



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

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## **PREAMBLE**

The international community of accreditation Regional Groups, recognized Accreditation Bodies, and their stakeholders cooperate through the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum, Inc. (IAF). A principal objective of ILAC and IAF is to put in place world-wide, multi-lateral Mutual Recognition Arrangements (Arrangements). Both ILAC and IAF 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.

ILAC and IAF are linking the existing multi-lateral, mutual recognition Arrangements of the regional accreditation cooperations (Regional Groups) and are encouraging the development of new Regional Groups to complete world-wide coverage. For the purposes of their Arrangements, both ILAC and IAF delegate authority to their “recognized” 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 ILAC and IAF Arrangements in that territory. Formal “Recognition” of a Regional Group with respect to the ILAC and IAF Arrangements is based on an external Evaluation of the Regional Group’s competence in mutual recognition Arrangement management, practice and procedures by a team composed of evaluators from other ILAC and IAF Member Regional Groups and Accreditation Bodies.

Evaluation relating to the development and maintenance of the ILAC and IAF 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 mutual recognition Arrangements.

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

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

## **PURPOSE**

To provide the ILAC and IAF with general requirements for evaluating single Accreditation Bodies for the purpose of qualifying them to sign applicable multi-lateral mutual recognition Arrangement(s).

## **AUTHORSHIP**

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

This latest version was endorsed by letter ballot in ILAC and IAF in 2007.

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## Section 1: Introduction

### 1.1 Scope

This document identifies general requirements for evaluation of a single accreditation body. It has to be used by ILAC and IAF and by Regional Groups. Section 3 is a framework with harmonized procedures. There are ten Annexes to describe in more detail the major steps of the process.

### 1.2 Definitions

- 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 Arrangement:** The ILAC Mutual Recognition Arrangement (Arrangement) or IAF Multi-Lateral Arrangement (Arrangement). The term can also refer to the Arrangements (Arrangements) of “recognized” Regional Groups which pre-date the establishment of the ILAC and IAF Arrangements and which, as a consequence of the “recognition” process, will be accepted as a subset of the ILAC or IAF Arrangements.
- 1.2.3 Regional Group:** A regional cooperation body member of ILAC or IAF. 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.
- 1.2.4 ISO/IEC Standard:** An ISO/IEC standard, guide or technical report related to accreditation and conformity assessment.
- 1.2.5 Peer Evaluation:** A structured process of assessment of a Regional Group or Accreditation Body.
- Note:** In ISO/IEC 17040: evaluation of a body, against specified requirements, by representatives of other bodies in, or candidates for, an agreement group
- 1.2.6 Proficiency Testing Activity:** For the purpose of this document, all those activities used by Accreditation Bodies to assess performance including proficiency tests (refer to ISO/IEC Guide 43, “Proficiency testing by means of interlaboratory comparisons”) interlaboratory comparisons and measurement audits conducted by Regional Groups, Accreditation Bodies, commercial organisations, or other providers.
- 1.2.7 Signatory:** A Member of ILAC and/or IAF who has signed one or more of the multi-lateral, mutual recognition Arrangements of a Regional Group or has signed the ILAC and/or IAF Arrangement.
- 1.2.8 Arrangement Group:** All signatories to the Arrangement (in IAF: Arrangement Group; in ILAC, Arrangement Signatories).
- 1.2.9 Management Committee (MC):** A small group responsible for the everyday management of the Arrangement process (In IAF: IAF Management Committee (MC); In ILAC: ILAC Arrangement Management Committee).

- 1.2.10 MC Secretariat:** Secretariat for the Management Committee (In IAF: IAF Management Committee (MC) Secretariat; in ILAC: ILAC Secretariat).
- 1.2.11 Regional Arrangement Group:** All signatories of an Arrangement of a Regional Group.
- 1.2.12 Decision-making Group:** A body that decides on the status of membership of an Arrangement (In IAF: MLA Group; In ILAC: MRA Council).
- 1.2.13 Evaluation Team Leader (TL):** A person responsible for leading an Arrangement peer evaluation team.
- 1.2.14 Evaluation Team Member (TM):** A person serving on an Arrangement peer evaluation team.
- 1.2.15 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.)
- 1.2.16 Accreditation program/scheme:** accreditation of bodies belong to a conformity assessment program/scheme

## 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. An AB shall operate according to applicable ILAC/IAF guidance documents

2.1.2 An Accreditation body shall also comply with supplementary requirements (see 2. 2) and any applicable requirements and guidance 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 enough experience in the assessment of its accredited organizations 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);

2.2.1.2 Ensure that it meets the suitable requirements for Proficiency Testing Activity (see 2.3);

2.2.1.3 Abide by the requirements and obligations of the applicable regional and international multi-lateral mutual recognition Arrangement(s);

2.2.1.4 Have a programme to promote the Arrangement with major stakeholders; and

2.2.1.5 Contribute its fair share of personnel resources for carrying out peer evaluations at the global level.

2.2.1.6 Have implemented a cross frontier accreditation policy in accordance with IAF GD 3:2003 (for IAF signatories) or taking into account ILAC Guide 21 (for ILAC signatories).

### 2.3 Proficiency Testing Activity

2.3.1 Proficiency Testing Activity is used to determine the performance of laboratories.

2.3.2 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.

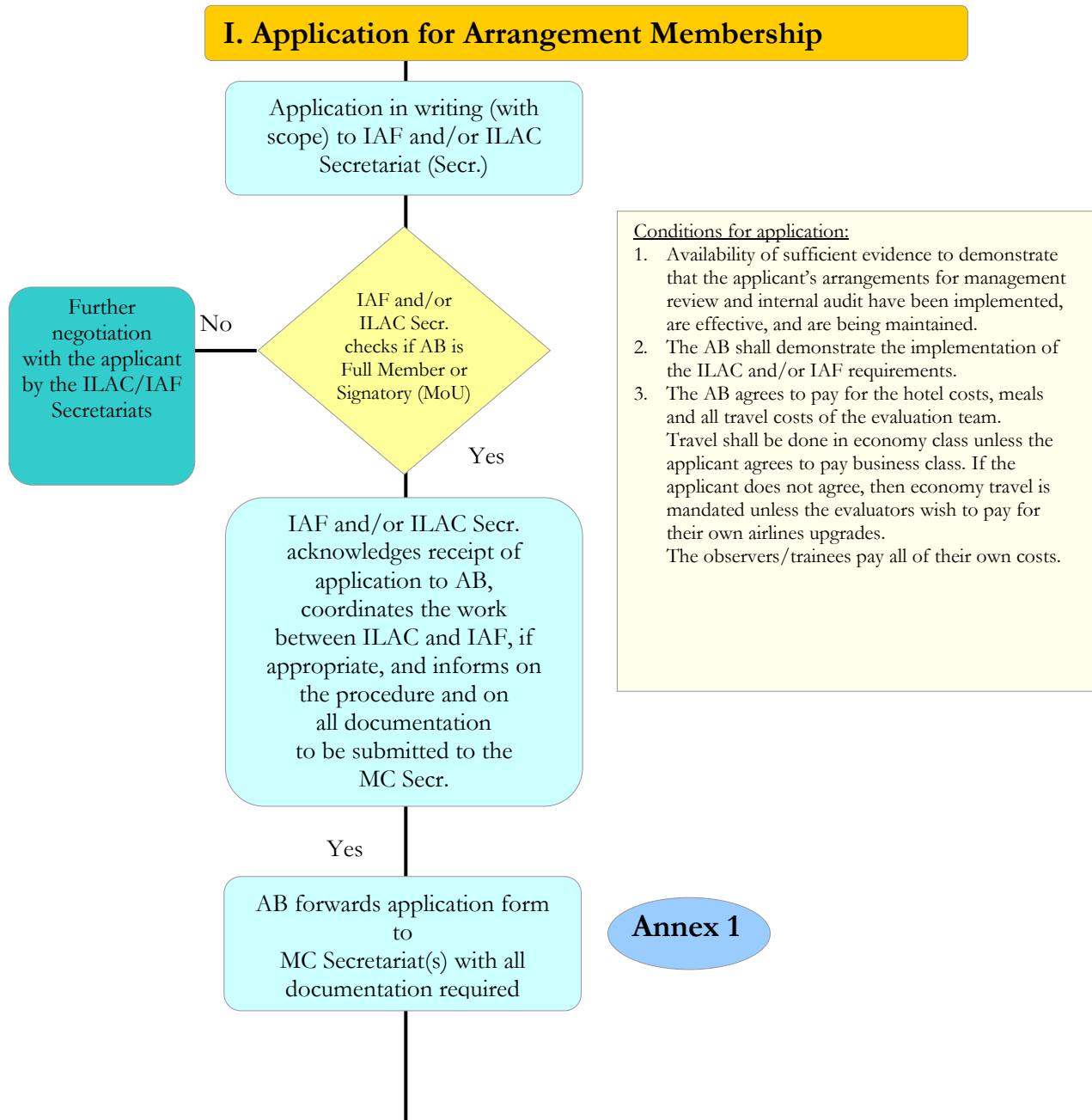
*NOTE One activity prior to gaining accreditation and one activity relating to each major sub-area of major disciplines of a laboratory's scope of accreditation at least every four years is recommended. It is recognised that there are particular areas where proficiency testing is just not practical.*

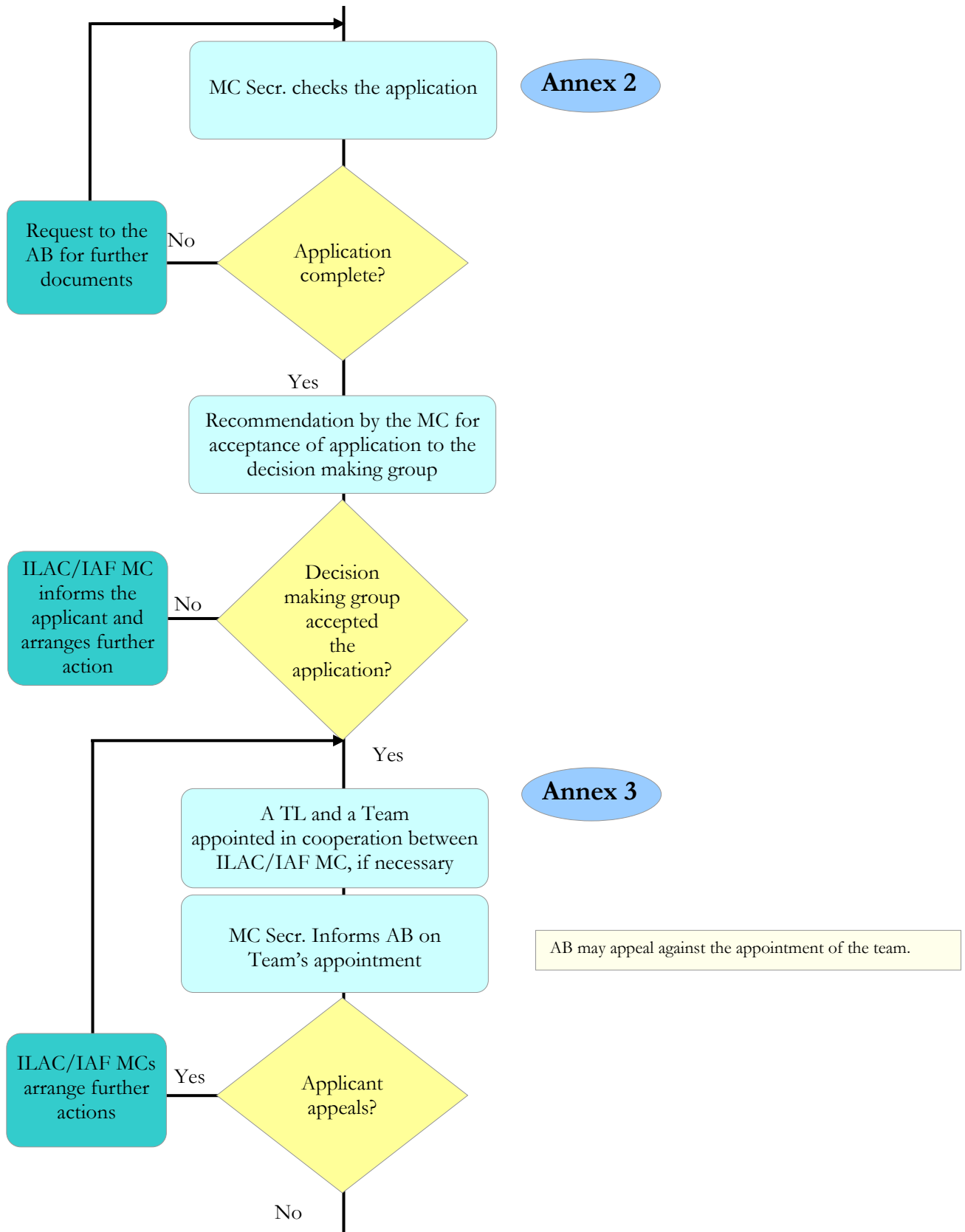
2.3.3 An Accreditation Body shall demonstrate that the Proficiency Testing Activity that its accredited or applicant laboratories undertake is effective, linked to the assessment process and that appropriate corrective action is carried out when necessary.

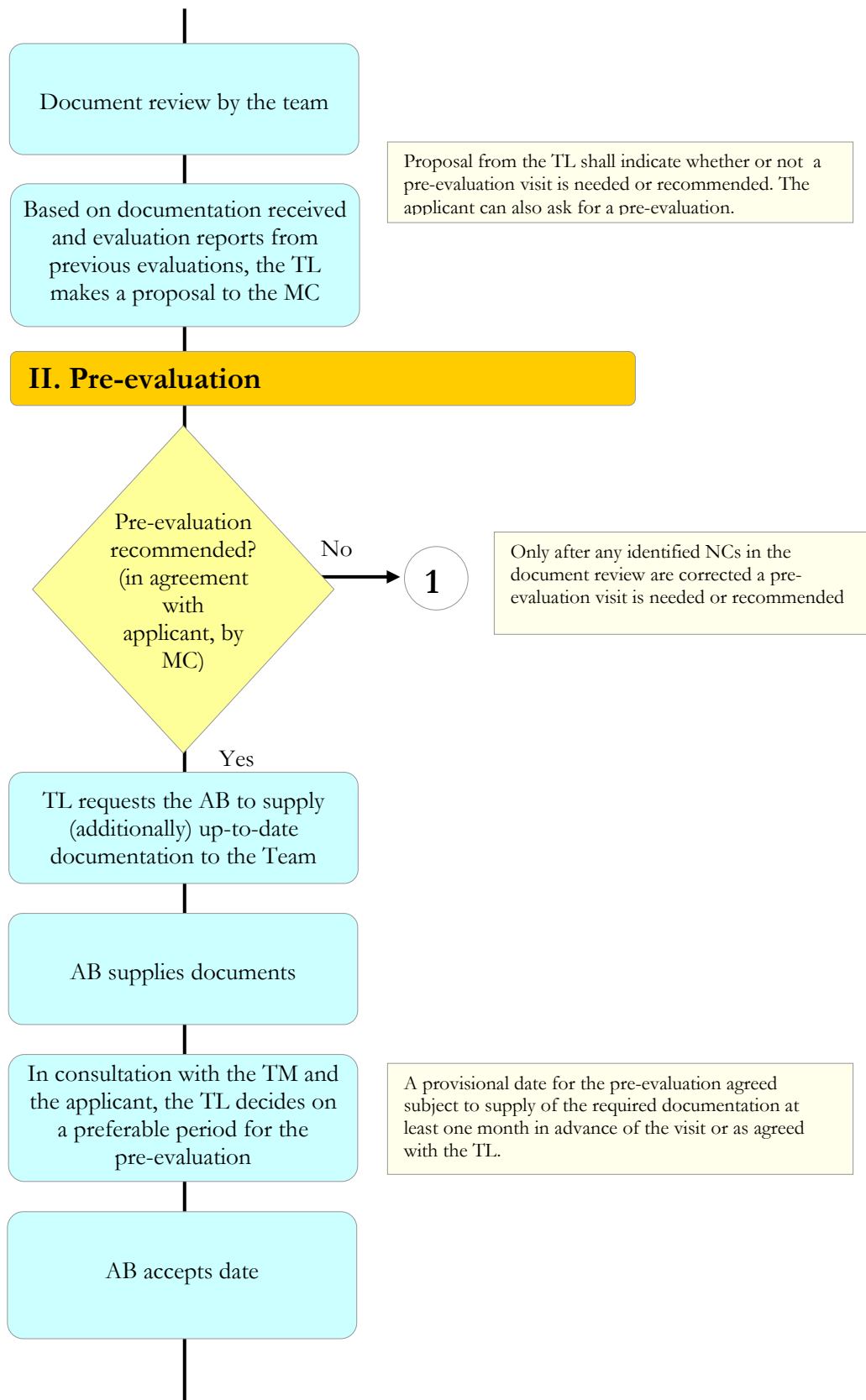
## 2.4 Confidentiality

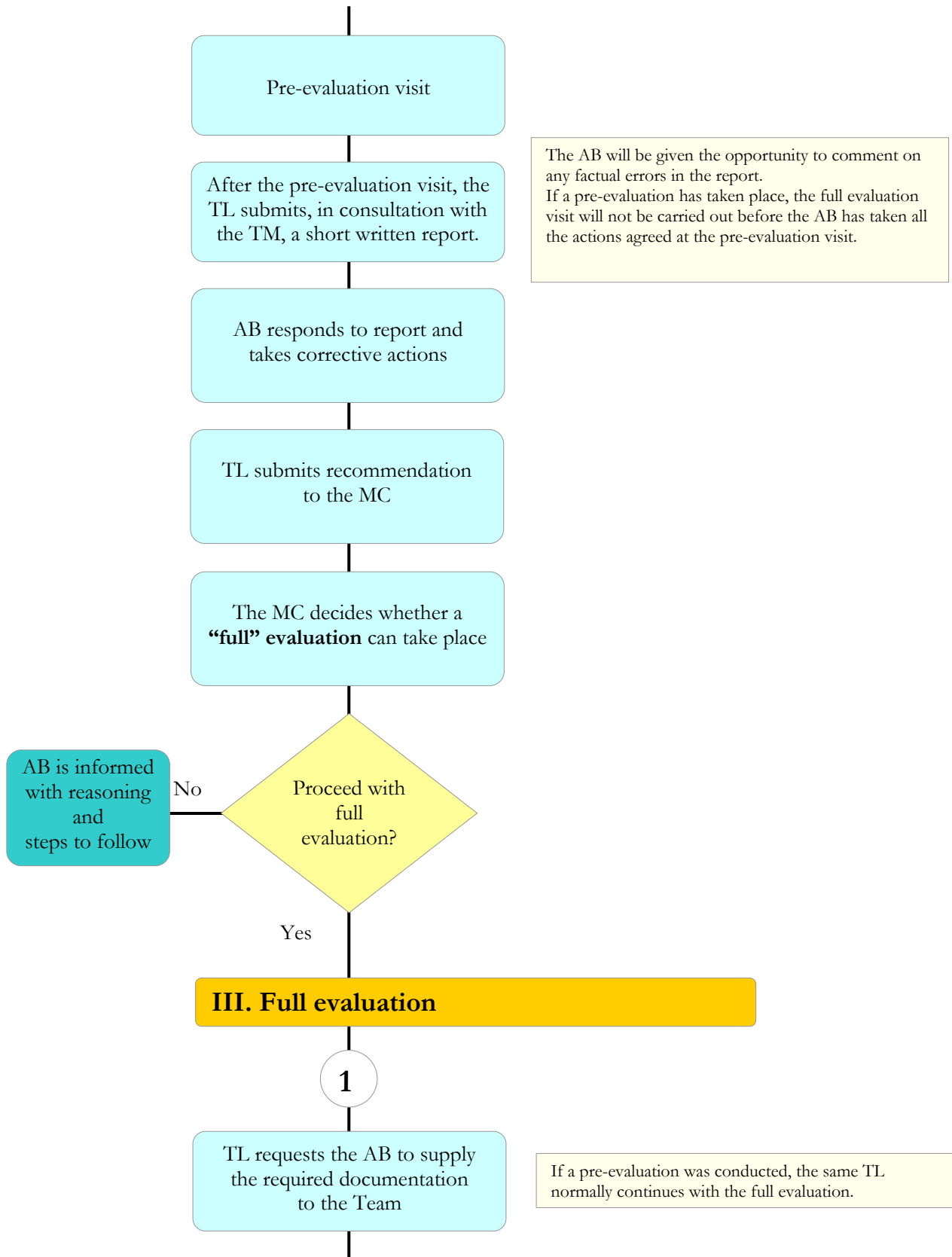
- 2.4.1 All oral and written information received relating to evaluations, re-evaluations, appeals and complaints (except that information which is already publicly accessible) shall be treated confidentially by all parties and persons concerned. This includes information relating to applicants and/or members of the Arrangement Group. All members and observers of the evaluation teams; all members, observers and secretariat personnel of the Management Committee (MC) and the Appeals Panel, other persons having access to confidential information and all applicants and members of the Arrangement Group which request access to any report on pre-evaluation, evaluation and re-evaluation of other applicants and members must have signed a declaration of confidentiality before being given access.
- 2.4.2 Reports on Evaluations, re-evaluations and interim visits may be copied to the representatives of members who have a role to play in decision making. Any such representative must have signed a declaration of confidentiality before being given access.
- 2.4.3 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 Cooperation; or
  - destroy the documentation, when it is determined there is no further need to maintain the documents.

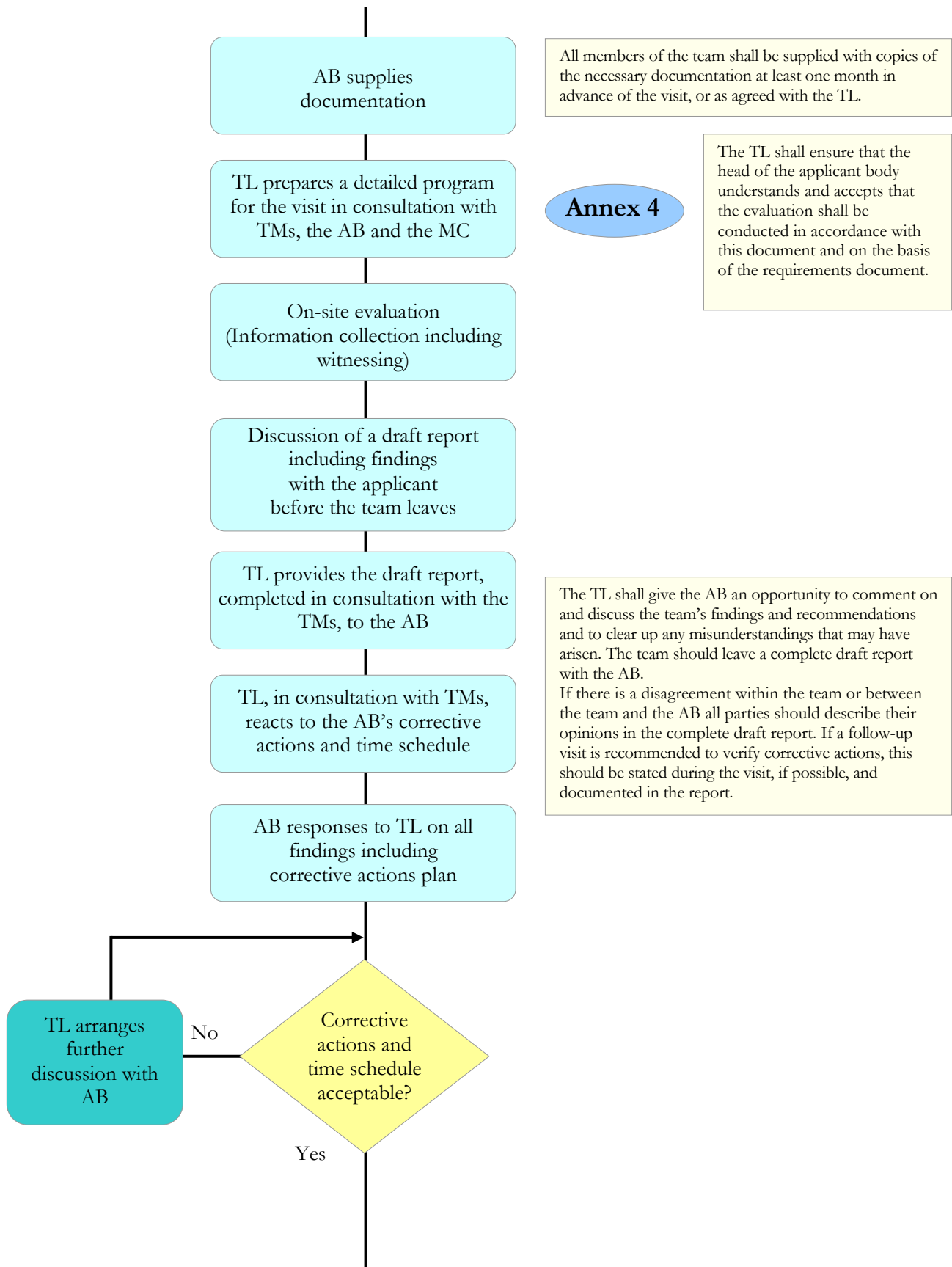
## Section 3: Flowchart for Peer Evaluation Procedures of a Single Accreditation Body

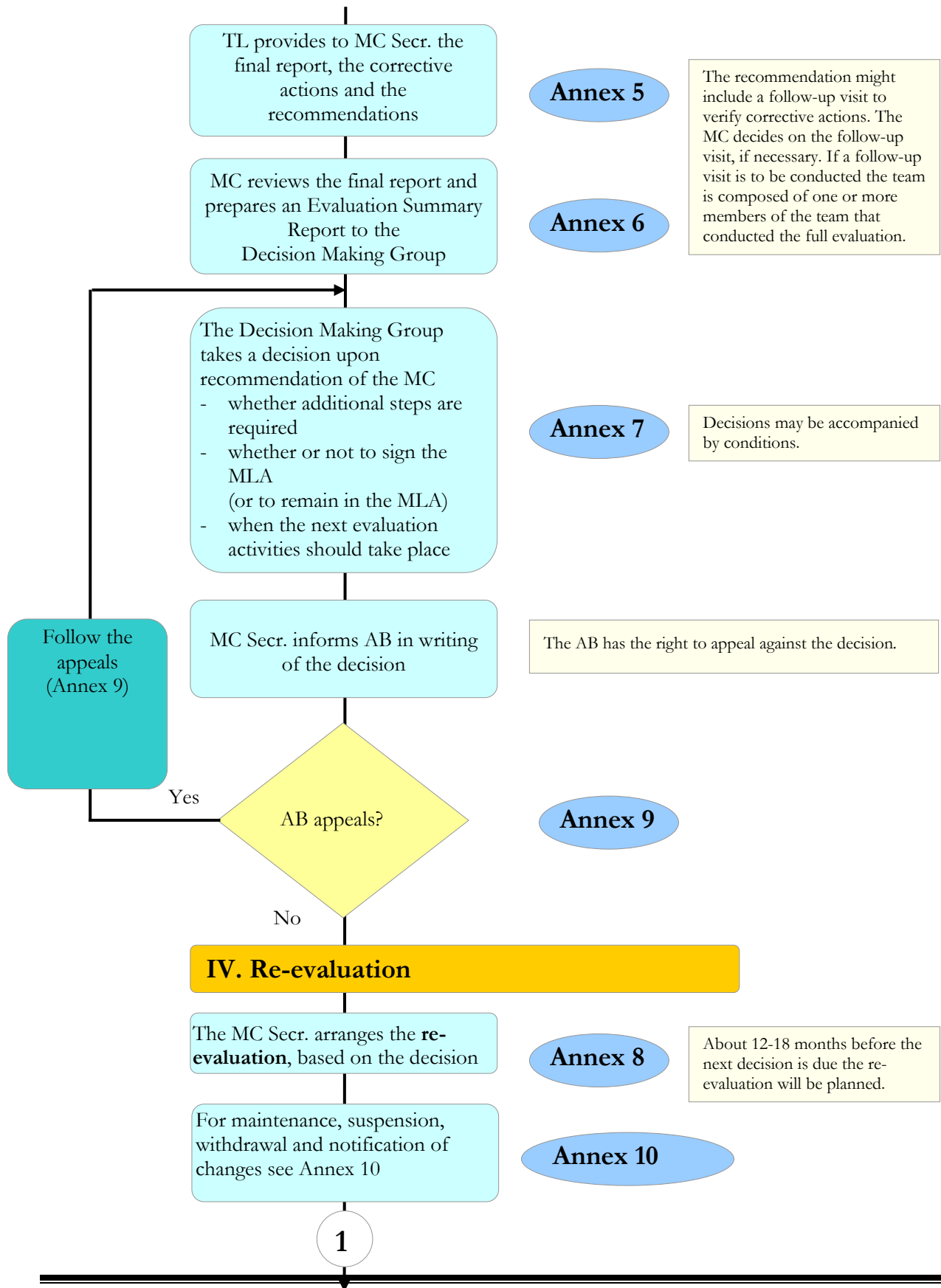












## Annex 1: Application, from a single Accreditation Body (Member of ILAC and/or IAF), to Join the Arrangement

**1. Please tick the Accreditation type being applied for:**

- Accreditation of calibration laboratories (Cal)
- Accreditation of testing laboratories (Test)
- Accreditation of inspection bodies (Insp)
- Accreditation of QMS Certification Bodies (QMS)
- Accreditation of EMS Certification Bodies (EMS)
- Accreditation of Product Certification Bodies (Product)
- Accreditation of Persons Certification Bodies (Persons)

**2. Name of Accreditation Body (Applicant):**

<b>3a. Head Office street address:</b>	<b>3b. Head Office postal address:</b>

**4. Do you have offices other than Head Office?**

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

**5. Economy. (If the applicant conducts accreditation in more than one economy, list all of them):**

**6. Economy falls in the following region (e.g. APLAC, EA, IAAC, PAC):**

If applicable, statement, why the AB wants to join the ILAC/IAF Arrangement:  
(While in principle it should apply to the region to which it belong)

**7. Name of Applicant contact person:**

**8. Position of contact person:**

**9. Telephone (including international access):**

10. Facsimile (including international access):
11. E-mail address:
12. Legal status of Applicant (attach documentary evidence of legal identity):
13. History of the Applicant (Foundation date, operational period, pertinent historical background).
14. Applicant's relationship to government, if any.
15. Membership, if any, in a Regional Group's Arrangement (identify the area of the Arrangement).

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

	Cal	Test	Insp	QMS	EMS	Product	Persons
16. Operational period of the Applicant in the area of the Arrangement applied for.							
17. Accreditation criteria							
18. Number of Staff including management staff and assessment personnel.							
19. Number of accreditations granted in each field (attach a list of the names of the accredited bodies in each field or a link to the database on the internet, if any)							
20. Preferred month and year, if any, for peer evaluation.							

21. Please list all other Operational field(s) of accreditation.
22. Please include one (1) copy via electronic means of each of the following documents written in/translated into English
  - 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 certification/registration bodies shall also be provided, if not contained in the quality manual;
  - all accreditation criteria and associated generally applicable criteria that the applicant publishes;
  - 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;
  - a cross-reference table between each clause, sub-clause or specific requirement of the reference text(s) and the documentation of the applicant.
  - Results of the self assessment based on the A3: KPIs or YES list (IAF-GM-02-001)
  - For ABs for laboratories/inspection bodies a report on interlaboratory comparisons and Proficiency Testing activities

23. Other information related to the integrity of accreditation activity (e.g. other activities of the applicant body, mutual recognition agreements, relationships with other bodies, subcontracting).
24. Please complete the Declaration on the following page.

Please send your completed, signed and dated application, along with all requested documents to

**for IAF MLA:**

BOTH

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53 Manuka Circle  
Cherrybrook NSW 2126  
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## Declaration

As an Accreditation Body Member of IAF and/or ILAC Associate, the Applicant, duly represented by the undersigned:

- 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;
- Applies to join the Arrangement Group(s)

\_\_\_\_\_  
Contact Person's Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

## 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 content filled in the application cover sheet and survey outline: Yes / No

Have all the following documents in English been supplied:

- Quality Manual: Yes / No
- Procedures supporting the Quality Manual: Yes / No
- Statement on the regional group(s) to which the applicant belongs, if any: Yes / No
- Full details of the staffing: Yes / No
- All accreditation criteria and procedures published by the applicant: Yes / No
- All other criteria published, which includes formal rules or regulations that apply to the applicant's operation and the responsibilities and obligations of its accredited bodies: Yes / No
- A cross reference table between appropriate international standards (Guides) and the applicant's quality system documentation): Yes / No
- Results of the self-assessment based on the A3: KPIs/ YES list Yes / No
- For ABs for laboratories/inspection bodies a report on inter-laboratory comparisons and PT activities Yes / No

6. Others, 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

## **Annex 3: Appointment, composition and requirements of the qualifications and personal attributes of peer evaluation team leaders and members**

### **1 APPOINTMENT AND DUTIES OF TEAM LEADER**

- 1.1** In appointing team leaders 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 used.*

- 1.2** Team leaders shall be chosen from a list of team leaders prepared and kept up-to- date by the MC. 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 MC. 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 IAF/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.

*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 Authorized Committees shall approve and oversee their performance in accordance with the criteria in the following sections.

3.1.2 IAF/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 IAF/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 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 organization 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 Authorized Committees shall approve team leaders for a three-year term.
- 3.2.4 Authorized Committees shall arrange periodic meetings for team leaders 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 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 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 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 organization.
- 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 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 despite pressure to change that is not based on evidence.

## 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 exists a large variety of circumstances under which an evaluation will take place, it should be the prerogative of the TL to deviate from the examples shown under 3.2.1 of this Annex. 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 of this Annex or when additional team capacity is required, the Arrangement Group secretariat 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

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/observing

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

At present 7 scopes of Arrangement are recognized:

- Calibration Laboratories
- Testing Laboratories
- Inspection bodies
- QMS Certification bodies
- EMS Certification bodies
- Product Certification bodies
- Personnel 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 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 (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 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.

## 2.5 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 the assessment planning. This gives the team the opportunity to carefully select and plan the witnessing/observation 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 arrangements.

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**

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 (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 shown on the following page.

**3.2.1 Full size scope AB**

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

**3.2.3 ABs with 2 scopes of accreditation**

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

**3.2.4 ABs with 3 fields of accreditation**

Day	Actions	Evaluators
Sunday	>= 4 hours for preparation with the team (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 +	TL + 3 TM

Day	Actions	Evaluators
	witnessing/observing assessments (split team)	
Friday	Preparation final Report + closing meeting + Discussing further actions for TMs + departure	TL + 3 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 labs, during a five day evaluation. The emphasis should be on witnessing enough to have confidence in the accreditation process, and very good confidence in the competence of the accredited bodies.

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.

## Annex 5: Evaluation Reporting on a Single Accreditation Body

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### 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 IAF Yes List and 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 Appendices**

**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

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**

<b>Finding</b>	To be used as a general term
<b>Nonconformity:</b>	Finding where the AB does not meet a requirement of the applicable standard (ISO/IEC 17011), its own management system or the Arrangement requirements in a way that discredits its competence or jeopardizes the quality of its work. The evaluated AB is expected to respond to any nonconformity by taking appropriate corrective action and providing the team with evidence of implementation.
<b>Concern:</b>	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.
<b>Comment:</b>	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 organizations):

**Findings of the evaluation team (nonconformities, 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 the listed members of the respective Management Committee(s).

1.2 The Management Committee(s) shall prepare a summary report for the Decision-making Group(s) 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 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-organisations.*

*NOTE 2 For voting rules see the By laws of ILAC/IAF.*

### 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/IAF-recognized Regional Accreditation Body Cooperations 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 recognized Regional Cooperation. This becomes a prerequisite to signing and maintaining Signatory status with the Arrangement.<sup>1</sup>

2.3 The ILAC Arrangement Council and IAF Arrangement Group 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:

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))

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

- 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 or IAF MLA Group 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. The Signatory under re-evaluation shall provide the evaluation team with all the documents which are required for an initial evaluation (see Annex 1, chapter 22).  
In addition the evaluation team shall get the full evaluation report from the last evaluation/re-evaluation or any special evaluation.
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.

## Annex 9: 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 ILAC and IAF 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 ILAC and/or IAF Secretariat.
- 2.2 After authentication of the appeal, the ILAC/IAF Secretariat shall inform the ILAC/IAF Chairmen, who will, in conjunction with the Chairmen of the Management Committee (MC), appoint an Appeal Panel comprising two impartial full members of ILAC/IAF and one ILAC/IAF evaluator from outside the applicant Cooperation to investigate the appeal.
- 2.3 No member of the Appeals Panel shall have been involved in the peer evaluation team that evaluated the appellant, or have a direct interest in the subject of the appeal, in any form. The ILAC/IAF 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 Chairmen, in conjunction with the Management Committee (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 AB's appeals against suspension or withdrawal of a signatory, 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 at the longest and inform the Chairmen, the Management Committee (MC) and the appellant, in writing, of the recommendation not later than five (5) business days after the date of decision.
- 3.2 The Management Committee (MC) shall forward the recommendation to the Arrangement Group for a decision.
- 3.3 That decision shall be final.

## **Annex 10: Maintenance, suspension and withdrawal of ILAC/IAF unaffiliated body signatories**

### **1 Notification of change**

Each Arrangement Group member shall report any significant changes in its status and/or its operating practices (e.g. as listed below) without delay to all Arrangement Group members through the Management Committee (MC).

- 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 Management Committee (MC) can not accept the corrective action taken by an AB with regard to the significant changes notified by the AB or major nonconformities which have been found or substantiated complaints from interested parties. The Management Committee (MC) shall report the situation to the Arrangement Group with a recommendation and ask the Arrangement Group to take appropriate action. This action can be suspension for a maximum period of 6 months or withdrawal from the Arrangement Group.

**2.2** Maintenance, suspension or withdrawal of a signatory shall be decided by the Arrangement Group after receipt of the recommendation by the Management Committee (MC) in accordance with the same procedures used for acceptance of an Arrangement Group member. Any suspension or withdrawal decided by regional Arrangement Group shall be accompanied by an appropriate explanation stating the reason for suspension or withdrawal to the signatory.

**2.3** The suspended or withdrawn AB may appeal the decision in accordance with Annex 9.

- 2.4 If the AB is suspended the AB must inform its accredited bodies there is no consequences for the CABs accredited before the suspension. Any new accreditation by the AB during the suspension period are not covered by the Arrangement and not recognized by ILAC/IAF.
- 2.5 If the signatory status of the AB is withdrawn the AB has to inform all applicants and accredited CABs that the accreditation is no longer accepted under the regional Arrangement and the ILAC/IAF Arrangement and the CAB shall no longer make reference to the regional Arrangement and to ILAC/IAF Arrangement.
- 2.6 When a withdrawn AB applies to become an Arrangement member again, the procedure for new applicants must be followed.

**Note:** This procedure for maintenance, suspension and withdrawal for single ABs which are not signatories of a regional Arrangement shall be carried out by ILAC/IAF.