



The route to signing the IAF/ILAC Arrangement

Good Practice Guidelines for Single Accreditation Bodies



Version 1 2009

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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-A2:05/2007, provides good practice guidelines for the evaluation process of single Accreditation Bodies (AB, applicant), for the purpose of qualifying them to sign applicable Mutual Recognition Arrangement(s).

This guideline deals with the evaluation procedure for a single accreditation body applying directly to the IAF/ILAC Arrangement, because either a Regional Accreditation Group does not exist in that region, or that this Regional Accreditation Group is not a member of the IAF/ILAC Arrangement for the required scopes. The described procedure is also used by the Regional Groups, namely APLAC, EA, IAAC, and PAC for evaluation of their members of the Arrangement. This is a requirement of IAF/ILAC-A1:05/2007.

The objective of the guideline is to highlight the necessary steps through the application and evaluation process and thus 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 Groups to better understand the evaluation process.

If the accreditation body is eligible to be a member of a Regional Arrangement Group which is a member of the IAF/ILAC arrangement, then the accreditation body must apply and go through the evaluation process via this Regional Arrangement Group. On gaining signatory status to the Regional MLA or MRA (where this Regional Group is a recognized member in the IAF and/or ILAC Arrangement), 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, without any additional IAF/ILAC evaluation, by completing an application form only.

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



2. Overview of the organizations of IAF and ILAC

For a better understanding of the procedure on how to approach membership in the Arrangement, an overview of the organization IAF and ILAC is given here.

The most important aim of IAF and ILAC is to demonstrate the equivalence of the operation of their AB members. Evaluation of each other (Peer Evaluation System) is used by these organizations as a control mechanism to ensure constantly competent services according to harmonized standards. Upon a positive evaluation outcome, the accreditation body may join an 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, international Arrangements for five scopes exist:

- 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 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 Joint Arrangement for Inspection bodies in IAF and 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 and procedures and all questions in conjunction with the Arrangement are discussed. All parties from 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 have only few members which handle the evaluation procedure day by day. The Management Committees are supported by a Secretariat.
- **IAF MLA Group/ILAC MRA Council:**
These are the Decision Making Groups in IAF and ILAC. In these groups are all signatories of the Arrangement, and they decide on the membership of 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).

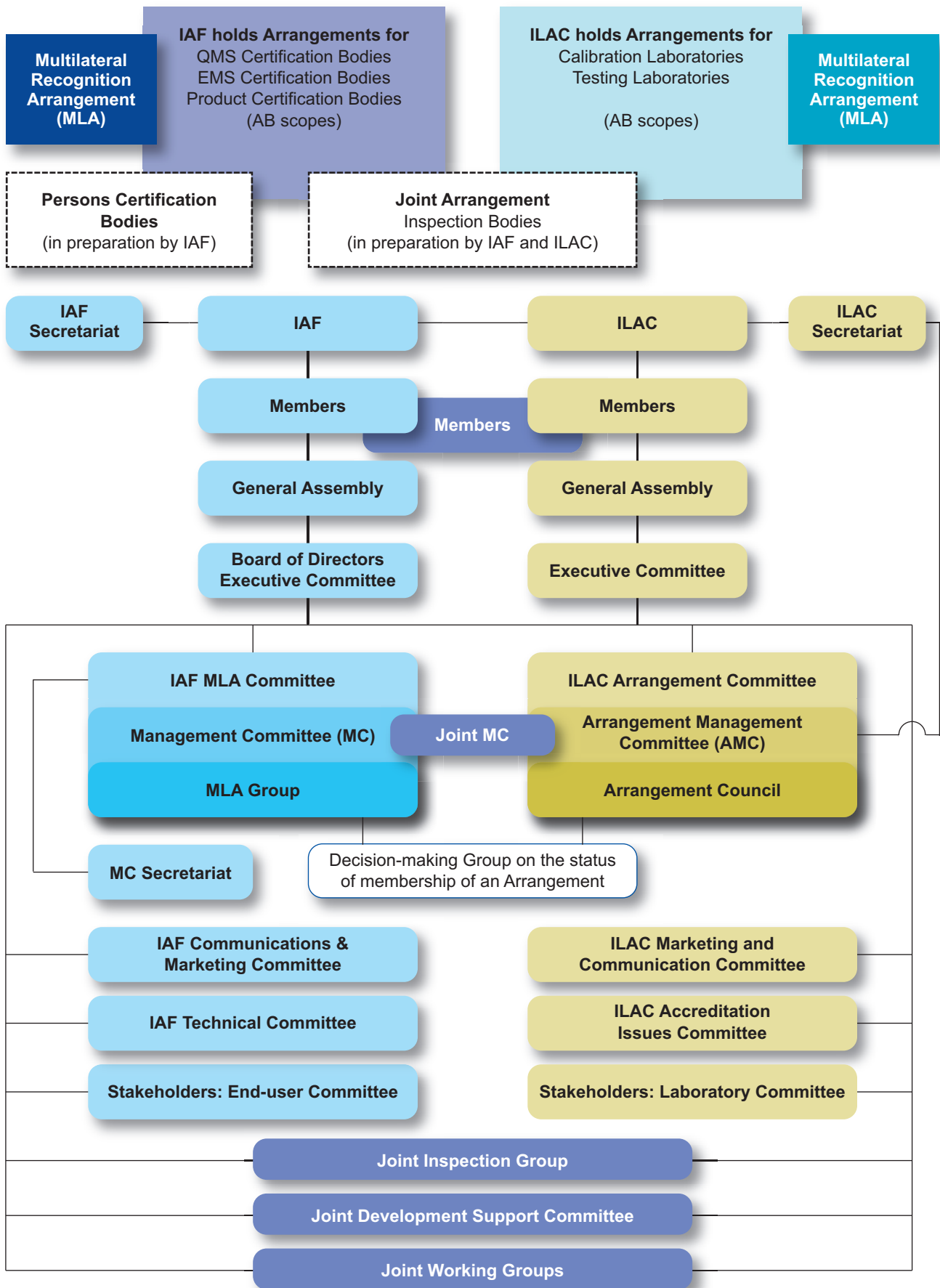


Figure 1: Overview of the organizational structure of IAF and ILAC



3. Prerequisites and requirements for application

(corresponding to Appendix 0)

Probably the key question an AB is facing at the beginning is “Which conditions have to be given so that our AB can apply in 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-07-002* and *IAF PL 4:2004*) and/or
 - ILAC (preferably Associate; see *ILAC-P6:2003* and *ILAC-S2:2003*) and
- pay membership fees in its category.

The accreditation body shall also comply with ISO/IEC 17011 and applicable IAF/ILAC documents. The accreditation body is required to have undertaken self-assessment based on the IAF/ILAC A3 Key Performance Indicators (*IAF/ILAC-A3:05/2007*).

Beyond that, the AB shall (see also *IAF/ILAC-A2:05/2007, Section 2*) meet the following requirements

- comply with any applicable requirements and guidance of the Regional Group to which it belongs, if any
- have carried out
 - a. at least one accreditation in each of the accreditation programs for which it applies
 - b. for laboratory accreditation: at least four (4) accreditations for testing and/or four (4) accreditations for calibration (at present this condition is under discussion, however, the adoption of condition a. also for laboratory accreditation is expected)
- for laboratory ABs: meet the suitable requirements for Proficiency Testing Activity (The minimum amount of proficiency testing required per laboratory shall be specified. 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 every four years are recommended. In particular areas proficiency testing may not be appropriate or available.)
- have implemented a cross frontier accreditation policy in accordance with
 - IAF GD 3:2003 (IAF signatories) and/or
 - ILAC-G21:2002 (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/translated into English (see *IAF/ILAC-A2:05/2007, Annex 1, pt 22*) and hold this documentation ready.



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-A2:05/2007, Annex 1, pt 1*). The IAF/ILAC Secretariat checks if the AB is a member.

Upon acknowledgement by IAF/ILAC Secretariat, the AB forwards the completed application form (see *IAF/ILAC-A2:05/2007, 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-A2:05/2007, Annex 2*).

After acceptance of the application, TL and Team members are appointed by IAF/ILAC MC (see *IAF/ILAC-A2:05/2007, Annex 3*), and 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 (if requested)

(corresponding to Appendix II)

A pre-evaluation can be helpful if the AB has some lack of knowledge and needs additional advice. It may be possible that UNIDO can give some financial aid for the pre-evaluation to ABs from developing economies. To this end, a request should be given to the Joint Development Support Committee.

The aim of a pre-evaluation is to ensure the AB is prepared for full evaluation and to minimize major 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 full evaluation.



6. Full evaluation

(corresponding to Appendix III)

The different steps of a full evaluation are described in the flow-chart 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-A2:05/2007, 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-A2:05/2007, 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-A2:05/2007 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 program 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-A2:05/2007, 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 first summary report including findings, if any. 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 first summary report to the AB which is preferably signed by the AB before departure of the team.

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 **Findings** (IAF/ILAC-A2:05/2007, 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 MLA-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.



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)

Finding about 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-A2:05/2007, 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 conducting the full evaluation shall be part of the follow-up team.

The MC prepares an Evaluation Summary Report (see *IAF/ILAC-A2:05/2007, Annex 6*) to the Decision Making Group which decides whether or not the applicant may enter the Arrangement. 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-A2:05/2007, 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-A2:05/2007, Annex 9*).



7. Re-evaluation

(corresponding to Appendix IV)

Once the AB is a member of 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 after signing the Arrangement by the Decision Making Group.

12-18 months before the next decision is due, the re-evaluation will be planned by the MC Secretariat (see *IAF/ILAC-A2:05/2007, Annex 8*).

Maintenance, suspension, withdrawal and notification of changes shall be treated according to *IAF/ILAC-A2:05/2007, Annex 10*.

8. Conclusions

This good practice guideline describes how single Accreditation Bodies may qualify themselves for signing the applicable Mutual Recognition Arrangement(s) of IAF and/or ILAC. The intention is to assist along this way by giving step-by-step explanation.

As one conclusion, we wish to accentuate that it usually 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 amount of documents as outlined in this paper. During an information and adaptation process which might take several months or even years, most often the accreditation body itself has 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 align mindset and method to those of IAF/ILAC.

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 Arrangement are the comparability of certificates and test reports issued under the accreditation of members of the IAF/ILAC Arrangement 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 that go further and numerous documents 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 (monika.wloka@deutscher-akkreditierungsrat.org) or the ILAC Secretariat (ilac@nata.com.au).



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 guidance documents.
- Comply with any applicable requirements and guidance of the Regional Group to which it belongs, if any
- Have implemented a cross frontier accreditation policy in accordance with IAF GD 3:2003 (IAF signatories) and/or ILAC-G21:2002 (ILAC signatories)

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

- Self-assessment based on the IAF /ILAC A3 Key Performance Indicators
- At least one accreditation in each of the accreditation programs for which it applies
- Only for laboratory accreditation:* at least four (4) accreditations for testing and/or four (4) accreditations for calibration
- Only for AB's for laboratories/inspection bodies:* have implemented a policy for proficiency testing activity
- Complete documentation required for application (see IAF/ILAC-A2:05/2007, 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 A3:KPI

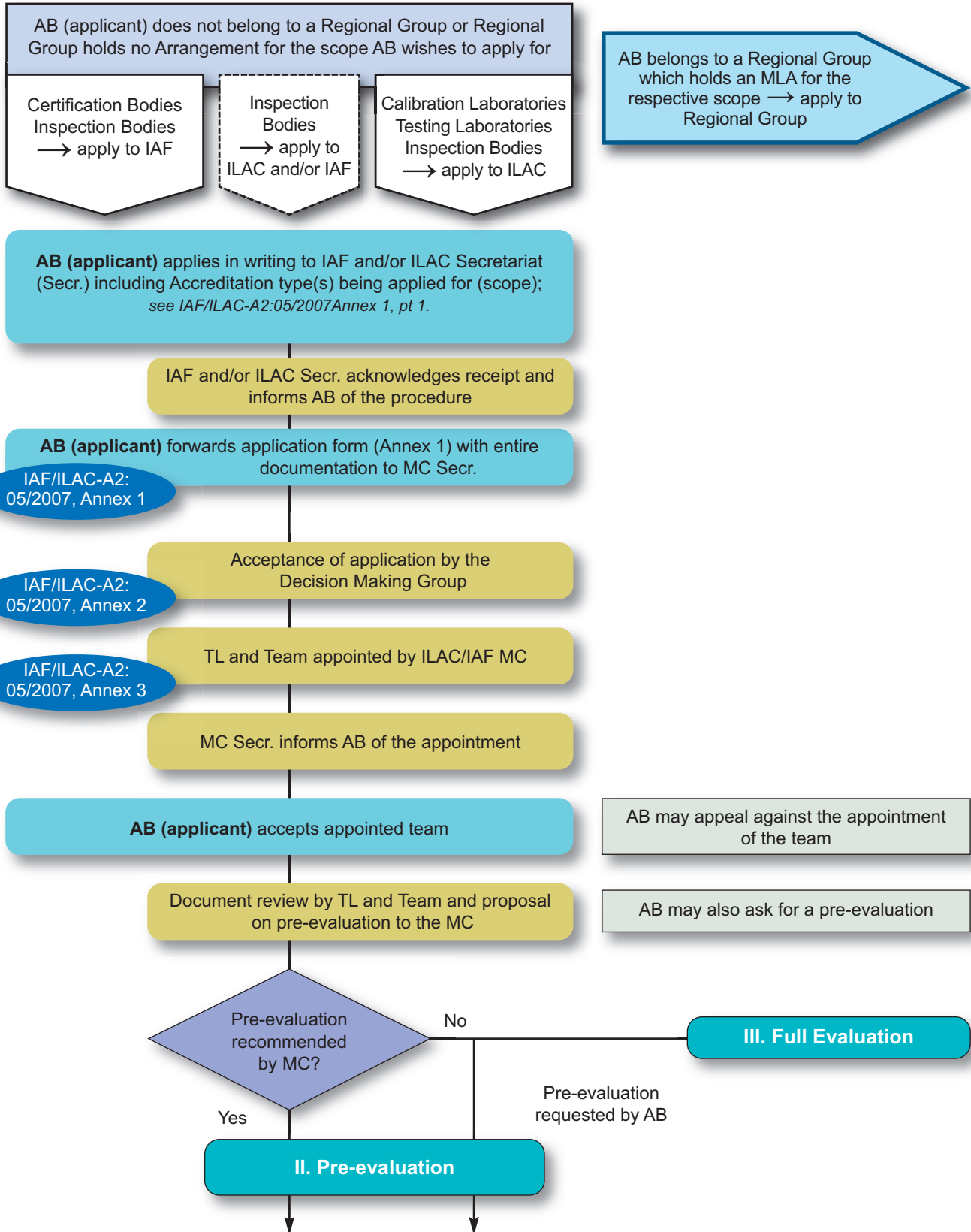
IAF/ILAC-A2:
05/2007, Annex 1

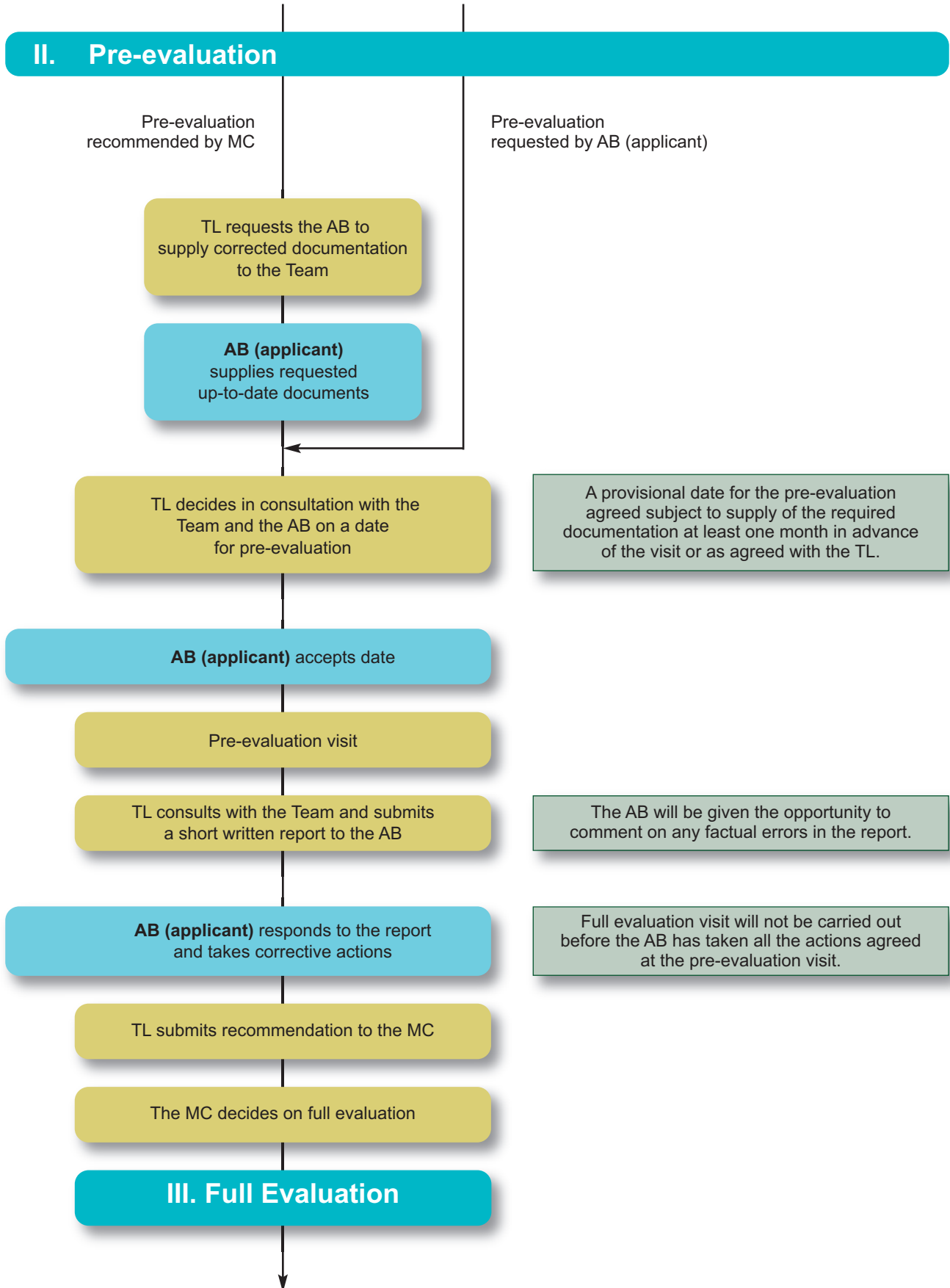
To be agreed by the AB (applicant) before application

- 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.



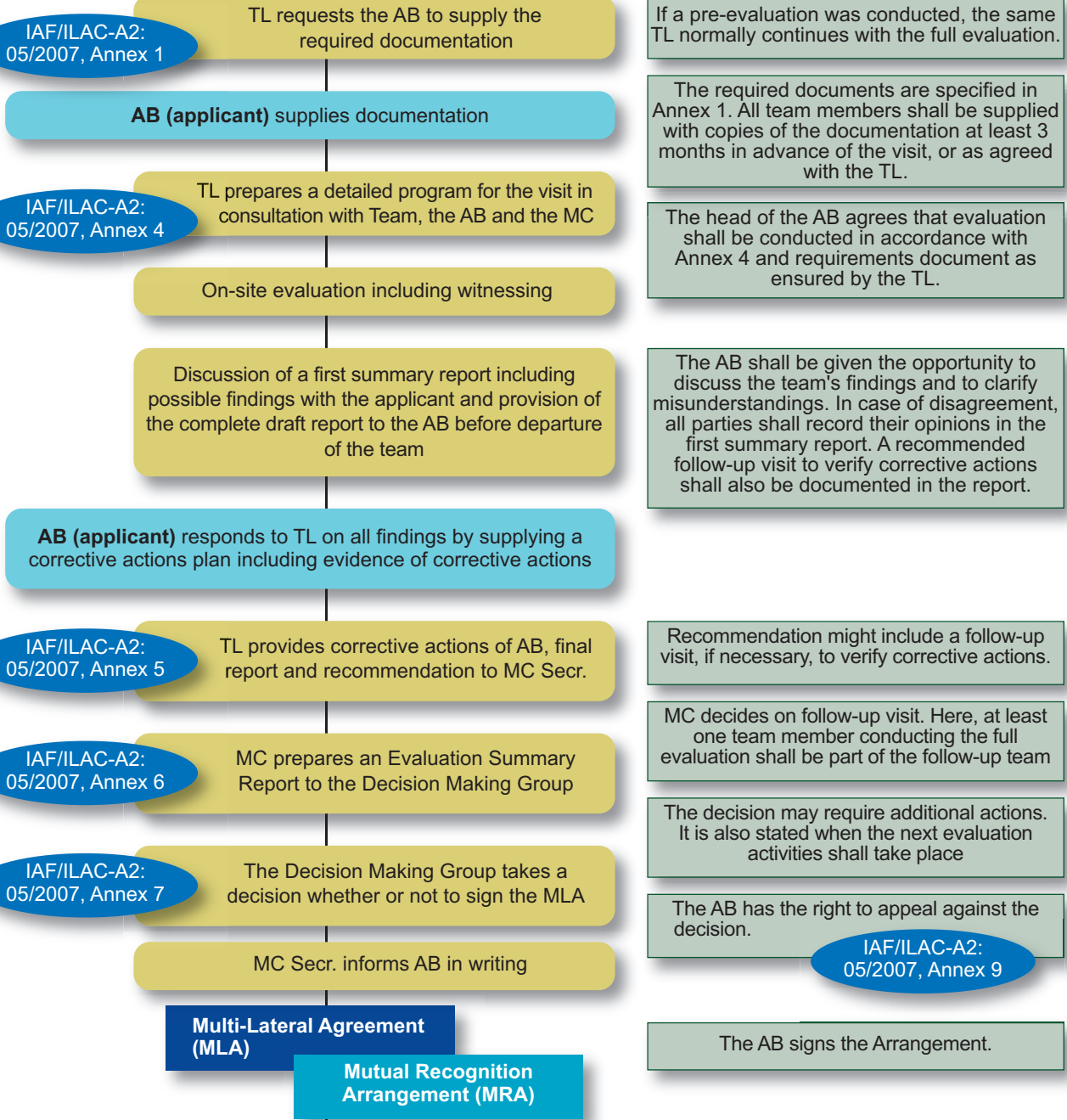
I. Application for Arrangement Membership







III. Full evaluation



If a pre-evaluation was conducted, the same TL normally continues with the full evaluation.

The required documents are specified in Annex 1. All team members shall be supplied with copies of the documentation at least 3 months in advance of the visit, or as agreed with the TL.

The head of the AB agrees that evaluation shall be conducted in accordance with Annex 4 and requirements document as ensured by the TL.

The AB shall be given the opportunity to discuss the team's findings and to clarify misunderstandings. In case of disagreement, all parties shall record their opinions in the first summary report. A recommended follow-up visit to verify corrective actions shall also be documented in the report.

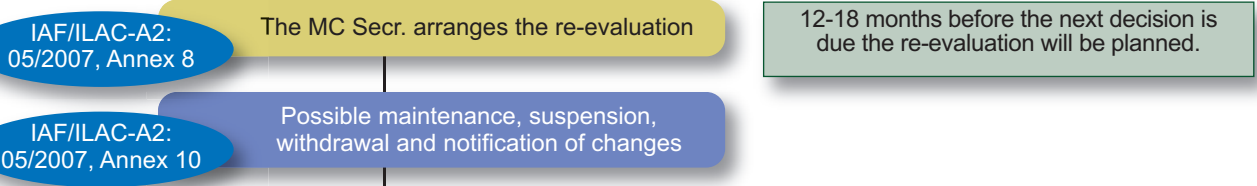
Recommendation might include a follow-up visit, if necessary, to verify corrective actions.

MC decides on follow-up visit. Here, at least one team member conducting the full evaluation shall be part of the follow-up team

The decision may require additional actions. It is also stated when the next evaluation activities shall take place

The AB has the right to appeal against the decision.

IV. Re-evaluation



12-18 months before the next decision is due the re-evaluation will be planned.



References

IAF/ILAC-A1:05/2007

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

IAF/ILAC-A2:05/2007

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

IAF/ILAC-A3:05/2007

IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements):
Key Performance Indicators A Tool for the Evaluation Process

IAF GD 3:2003

Guidance on Cross Frontier Accreditation

IAF-MM-07-002

Application for Membership in IAF

IAF PL 4:2004

Rules for IAF Membership Fees

ILAC-G21:2002

Cross Frontier Accreditation – Principles for Avoiding Duplication

ILAC-P6:2003

Application for Full Member Status

ILAC-S2:2003

ILAC Rules

ISO/IEC 17011

Conformity assessment – General requirements for accreditation bodies accrediting conformity
assessment bodies (ISO/IEC 17011:2004)



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