



**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 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 accredit;
- ◆ the evaluation of a Regional Group’s competence in managing the operations of regional Arrangements.

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.

PURPOSE

To provide IAF and/or ILAC with general requirements for evaluating single accreditation bodies for the purpose of qualifying them to sign applicable Arrangement(s).

AUTHORSHIP

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

This latest version was endorsed by letter ballot in IAF and ILAC in 2010.

SECTION 1: Introduction

1.1 Scope

This document identifies general 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). Regional Groups shall adopt the requirements of Section 2 and develop procedures consistent with those described in Section 3 and the relevant annexes. Section 3 is a flowchart with harmonized procedures. There are ten 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 (AB)*: An organization that operates an accreditation system for one or more types of conformity assessment bodies.
- 1.2.2 *Accreditation program*: set of criteria specified in a standard or normative document included in IAF and/or ILAC Arrangements used for the accreditation of conformity assessment bodies.
- 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).
- 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 an Arrangement peer evaluation team.
- 1.2.7 *Evaluation Team Member (TM)*: A person serving on an Arrangement peer evaluation team.
- 1.2.8 *ISO/IEC Standard*: An ISO/IEC standard, guide or technical report related to accreditation and conformity assessment.
- 1.2.9 *Management Committee (MC)*: A small group responsible for the everyday management of the Arrangement process (In IAF: IAF MLA MC; In ILAC: ILAC Arrangement Management Committee).

- 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*: Observing of an AB assessing the premises of the conformity assessment body (CAB), 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 Standards**

- 2.1.1 An accreditation body shall comply with the provisions of ISO/IEC 17011 requirements and mandatory documents in IAF and ILAC. An AB should operate according to applicable IAF and ILAC guidance documents.
- 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 in each of the scopes of the Arrangement for which it applies;

NOTE: This experience may be obtained by having accredited more than one CAB in a particular accreditation program and/or having accredited one CAB in a particular accreditation program and having carried out on site surveillance and reassessment of the CAB.
 - 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 testing or calibration laboratories is less than 4 at the time of evaluation, the need for a follow-up evaluation before the normal 4 year period shall be considered by the Decision Making Group.
 - 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 a program to promote 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).

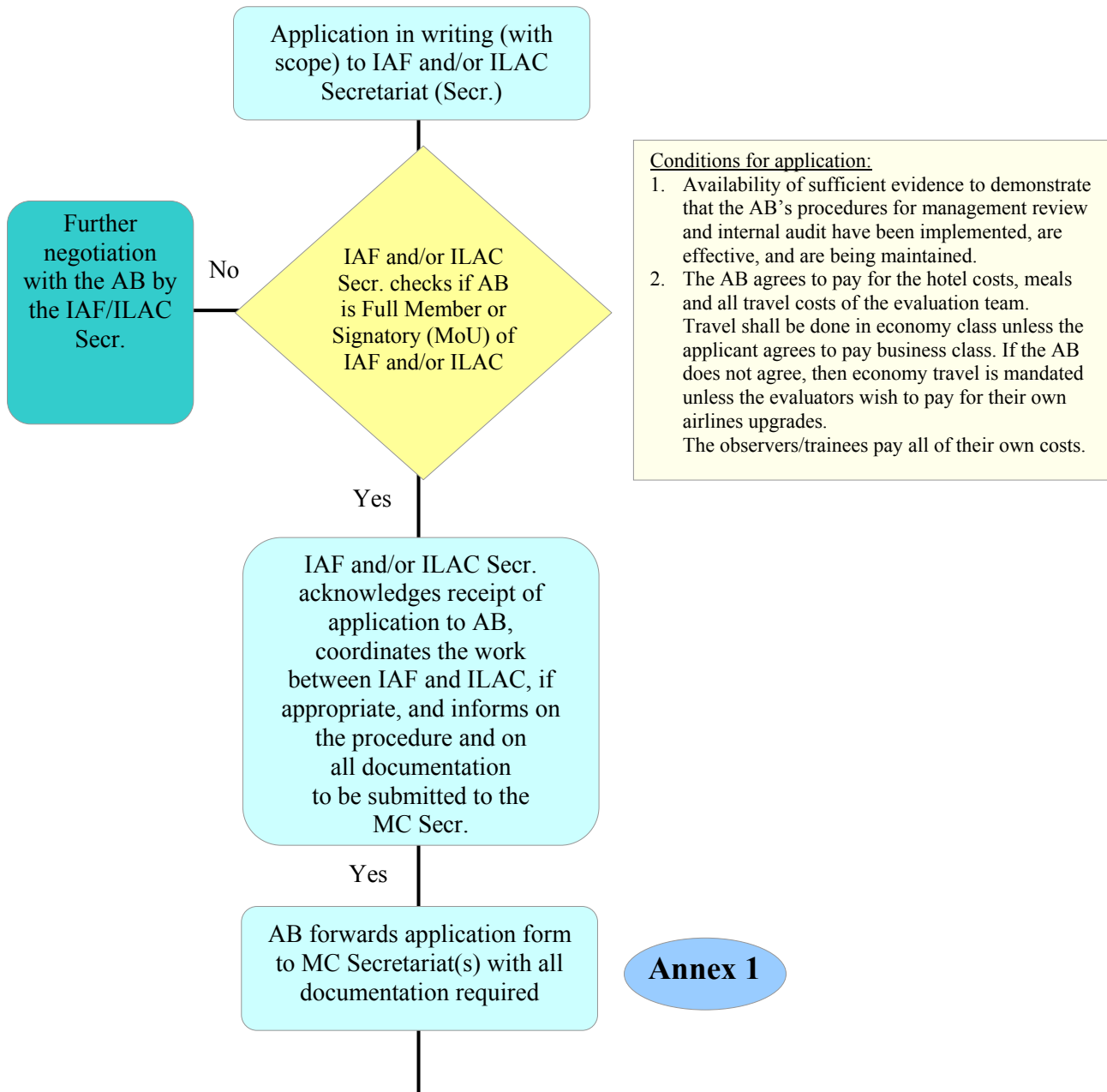
2.3 Confidentiality

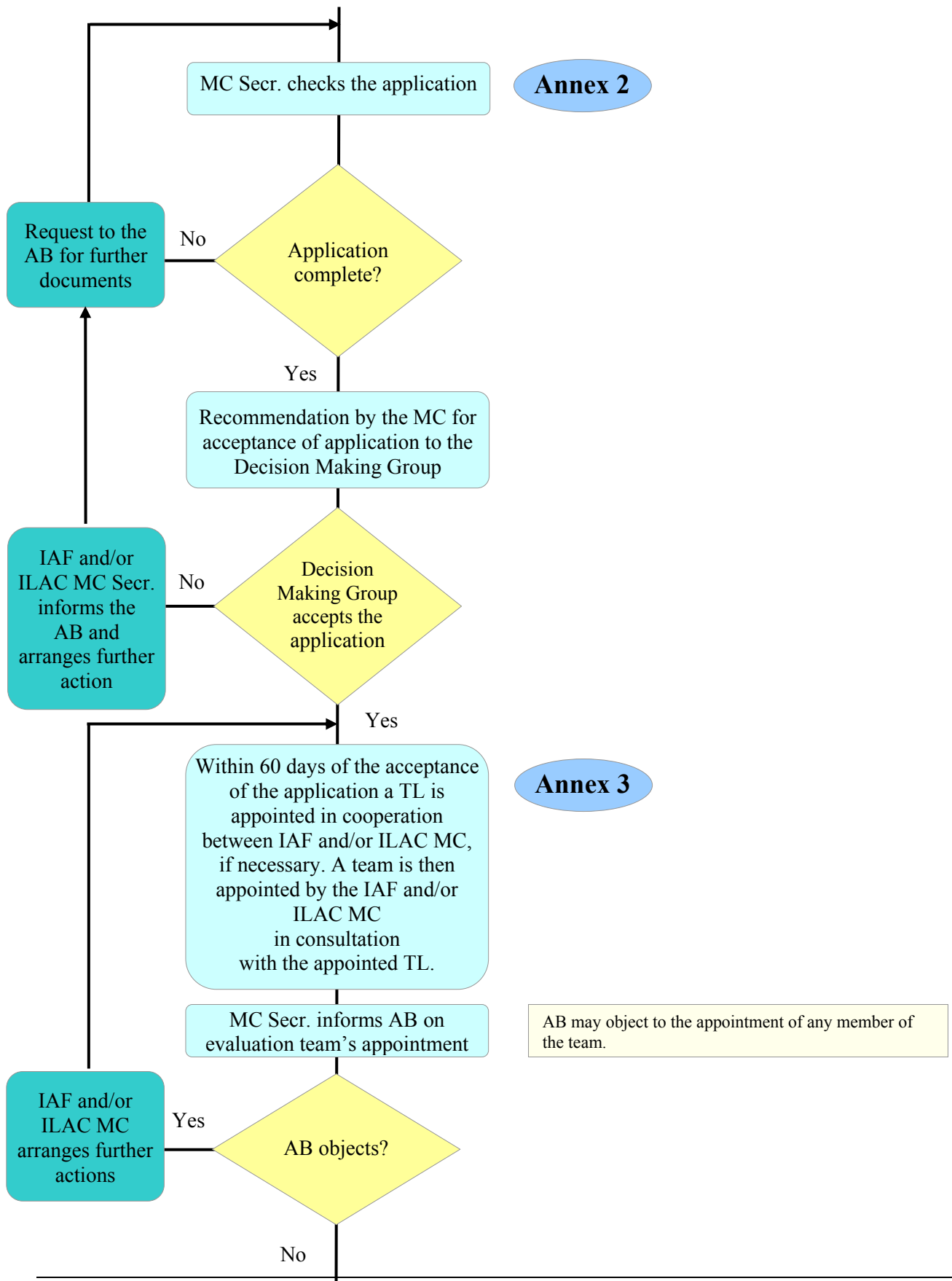
- 2.3.1 All oral and written information received through the operation of the arrangement group relating to evaluations, re-evaluations, appeals and complaints (except that information which is already publicly accessible) shall be treated confidentially by all parties and persons concerned. This includes information relating to applicants and/or signatories of the Arrangement. All individuals having access to confidential information shall sign a declaration of confidentiality before being given access.
- 2.3.2 Reports on evaluations, re-evaluations and interim visits may be copied to the representatives of signatories who have a role to play in decision making.
- 2.3.3 The AB under evaluation shall advise the team members how to treat the documents it has provided. This advice 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.

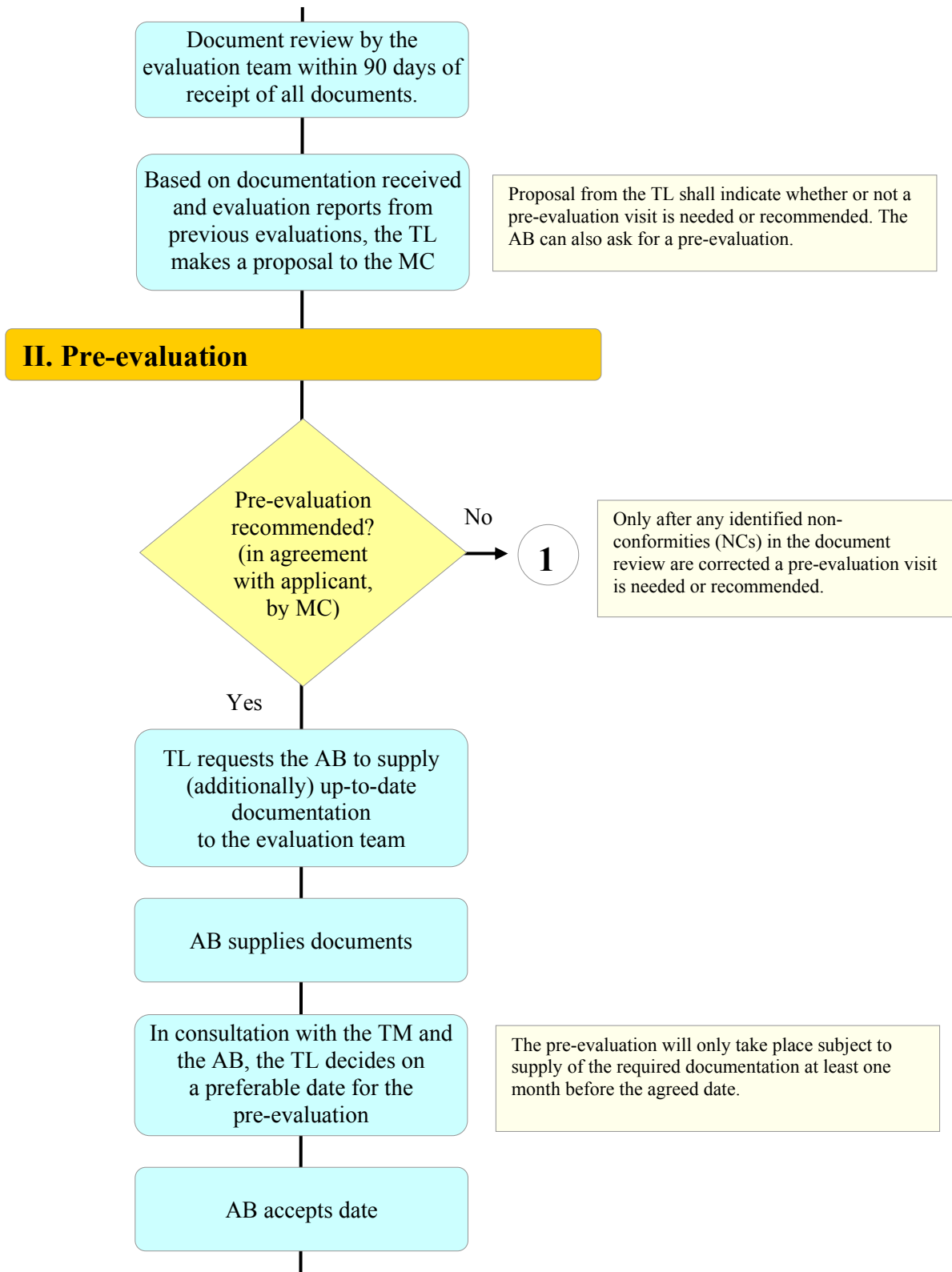
SECTION 3: Flowchart for Peer Evaluation Procedures of a Single Accreditation Body

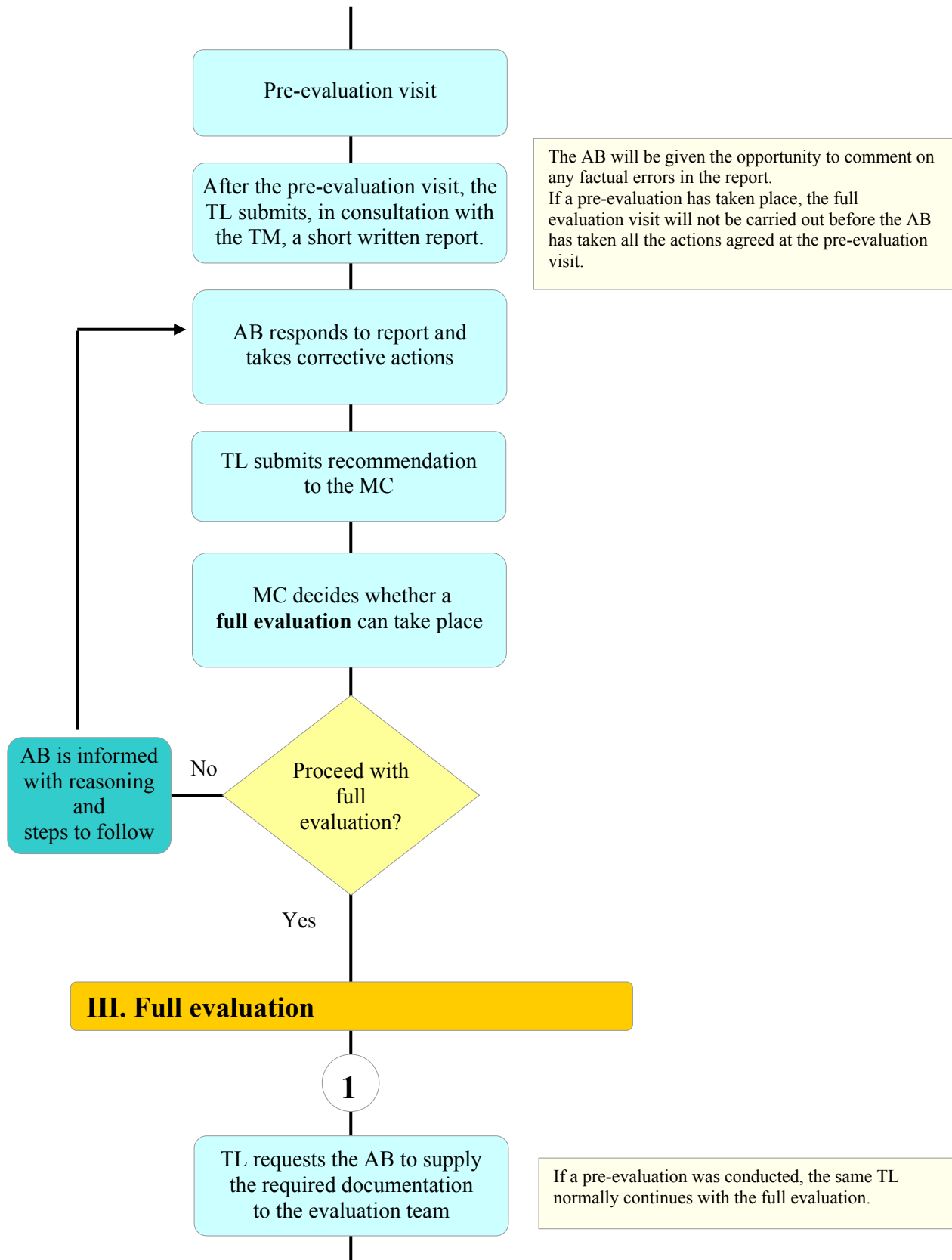
The following procedures shall be used by IAF and/or ILAC for the evaluation of single ABs (also called: unaffiliated accreditation bodies). Regional Groups shall develop procedures consistent with these harmonized procedures and those described in the Annexes.

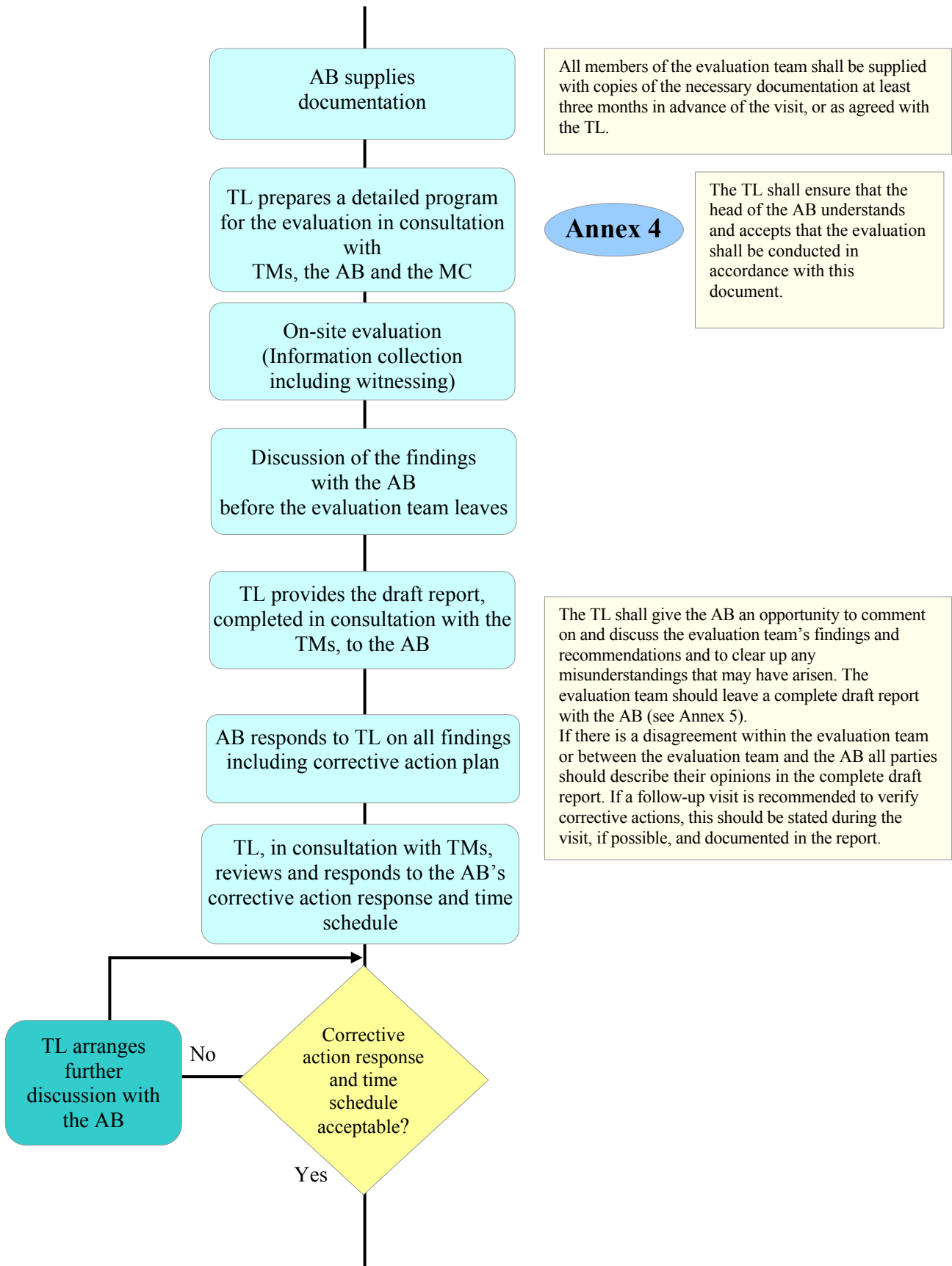
I. Application for Arrangement Membership

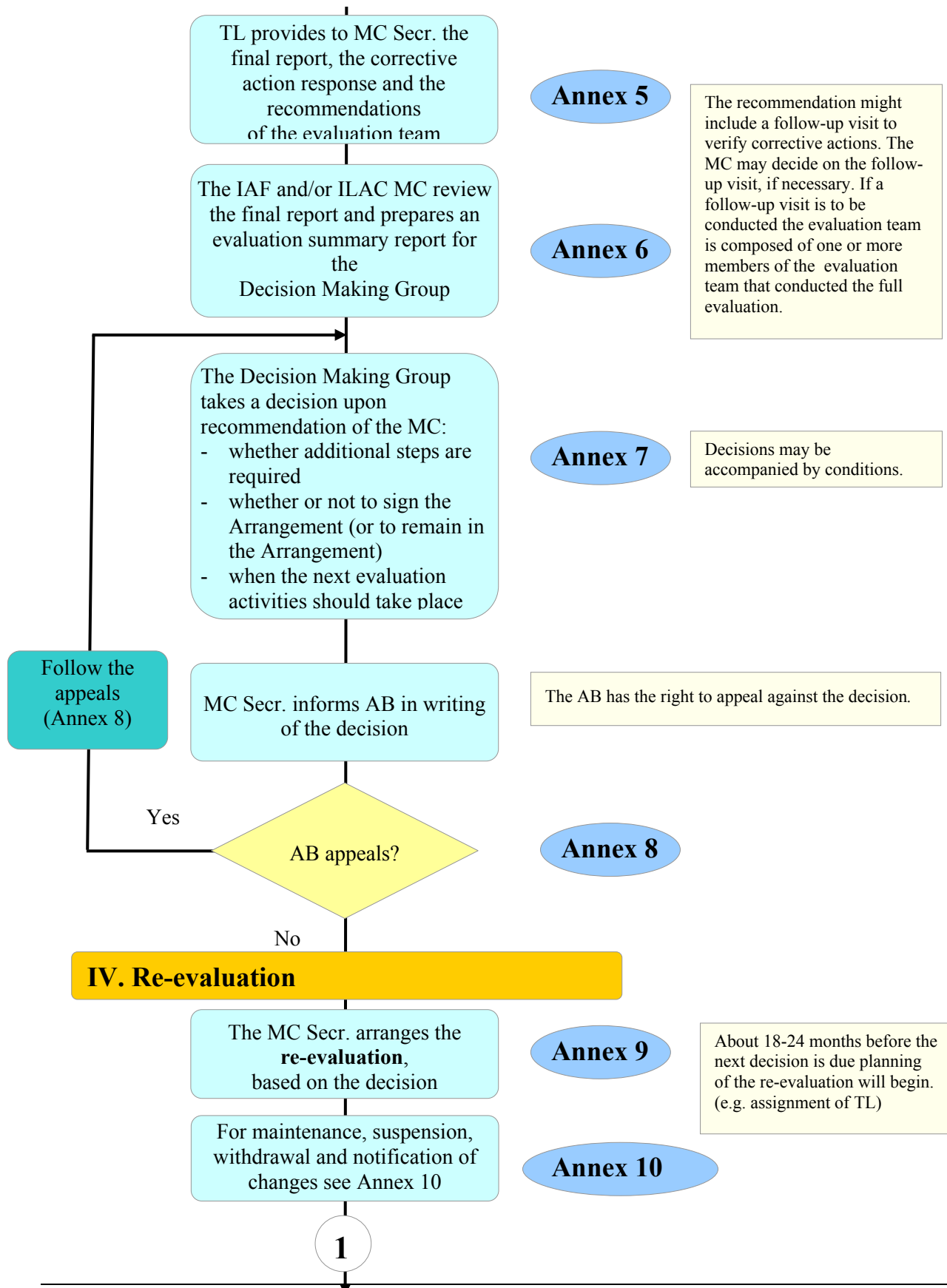












ANNEX 1: Application From a Single Accreditation Body (Member of IAF and/or ILAC), to Join the Arrangement
1. Please select the Arrangement scope(s) being applied for:

- Accreditation of Testing Laboratories (Test) (ISO/IEC 17025; ISO 15189)
- Accreditation of Calibration Laboratories (Cal) (ISO/IEC 17025)
- Accreditation of Inspection Bodies (Insp) (ISO/IEC 17020)
- Accreditation Management Systems (ISO/IEC 17021)
- QMS
- EMS
- ISMS
- FSMS
- Accreditation of Product Certification Bodies (Product) (ISO/IEC Guide 65)
- Accreditation of Personnel Certification Bodies (Persons) (ISO/IEC 17024)
- Others

2. Name of Accreditation Body (applicant):**3. Head office address**

3a. street address:	3b. postal address, if different from 3a:

4. Do you have offices other than Head Office?

If yes, attach a list of the addresses of all other offices.

5. Economy(ies) of accreditation activity (If the applicant conducts accreditation in more than one economy, list all of them):**6. Economy(ies) of the location of the Head Office falls in the following region(s) (e.g. APLAC, EA, IAAC, PAC):**

6a. If applicable, please explain why the applicant wants to apply directly to IAF and/or ILAC, rather than to the Regional Group in which the economy(ies) falls.

-
-
7. **Name of applicant contact person:**
 8. **Position of contact person:**
 9. **Telephone no. (including country code):**
 10. **Facsimile no. (including country code):**
 11. **E-mail address:**
 12. **Legal status of the applicant (attach documentary evidence of legal identity):**
 13. **History of the applicant (date of establishment; relevant background):**
 14. **Applicant's relationship to government, if any:**
 15. **Membership, if any, in a Regional Group's Arrangement (identify the scope(s) of the Arrangement):**

Please answer the following questions for each area in which the applicant is seeking signatory status to the respective Arrangement

	Test 17025/15189	Cal	Insp.	Management systems QMS//EMS/ISMS/FSMS				Product	Persons	Others
16. Operational period of the applicant in the scope(s) of the Arrangement applied for.										
17. Accreditation criteria										
18. Number of staff including management staff and assessment personnel.										
19. Number of accreditations granted for each applicable scope (attach a list of the names of the accredited										

bodies for each scope or a link to the database on the internet, if any)											
20. Preferred month and year, if any, for initial evaluation.											

- 21. Please list all other operational accreditation programs.**

- 22. Please send electronically one (1) copy of each of the following documents (in English translation if not written originally in English)**
 - 1. the applicant's quality manual in which the policies and procedures of the applicant and the responsibility for implementation of the quality system are clearly designated. Full details of the staffing of the applicant including numbers and functions of its operational staff, their backgrounds and length of experience in assessment and accreditation of conformity assessment bodies shall also be provided, if not contained in the quality manual;
 - 2. all accreditation criteria and associated generally applicable criteria that the applicant publishes;
 - 3. all other published criteria, including formal rules or regulations that apply to the applicant's operation and the responsibilities and obligations of its accredited bodies;
 - 4. a cross-reference table between each clause, sub-clause or specific requirement of the recognition criteria in section 2 of this document and the documentation of the applicant;
 - 5. results of the self assessment based on IAF/ILAC A3;
 - 6. for ABs for laboratories/inspection bodies a report on interlaboratory comparisons and proficiency testing activities organized by the applicant;
 - 7. all procedures and policies required by ISO/IEC 17011;
 - 8. for certification bodies, list of foreign critical locations; and
 - 9. for testing and calibration laboratories, information about the available sources of traceability of measurement, e.g. a list of recent international comparisons in which the economy's national metrology institute (NMI) or designated institutes have been involved and/or, when applicable, reference to the NMI's calibration and measurement capabilities (CMC) as published on the BIPM website.

- 23. Other information related to the integrity of accreditation activity (e.g. other activities of the applicant body, Arrangements, relationships with other bodies, subcontracting and access to the traceability of results to SI units).**

- 24. Please complete the Declaration on the following page and then proceed with 25.**

Declaration

As an Accreditation Body Member of IAF and/or ILAC Associate, the applicant,

_____, duly represented by the undersigned:
Name of applicant

- ◆ Accepts the IAF and/or ILAC evaluation procedures for single accreditation bodies;
- ◆ Accepts the respective requirements and agrees with the terms of the Arrangement(s);
- ◆ Confirms that the operations of the applicant comply with ISO/IEC 17011;
- ◆ Submits the completed application; and
- ◆ Applies to join the Arrangement Group(s).

Contact person's name and contact details

Contact person's position

Date

Signature

25. Please send your completed application (items 1 to 21 and 23) along with all requested documents (item 22), and the signed and dated Declaration (item 24):

for IAF Arrangement:

BOTH TO

IAF Secretariat

P.O. Box 819
Cherrybrook, NSW 2126
Australia
Fax: +61 2 9481 7343
Email: secretary1@iaf.nu

AND

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Silverwater NSW 2128
Australia
Phone: +61 2 9736 8374
Fax: +61 9736 8373
Email: ilac@nata.com.au

ANNEX 2: Check-report On Application

1. **Name of the accreditation body applicant:**
2. **Date of application:**
3. **Reason for direct application:**
4. **Date of this report:**
5. **Name of person preparing this report:**
6. **General observations:**

Has the applicant provided all information required in the application form (Annex 1) Yes / No
 Have all the following documents in English been supplied:

1. the applicant's quality manual in which the policies and procedures of the applicant and the responsibility for implementation of the quality system are clearly designated. Full details of the staffing of the applicant including numbers and functions of its operational staff, their backgrounds and length of experience in assessment and accreditation of conformity assessment bodies shall also be provided, if not contained in the quality manual, Yes / No
2. all accreditation criteria and associated generally applicable criteria that the applicant publishes; Yes / No
3. all other published criteria, including formal rules or regulations that apply to the applicant's operation and the responsibilities and obligations of its accredited bodies; Yes / No
4. a cross-reference table between each clause, sub-clause or specific requirement of the recognition criteria in section 2 of this document and the documentation of the applicant; Yes / No
5. results of the self assessment based on IAF/ILAC A3; Yes / No
6. for ABs for laboratories/inspection bodies a report on interlaboratory comparisons and proficiency testing activities organized by the applicant; Yes / No
7. all procedures and policies required by ISO/IEC 17011; Yes / No
8. for certification bodies, list of foreign critical locations; Yes / No
9. for calibration and testing laboratories, information on measurement traceability. Yes / No

7. Other observations, if any:
Recommendation:

- ◆ Does the applicant comply with all application criteria as specified in Annex 1: Yes / No
- ◆ Acceptance of application: Yes / No
- ◆ If "No", the reason for rejecting the application:

Signature

Date

Name and position
Contact details

ANNEX 3: Requirements For the Qualifications and Personal Attributes of Peer Evaluation Team Leaders and Members, and Appointment and Composition of the Evaluation Team**1. Appointment and duties of the evaluation team leader**

- 1.1** 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.

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

- 1.2** Team leaders shall be chosen from a list of team leaders prepared and kept up-to-date by the MC on the basis of the proposals made by the Regional Groups or the unaffiliated members. This list should record the experience of team leaders. The minimum qualifications of 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 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" (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.

2. Composition of the evaluation team

- 2.1** 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.

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's readiness for a full evaluation visit.

- 2.2** Team members shall be chosen, in consultation with the TL, from a list of team members prepared and kept up-to-date by the MC on the basis of the proposals made by the Regional Groups or the unaffiliated members. This list should record the experience of team members. At least one member of the evaluation team shall have sound experience with these evaluations. For laboratory accreditation, one member of the evaluation team should be familiar with proficiency testing. The minimum qualifications of team members shall be as described in clause 3.3.
- 2.3** The evaluation team chosen shall consist of representatives from a cross-section of Member Accreditation Bodies of IAF and/or ILAC. The evaluation team shall be chosen to provide a balanced set of skills so as to be able to conduct an effective evaluation of the key components of the system under examination.

NOTE 1: There should be no more than one team member from each economy.

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 evaluation team.

- 2.4** 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.

3. Requirements for qualifications of peer evaluators

3.1 Selection of Evaluators

3.1.1 The MC shall approve and oversee the performance of evaluators in accordance with the criteria in the following sections.

3.1.2 IAF/ILAC Regional Groups and unaffiliated bodies 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 the IAF and/or ILAC MC.

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 ISO/IEC 17011 and IAF/ILAC A5 and its accredited bodies comply with the requirements of the appropriate ISO/IEC standard(s) and corresponding IAF/ILAC mandatory/guidance documents;

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 organization who has relevant working experience with accreditation and has the appropriate technical background and at least three years of assessment experience;
 - 3.2.2.2 have successfully 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 used by the AB that is the object of the evaluation;
 - 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 MC shall approve team leaders for a three-year term.
- 3.2.4 MC shall ensure that team leaders participate in periodic meetings arranged by ILAC, IAF or the Regional Groups in order to improve and maintain the harmonization 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 ISO/IEC 17011 and IAF/ILAC A5 and its accredited bodies comply with the requirements of the appropriate ISO/IEC standard(s) and corresponding IAF/ILAC mandatory/guidance documents;
 - 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 an accreditation body or an organization 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 IAF/ILAC mandatory/guidance documents;

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 shall:

3.4.1.1 be open minded and mature;

3.4.1.2 possess sound judgment, 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 organization.

3.4.2 Evaluators shall 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 favor;

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 that is based on objective evidence, despite pressure to change.

ANNEX 4: 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);
- ◆ Measurement traceability routes (for testing and calibration accreditation). In some cases it may be necessary to visit the NMI;
- ◆ Witnessing one or more assessments, if possible.

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 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.

At present 9 scopes of Arrangement are recognized:

- Calibration Laboratories
- Testing Laboratories
- Inspection bodies
- QMS Certification bodies
- EMS Certification bodies
- ISMS Certification bodies
- FSMS Certification bodies
- Product Certification bodies
- Person Certification bodies

For laboratory accreditation, the evaluation team shall witness at least one initial assessment or reassessment for each of calibration and testing (where applicable), plus other reassessments and surveillance assessments as determined by the team leader.

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

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 self-assessment document (IAF/ILAC A3) and the checklist relating the accreditation standard(s) to the AB's procedures/documents shall be detailed and accurate. These two documents will greatly assist the evaluation team in preparation. The AB shall send all documents at least 3 months in advance of a visit to allow for preparation and for requesting additional information. 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 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 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 has applied for accreditation activities for an industry or regulator specific program, then the requirements set by that industry group or by regulators for accreditation bodies shall also be considered.

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
- Normally one witness of an initial assessment or a re-assessment of a CAB for every scope (see clause B 2.3 of this annex) or two surveillances
- 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.

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 witnessing assessments	TL + 4 TM
Tuesday	Office + witnessing staff + witnessing assessments (split evaluation team)	TL + 4 TM
Wednesday	Office + witnessing staff + vertical audits + witnessing	TL + 4 TM

Day	Actions	Evaluators
	assessments (split evaluation team)	
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.

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

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

The evaluation team needs to spend time on reviewing the AB's 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. Finally the TL shall prepare a recommendation to the Decision Making Group. Typically these activities may take 2-3 days for the TL. For TMs, the time involved may be limited to 0.5 days.

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

1. **Preparation of the summary section of the report** (see B.3 of this annex) including as an appendix the nonconformities, concerns and comments presented, preferably in table format. This shall be completed and confirmed with the applicant at the end of the on-site evaluation visit.
2. **Preparation of the draft report of the on-site evaluation visit** (within 2 months after closing of the on site evaluation). This report is the agreed report of the evaluation team and the accreditation body and includes the results of the witness activities. This includes the full text of the summary section of the report.
3. **Formal response of the accreditation body to the findings** (within one month of step 2 for re-evaluations and three months of step 2 for initial evaluations and extensions of scope). 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 section C below as to what is expected of the AB's response and corrective action).
4. **Formal reaction of the evaluation team to this response** (within one month of step 3). The evaluation team's reaction to each response to every finding shall be submitted in writing to the accreditation body for consideration.
5. **Steps 3 and 4 may be repeated.**
NOTE: Any problems completing steps 3 or 4 should be reported to the Chair of the MC.
6. **Preparation of a final report to the Arrangement Group** (within one month of step 4). This report consists of the items identified under steps 2, 3 and 4 (i.e., formal evaluation team report, formal AB response and formal evaluation team reaction). In addition, the recommendation of the evaluation team is stated as the leading page of the evaluation team's final report. Items included in steps 3 and 4 should be combined into one table stating the non-conformities/concerns, the formal AB response including corrective actions, and the evaluation 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

1. 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 organization to which they belong, and a clear indication that the report is confidential.

2. Contents

A page should list the contents of the report, including the appendices.

3. Summary

The name and type of accreditation body and the organizations involved in the evaluation shall be given. The summary should include the next steps in the process, any recommendations and reference to the non-conformities, concerns and comments and shall be signed by all team members.

4. 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 witnessed and institutions visited.

5. Background on the accreditation body

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

6. Performance of the system

The subsections of this section are based upon IAF/ILAC A3.

7. Arrangement obligations

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

8. Appendices

8.1 Non-conformities, concerns and comments (to be left at the end of the on-site evaluation visit).

8.2 Lists of documents supplied before evaluation

- 8.3 Evaluation program and agenda
- 8.4 Organization chart of the accreditation body
- 8.5 List of witnessed assessments with the type of conformity assessment bodies involved and their accreditation scopes, and type of assessment identified
- 8.6 Declaration of confidentiality statement signed by all team members and observers

NOTE.: If reference is made to appendices in the full report a clear indication to the specific appendix number that is referenced shall be included.

C. Guidance on Classification of Findings

Finding: To be used as a general term

Non-conformity: Finding where the AB does not meet a requirement of the applicable standard (ISO/IEC 17011), its own management system and the Arrangement requirements.

The evaluated AB is expected to respond to each non-conformity by taking appropriate corrective action and providing the evaluation team with evidence of effective implementation.

Concern: Finding where the AB's practice may develop into a non-conformity. The evaluated AB is expected to respond to a concern by providing the evaluation team with an appropriate action plan and time schedule for implementation.

Comment: Finding about documents or AB's practices with a potential of improvement; but still fulfilling the requirements. The evaluated AB is encouraged to respond to comments.

ANNEX 6: 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:

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 listed members of the respective MC(s).
- 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.

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 "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.
- 2.2** Decisions on applications from affiliated bodies 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.¹
- 2.3** The IAF MLA Group and ILAC Arrangement Council make 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.
- 2.4** 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);

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

- ◆ 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; or
- ◆ 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.

2.5 Decisions on signatory unaffiliated single accreditation bodies:

- ◆ Approval without conditions (re-evaluation to occur 4 years hence);
- ◆ Approval with conditions (e.g., shortened interval for re-evaluation, completion of one or more ILCs);
- ◆ Defer re-approval pending submittal of required evidence of corrective actions and/or re-visit by one or more members of the evaluation team;
- ◆ Suspension or withdrawal of recognition for one or more scopes of the Arrangement; or
- ◆ Withdrawal of a scope(s) of the Arrangement or signatory status, subject to Appeals Process. In this case a new application and evaluation would be required to re-enter the Arrangement.

ANNEX 8: 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.

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.

2.3 No member of the Appeals Panel shall have been involved in the evaluation team that evaluated the appellant, 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.

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, the MC and the appellant, 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.

ANNEX 9: 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 4).
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 Annex 1, 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 annex 10, clause 1).
6. Re-evaluation visits should be led by an evaluation team, in which the majority of members will not have been on the evaluation team that undertook the previous evaluation.

ANNEX 10: Maintenance, Suspension and Withdrawal of IAF and/or ILAC Signatories**1. Notification of change**

Each signatory of the IAF/ILAC Arrangement shall report any significant changes in its status and/or its operating practices (e.g. as listed below) without delay to all IAF and/or ILAC signatories through the MCs.

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

2. Maintenance, suspension and withdrawal

- 2.1** 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.
- 2.2** 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.
- 2.3** 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.
- 2.4** The suspended or withdrawn accreditation body may appeal the decision in accordance with Annex 8.

- 2.5** If the accreditation body is suspended, the accreditation body shall advise its accredited bodies of any consequences for the CABs accredited before the suspension, depending on the resolutions of the Decision Making Group. Any new accreditation by the accreditation body during the suspension period is not covered by the Regional Group Arrangement and not recognized by IAF and/or ILAC.
- 2.6** If the signatory status of the accreditation body is withdrawn, the accreditation body shall inform all applicants and accredited CABs that the accreditation is no longer accepted under the Regional Group Arrangement and the IAF/ILAC Arrangement and the CABs shall no longer make reference to the Regional Group Arrangements and to the IAF and/or ILAC Arrangements.
- 2.7** 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.