



The route to signing the IAF or ILAC Arrangements

Good Practice Guidelines for Single Accreditation Bodies







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Authorship

This document has been prepared by IAF CMC and ILAC MCC





1. Purpose

This document in combination with IAF/ILAC-A2, provides good practice guidelines for the evaluation process of single Accreditation Bodies (AB, applicant), for the purpose of qualifying them to sign the IAF Multilateral Recognition Arrangement (MLA) or the IAC Mutual Recognition Arrangement (MRA).

This guideline deals with the evaluation procedure for a single accreditation body applying to sign the IAF MLA or ILAC MRA directly, because either a Regional Accreditation Group does not exist in that region, or the Regional Accreditation Groups are not recognised via the IAF/ILAC Arrangement for the required scopes. The described procedure is also used by the Regional Accreditation Groups, namely APLAC, EA, IAAC, and PAC for evaluation of their members of the Arrangement. This is a requirement of IAF/ILAC-A1.

The objective of the guideline is to highlight the steps in the application and evaluation process to enable single AB members of IAF and/or ILAC to sign the Arrangement. The intention is to help new accreditation bodies in IAF and ILAC and also newcomers in Regional Accreditation Groups to better understand the evaluation process.

If the accreditation body is eligible to be a member of a Regional Accreditation Group which is recognized via the IAF/ILAC Arrangement, then the accreditation body must apply and go through the evaluation process via this Regional Accreditation Group. On gaining signatory status to the Regional MLA or MRA (where this Regional Accreditation Group is a recognized member in the IAF and/or ILAC Arrangement); and providing the accreditation body is a member of IAF and/or an Associate member of ILAC, it is then able to apply to become a signatory to the IAF MLA and/or ILAC MRA for the same scope they have gained signatory status to the Regional MLA/MRA. This signatory status to the IAF or ILAC Arrangement can then be achieved by the completion of paperwork only, ie. no additional IAF/ILAC evaluations are required.

A flow chart of the major steps of the process is given in the APPENDIX.



2. Overview of the organizations of IAF and ILAC

The most important role of IAF and ILAC is to demonstrate the equivalence of the operation of the AB members. A Peer Evaluation System is used as the control mechanism to ensure constantly competent services are delivered according to harmonized standards. Upon positive evaluation outcome, the accreditation body may sign the Arrangement between accreditation bodies, confirming systematic reliability and competence of the results produced by accredited organizations to the market.

For this Arrangement different terms have emerged, MLA (Multilateral Recognition Arrangement) is used by IAF, whereas MRA (Mutual Recognition Arrangement) is used by ILAC.

Figure 1 highlights the organizational structure of IAF and ILAC and displays the present scopes of the Arrangements (also called accreditation types). At present, the IAF and ILAC Arrangements cover the following five scopes:

- Certification body accreditation for Quality Management System (QMS), ISO 9001 (IAF)
- Certification body accreditation for Environmental Management System (EMS), ISO 14001 (IAF)
- Certification body accreditation for Food Safety Management Systems (FMS), ISO 22000 (IAF)
- Certification body accreditation for Information Security Management Systems (IMS), ISO 27001 (IAF)
- Certification body accreditation for Medical Devices, ISO 13485 (IAF)
- Certification body accreditation for products (IAF)
- Testing laboratory accreditation, ISO/IEC 17025, ISO 15189 (ILAC)
- Calibration laboratory accreditation, ISO/IEC 17025 (ILAC)

The Arrangement for Persons Certification Bodies in IAF and the Arrangement for Inspection bodies in ILAC are currently under development. In both organizations, three committees work for the purpose of the Arrangement.

- **IAF MLA Committee/ILAC Arrangement Committee:**
In these committees the evaluation rules, policies and procedures and questions relating to the Arrangements are discussed. All members of IAF/ILAC interested in the Arrangement are participants in these committees.
- **Management Committees (IAF MLA MC, ILAC AMC and Joint MC):**
In these committees the evaluations are managed and organized. The committees consist of only a few members who manage the day to day activities of the evaluation process. The Management Committees are supported by a Secretariat.
- **IAF MLA Group/ILAC Arrangement Council:**
These are the Decision Making Groups in IAF and ILAC. These groups consist of all the signatories to the Arrangement, and decide on the status of the signatories to the Arrangement on the basis of the evaluation results (in the case of ILAC, the Associate members may participate in the Council, but do not have voting rights).

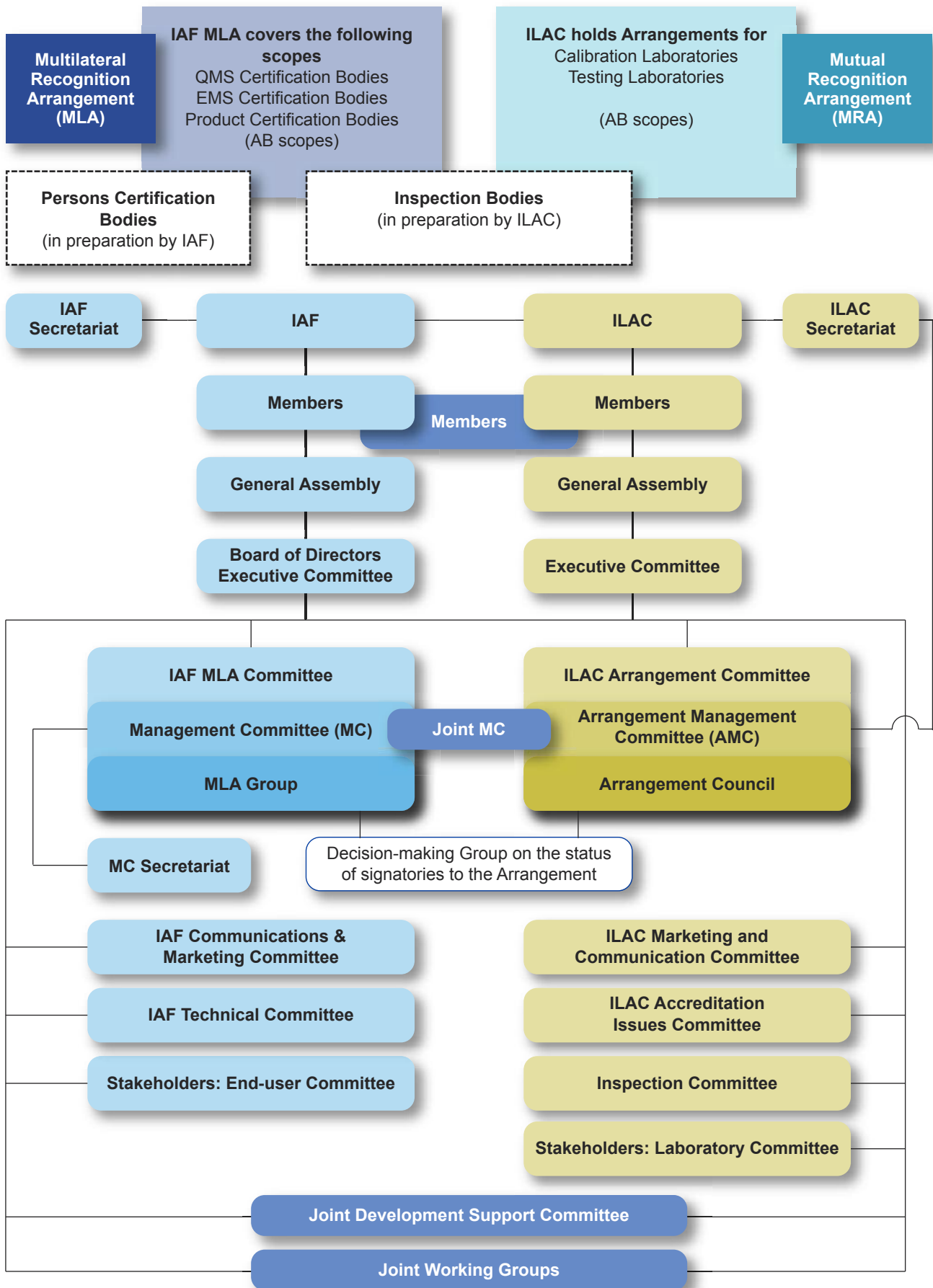


Figure 1: Overview of the organizational structure of IAF and ILAC



3. Prerequisites and requirements for application

(corresponding to Appendix 0)

The key question an AB faces at the beginning is "Which conditions have to be met so that our AB can apply to be a signatory to the Arrangement?"

First of all, the AB has to fulfil a number of prerequisites in order to file an application, i.e. the AB has to

- be a member in
 - IAF (Accreditation Body Member; see IAF-MM-07) and/or
 - ILAC (*preferably Associate*; see ILAC-R2) and
- pay membership fees in its category; see IAF PL 4

The accreditation body shall also comply with ISO/IEC 17011 and applicable IAF/ILAC documents. The accreditation body is required to have undertaken a self-assessment based on IAF/ILAC A3 Narrative Framework for Reporting on the Performance of an Accreditation Body.

In addition, the AB shall (*see also IAF/ILAC-A2, Section 2*) meet the following requirements:

- have carried out at least one accreditation in each of the accreditation scopes for which it applies
- for laboratory ABs: meet the suitable requirements for Proficiency Testing as defined in ILAC P13
- have implemented a cross frontier accreditation policy in accordance with
 - IAF GD 3: (IAF signatories) and/or
 - ILAC-G21: (ILAC signatories)
- agree to pay the expenses of hotel, meals and travel of the evaluation team but not of observers/trainees; this applies to pre-evaluations, full evaluation, and re-evaluations
- offer relevant training for AB staff and be prepared to contribute personnel resources for carrying out peer evaluations in other ABs of the Regional Arrangement Group, ILAC or IAF.

The AB shall prepare the entire documentation written in or translated into English (*see IAF/ILAC-A2, Annex 1 pt. 22*) and provide this documentation as required.



4. Application for Arrangement Membership

(corresponding to Appendix I)

Once the AB has laid the foundations, it is now ready to apply. At this point, most likely the question arises “What steps are necessary to file an application for the Arrangement?”

The AB applies in writing to IAF and/or ILAC Secretariat including the Accreditation type(s) or scope being applied for (*see IAF/ILAC-A2, Annex 1, pt 1*). The IAF/ILAC Secretariat checks if the AB is a member.

Upon acknowledgement by the IAF/ILAC Secretariat, the AB forwards the completed application form (*see IAF/ILAC-A2, Annex 1*) accompanied by the entire documentation to the Management Committee (MC) Secretariat.

The MC Secretariat checks the application, and if correct, asks for acceptance of the application by the Decision Making Group (*see IAF/ILAC-A2, Annex 2*).

After acceptance of the application, Team Leader (TL) and Team members are appointed by the IAF/ILAC MC (*see IAF/ILAC-A2, Annex 3*). The MC Secretariat informs the AB of the appointment. The AB has the right to appeal against the appointment of the TL and Team members; however, if it does accept the appointed team, the process starts.

The TL and Team members review the documents and make a proposal to the MC whether or not a pre-evaluation is recommended. The MC decides together with the TL and the AB whether to carry out a pre-evaluation. The AB itself may also request a pre-evaluation.



5. Pre-evaluation

(corresponding to Appendix II)

The aim of a pre-evaluation is to ensure the AB is prepared for the full evaluation and to minimize the number of findings (*for definition see 6*).

The AB supplies the corrected up-to-date documentation requested by the TL (if applicable). The possible need for translators shall be considered.

The TL decides in consultation with the Team members and the AB on a date for pre-evaluation and the schedule. The pre-evaluation visit is performed by the TL and the Team members. At the conclusion of the pre-evaluation visit, the TL consults with the Team members and submits a short written report to the AB. The AB responds to any issues raised in the report and takes corrective actions. The TL provides a recommendation to the MC, which then decides whether to proceed with the full evaluation.



6. Full evaluation

(corresponding to Appendix III)

The steps involved in a full evaluation are described in the flow-chart included in Appendix III.

If a pre-evaluation was conducted, the same TL where possible continues with the full evaluation. The AB provides the documentation as specified in IAF/ILAC-A2, Annex 1. The TL and all members of the Team shall be supplied with copies of this documentation at least 3 months in advance of the visit, or as agreed with the TL.

The TL prepares a detailed program for the visit in consultation with Team members, the AB and the MC (see IAF/ILAC-A2, Annex 4). The TL shall ensure that the manager of the AB agrees that the evaluation shall be conducted in accordance with Annex 4 of IAF/ILAC-A2 and the requirements documents. The evaluation shall take place in the shortest possible time to appropriately cover the scope or range of activities, i.e. at a maximum within one full week (7 days).

The AB is responsible for organizing the relevant activities as agreed with the TL, especially the possible need for translators and the necessary activities for witnessing by the team. Usually, one witness of an initial accreditation or re-accreditation for every accreditation scope or two surveillances are performed. For laboratory accreditation, the evaluation team shall witness at least one initial assessment for each of calibration and testing (where applicable), plus other reassessments as determined by the TL (see IAF/ILAC-A2, Annex 4, pt. 2.3).

At the appointed time, the on-site full evaluation including witnessing takes place. At the end of the visit, the TL in consultation with the team members prepares a summary report including any findings. The TL shall give the AB an opportunity to discuss the team's findings and to clarify any misunderstandings during the evaluation visit. The TL provides the summary report to the AB which is preferably signed by the AB before the departure of the evaluation team.

Following the visit, the TL and the Team members prepare a Draft Report which is provided to the AB.

The AB responds to the TL by supplying a corrective actions plan and evidence of the corrective actions for all non-conformities and concerns (IAF/ILAC-A2, Annex 5 C):

Non-conformity (NC)

Finding where the AB does not meet a requirement of the applicable CEN/ISO/IEC standard(s), its own QM system or the Arrangement rules (obligations) in a way that discredits its competence or jeopardizes the quality of its work. The evaluated AB is expected to respond to a NC by taking immediate corrective action and providing the team with evidence of implementation of the corrective action.



Concern (CN)

Finding where the AB's practice may develop into a NC or the team is not fully satisfied. The evaluated AB is expected to respond to a CN by providing the team with an appropriate action plan and time schedule.

Comment (Cm)

Findings relating to documents or AB's practices with a potential of improvement; but still fulfilling the requirements. The evaluated AB is not required to respond to a Cm but may do so if it wishes.

All non-conformities are closed when the evaluation team agrees with the corrective actions and writes a Final Report. If there is a disagreement between TL, Team members and/or AB, the opinions of parties shall be recorded in the report. A recommended follow-up visit to verify corrective actions, if required, shall also be documented in the report.

The TL forwards the corrective actions of the AB, the Final Report and a recommendation to the MC Secretariat (see IAF/ILAC-A2, Annex 5). The recommendation might include a follow-up visit, if necessary, to verify corrective actions. If a follow-up visit is advised, at least one Team member that was involved in the full evaluation shall be part of the follow-up team.

The MC prepares an Evaluation Summary Report (see IAF/ILAC-A2, Annex 6) including a recommendation to the Decision Making Group. Finally, the Decision Making Group takes a decision as to whether or not the AB meets the requirements to sign the Arrangement (see IAF/ILAC-A2, Annex 7). The decision may be subject to conditions requiring additional actions and also states when the next evaluation activities shall take place.

The MC Secretariat informs AB in writing on the decision.

The AB has the right to appeal against the decision (see IAF/ILAC-A2, Annex 8).



7. Re-evaluation

(corresponding to Appendix IV)

Once the AB is a signatory to the Arrangement, periodic monitoring will be conducted. Typically, a re-evaluation has to be carried out at a maximum interval of 4 years but the Decision Making Group can determine shorter time intervals if needed. The period for the next evaluation will be fixed normally as part of the decision making process.

12-18 months before the next decision is due, the re-evaluation will be planned by the MC Secretariat (*see IAF/ILAC-A2, Annex 9*).

Maintenance, suspension, withdrawal and notification of changes shall be treated according to IAF/ILAC-A2:, Annex 10.

8. Conclusions

This good practice guideline describes how single Accreditation Bodies can become signatories to the IAF MLA or the ILAC MRA. The intention is to assist by providing step-by-step explanation and guidance.

It generally takes some time for an accreditation body to achieve MRA / MLA signatory status. This is not only because the accreditation body has to prepare a substantial number of documents as outlined in this brochure. In addition, during an information and adaptation process which might take several months or even years, the accreditation body itself may have to undergo organizational change within its institution/facility and may also have to exert influence on organizations in its area of responsibility in order to meet the requirements of signatory status to the of IAF/ILAC Arrangements.

The benefits of being a signatory are quite obvious. Accreditation reduces risk for business and its customers by assuring them that accredited bodies are competent, impartial and capable of the work they undertake. Both IAF and ILAC member accreditation bodies are obliged to operate at the highest standards and in turn require the bodies they accredit to comply with appropriate international standards. The aims of the Arrangements are the comparability of certificates and test reports issued under the accreditation of signatories to the IAF/ILAC Arrangements and the worldwide acceptance of these documents. Thus, the Arrangements are to create an international framework to support international trade through the removal of technical barriers.

Valuable information and numerous documents providing additional detail may be found at the websites of IAF (www.iaf.nu) and ILAC (www.ilac.org). Specific questions that may arise throughout the process can be directed to the IAF MLA MC Secretariat (Steve.Keeling@jas-anz.org) or the ILAC Secretariat (ilac@nata.asn.au).



Appendix 0. Prerequisites and requirements for application

To be **fulfilled** by the AB (applicant) **before** application

- Be a member (signatory of Memorandum of Understanding, MoU) in IAF and/or ILAC
- Pay membership fees in its category
- Comply with ISO/IEC 17011 and applicable ILAC/IAF documents
- Have implemented a cross frontier accreditation policy in accordance with IAF GD 3 (IAF signatories) and/or ILAC-G21 (ILAC signatories)

To be **performed/prepared** by the AB (applicant) **before** application

- Self-assessment based on the IAF/ILAC A3
- At least one accreditation in each of the accreditation programs for which it applies
- Only for AB's for laboratories/inspection bodies:* have implemented a policy for proficiency testing activity
- Complete documentation required for application (*see IAF/ILAC-A2, Annex 1*):
 - **Pt. 1 to 21:** Accreditation type being applied for and details on AB
 - **Pt. 22:** One copy of each document in English:
 - Quality manual including policies, procedures and full details of staffing
 - All accreditation criteria and associated generally applicable criteria the applicant publishes
 - All other published criteria (e.g. laws)
 - 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 IAF/ILAC A3

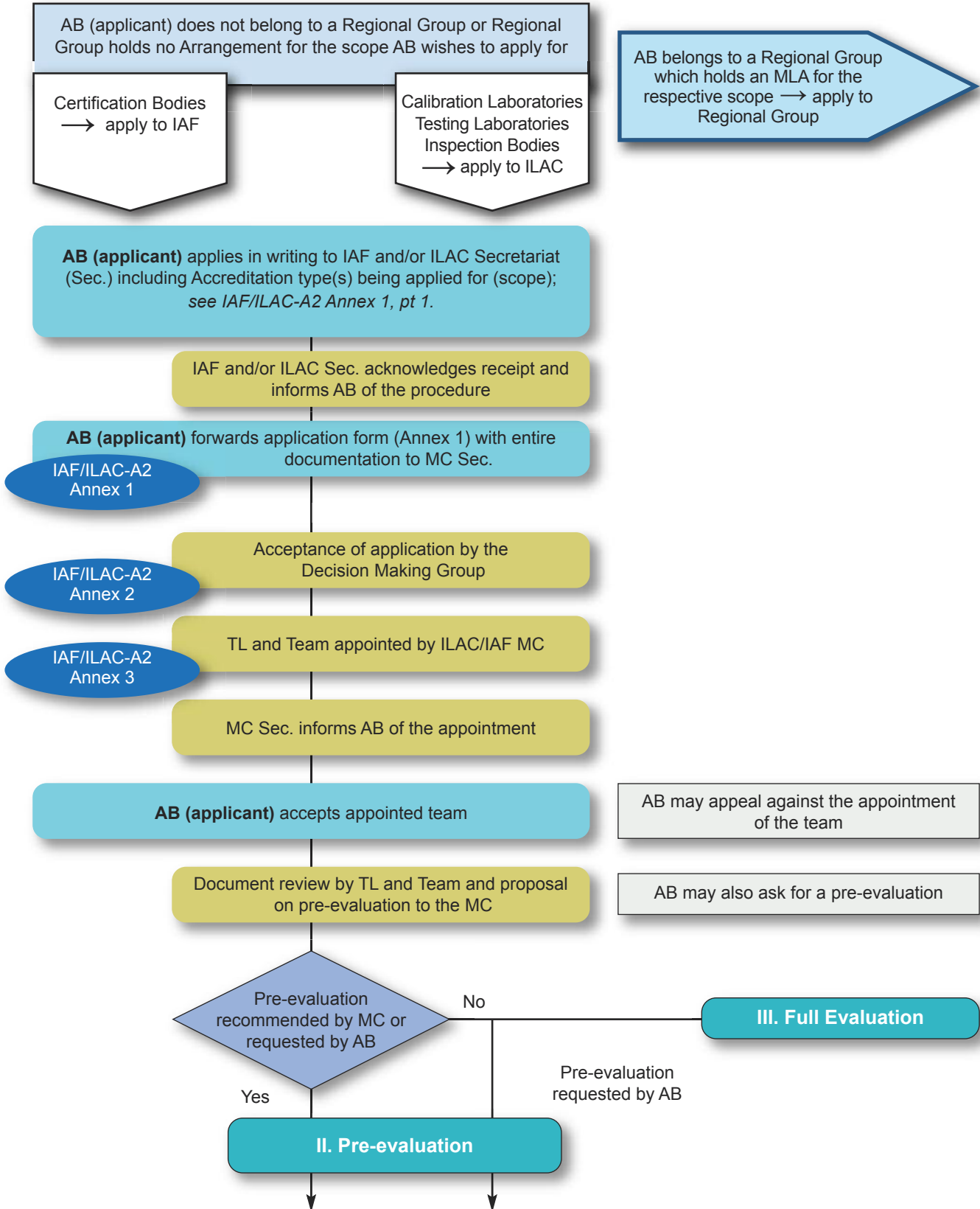
IAF/ILAC-A2
Annex 1

To be **agreed** by the AB (applicant) **before** application

- Pay the expenses of hotel, meals and travel (economy class) of the evaluation team but not of observers/trainees
- Offer relevant training for AB staff and be prepared to contribute personnel resources for carrying out peer evaluations in other ABs of IAF and ILAC



Appendix I. Application for Arrangement Membership





Appendix II. Pre-evaluation

Pre-evaluation recommended by MC

TL requests the AB to supply corrected documentation to the Team

AB (applicant) supplies requested up-to-date documents

TL decides in consultation with the Team and the AB on a date for pre-evaluation

A provisional date for the pre-evaluation agreed subject to supply of the required documentation at least one month in advance of the visit or as agreed with the TL

AB (applicant) accepts date

Pre-evaluation visit

TL consults with the Team and submits a short written report to the AB

The AB will be given the opportunity to comment on any factual errors in the report

AB (applicant) responds to the report and takes corrective actions

Full evaluation visit will not be carried out before the AB has taken all the actions agreed at the pre-evaluation visit

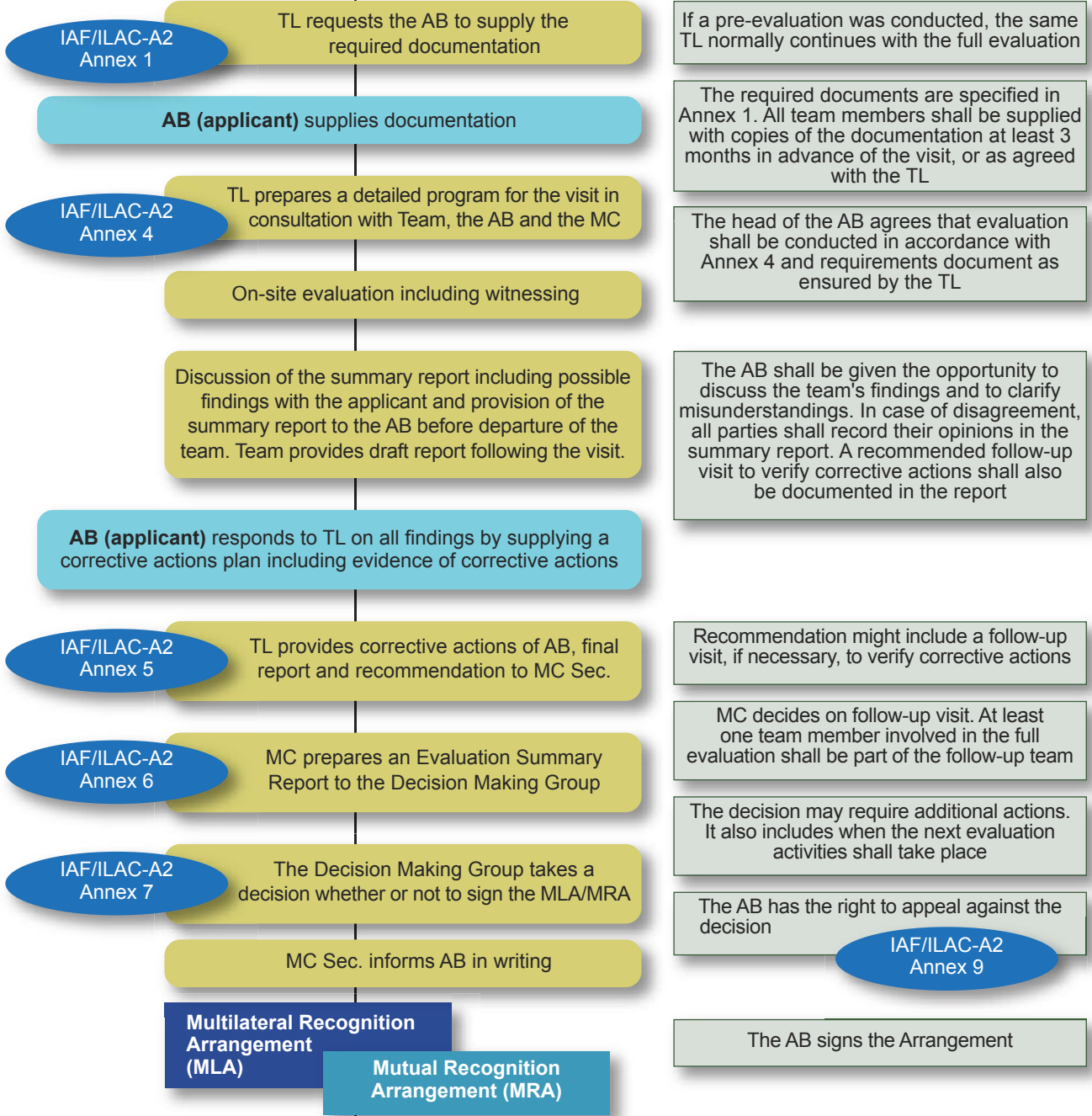
TL submits recommendation to the MC

The MC decides on full evaluation

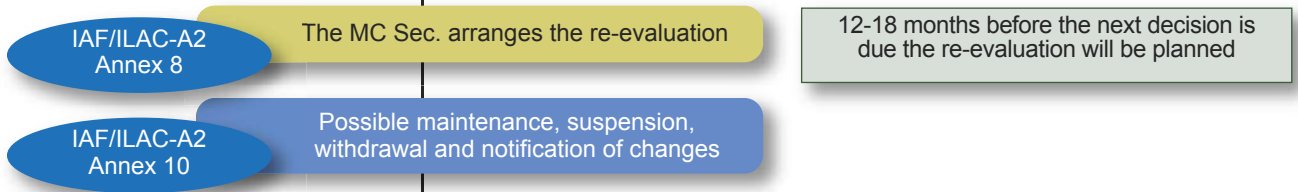
III. Full Evaluation



Appendix III. Full evaluation



Appendix IV. Re-evaluation





References

In all cases the current version of the document is used.

IAF/ILAC-A1

IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements):
Requirements for Evaluation of a Regional Group

IAF/ILAC-A2

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

IAF/ILAC-A3

IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements):
Narrative Framework for Reporting on the Performance of an Accreditation Body – A Tool for the
Evaluation Process

IAF GD 3

Guidance on Cross Frontier Accreditation

IAF-MM-07-002

Application for Membership in IAF

IAF PL 4

Rules for IAF Membership Fees

ILAC-G21

Cross Frontier Accreditation – Principles for Avoiding Duplication

ILAC-R2:2003

ILAC Rules

ISO/IEC 17011

Conformity assessment – General requirements for accreditation bodies accrediting conformity
assessment bodies (ISO/IEC 17011)



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