The route to signing the IAF or ILAC Arrangements



Purpose

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

If the accreditation body is eligible to be a member of a Regional Cooperation Group which is recognized via the IAF/ILAC Arrangement, then the accreditation body is strongly encouraged to apply and go through the evaluation process via this Regional Cooperation Group. On gaining member status to the recognised Regional MLA or MRA, 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 member to the IAF MLA and/or ILAC MRA for the same scope they have gained member status to the Regional MLA/MRA. This member 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.

In addition, an outline of the process as required by IAF/ILAC A2 is provided for single accreditation bodies applying to sign the IAF MLA or ILAC MRA directly, because either a Regional Cooperation Group does not exist in that region, or the Regional Cooperation Group is not recognised via the IAF/ILAC Arrangement for the required scopes. The process described is similar to that used by the recognised Regional Cooperation Groups, that is APLAC, EA, IAAC and PAC for the evaluation of an accreditation body as required by IAF/ILAC A1.

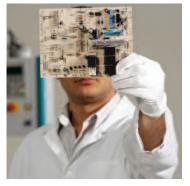
Appendix 1 provides a flow chart describing the overall process.











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 accreditation body members. A peer evaluation system is used as the mechanism to ensure constantly competent services are delivered according to harmonized standards. Upon a 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.

Different terms have emerged for these Arrangements, MLA (Multilateral Recognition Arrangement) is used by IAF, whereas MRA (Mutual Recognition Arrangement) is used by ILAC.

At present, the IAF and ILAC Arrangements cover the following activities:

- 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)
- Certification body accreditation for persons ISO/IEC 17024
- Testing laboratory accreditation, ISO/IEC 17025, ISO 15189 (ILAC)
- Calibration laboratory accreditation, ISO/IEC 17025 (ILAC)
- Inspection body accreditation, ISO/IEC 17020 (ILAC)

*The scope of the IAF MLA includes ISO 22000 and ISO 27001, but IAF will not yet accept applications.

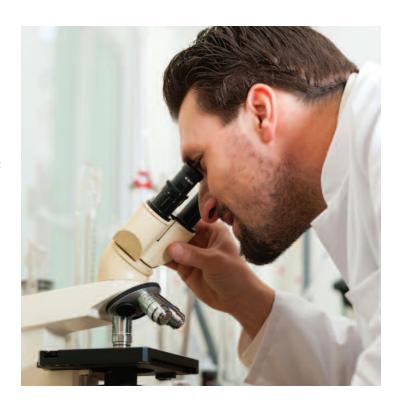


The overall organizational structures of IAF and ILAC are available from the websites, **www.iaf.nu** and **www.ilac.org**. The committees involved in the management of the Arrangements in IAF and ILAC are:

- 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 organized and managed. 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.

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 members 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).



Application to become a Member of the Arrangement

Once the accreditation body has established and gained experience in their accreditation programs, they are ready to apply. At this point, most likely the question arises "What steps are necessary to file an application for the Arrangement?"

If the accreditation body is eligible for membership of a recognised Regional Cooperation Group of ILAC or IAF, then application for membership and peer evaluation must be submitted to that Regional Cooperation Group.

The recognised Regional Cooperation Groups are APLAC www.aplac.org, EA www.european-accreditation.org, IAAC www.iaac.org.mx, and PAC www.apec-pac.org. The contact details for the Secretariats are available from the websites. The Secretariat of the Regional Cooperation Group should be contacted in the first instance.

If the accreditation body is not eligible for membership of a recognised region or the regional MRA or MLA does not cover the relevant activities, the accreditation body should apply to IAF and/or ILAC directly.

The AB will need to fulfill a number of prerequisites in order to file an application, that is:

be a member in

IAF (Accreditation Body Member; see IAF PL2) and/or

ILAC (preferably Associate; see ILAC-R2) and

 pay membership fees in its category (see IAF PL 4 and ILAC P4). 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 – A Tool for the Evaluation Process.

The AB applies in writing to the IAF and/or ILAC Secretariat including details of the Accreditation type(s) or activities being applied for (see IAF/ILAC-A2). 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 available from the Secretariat (see IAF/ILAC-A2) accompanied by the entire documentation to the Management Committee (MC) Secretariat.

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. Once the appointed team is accepted, the process starts.





Pre-evaluation

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

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 takes corrective actions and responds to any issues raised in the report. The TL provides a recommendation to the MC, which then decides whether to proceed with the full evaluation.





Full evaluation

The steps involved in a full evaluation are described in the detailed flow-chart included in IAF/ILAC A2.

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 at the end of the visit.

The AB responds to the TL by supplying a corrective actions plan and evidence of the corrective actions for all findings as defined in IAF/ILAC-A2.

The TL forwards the corrective actions from the AB, the Final Report and a recommendation to the MC Secretariat (see IAF/ILAC-A2). The recommendation might include a follow-up visit, if necessary, to verify corrective actions. If a follow-up visit is recommended, 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) 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). The decision may be subject to conditions requiring additional actions and also states when the next planned evaluation activities shall take place.

The MC Secretariat informs the AB in writing of the decision.

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



Re-evaluation

Once the AB is a member of the Arrangement, periodic monitoring will be conducted. Typically, a re-evaluation is carried out every 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).

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

References

Information and the mandatory documents used in the peer evaluation process 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 (mla@iaf.nu) or the ILAC Secretariat (ilac@nata.com.au).

In particular the mandatory documents include the IAF/ILAC A-series documents, the IAF MD series and the ILAC P series as well as the regional documents if the peer evaluation is being carried out by recognized Regional Cooperation Group.

Conclusions

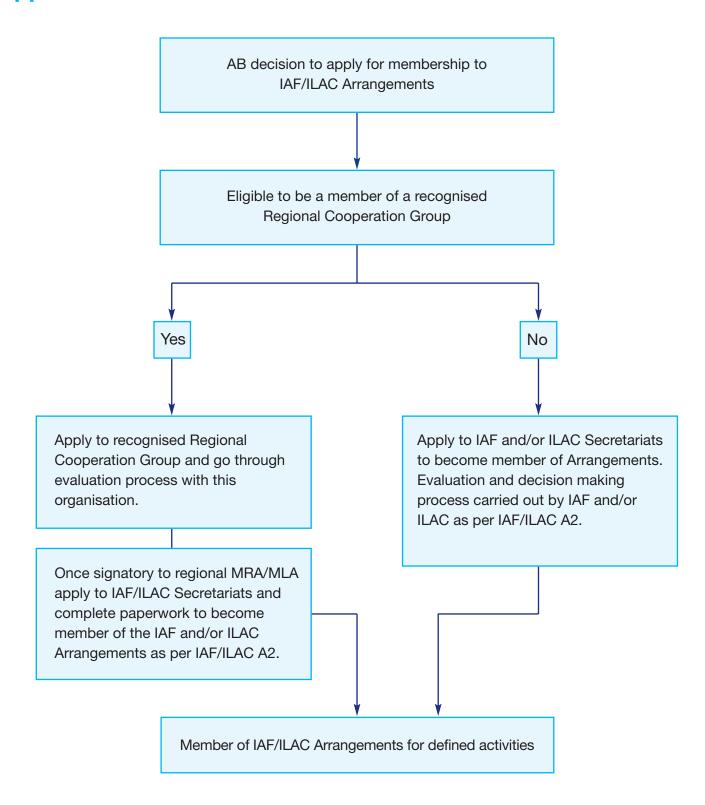
It generally takes some time for an accreditation body to achieve MRA/MLA member status. The accreditation body has to not only prepare a substantial number of documents detailed in IAF/ILAC A2 but also have fully implemented the accreditation programs. In addition, during an information and adaptation 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 member status to the of IAF/ILAC Arrangements.

Accreditation reduces risk for business and its customers by assuring them that accredited bodies are competent, impartial and capable of the work they undertake. The aims of the Arrangements are the comparability of results contained in certificates and reports issued under the accreditation of the members to the IAF/ILAC Arrangements and the worldwide acceptance of these documents. Thus, the Arrangements provide an international framework to support international trade through the removal of technical barriers and to support decision making processes relating to issues such as health and environment at a national level.





Appendix 1







About ILAC

ILAC is the international authority on laboratory and inspection accreditation, with a membership consisting of accreditation bodies and affiliated organisations throughout the world. Its internet site at **www.ilac.org** can provide a range of information on laboratory and inspection accreditation, as well as the location of its members worldwide.

ILAC promotes the increased use and acceptance, by industry as well as by government, of the results from accredited laboratories and inspection bodies, including results from accredited organisations in other countries. ILAC liaises with many international bodies and stakeholders to achieve shared objectives.

About IAF

The International Accreditation Forum (IAF) is a global association of Accreditation Bodies, Certification Body Associations and other organisations involved in conformity assessment activities in a variety of fields including management systems, products, services and personnel. Its internet site from which further information can be obtained is www.iaf.nu

IAF promotes the worldwide acceptance of certificates of conformity issued by certification bodies accredited by an Accreditation Body Member, and seeks to add value for all stakeholders through its activities and programs.



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