
- 3.3.2 The evaluation team needs to spend time on reviewing the AB's corrective actions and on the preparation of the evaluation team's comment to these corrective actions. The TL should take the lead in preparing this reaction.
- 3.3.3 Finally the TL shall prepare a recommendation to the Decision Making Group.
- 3.3.4 Typically these activities may take 2-3 days for the TL. For TMs, the time involved may be limited to 0.5 days.
- 3.3.5 Writing the Evaluation Report: IAF/ILAC A3 contains information concerning the structure and timeline for writing and presenting a report.

ANNEX 3: Content of the Evaluation Summary Report on a Single Accreditation Body

(This report is prepared by the IAF and/or ILAC MC for presentation to the Decision Making Groups)

Applicant:

Evaluation team:

Identification of the full evaluation report:

Evaluation sites and dates:

Applicant's office(s):

Witnessed assessments:

Scope of evaluation:

Applicant organisation

Number of staff:

Accreditation programs:

Number of bodies accredited:

Organizational structure:

Decision making process:

Relationships (e.g., government, other bodies, international organizations):

Findings of the evaluation team (non-conformities, concerns and comments):

Conclusions:

Statements of closeout of nonconformities and concerns:

Unresolved issues:

Conclusion and recommendation:

NOTE: In cases where a task force group (TFG) reviews the report and completes an evaluation summary report on behalf of the MC, this report may address TFG remarks and conclusions, composition of the TFG, and comments on the process. Issues for consideration may include:

- ◆ Were IAF/ILAC procedures followed?
- ◆ Was the appropriate normative documents applied?
- ◆ Does the report contain sufficient information to support a decision?
- ◆ Are the conclusions and recommendations supported by the report?
- ◆ Are the findings appropriately classified, clear and concise?
- ◆ Is the proposed/implemented corrective action appropriate to the finding?
- ◆ Were the findings appropriately closed?
- ◆ Were there any issues raised by the TFG that required a response from the team?

ANNEX 4: Procedure for Decision Making Regarding Evaluations of a Single Accreditation Body

1. Decision making regarding IAF or ILAC evaluations

1.1 The evaluation report, the corrective actions and the recommendations of the team leader shall be submitted as the final report to listed members of the respective MC(s).

1.1.1 Reports on all evaluation visits may be copied to the representatives of signatories who have a role to play in decision making.

1.1.2 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.

1.2 The IAF and/or ILAC MCs may prepare a summary report for the respective Decision Making Groups of IAF and/or ILAC which shall decide:

- in the case of an initial evaluation, whether or not the applicant may enter the Arrangement;
- in the case of a re-evaluation, whether or not the accreditation body will remain a signatory to the Arrangement. Positive decisions can be accompanied by conditions (see Clause 2 of this Annex).

NOTE 1: The Decision Making 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 Bylaws of IAF and/or ILAC.

1.3 Any Team Leader or Team Member involved in an evaluation cannot cast the vote when that evaluation decision is made.

2. Decision making regarding joint IAF/ILAC evaluations

2.1 When IAF and ILAC carry out a joint evaluation of a single accreditation body, both IAF and ILAC will need to review and make a decision on that particular evaluation. This section provides a process for the IAF MLA MC and ILAC AMC to jointly review reports from those joint evaluations, while ensuring that each organization will make its own separate decision.

2.2 The IAF MLA MC and ILAC AMC will appoint a Task Force Group (TFG), with four to six members to review the evaluation report. The IAF MLA MC and ILAC AMC will appoint one of the members of the TFG to be the convener (see point 3 below). The role of convener for these TFGs will alternate between IAF and ILAC. The TFG members shall be members of the IAF MLA MC or members of the ILAC AMC. It is also possible for the IAF MLA MC to assign other experienced IAF members from outside the

IAF MLA MC. Members of the TFG will have signed a confidentiality statement. The evaluation team and the evaluated body should be informed about the establishment of the TFG and the members.

2.3 All members and observers of the IAF MLA MC and the ILAC AMC will have access to the evaluation report and may send their comments to the TFG for their consideration.

2.4 The task of the TFG is to evaluate the report for comprehensiveness, clarity and the classification of findings. The TFG is to complete a proposal for an Evaluation Summary Report. The TFG shall provide the proposed Evaluation Summary Report to the IAF MLA MC and ILAC AMC within 30 days of the TFG receiving the evaluation report. The Evaluation Summary Report template can be found in IAF/ILAC A2, Annex 3.

2.4.1 The TFG is expected to communicate with the evaluation team and, if necessary, with the AB under evaluation; in cases where there are open, missing or unclear issues in the report, in order to solve or clarify them. The Chair of the IAF MLA MC and the Chair of the ILAC AMC shall be copied on all communications.

2.5 TFG Competencies

2.5.1. To appreciate comprehensiveness the TFG will need to have an understanding of what should be in a report from a generic and specific perspective. The TFG shall have collective expertise at levels 1, 2 and 3 of the IAF MLA and the ILAC Arrangement.

2.5.2 The TFG needs to understand; the planning and conduct of the evaluation, its breadth and depth, the findings and their classification, and the adequacy of the conclusions, and recommendations. The competencies required would be consistent with that of an individual with experience as a CB auditor or an AB assessor, and exposure to the A series documents, IAF MLA P&P, ILAC P-Series as well as practical experience in the peer evaluation process.

2.5.3. To be able to effectively correspond with the team, the TFG convener requires good communication skills and an understanding of the criteria and process. The competencies would be similar to those listed in point 2.5.2 above.

2.5.4. At least one member each from IAF and ILAC appointed to the TFG, shall be a qualified peer evaluator.

2.5.5. There should be a balance of members with competencies on the IAF MLA and on the ILAC Arrangement.

2.5.6 The IAF MLA MC and the ILAC AMC will review the draft Evaluation Summary Report prepared by the TFG, in 30 days after the reception, and make any changes as necessary before submitting it to the IAF MLA Committee and to the ILAC Arrangement Council for the separate decision making process. Issues of common interest for both organizations will be discussed jointly by both management committees, while issues that apply only to IAF or ILAC may either be discussed in a joint meeting or in separate meetings of the respective management committee.

3. Hierarchy of decisions

- 3.1** Decisions made as a result of peer evaluations can take many forms. Implicit in these decisions is the possibility of a variety of "conditions". This guidance outlines a hierarchy of the major types of decisions from the most positive decision to the least positive decision; conditions of increasing severity are imposed.
- 3.2** Decisions on applications from affiliated bodies, including extensions, of IAF and/or ILAC-recognized Regional Groups are made by the Decision Making Group of their respective Regional Group. Decisions on the on-going re-evaluations of signatory affiliated bodies also reside with the recognized Regional Group. This becomes a prerequisite to signing and maintaining signatory status with the IAF/ILAC Arrangement, in accordance with a documented IAF procedure ML-4 and/or ILAC P4.¹
- 3.3** The IAF MLA Committee and ILAC Arrangement Council make all decisions on unaffiliated bodies, the decision shall be made in a period of 30 days after the review made by IAF MLA MC and/or the ILAC AMC. The persons participating in the decision making shall have an understanding of: objective and purpose of the arrangement; criteria used for the evaluation; the evaluation process and the arrangement structure. There are primarily two situations to address: *new applicant unaffiliated single accreditation bodies* and *signatory unaffiliated single accreditation bodies*. A third situation that is not addressed below is the possibility of adverse decisions or sanctions imposed on an Arrangement signatory which fails to abide by its obligations under the Arrangement itself.
- 3.4** Decisions on new applicant unaffiliated single accreditation bodies:
- ◆ Approval without conditions (re-evaluation to occur 4 years hence);
 - ◆ Approval with conditions (e.g., shortened interval for re-evaluation);
 - ◆ Defer approval pending submittal of required evidence of corrective actions and/or re-visit by one or more members of the evaluation team to confirm implementation of corrective actions;
 - ◆ Disapproval with a new evaluation required;
Note: Disapproval should rarely happen for new applicant unaffiliated single accreditation bodies since an evaluation report is normally only submitted for a decision once a consensus of the evaluation team and the IAF MLA MC or ILAC Arrangement Management Committee has concluded that all requirements have been met.

¹ Provided that IAF/ILAC dues are paid and other obligations are fulfilled

ANNEX 5: IAF and ILAC Procedure for Handling Appeals.**1. Scope**

This annex describes the procedures for appeals, to ensure that matters related to the Arrangement are settled objectively and impartially. This procedure applies to accreditation bodies affiliated with Regional Groups recognized by IAF and/or ILAC, as well as unaffiliated accreditation bodies.

2. Handling of appeals

2.1 When an applicant or a signatory does not agree with the decision it may appeal in writing to the IAF and/or ILAC Secretariat within 30 days from notification of the decision.

2.2 After authentication of the appeal, the IAF and/or ILAC Secretariat shall inform the IAF and/or ILAC Chairmen, who will, in conjunction with the Chairmen of the Management Committee (MC), appoint an Appeals Panel comprising two impartial representatives of full members of IAF and/or ILAC and one IAF and/or ILAC evaluator to investigate the appeal.

2.2 No member of the Appeals Panel shall have been involved in the evaluation team that evaluated the appellant nor have been involved as part of the TFG or decision making process, or have a direct interest in the subject of the appeal, in any form. The IAF and/or ILAC Chairmen shall ensure that the composition of the Appeals Panel satisfies the requirements of objectivity and impartiality and no conflict of interests exists. The Appeals Panel should be normally set up within 30 days after its authentication and the names of the Appeals Panel communicated to the appellant.

2.4 The appellant has the right to object to the appointment of any member of the Appeals Panel for valid reason(s). The IAF and/or ILAC Chairmen, in conjunction with the MC, shall make a decision on any objection by the appellant to an appointment. That decision shall be final.

2.5 During the course of the accreditation body's appeal against suspension or withdrawal of its signatory status, the signatory status shall remain in effect.

3. Recommendation and decision

3.1 The Appeals Panel shall decide its recommendation on the appeal within 6 months after setting up the Panel and inform the IAF and/or ILAC Chairmen and the MC, in writing, of the recommendation not later than five (5) business days after the date of decision.

3.2 The MC shall forward the recommendation to the Arrangement Group for a decision.

3.3 That decision shall be final and communicated to the appellant.

ANNEX 6: Procedure for Re-evaluation of an IAF and/or ILAC Signatory and On-going Confidence Building Activities

1. Periodic monitoring and re-evaluation of the Arrangement(s) signatories is necessary (see also Annex 1).
2. All Arrangement signatories shall be formally re-evaluated at maximum intervals of four years from the last day of the previous evaluation.
3. The Signatory under re-evaluation shall provide the evaluation team with all the documents which are required for an initial evaluation (see *Application from a Single Accreditation Body to join the Arrangement* (IAF/ILAC-F2.1:A2, item 22). In addition the evaluation team shall get the full evaluation report from the last evaluation/re-evaluation or any special evaluation.
4. Partial to total re-evaluation may be conducted at an earlier date as directed by the Decision Making Group, should there be due cause such as notification of significant changes in administration, finances, operational practices or an extension of the scope of accreditation available.
5. The impact of changes notified by an arrangement signatory shall be evaluated (see Section 2, Clause 2.2.2).
6. Re-evaluation visits should be led by an evaluation team, in which the majority of members will not have been in the evaluation team that undertook the previous evaluation.

ANNEX 7: Procedures for Maintenance, Suspension and Withdrawal of IAF and/or ILAC Signatories

1. Maintenance, suspension and withdrawal

- 1.1** It may be that the MC cannot accept the significant changes notified by the accreditation body, the corrective action taken by this accreditation body, major non-conformities which have been found or substantiated complaints from interested parties. The MC shall report the situation to the Regional Group with a recommendation and ask the Regional Group to take appropriate action. This action can be suspension for a maximum period of 6 months or withdrawal from the Regional Group.
- 1.2** Maintenance, suspension or withdrawal of a signatory unaffiliated body shall be decided by IAF and/or ILAC Decision Making Group after receipt of the recommendation by the IAF and/or ILAC MC. Any suspension or withdrawal decided by the Decision Making Group shall be accompanied by an appropriate explanation stating the reason for suspension or withdrawal.
- 1.3** A signatory shall be suspended or withdrawn from the IAF and/or ILAC Arrangement, if its signatory's status was based on membership in a Regional Arrangement Group and the accreditation body is suspended or withdrawn from the Regional Arrangement, or the Regional Group is suspended or withdrawn from the IAF and/or ILAC Arrangement. Any suspension or withdrawal decided by the Regional Group shall be accompanied by an appropriate explanation stating the reason for suspension or withdrawal to the signatory.
- 1.4** An accreditation body shall not remain a signatory of the Arrangement if it is, for any reason, suspended or withdrawn as a member of ILAC/IAF. The IAF/ILAC Secretary shall immediately notify the MC and the Decision Making Group when any signatory is suspended or withdrawn from the organization for any reason, and the MC shall immediately suspend or withdraw the accreditation body from the Arrangement.
- 1.5** In the event of a decision to suspend, the IAF/ILAC shall:
- a) officially notify the unaffiliated body of the decision to suspend, the reasons for the decision to suspend, the period of the suspension, and the conditions for lifting of the suspension;
 - b) Prior to taking further action on the decision to suspend, notify the accreditation body of their right to Appeal the decision (see Annex 4);
 - c) If the appeal is not upheld, amend the list of Arrangement signatories to identify that the body is suspended;
 - d) notify all Arrangement signatories of the suspension; and
 - e) remind the accreditation body of the consequences of suspension.

- 1.6** The consequences of suspension shall be decided by the Decision Making Group on a case-by-case basis, depending on the reason for suspension. The consequences of suspension may include, for the applicable main scope and/or sub-scope that the AB shall:
- a) not actively promote the fact that they are a signatory to the Arrangement;
 - b) not issue any accreditation documents that bear the IAF MLA Mark and/or the ILAC MRA Mark, as applicable;
 - c) not participate in any ballots associated with the Arrangement;
 - d) notify all accredited CABs of the suspension and the consequences of the suspension as it relates to them; and
 - e) notify stakeholders in their economies of the suspension.
- 1.7** The obligations of the accreditation body while suspended are:
- a) continue to comply with the obligations of full membership;
 - b) cooperate fully with the MC and the Decision Making Group to enable a speedy resolution of the suspension;
 - c) maintain oversight of their accredited CABs; and
 - d) continue to vote on IAF/ILAC ballots, other than those associated with the Arrangement.
- 1.8** In the event of withdrawal, the IAF/ILAC shall:
- a) officially notify the unaffiliated body of the withdrawal and the reasons for the withdrawal;
 - b) prior to taking action on the decision to withdraw, notify the accreditation body of their right to Appeal the decision;
 - c) if the appeal is not upheld, amend the list of Arrangement signatories to withdraw the signatory;
 - d) notify all Arrangement signatories of the withdrawal;
 - e) terminate the agreement for use of the IAF Mark and/or the ILAC MRA Mark, as applicable; and
 - f) remind the accreditation body of the consequences of withdrawal.
- 1.9** The consequences of withdrawal are, for the applicable main scope or sub-scope of the Arrangement are that the AB shall

- a) immediately stop promoting the fact that they are a signatory to the Arrangement;
- b) immediately stop issuing any accreditation documents that bear the IAF MLA Mark and/or the ILAC MRA Mark, as applicable; and
- c) notify all accredited CABs of the withdrawal and terminate all relevant Agreements for the Use of the IAF MLA Mark and/or the ILAC MRA Mark, as applicable.

1.10 When a withdrawn accreditation body applies to become an Arrangement member again, the procedure for new applicants shall be followed.

NOTE: This procedure for maintenance, suspension and withdrawal for single accreditation bodies which are not signatories of a Regional Group shall be carried out by IAF and/or ILAC.