



**ILAC Mutual Recognition  
Arrangement (Arrangement):  
Procedures for the Evaluation of  
Unaffiliated Bodies for the Purpose of Recognition**

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**PREAMBLE**

The international community of accreditation cooperations, recognised laboratory Accreditation Bodies and their stakeholders cooperate through the International Laboratory Accreditation Cooperation (ILAC). A principal objective of ILAC is to put in place a world-wide Mutual Recognition Arrangement (Arrangement). ILAC aims to demonstrate the equivalence of the operation of its Member Accreditation Bodies through this Arrangement. As a consequence, the competence (within the accredited scopes) of laboratories accredited by these bodies is demonstrated and recognised by all signatory accreditation bodies. The market can then be more confident in accepting certificates and reports issued by the accredited laboratories.

At present, this Arrangement covers only the accreditation of testing and calibration laboratories. It is envisaged that a mutual recognition Arrangement will evolve to cover the accreditation of inspection bodies. ILAC is cooperating with IAF (International Accreditation Forum), the inspection industry and its stakeholders in the development of such an Arrangement and its associated procedures.

ILAC is linking the existing mutual recognition Arrangements of the regional accreditation cooperations (Regional Groups) and is encouraging the development of new Regional Groups to complete world-wide coverage. For the purposes of its Arrangement, ILAC shall delegate authority to ILAC-Recognised Regional Groups for the Evaluation, surveillance and re-evaluation of ILAC full Member Accreditation Bodies within their defined territory and associated decision-making relating to the membership of the ILAC Arrangement in that territory. Formal "Recognition" of a Regional Group with respect to the ILAC Arrangement is based on an external Evaluation of the Regional Groups' competence in mutual recognition Arrangement management, practice and procedures by an ILAC team composed of evaluators from other ILAC Member Regional Groups and Accreditation Bodies.

Evaluation relating to the development and maintenance of the ILAC Arrangement operates at two levels:

- the Evaluation of the competence of individual ILAC Member Accreditation Bodies to accredit; and
- the Evaluation of a Regional Group's competence in managing the operations of regional mutual recognition Arrangements.

The essential requirements to be used for the first of these are set out in document ILAC-P1 (aligned with IAF/ILAC A2).

The procedures used by ILAC when evaluating the competence of a Regional Group in managing, maintaining, and extending a regional mutual recognition Arrangement for the purposes of ILAC "Recognition" are set out in IAF/ILAC A1 (replaces ILAC P2).

The procedures used by ILAC when evaluating the competence of bodies not affiliated to an ILAC-Recognised Regional Group are set out in this document.

Note: This document meets ISO/IEC 17040 (2005): General requirements for peer assessment of conformity assessment bodies and accreditation bodies.

## **PURPOSE**

This document provides the ILAC Arrangement Council with a procedure for evaluating bodies either not currently affiliated to or having a bilateral mutual recognition with an ILAC-Recognised Regional Group which it requests to be used for the purpose of Recognition. The effective date for application of this procedure is the date when membership is notified of its availability on the ILAC Website.

## **AUTHORSHIP**

This publication was initially prepared by the ILAC Accreditation Policy Committee and endorsed for publication by the ILAC General Assembly in 2001. It was revised in 2002 to allow an unaffiliated body to utilise a bilateral MRA with a recognised regional arrangement as an alternative to direct evaluation and decision by ILAC. The ILAC Arrangement Committee updated this edition to be aligned with IAF/ILAC A2.

## PART A: INTRODUCTION

### 1. Scope

This document sets out the procedures to be used by ILAC in the Evaluation of a body that is neither a signatory to a multi-lateral mutual recognition arrangement nor wants any bilateral mutual recognition arrangement as a contract cooperator of a recognised Regional Cooperation (Unaffiliated Body) to be used for the purpose of becoming a Signatory to the ILAC mutual recognition arrangement (Arrangement).

PART B contains the requirements for peer evaluation of a single Accreditation Body

PART C provides a flow chart for the peer evaluation procedures. There are eight Annexes to describe in more detail the major steps of the process.

The criteria and procedures specified below are applicable for the initial Evaluation of an Unaffiliated Body and for subsequent re-evaluations.

### 2. Definitions

- 2.1 **Accreditation Body (AB):** An organisation that operates an accreditation system for one or more types of conformity assessment bodies.
- 2.2 **Accredited Laboratory:** A calibration laboratory or testing laboratory accredited by an Accreditation Body.
- 2.3 **ILAC Secretariat:** Secretariat for the Arrangement Management Committee.
- 2.4 **Applicant Body:** An ILAC Associate that is an Unaffiliated Body, which has applied for Recognition.
- 2.5 **Arrangement: the ILAC Mutual Recognition Arrangement:** This term, also can refer to the Arrangements (MRAs or MLAs) of ILAC-Recognised Regional Groups which pre-date the establishment of the ILAC Arrangement and which, as a consequence of the recognition process, will be accepted as a subset of the ILAC Arrangement.
- 2.6 **Arrangement Council:** The ILAC decision-making body on recognition of Regional Groups and on the Signatory status of individual Accreditation Bodies.
- 2.7 **Arrangement Management Committee:** The ILAC committee with responsibility to manage the day-to-day operation of the Arrangement including selection of evaluation teams and making recommendations for decisions on recognition of Regional Groups and on the Signatory status of individual Accreditation Bodies.
- 2.8 **Evaluation Manager:** The lead evaluator (or **Team Leader, TL**) appointed by the ILAC Arrangement Management Committee to evaluate an Unaffiliated Body.
- 2.9 **Evaluation Team Member (TM):** A person serving on an Arrangement peer evaluation team.

- 2.10 **ILAC-Recognised Regional Group:** A regional cooperation body member of ILAC which has been acknowledged as competent by the ILAC Arrangement Council to manage a regional mutual recognition Arrangement which can then be integrated into the ILAC Arrangement.
- 2.11 **ISO/IEC Standard:** An ISO/IEC standard, guide or technical report related to accreditation and conformity assessment.
- 2.12 **Peer Evaluation (or Evaluation):** The structured process of assessment of a Regional Group or Accreditation Body.
- 2.13 **Proficiency Testing Activity:** For the purpose of this document, all activity used by Accreditation Bodies to assess performance including proficiency tests (refer to ISO/IEC Guide 43, “Proficiency testing by means of interlaboratory comparisons”) and measurement audits conducted by Regional Groups, Accreditation Bodies, commercial organisations, or other providers.
- 2.14 **Member:** An Accreditation Body that is a signatory to the ILAC Arrangement.
- 2.15 **Recognition:** The action taken by ILAC, following an evaluation conducted according to the ILAC P2 procedures, whereby ILAC acknowledges a Regional Group’s competence to manage a regional mutual recognition Arrangement which can then be integrated into the ILAC Arrangement, or the action taken after an evaluation, conducted according to the procedures of this document, whereby ILAC acknowledges an Unaffiliated Body’s competence to qualify for signatory status under the ILAC Arrangement.
- 2.16 **Regional Group:** A regional cooperation body member of ILAC. This term can also refer to a group of Accreditation Bodies (possibly involving other stakeholders) whose purpose is to develop and maintain a multi-lateral, mutual recognition Arrangement and is a group of different Accreditation Bodies representing different economies.
- 2.17 **Signatory:** A Full Member of ILAC which has signed the ILAC Arrangement or an Accreditation Body which has signed one or more of the multi-lateral, mutual recognition Arrangements of a Regional Group.
- 2.18 **Unaffiliated Body:** An Accreditation Body that is not a member or contract cooperator of an ILAC-Recognised Regional Group.
- 2.19 **Witnessing:** Observing of an AB assessing the CAB’s 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.)

### 3. Objective

- 3.1 The objective of the ILAC Arrangement is to establish cross-border stakeholder confidence in the competence of Accredited Laboratories and the technical equivalence of reports and certificates issued by these laboratories. In this context, the objective of the Evaluation of an Unaffiliated Body is to establish that it meets the requirements as defined in Part B.

- 3.2 Evaluations are conducted according to the procedures in Part C against the criteria stated in Part B.
- 3.3 The evaluators must evaluate an Applicant Body's ability to accredit laboratories, including an appraisal of whether the Applicant Body obtains sufficient evidence that laboratories are technically competent to perform the work for which they have been accredited.
- 3.4 The Evaluation process will require the exercise of some judgement and perhaps interpretation as it is likely that some requirements or activities may not be addressed in exactly the same way in all Accreditation Bodies. The Evaluation team must therefore collect sufficient information on each topic to enable it to appraise the suitability of the practices used by the Applicant Body. Any unusual approach must be highlighted, since it must be made known to all Signatories to the Arrangement.

#### **4. Costs**

See IAF/ILAC A2, section 3 (flowchart), Conditions for Application.

#### **5. Confidentiality**

- 5.1 See IAF/ILAC A2, section 2.4

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**PART B: Requirements for a Single Accreditation Body****1. Standards**

- 1.1 An Accreditation Body shall comply with the provisions of ISO/IEC 17011:2004, ILAC P-series documents and other normative documents relevant to the function(s) performed.

**2. Supplementary Requirements**

An Accreditation body shall:

- 2.1 Have enough experience in the assessment of its accredited organisations and have carried out at least one accreditation in each of the accreditation programs for which it applies (for laboratory accreditation at least four accreditations for testing and four for calibration);
- 2.2 Ensure that it meets the suitable requirements for Proficiency Testing Activity (see clause 3);
- 2.3 Abide by the requirements and obligations of the ILAC Arrangement;
- 2.4 Have a programme to promote the Arrangement with major stakeholders; and
- 2.5 Contribute its fair share of personnel resources for carrying out peer evaluations at the global level.
- 2.6 Every applicant or Signatory to the Arrangement shall have a cross-frontier accreditation policy taking into account ILAC G21.

**3. Proficiency Testing Activity**

- 3.1 Proficiency Testing Activity can be used to determine the performance of laboratories and certain types of inspection bodies.
- 3.2 An Accreditation Body shall require its accredited laboratories to demonstrate their technical competence by their satisfactory participation in Proficiency Testing Activity. The minimum amount of Proficiency Testing Activity appropriate proficiency testing required per laboratory shall be specified.

*NOTE One activity prior to gaining accreditation and one activity relating to each major sub-area of major disciplines of a laboratory's scope of accreditation at least every four years is recommended. It is recognised that there are particular areas where proficiency testing is just not practical.*

- 3.3 An Accreditation Body shall demonstrate that the Proficiency Testing Activity that its accredited or applicant laboratories undertake is effective, linked to the assessment process and that appropriate corrective action is carried out when necessary.

- 3.4 Every applicant Accreditation Body or Signatory to an Arrangement for calibration, testing and inspection shall participate in and use, as far as available and practicable, Proficiency Testing Activity offered by 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.

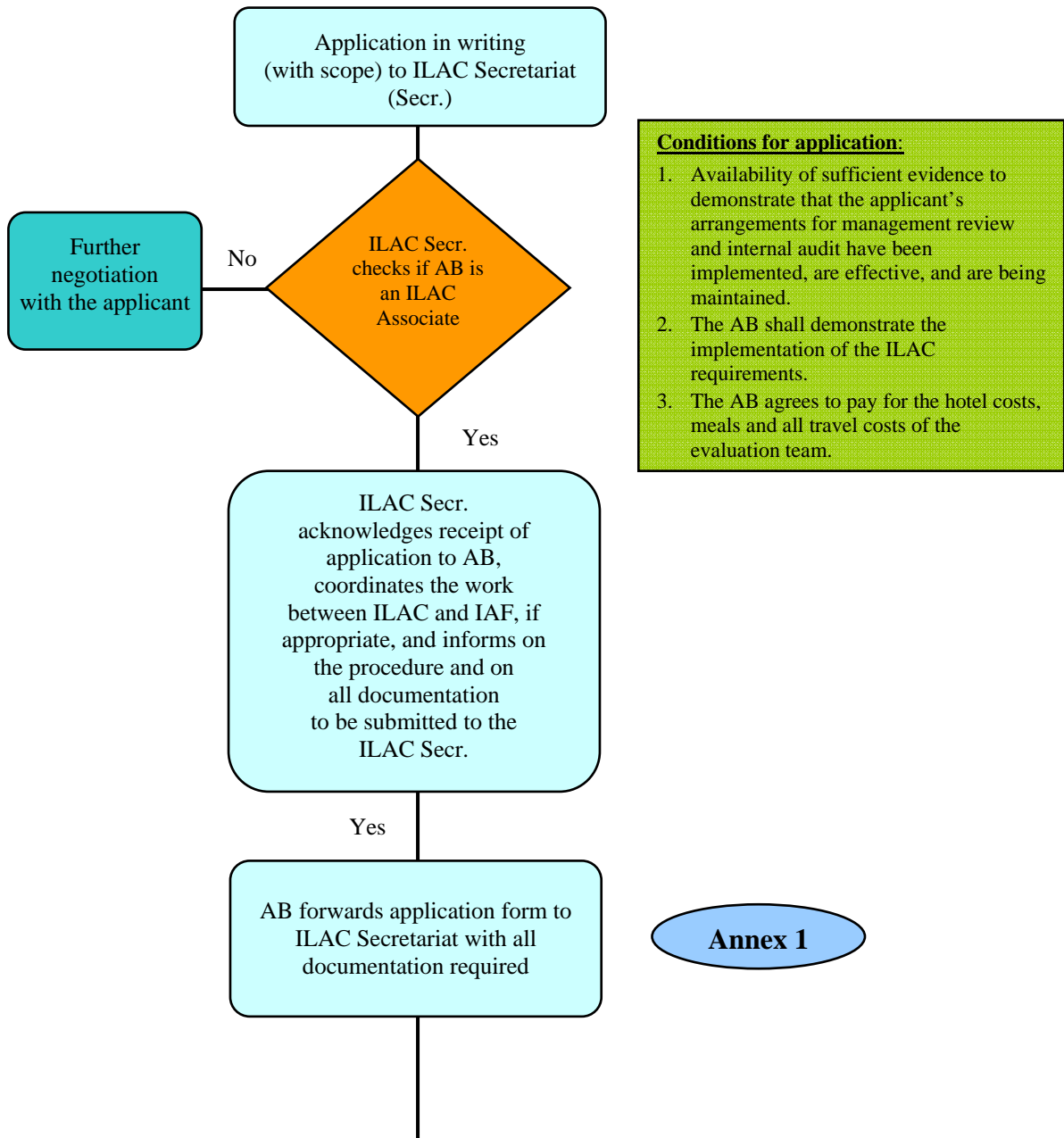
#### **4. Traceability and Measurement Uncertainty**

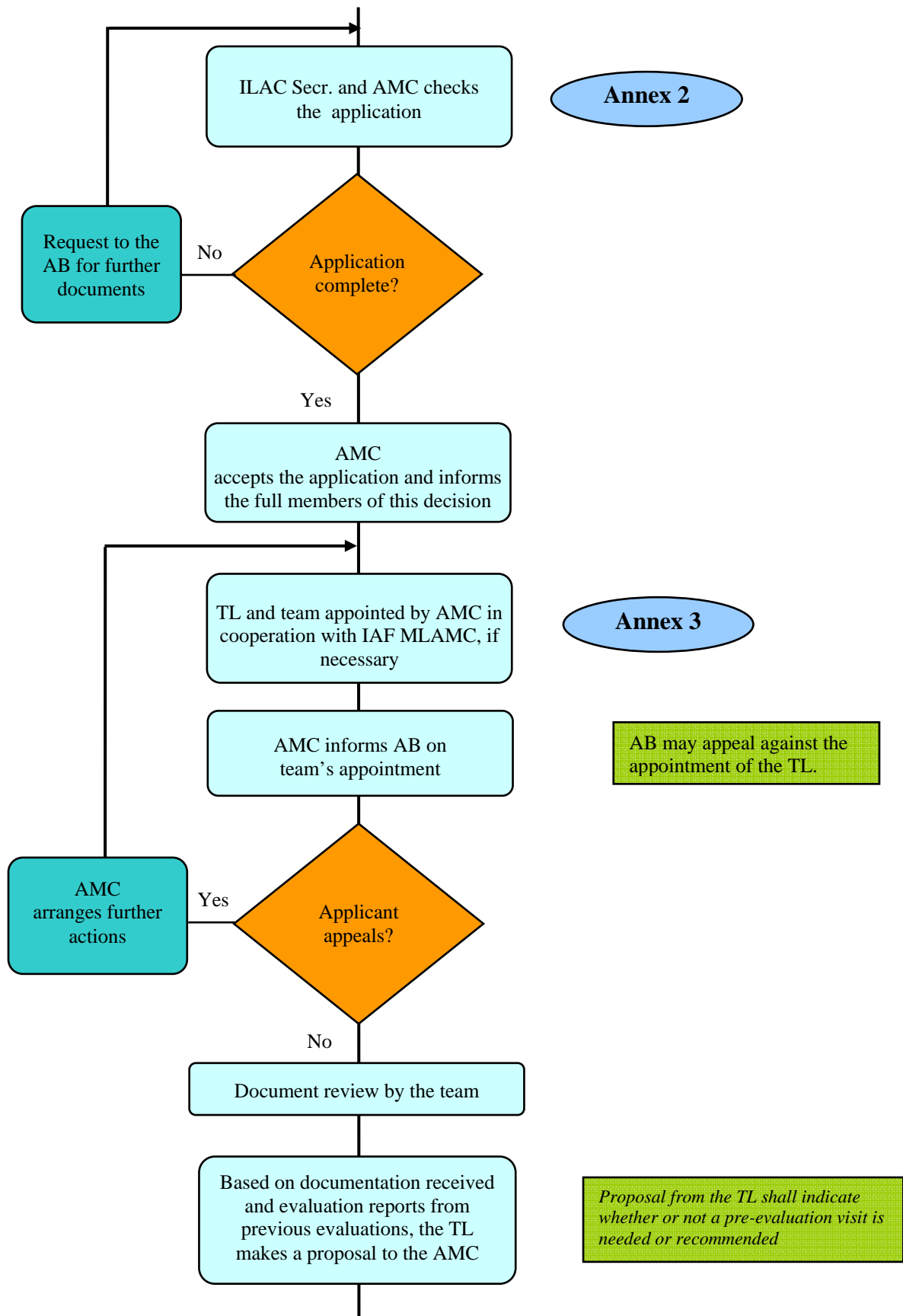
The team shall evaluate how traceability of measurement results and associated estimates of measurement uncertainty are established wherever applicable in accordance with the provisions of ILAC P10 and the ISO Guide for the Expression of Uncertainty in Measurement or equivalent.

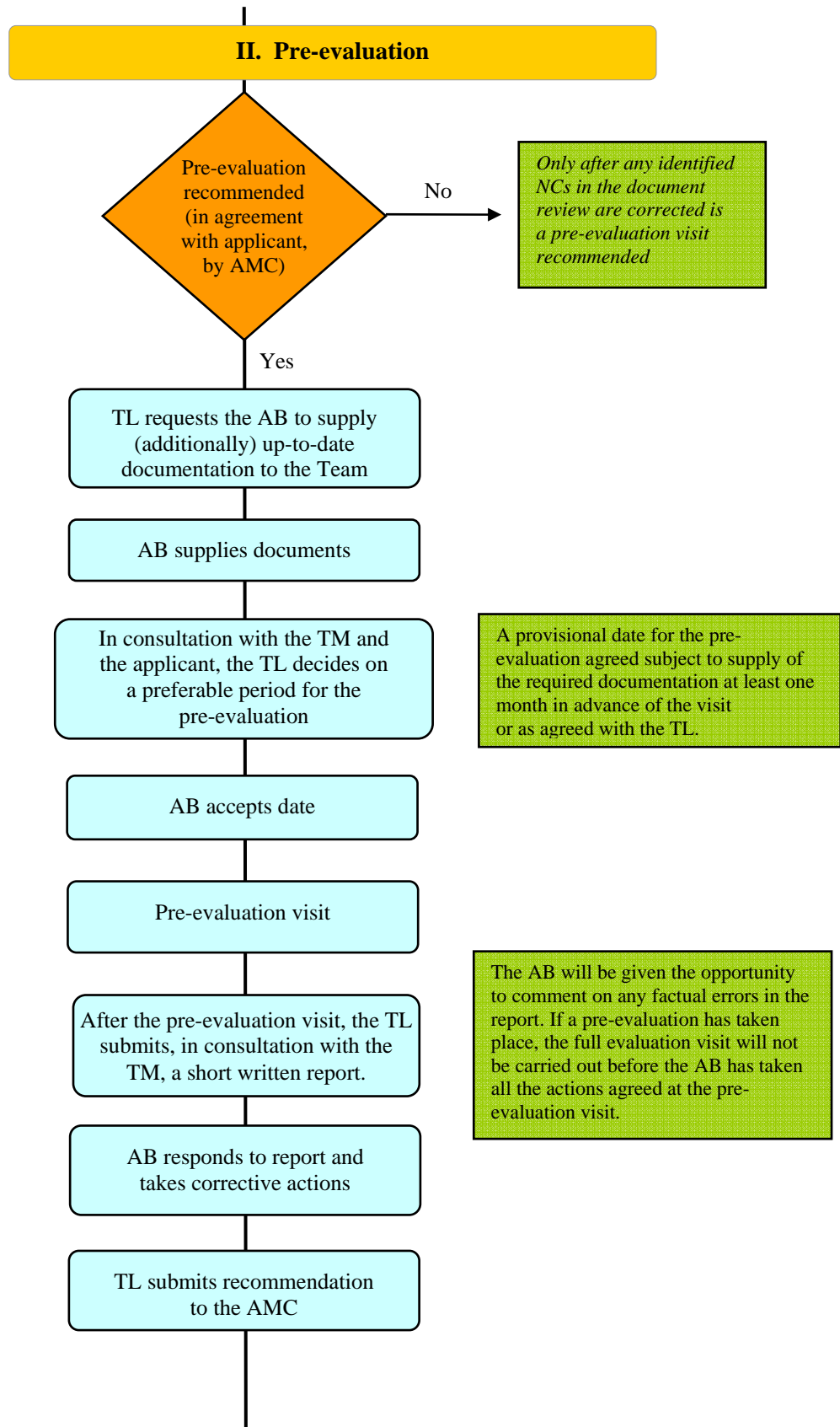
*NOTE: If the calibration laboratories providing measurement support to the testing laboratories are accredited by a separate Accreditation Body, it may be necessary to hold discussions with the secretariat of that body as part of the overall agenda for the evaluation, particularly if the Accreditation Body is not a Member of the Cooperation.*

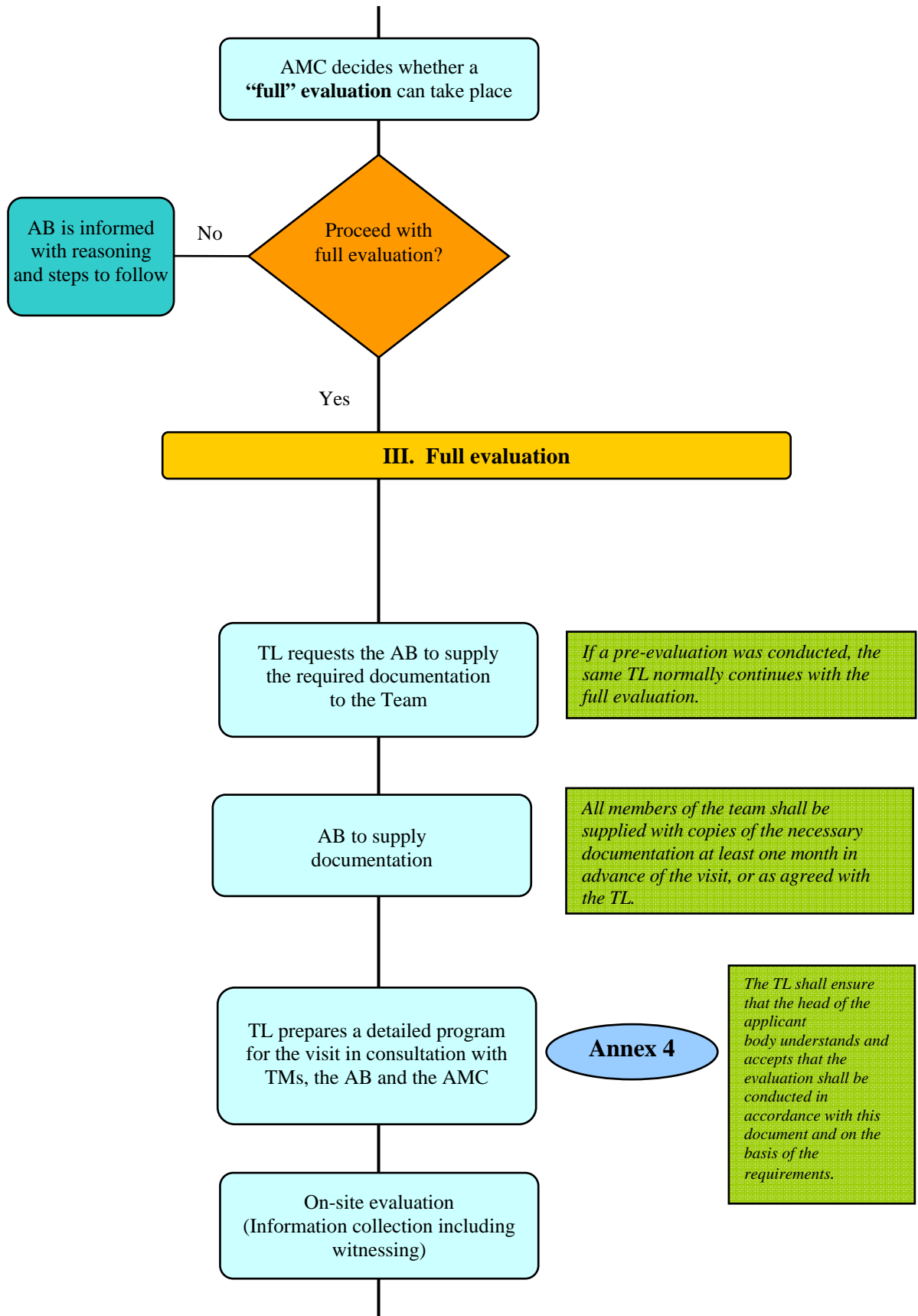
**PART C: Flowchart for Peer Evaluation Procedures of a Single Accreditation Body**

**I. Application for Arrangement Membership**

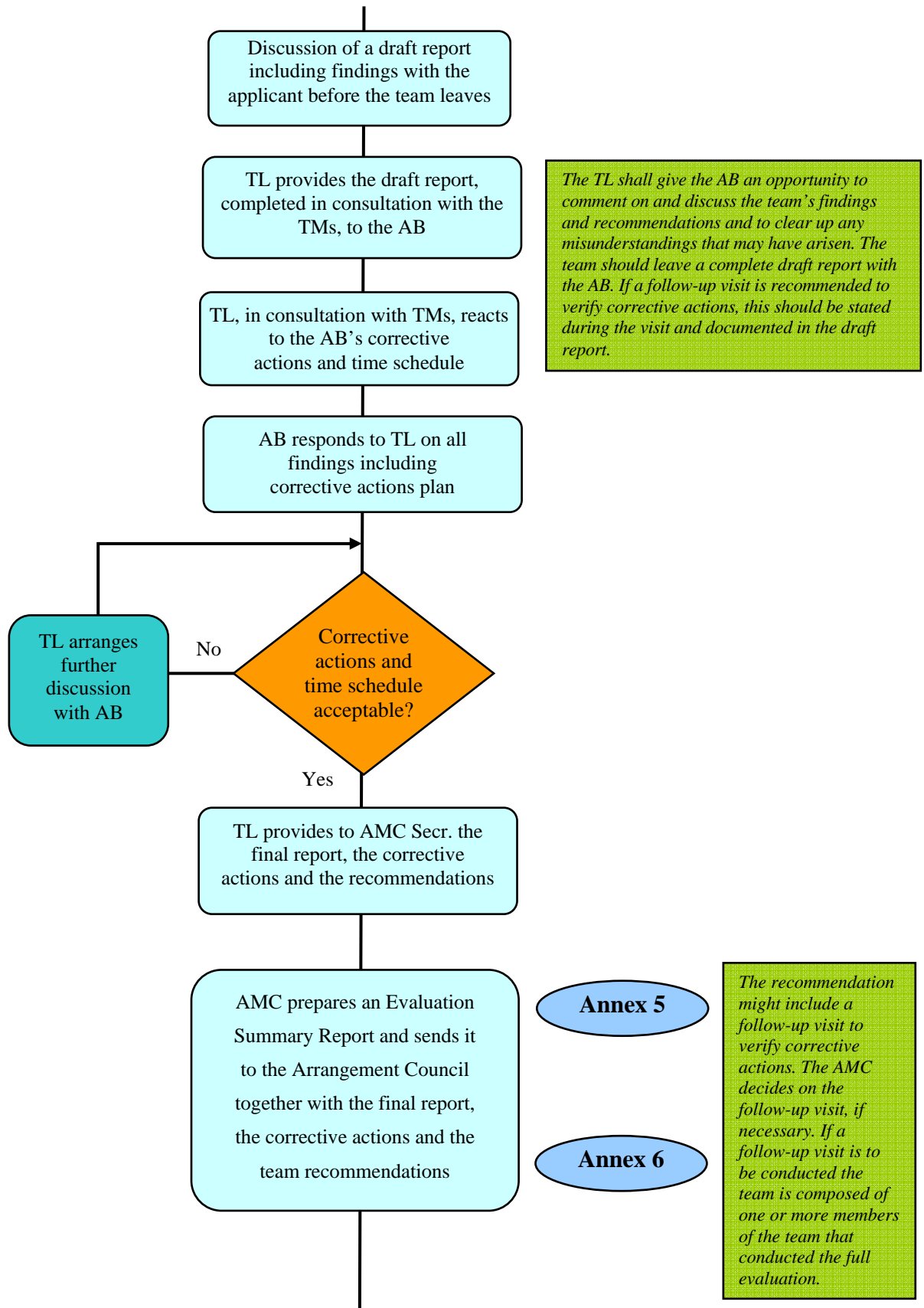


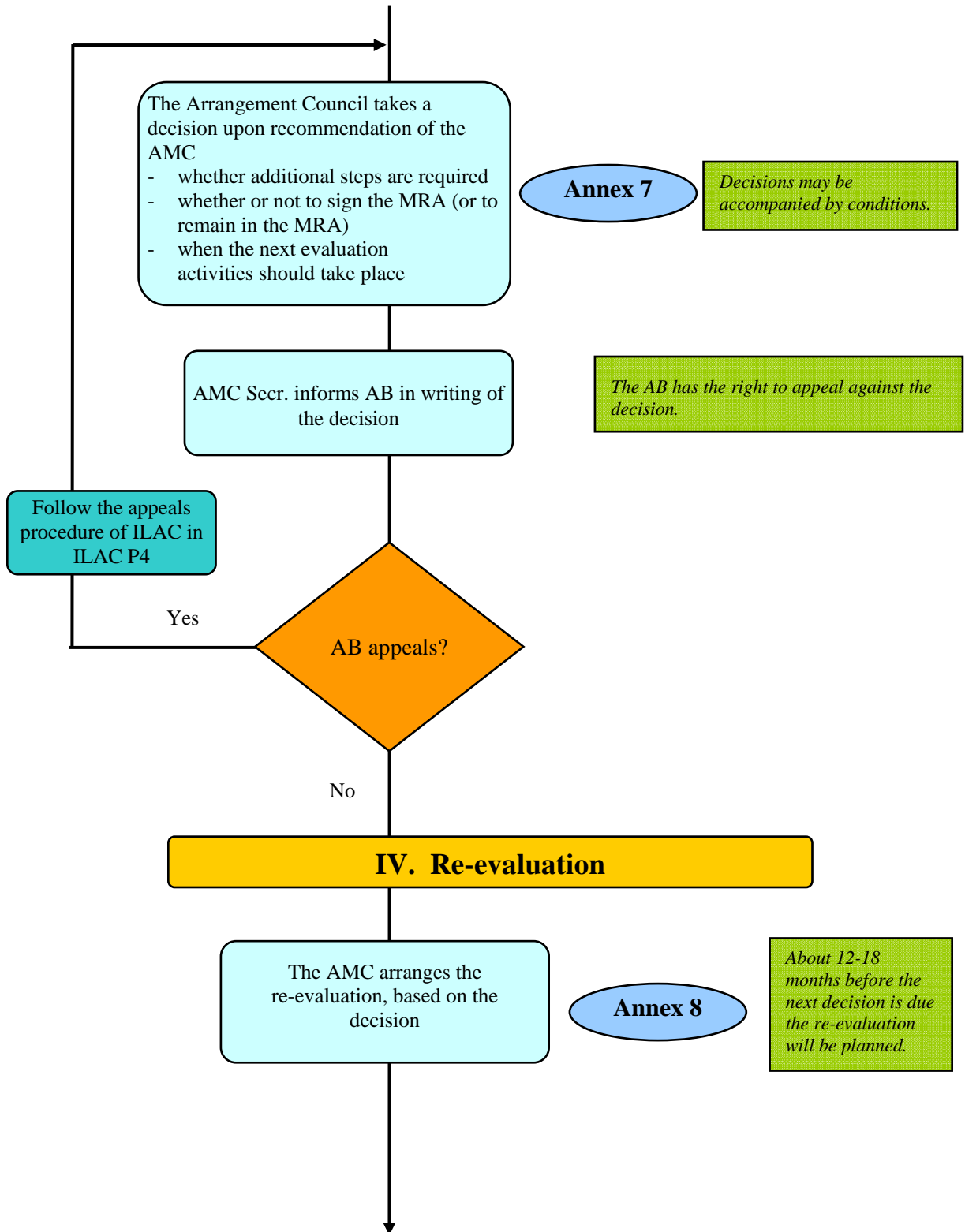






ILAC Mutual Recognition Arrangement (Arrangement):  
 Procedures for the Evaluation of Unaffiliated Bodies for the Purpose of Recognition





## ANNEX 1

### Application from a Single Accreditation Body (Associate of ILAC) to Join the Arrangement

#### 1. Application Form

**ILAC P6: 2003, Application for Full Member Status** is the form is for use by ILAC Associates wishing to apply for ILAC Full Member status. An electronic version of this form is available from the ILAC website: [www.ilac.org](http://www.ilac.org) or by emailing the ILAC Secretariat.

#### 2. Documentation to be Supplied by the Applicant Unaffiliated Body

- 2.1 The documents to be supplied to the Evaluation Manager shall include:
  - 2.1.1 A listing of all documents, forms, checklists, etc., used by the Applicant Body;
  - 2.1.2 The Applicant Body's quality manual in which the policies and procedures of the Applicant Body and the responsibility for implementation of the quality system are clearly designated. Full details of the staffing of the Applicant Body including their backgrounds and length of experience in each type of accreditation shall also be provided if not given in the quality manual;
  - 2.1.3 Accreditation criteria and associated generally applicable criteria that the Applicant Body publishes;
  - 2.1.4 All other general criteria published which include formal rules or regulations affecting the Applicant Body's operation and the responsibilities and obligations of its accredited laboratories;
  - 2.1.5 A document giving a clause-by-clause cross referencing of the Applicant Body's requirements and those of the appropriate ISO/IEC standard(s) and ILAC P1 clauses 5.2 and 5.3;
  - 2.1.6 The policy for traceability of measurement results;
  - 2.1.7 In the case of a calibration laboratory Accreditation Body, the written requirement document(s) provided to those laboratories for the calculation and reporting estimation of measurement uncertainty (this may a simple reference to a document prepared by another international/regional body);
  - 2.1.8 The policy on the surveillance and re-assessment of accredited laboratories;
  - 2.1.9 The policy on the implementation and use of Proficiency Testing Activity;
  - 2.1.10 Summary listing of all Proficiency Testing Activity over the past five years, including a list of all programs organised by Cooperations in which accredited and applicant laboratories have participated;
  - 2.1.11 Operational procedures covering Proficiency Testing Activity including (where available) criteria for statistical evaluation and corrective action procedures;

- 2.1.12 If available, a list of recent international comparisons in which the economy's national metrology institute or designated bodies have been involved (e.g., BIPM or regional metrology organisation) or, when applicable, reference to the NMI's capabilities as published on the BIPM website;
- 2.1.13 Any other documentation that describes the mechanics of operation of the accreditation system, including annual reports, questionnaires, newsletters, guidance documents, etc;
- 2.1.14 A copy of the body's directory or other listings providing the name and scope of accreditation of each accredited laboratory;
- 2.1.15 Detailed scopes of accreditation and draft scopes of accreditation of all laboratories to be visited during the pre-evaluation and evaluation visits;
- 2.1.16 Descriptions of any separate functions or affiliations of the body to activities other than accreditation (such as standards writing, etc);
- 2.1.17 Details of any formal arrangement or recognition to which the body is party either nationally or internationally, including government authorities, private sector organisations, other accreditation systems, etc;
- 2.1.18 Reports on any recent evaluations carried out by other relevant organisations, if applicable;
- 2.1.19 Self-evaluation report against the KPIs;
- 2.1.20 Latest internal audit report; and
- 2.1.21 Latest management review report.

### **3. Document Review**

- 3.1 The documents shall be reviewed by the Evaluation Manager (team leader). A report stating any documentation nonconformities shall be issued with a request for correction before proceeding with the evaluation.
- 3.2 The team leader should confirm that all necessary documents have been provided by examination of the list of all documents.
- 3.3 The team leader should request any additional documents considered necessary for the document review, to be provided in English and with copies also to other team members.
- 3.4 The document review should be conducted by the team leader, liaising as appropriate with the team members and using ISO/IEC 17011 and relevant ILAC P-series documents as the requirements.

- 3.5 The record should indicate conformity or nonconformity with the requirements and identify any gaps in the documentation of the system. For nonconforming areas the reason for the nonconformity should be stated in a report.
- 3.6 The team leader should submit the document review report to the Applicant Body with a request for a response to provide clarifications, corrective actions and an estimate of the time-scale to submit revised documents if required.
- 3.7 Where feasible, the Applicant Body should provide all amended or additional documents to the team for a further review. The team members should review the documents, and if necessary seek further clarification.
- 3.8 When the document review is complete and satisfactory, the team leader should issue a report confirming the documents are acceptable and that the evaluation (or pre-evaluation) of the accreditation body can commence.
- 3.9 The team leader should agree on mutually convenient dates for the evaluation (or pre-evaluation) with all parties concerned.

**ANNEX 2****Check-Report on Application**

1. Name of the Accreditation Body applicant:
2. Date of Application:
3. Date of this report:
4. Name of person preparing this report:
5. General observations:

The completeness of the application: Yes / No

- Have all the following documents in English been supplied:

- Scope of accreditation services Yes / No
- Statement on the regional group(s) to which the applicant belongs, if any: Yes / No
- Organisation chart (and parent organisation if any): Yes / No
- Signature of applicant committing to fulfil the obligations of Full Member Status Yes / No

6. Other information, if any:

**Recommendation:**

- Does the Applicant comply with all Application Criteria: Yes / No
- Acceptance of application: Yes / No
- If "No", the reason for rejecting the application:

*Signature:*

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## ANNEX 3

### **Appointment, Composition and Requirements of the Qualifications of Peer Evaluation Team Leaders and Members**

#### **1 Appointment and Duties of Evaluation Manager (Team Leader)**

- 1.1 In appointing the Evaluation Managers (team leaders) for a specific evaluation, the AMC should not appoint the same team leader for two successive evaluations of the same Applicant.

*NOTE It is normal practice that evaluators from as many members as possible are used.*

- 1.2 Team leaders shall be chosen from a list of team leaders prepared and kept up-to-date by the AMC in cooperation with the recognised Regional Groups. This list should record the experience of team leaders. The minimum qualifications for team leaders shall be as given in Clause 3.2.
- 1.3 The team leader shall have ultimate responsibilities for all phases of evaluation and is delegated authority by the Arrangement MC to make final decisions regarding the conduct of evaluation.
- 1.4 The team leader shall normally, in addition to the responsibility for managing the evaluation and preparing the evaluation report, mentor any "trainee peer evaluator" assigned to the 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.

#### **2 Composition of Evaluation Team**

- 2.1 For the full evaluation visit, members of the team shall be chosen as needed to cover the types of accreditation, the technical fields, size and complexity of the accreditation system under evaluation.

*Note: 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.*

- 2.2 Team members shall be chosen from a list of team members prepared and kept up-to-date by AMC in cooperation with the ILAC-recognised Regional Groups. This list should record the experience of team members. At least one member of the team shall have sound experience with these evaluations. For laboratory accreditation, one member of the team should be familiar with proficiency testing. The minimum qualifications of team members shall be as described in Clause 3.3.
- 2.3 The team chosen shall consist of representatives from a cross-section of Accreditation Body members of ILAC. The 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.

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*NOTE 1 There should only be one team member from each accreditation member body taking part.*

*NOTE 2 The team members should have working knowledge of the English language. Knowledge of the local language should be taken into account.*

*NOTE 3 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 team.*

- 2.4 No team member should be associated with any Accreditation Body that has provided consultancy service to the body being evaluated for the last three years.

### **3 Requirements for Qualifications of Peer Evaluators**

#### **3.1 Selection of Evaluators**

- 3.1.1 The AMC shall approve and oversee their performance in accordance with the criteria in the following sections.
- 3.1.2 ILAC Members may nominate evaluators (i.e., team leaders and team members) in writing, including a description of the experience and the scope of each proposed evaluator to ILAC AMC.

#### **3.2 Team Leaders**

- 3.2.1 A team leader shall be able:
- 3.2.1.1 to lead the Peer Evaluation team in an efficient and effective way, including the distribution of the tasks among the team members;
  - 3.2.1.2 to evaluate whether an applicant complies with the requirements of the appropriate ISO/IEC Standard(s) and its accredited bodies comply with the requirements of the appropriate ISO/IEC Standard(s);
  - 3.2.1.3 to decide from the submitted documentation any features requiring special study during the evaluation;
  - 3.2.1.4 to report clearly and succinctly the findings of all team members, in conformity with the Arrangement requirements;
  - 3.2.1.5 to evaluate whether the corrective actions decided by the applicant are likely to be effective and to evaluate the corrective actions carried out;
  - 3.2.1.6 to determine the criticality of the findings;

- 3.2.1.7 to understand quickly and easily cultural differences, as far as essential in the evaluation process.
- 3.2.2 In order to meet these criteria, a team leader shall:
  - 3.2.2.1 be an experienced person within an Accreditation Body or organisation which has relevant working experience with accreditation and have the appropriate technical background and experience (at least three years) of assessment;
  - 3.2.2.2 have participated in at least two peer evaluations of Accreditation Bodies as a team member;
  - 3.2.2.3 have sound knowledge of the application of the appropriate ISO/IEC Standards and relevant Arrangement requirements;
  - 3.2.2.4 be able to understand and to express him/herself clearly, in speaking and writing in English or the primary language of the Region;
  - 3.2.2.5 have experience in chairing meetings and in reaching consensus on delicate points;
  - 3.2.2.6 have good interpersonal skills.
- 3.2.3 The AMC shall approve team leaders for a three-year term.
- 3.2.4 AMC shall arrange periodic meetings for team leaders in order to improve and maintain the harmonisation of the evaluations.

### **3.3 Team Members**

- 3.3.1 A team member shall be able:
  - 3.3.1.1 to evaluate whether an applicant complies with the requirements of the appropriate ISO/IEC Standard(s) and its accredited bodies comply with the requirements of the appropriate ISO/IEC Standard(s);
  - 3.3.1.2 to report clearly and succinctly the findings;
  - 3.3.1.3 to determine the criticality of the findings.
- 3.3.2 A team member shall:
  - 3.3.2.1 be an experienced person or assessor within his/her Accreditation Body or a organisation who has relevant working experience with accreditation and has the appropriate technical background in the assigned areas of the evaluation (at least 3 years);

- 3.3.2.2 successfully completed a relevant training course(s) and have experience, as a trainee, in Peer Evaluation of Accreditation Bodies;
- 3.3.2.3 have sound knowledge of the application of the appropriate ISO/IEC Standard(s), and relevant Arrangement requirements;
- 3.3.2.4 have good interpersonal skills; and
- 3.3.2.5 be able to understand and to express him/herself clearly, in speaking and in writing in English.
- 3.3.2.6 follow the instruction given by the team leader.

### **3.4 Evaluator Attributes**

#### 3.4.1 Evaluators should:

- 3.4.1.1 be open minded and mature;
- 3.4.1.2 possess sound judgement, analytical skills, and tenacity;
- 3.4.1.3 have the ability 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 organisation.

#### 3.4.2 Evaluators should be able to apply the attributes of 3.4.1 in order to:

- 3.4.2.1 obtain and assess objective evidence fairly;
- 3.4.2.2 remain true to the purpose of the evaluation without fear or favour;
- 3.4.2.3 evaluate constantly the effects of evaluation observations and personal interactions during an evaluation;
- 3.4.2.4 treat concerned personnel in a way that will best achieve the evaluation objective;
- 3.4.2.5 react with sensitivity to the local conventions of the area in which the evaluation is performed;
- 3.4.2.6 perform the evaluation process without deviating due to distractions;
- 3.4.2.7 commit full attention and support to the evaluation process;
- 3.4.2.8 react effectively in stressful situations;

- 3.4.2.9 arrive at generally acceptable conclusions based on evaluation observations;
- 3.4.2.10 remain true to a conclusion despite pressure to change that is not based on evidence.

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## ANNEX 4

### Typical Evaluation Program of a Single AB

#### 1 Introduction

In principle it is the task of the TL to create a timetable 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.

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 4.2. 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 4.2 or when additional team capacity is required, the AMC should also be consulted at an early stage.

#### 2 Considerations

##### 2.1 Maximum duration

The TL must try to arrange the evaluation to take place in the shortest possible time, preferably within one full (7 days) week.

If witnessing or observing is not possible during the week of the formal evaluation and if no alternatives are possible, the TL should make arrangements to have witnessing and/or observations 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-evaluations, for follow-up evaluations and for scope extensions that are conducted separately from a re-evaluation.

##### 2.3 Witnessing/observing

- The team has to consider how to deal with observing.

At present 2 scopes of Arrangement are recognised:

- Calibration Laboratories
- Testing Laboratories

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.

It must be stressed that despite spending time on observing, 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.

#### 2.4 Size of the AB

The influence of the AB's scope on the duration of the evaluation (on-site part) relates primarily to the number of witnessing and observing activities. The AB's management system may not differ (especially when ISO/IEC 17011:2004 is implemented) 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 Other factors

Factors that may negatively influence the duration include:

- Need for translators and their effect of slowing down the evaluation
- Extensive travel and travel circumstances
- Cultural differences

This annex cannot provide guidance on all these items. It is left to the 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 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 Annex 1. Accurate translation of the documents into English is essential. The KPI self-assessment document and the checklist 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 must send all documents at least 3 months in advance of a visit to allow for preparation and for requesting additional information. 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.

For planning of the witnessing, the AB must provide, at an early stage, the evaluation team with a list of assessments that will take place from about 6 weeks before the

proposed on-site evaluation date. This gives the team the opportunity to carefully select and plan the witnessing/observation activities.

### 3.2 On-site evaluation

The 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 KPI's self-assessment report
- Evaluation of the assessment report and preparation of 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
- Normally one witness of an initial accreditation or a re-accreditation of a CAB for every accreditation program (7 witnesses, see clause 2.3) or two surveillances
- Discussing about the results of the witnessing with the AB team and AB
- Closing meeting, presentation and discussing of findings.

Some timetable examples are:

#### 3.2.1 Full size scope AB

| Day       | Actions                                                                                                                                                      | Evaluators |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Sunday    | >= 4 hours for preparation with the team<br>(key issues to be addressed + evaluation plan)                                                                   | TL + 4 TM  |
| Monday    | Office, opening meeting, records etc + preparation for<br>witnessing/observing assessments                                                                   | TL + 4 TM  |
| Tuesday   | Office + witnessing staff + witnessing/observing<br>assessments (split team)                                                                                 | TL + 4 TM  |
| Wednesday | Office + witnessing staff + vertical audits + witnessing<br>/observing assessments (split team)                                                              | TL + 4 TM  |
| Thursday  | Office + witnessing staff + vertical audits (specially<br>directed for confirmation of previous findings +<br>witnessing/observing assessments (split team)) | TL + 4 TM  |
| Friday    | Same + preparation final Report + closing meeting                                                                                                            | TL + 4 TM  |
| Saturday  | 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 team<br>Office, opening meeting, records etc<br>(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 team<br>Office, opening meeting, records etc<br>(key issues to be addressed + evaluation plan) | TL + 2 TM  |
| Day 2         | Office, opening meeting + preparation for witnessing assessments                                                                | TL + 2 TM  |
| Day 3         | Office + witnessing staff + witnessing assessments (split team)                                                                 | TL + 2 TM  |
| Day 4         | Same + preparation final Report + closing meeting                                                                               | TL + 2 TM  |
| Day 5 morning | Discussing further actions for TMs + departure                                                                                  | TL + 2 TM  |

### 3.2.4 ABs with 3 fields of accreditation

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

During the evenings 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

Since the major part of the reporting can be drafted during the 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 team needs to spend time on reviewing the AB's corrective actions and on the preparation of the team's comment to these corrective actions. The TL should take the lead in preparing this reaction. Finally the TL has to prepare a recommendation to the decision-making committee. Typically this may take 2-3 days for the TL. For TMs, the time involved may be limited to 0.5 days.

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**ANNEX 5****Evaluation Reporting on a Single Accreditation Body****A) Steps in Evaluation Reporting on a Single Accreditation Body:**

- 1 Preparation of Summary report** (including as an appendix the nonconformities, concerns and comments presented in table format, and perhaps a completed checklist). This has to be completed and is preferably to be confirmed by the applicant at the end of the on-site evaluation visit.
- 2 Preparation of the Draft Report of the On-site Evaluation Visit.** This report is the agreed report of the team and the Accreditation Body and includes the results of the Witness activities. This includes the full text of the summary report.
- 3 Formal Response of the Accreditation Body to the Findings.** Ideally, the accreditation body's response can simply be inserted text under each finding presented in table format with attachments of supporting evidence of corrective action as appropriate. (see what is expected of the AB's response and corrective action described in C).
- 4 Formal Reaction of the Team to this Response.** The team's reaction to each response to every finding is submitted to the Accreditation Body for consideration.
- 5 Steps 3 and 4 may be Repeated.**
- 6 Preparation of a Final Report to the Arrangement Group.** This report consists of the items identified under steps 2, 3 and 4 (i.e, formal team report, formal AB response and formal team reaction). In addition, the recommendation of the team is stated as the leading page of the team's final report. Items included in steps 3 and 4 should be combined into one table stating the nonconformities/concerns, the formal AB response including corrective actions, and the team's reaction. This will ease the review process of the Arrangement Group and its Decision-making Group.

**B) Typical Structure and Content of a Final Evaluation Report on a Single Accreditation Body**

- 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, other team members and observers, specifying the organisation to which they belong, and a clear indication that the report is confidential.
- 1 Contents**

For a full evaluation, a page should list the contents of the report, including the annexes.
- 2 Summary**

For a full evaluation, the name and type of Accreditation Body and the organisations involved in the evaluation. The summary should include the next steps in the process, any recommendations and reference to the nonconformities, concerns and comments (see Annex) and must be signed by all team members

**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, activities undertaken during the evaluation, provisions of documentation and translation, types of assessments observed and institutions visited.

**4 Background on the Accreditation Body**

This section should state the history and background of the accreditation body, including fields of accreditation, relationship to government, responsibilities, management, number of accreditations, staffing levels, number of assessors and arrangements with other bodies.

**5 Performance of the System**

The subsections of this section are based upon the Key Performance Indicators (ILAC-IAF A3).

**6 Arrangement Obligations**

For re-evaluations, the steps taken by the signatory to implement the obligations stated in the Arrangement document(s).

**7 Annexes**

- 7.1 Nonconformities, concerns and comments (to be left at the end of the on-site evaluation visit).
- 7.2 Lists of documents supplied before evaluation
- 7.3 Evaluation programme and agenda
- 7.4 Organisation chart of the Accreditation Body
- 7.5 List of observed assessments with the type of conformity assessment bodies involved and their accreditation scopes, and type of assessment identified
- 7.6 Declaration of confidentiality statement signed by all team members and observers

**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(s) (e.g., ISO/IEC 17011), its own management system or the Arrangement requirements in a way that discredits its competence or jeopardises the quality of its work.

The evaluated AB is expected to respond to a nonconformity by taking appropriate corrective action and providing the team with evidence of implementation.

**Concern:** Finding where the AB's practice may develop into a non-conformity or the team is not fully satisfied.

The evaluated AB is expected to respond to a concern by providing the team with an appropriate action plan and time schedule or a clarification.

**Comment:**

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

The evaluated AB is not expected to respond to comments but may do so if it wishes.

**ANNEX 6**

**Evaluation Summary Report For a Single Accreditation Body**

**Applicant:**

**Dates of evaluation:**

**Evaluation team:**

**Identification of the Full Evaluation Report:**

**Evaluation sites:**

**Applicant's office(s):**

**Witnessed assessments:**

**Scope of evaluation:**

**Applicant organisation**

**Number of staff:**

**Areas of accreditation activity:**

**Number of bodies accredited:**

**Organisational structure:**

**Decision making process:**

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

**Findings of the evaluation team (nonconformities and concerns):**

**Conclusions:**

**Statements of closeout of nonconformities and concerns:**

**Unresolved issues:**

**Conclusion and recommendation:**

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## ANNEX 7

### Decision Making Regarding Evaluations of a Single Accreditation Body

#### 1. Decision Making Regarding Evaluations

- 1.1 The evaluation report, the corrective actions and the recommendations of the team leader shall be submitted as the final report to the ILAC Secretariat who will distribute the report to the members of the AMC.
- 1.2 The AMC shall prepare a summary report for the Arrangement Council 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 Arrangement Council 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-organisations.*

*NOTE 2 For voting rules see the Bylaws of ILAC.*

#### 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., conditions or sanctions of increasing severity are imposed).
- 2.2 Decisions on new applicants from affiliated bodies of ILAC-recognised Regional Groups are made by the decision-making group of their respective multi-lateral mutual recognition arrangement (Regional Cooperation). Decisions on the on-going re-evaluations of Signatory affiliated bodies also reside with the recognised Regional Group. This becomes a prerequisite to signing and maintaining Signatory status with the Arrangement.<sup>1</sup>
- 2.3 The ILAC Arrangement Council makes all decisions on unaffiliated bodies. 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.

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<sup>1</sup> Provided that ILAC dues are paid and other obligations are fulfilled.

2.4 *Decisions on New Applicant Unaffiliated Single Accreditation Bodies:*

- 2.4.1 Approval without conditions (re-evaluation to occur 4 years hence)
- 2.4.2 Approval with conditions (e.g., shortened interval for re-evaluation, completion of one or more Interlaboratory Comparisons (ILCs))
- 2.4.3 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
- 2.4.4 Disapproval with a new evaluation required<sup>2</sup>

2.5 *Decisions on Signatory Unaffiliated Single Accreditation Bodies:*

- 2.5.1 Approval without conditions (re-evaluation to occur 4 years hence)
- 2.5.2 Approval with conditions (e.g., shortened interval for re-evaluation, completion of one or more ILCs)
- 2.5.3 Defer re-approval pending submittal of required evidence of corrective actions and/or re-visit by one or more members of the evaluation team
- 2.5.4 Reduction of recognition for one or more types of accreditation
- 2.5.5 Withdrawal of Signatory status (subject to Appeals Process) -- if ultimately a Signatory were withdrawn, a new application and evaluation would be required to re-enter the Arrangement

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<sup>2</sup> 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 ILAC Arrangement Management Committee has concluded that all requirements have been met.

## ANNEX 8

### Monitoring and Re-Evaluation of a Single Accreditation Body

1. Periodic monitoring and re-evaluation of the Arrangement(s) is necessary.
2. All Arrangement Signatories shall be formally re-evaluated at maximum intervals of four years.
3. Partial to total re-evaluation may be conducted at an earlier date as directed by the Arrangement Group Decision-making Group, should there be due cause such as notification of significant changes in administration, finances, operational practices or an extension in the scope of accreditation available.
4. Monitoring of changes notified by an Arrangement signatory shall be appropriately examined.
5. Re-evaluation visits should be led by a team, in which the majority of members will not have been on the team that undertook the previous evaluation.