

POLICIES AND PROCEDURES FOR A MULTI-LATERAL RECOGNITION ARRANGEMENTAMONG ACCREDITATION BODIES

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Section 1. Introduction

1.1 Purpose

This document defines the policies and procedures of the Inter American Accreditation Cooperation (IAAC) to grant, maintain and extend a Multilateral Recognition Arrangement (IAAC MLA) among accreditation bodies that are signatories to the Memorandum of Understanding (MoU) of IAAC.

1.2 Scope

This document identifies general requirements for evaluation of a single accreditation body. Section 3 establishes procedures for the peer evaluation process. The Annexes describe in moredetail the major steps of the process.

Note: This document has been based on IAF/ILAC A2.

1.3 Confidentiality

- **1.3.1** All oral and written information received relating to preliminary visits, evaluations, reevaluations shall be treated confidentially by all parties and persons concerned. This includes information relating to applicants and/or members of the MLA Group. All evaluation teams members and observers, the MLAG members and MLAC Secretary, as well as other people having access to any report on preliminary visits, evaluations and re-evaluations of other applicants and members, as well as any other information concerning the applicants and/or members of the MLA Group must have signed a declaration of confidentiality before being given access. (See FM 011 Declaration of Confidentiality and Impartiality).
- **1.3.1.1** Form FM 011 shall be signed by evaluators before they are accepted as IAAC evaluators.
- **1.3.1.2** Form FM 011 shall be signed by representatives of MLA Group members before they are given access to the first evaluation report.

Note: Only one Declaration of Confidentiality will be signed by MLA Group representatives. It is not necessary to sign form FM 011 for each MLAG meeting.

- **1.3.1.3** Observers to the MLA Group meetings shall sign form FM 011 at each meeting, before they are given access to evaluations reports.
- **1.3.1.4** Any other person who has access to any reports of preliminary visits, evaluations and re-evaluations of applicants and MLA Group members will sign the FM 011 form on each occasion, before being given access to the evaluation reports.
- **1.3.2** Unless there is an agreement with the accreditation body that has been communicated to the IAAC Executive Secretariat in writing, the Team Leader (TL) and Team Members (TM) shall destroy all documents they have received, when the final decision has been made by the MLA Group.

1.4 Definitions and Acronyms

The following definitions apply for the purpose of this document:

1.4.1 Accreditation Body (AB): Organization that operates an accreditation scheme for one or more types of conformity assessment bodies.



- Note 1: The authority of an accreditation body may be derived from government, public authorities, contracts, market acceptance, or scheme owners. (ISO/IEC 17000:2020, 4.7).
- **1.4.2 Accreditation Scheme:** set of criteria specified in a standard or normative document included in IAF and/or ILAC Arrangements used for the accreditation of conformity assessment bodies, for which the same requitements apply.
- **1.4.3 MLA Arrangement**: Agreement between IAAC member accreditation bodies, managed by IAAC, whose purpose is to ensure mutual recognition of accredited conformity assessment activities among MLA signatories, based on a single accreditation performed by one of the MLA signatories.
- **1.4.4 Scope of recognition agreement:** The different levels of the MLA structure and the respective normative documents correspond to Level 1, 2, 3, 4 and 5 (See PR 025: Structure of the IAAC Multilateral Recognition Agreement and procedure for the extension of the Agreement).
- **1.4.5 IAAC**: Inter-American Accreditation Cooperation.
- **1.4.6 MLA Committee (MLAC):** The committee responsible for planning and managing the implementation and maintenance of IAAC Multilateral Recognition Arrangement. This committeeincludes the MLA Group, and may also include non-signatory members.
- **1.4.7 MLA Group (MLAG):** All signatories to the IAAC Arrangement. The MLAG decides on and manages membership in the IAAC Arrangement.
- **1.4.8 MLAG Secretary:** IAAC Executive Secretary
- 1.4.9 MLAC Secretary: IAAC Technical Secretary
- **1.4.10 Peer Evaluation**: A structured process of evaluation of an Accreditation Body by representatives of other accreditation bodies.
- **Note 1**: ISO/IEC 17000 defines peer assessment as the assessment of an organization against specified requirements by representatives of other organizations that are part of an agreement group, or are candidates for agreement.
- **1.4.11 Signatory**: A Member of IAAC who has signed the IAAC multi-lateral recognition Arrangement for one or more scopes of recognition agreement.
- **1.4.12 Standard:** a document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.
- **1.4.13 (Peer-evaluation) Team Leader (TL):** A lead evaluator responsible for leading a peer evaluation team.



- **1.4.14 (Peer-evaluation) Team Member (TM):** An evaluator or trainee evaluator serving on a peer evaluation team.
- **1.4.15 (Peer evaluation) Deputy Team Leader:** An evaluator who may be in training and is appointed as appropriate, to assist with the management of the evaluation, and in the coverage of a large scope of IAAC MLA recognition. For example, a TL may be selected to ensure adequate coverage of one of the IAAC MLA schemes of recognition and the Deputy TL can assist with coverage of the another.
- **1.4.16 Witnessing:** Observation of an activity. Witnessing may be the observation by the accreditation body of a Conformity Assessment Body (CAB) that is carrying out conformity assessment activities within its scope of accreditation or it may be the observation of an accreditation body in carrying out activities associated with the accreditation process.

Note: Witnessing can be accomplished with on-site evaluation, remote evaluation, or a combination of both, as appropriate.

1.4.17 Remote Evaluation: Peer Evaluation of an AB, including associated witnessing activities, using electronic means.

Section 2: Requirements for a Single Accreditation Body

- **2.1** An Accreditation body shall comply with the provisions of ISO/IEC 17011.
- **2.2** Every applicant or signatory to the IAAC MLA shall operate according to applicable IAF and ILAC mandatory documents, as specified in the IAF/ILAC A series documents, IAF MD series and ILAC P series, as well as any mandatory documents issued by sector specific schemes that have been endorsed by IAAC, IAF or ILAC. Every applicant or signatory of the IAAC MLA shall comply with any decision made by IAAC, IAF or ILAC regarding the implementation date of these mandatory documents.
- **2.3** Every applicant or signatory to the IAAC MLA shall contribute its fair share of personnel resources for carrying out peer evaluations at the regional and/or international level.

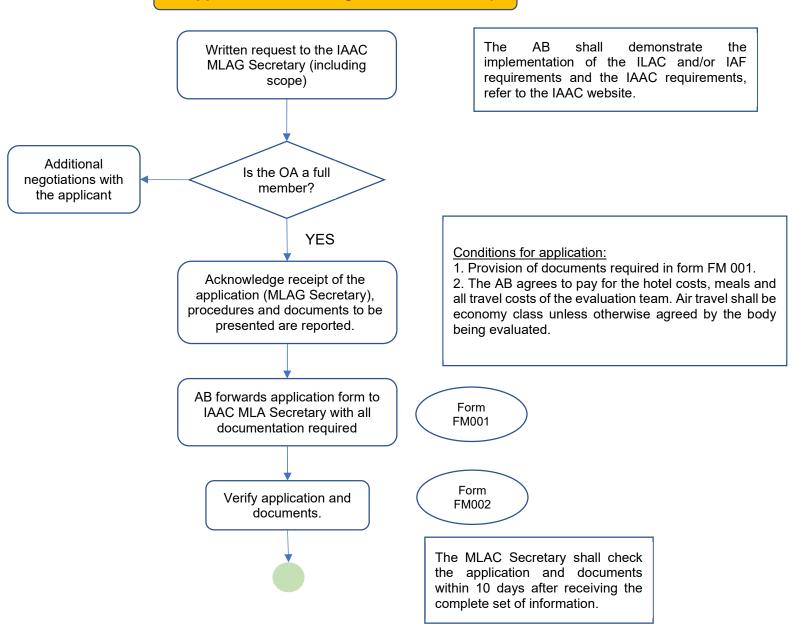
Every MLA signatory shall, within each MLA recognition cycle, contribute to IAAC at least the same number of peer evaluator days as IAAC has provided to carry out their peer evaluations.

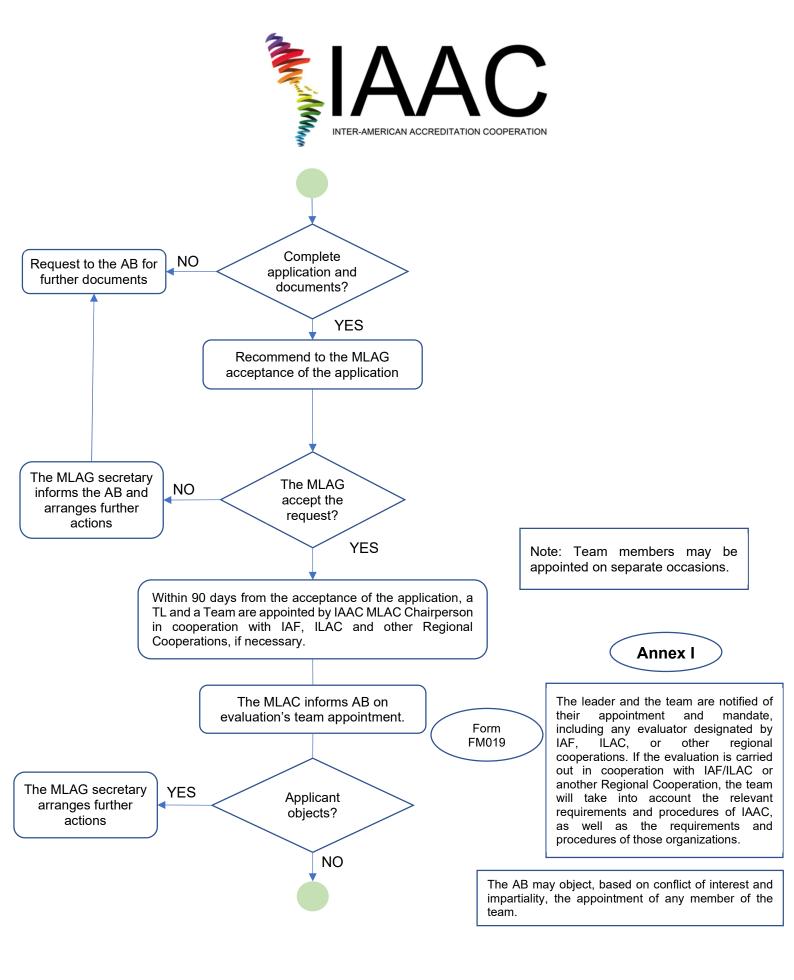
Every MLA signatory, if it has at least one lead evaluator, shall provide a peer evaluation Team Leader (AB staff or contracted) within its recognition cycle. If the AB does not have a qualified and available Team Leader then it shall either nominate an individual to be trained by IAAC to become a Team Leader or contract an authorized Team Leader.



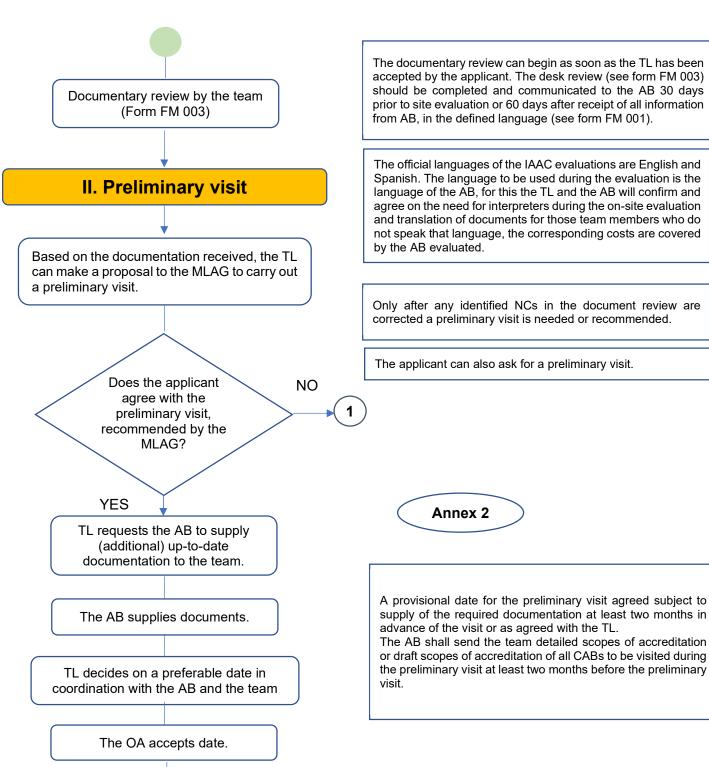
Section 3: Flowchart for Peer Evaluation Procedures of a Single AccreditationBody

I. Application for Arrangement Membership

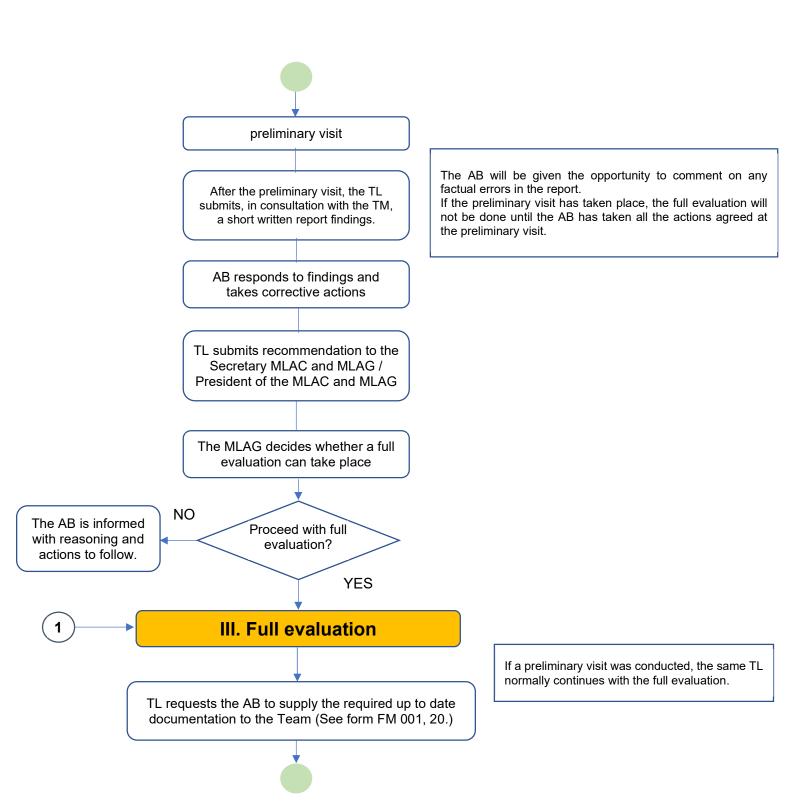




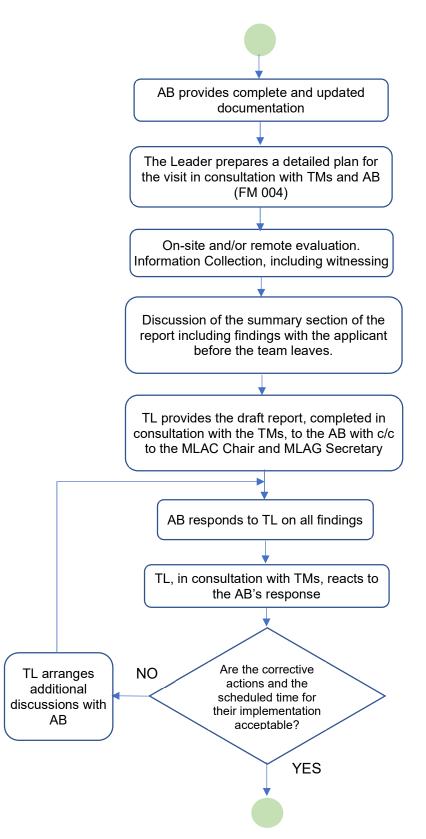












All team members must be provided with updated copies of the necessary documentation, in the agreed language, at least three months prior to the visit, or as agreed with the Leader.

The AB must provide detailed information to coordinate the witnessing according to Annex 2, clause 2.3.1, six weeks before.

If the documentation is not provided in time, the MLAC Chair may cancel the evaluation (see also annex 4 clause 2.7.1 in case of suspension).

Annex 2

The TL shall give the AB an opportunity to comment on and discuss the summary section and the team's findings and recommendations and to clear up any misunderstandings that may have arisen.

The team shall leave a summary section of the report with the AB (see Annex 3) together with the list of finding using form IAF-ILAC A3 Annex IV. The summary section and the findings shall be provided to the MLA Secretary and MLAC Chairperson immediately after the evaluation.

If a follow-up visit is recommended to verify corrective actions, this should be stated during the visit, if possible, and documented in the summary section of report (see Annex 3 clause 2.1). Decision to authorize a follow up visit may be made by the MLAC

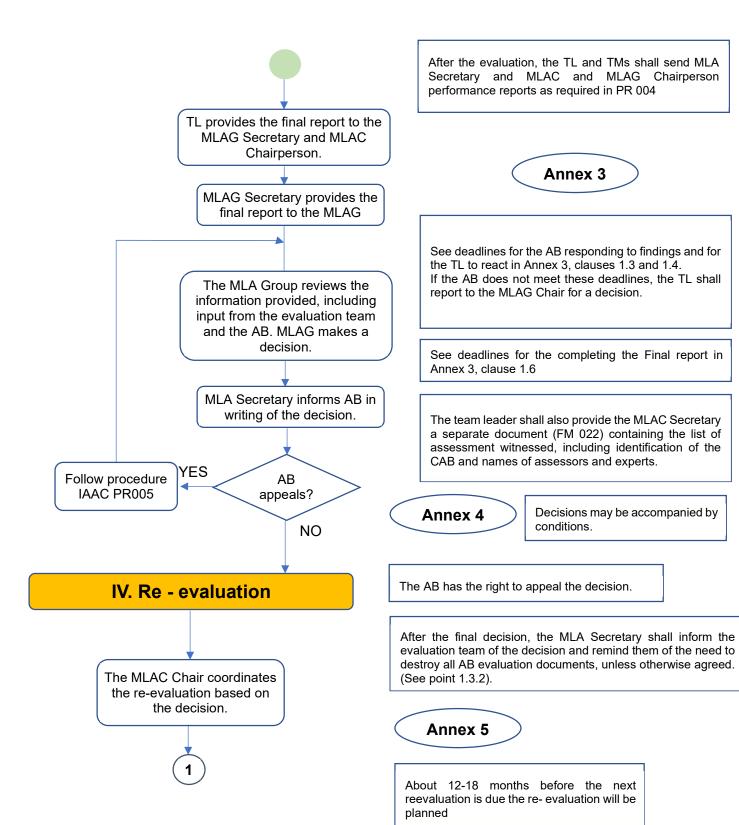
Decision to authorize a follow up visit may be made by the MLAC Chair based on the Summary Report. This decision will be recorded in an MLAG resolution. If a follow-up visit is to be conducted the evaluation team shall be composed of one or more members of the evaluation team who carried out the full evaluation.

If the team recommends suspension of the AB (see clause 2.4), the MLAC Chair shall initiate the decision making process as per Annex 4

If possible, the team should leave a complete, draft report with the AB (see Annex 3, clause 1.2).

If there is a disagreement within the evaluation team or between the evaluation team and the accreditation body all parties should describe their opinions in the complete draft final evaluation report. For any AB appeals of findings or adverse decisions by an evaluation team during the evaluation process, see PR 005, Procedure for Handling Appeals and Complaints.







Annex 1

Appointment and Composition of the Peer Evaluation Team

1 Appointment and duties of Team Leader

- **1.1** Team leaders shall be chosen by the MLAG Secretary from the list of authorized lead evaluators of the IAAC PeerEvaluators List.
- 1.2 In appointing team leaders for a specific evaluation, the MLAG Secretary shall not select the same team leader for two successive evaluations of the same accreditation body and considering the provisions of section 2, clause 2.3. The teamleader appointed for an evaluation should not be from the same AB as the team leader from the previous evaluation. The designation of the TL will be approved by the MLAG Chair.
- **1.3** The team leader shall have ultimate responsibilities for all phases of evaluation and is delegated authority by the MLA Group 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 evaluator assigned to the evaluation team.

2 Composition of Evaluation Team

2.1 For the full evaluation visit, members of the evaluation team shall be chosen as needed tocover the activities and standards of the MLA Scopes to be evaluated with consideration of the levels defined in PR 025. As well as knowledge of flexible scopes of accreditation and/or remote assessment techniques (as applicable), size and complexity of the accreditation system under evaluation.

For Management System Certification Bodies scope, the recommendation of the MLA Group must be considered, with respect to the witness to be carried out during the following evaluation.

- Note 1 A team leader should normally be accompanied by at least one other team member for apreliminary visit to ensure more than one person is involved in establishing an Applicant Body's readiness for a full evaluation visit.
- Note 2: See procedure PR 004 Procedure for selection, training, authorization and monitoring the performance of IAAC peer evaluators.
- 2.2 The evaluation team members shall be chosen from the IAAC Peer Evaluators List. Lead evaluators, evaluators and trainee evaluators may be appointed as evaluation team members. The evaluation team proposed by MLAG Secretary shall consist of representatives from a cross-section of accreditation body members of IAAC. The MLAG Chair approves this team allocation. The evaluation team shall be chosen to provide a balanced set of skills to be able bounduct an effective evaluation of the key components of the system under evaluation.

Note 1: Team members should have knowledge of the language to be used, preferably that of the



AB's country of origin, for this purpose the leader and the AB will confirm and agree on the need for interpreters during the assessment, the associated costs will be borne by the AB being assessed.

- Note 2: Some of the team members may have as their only task to perform witnessing at different geographical places or at different times than the rest of the evaluation team.
- Note 3: Where an evaluation is conducted jointly by IAAC and ILAC, IAF or other recognized regional cooperation, the Chair of the MLAG will work in cooperation with the other organization and the team leader to set up a team that meets the needs of IAAC. Apart from that, all other steps in this and IAAC MD 043 procedure apply.
- Note 4: The number of members of the team for each scope of the MLA depend on several factors, such as the variety of schemes in which the AB accredits, the complexity of the AB's management system, the time required for witnessing and office evaluation, the experience of the team members and their scope of authorization, the need for IAAC to involve trainee evaluators so as to increase the number of authorized evaluators.
- **2.3** When a person is invited to participate in an evaluation team, he/she or his/her AB shall inform the MLAG Chair or MLAG Secretary of previous involvement with the AB being evaluated. No team member shall be associated with any Accreditation Body that has provided consultancy service to the body being evaluated for the last four years. The following activities performed by the person in the last two years may be considered a threat to a team member's impartiality:
 - Participation in recent internal audits (last 4 years);
 - Provision of training specially tailored for the design and development of the AB's accreditation system;
 - Participation as an assessor in joint assessments of CABs.
- **2.4** A re-evaluation visit should be carried out by a team, in which none of the members has been on the evaluation team that undertook the previous evaluation.
- 2.5 The assessment team shall consist of a lead evaluator and an evaluator for each accreditation standard of the MLA recognition agreement to be assessed (Level 3), covering the scope within the recognition or as requested for initial assessments or extensions. A deputy team leader may be appointed as necessary. A trainee evaluator may be appointed to evaluate one of the activities or programs with the support of the lead evaluator or evaluator who is qualified for the applicable activity or standard.
- **2.6.** When a trainee evaluator is appointed as a team member, he/she may be assigned evaluation tasks by the team leader and shall be mentored and supervised by the team leader and/or another evaluator so as to ensure those tasks are appropriately carried out. During the evaluation at the AB's facilities, the trainee evaluator shall always be supervised by an authorized lead evaluator or evaluator for this scope; during witnessing of assessments the trainee evaluator may work on his/her own.
- **2.6.1** The MLAG Secretary or MLAG Chair shall provide the team leader with information on the training and experience of the trainee evaluator and on the task that may be performed by the trainee evaluator.
- Note 1: Costs of the participation of a trainee evaluator as a team member in an evaluation are to be covered by the AB being evaluated.



2.7 If the team leader or a team member is from another recognized regional cooperation, the MLAG Chair and/or the MLAG Secretary shall provide him with instructions about IAAC procedures and requirements for peer evaluations as well as the main differences from the procedures used by IAF/ILAC.

Annex 2

Planning and Managing the Evaluation

1. Preliminary visit plan and Full Evaluation plan

1.1. Preliminary Visit Plan

If it is determined by IAAC or the applicant AB that a preliminary visit to the AB is needed beforethe full evaluation can take place, a preliminary visit plan shall be prepared. Based on the resultsof the document review, the preliminary visit team may consider reviewing the following in the context of the preliminary visit:

Issues to be considered:

- · Management system policies and procedures;
- Legal identification of the AB;
- Relationships with the regulators and other specifiers (recognition; possible competition);
- Job descriptions and backgrounds of top management, organization chart;
- Impartiality and conflict of interest; related bodies
- Access to technical expertise;
- Application documents;
- · Assessor records and documents;
- Sampling of CAB assessment records, including the decision making process;
- Proficiency testing participation levels (for testing and calibration accreditation);
- Measurement traceability routes (for testing and calibration accreditation and inspectionbodies where relevant). In some cases it may be necessary to visit the NMI.
- Witnessing one or more assessments, if possible.

1.2. Full Evaluation

PlanIntroduction

In principle it is the task of the TL to create a timetable (see form FM 004) 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.

It is recommended that the TL start planning the evaluation as soon as the evaluation team is appointed.

Because there exist a large variety of circumstances under which an evaluation will take



place, itshould be the prerogative of the TL to deviate from the examples shown under 3.2. The TL shouldagree 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 3.2 or when additionalteam capacity is required, the MLAC Chair should also be consulted at an early stage.

The following criteria shall be considered for the planning of the evaluation in the Management Systems Certification sub-scope:

- New sub scopes recognized by self-declaration shall be witnessed.
- Evaluation shall be performed, including a witnessing for half (rounded up to the next whole number) of the sub-scopes included in the recognition.
- Based on the decision of the MLA group regarding the reassessment where the witnessing plan shall be determined, the team leader shall perform a risk analysis indicating whether the plan is adequate. The risk analysis shall be performed according to the following criteria:
 - Non-conformities
 - Complaints
 - Ongoing upgrades or transition plans
 - o Other available information regarding the AB performance.

Resulting from this analysis, the evaluation team may determine the need to include additional witnessing for a specific sub-scope, to update the assessment plan, this must be approved by the MLAG Chair.

2 Considerations

2.1 Maximum duration

The TL should try to arrange the evaluation to take place, preferably within one full (7 days) week. If witnessing is not possible during the week of the formal evaluation and if no alternatives are possible, the TL should make arrangements to have witnessing 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.

The TL in conjunction with the MLAG Secretary and MLAG Chair will consider if remote peer evaluation techniques could be used to make more effective use of the time available for the evaluation. The decision to use remote evaluation techniques is left to the discretion of the TL inconjunction with the AB and should not normally be used to fully replace the on-site evaluation. The MLAG Chair and the MLAG Secretary must be informed of what has been agreed for their approval.

Once the evaluation techniques have been defined the TL may determine, in coordination with the AB and team members, that some interviews, review of documents and / or records, etc. could be reviewed remotely prior to the office evaluation. The use of remote peer evaluation techniques must achieve the same objectives as the on-site peer evaluation being replaced and the use of such techniques shall be justified.

The TL should arrange the evaluation to take place within a defined timeframe taking into accountboth on-site and remote evaluation activities, as applicable. The on-site evaluation should not exceed one full week (7 days) unless special circumstances or scheduling issues



arise. Remoteevaluation activities should be completed in advance of or during the on-site evaluation to ensureassistance can be provided during the on-site evaluation. The evaluation findings must be provided to the AB at the closing meeting and remote evaluation activities must be arranged suchthat they do not delay the delivery of the findings to the AB at the closing meeting.

2.2 Types of evaluation

There are different kinds of evaluation: e.g. initial evaluation, pre-evaluation, follow-up evaluation, evaluation for scope extension, re-evaluation.

Given the interval (approximately 4 years) between evaluations, the duration of a reevaluation is comparable to that of an initial evaluation. A shorter duration applies for preliminary visits, for follow-up evaluations and for scope extensions that are conducted separately from a re- evaluation. Specific instructions about evaluations for extensions of the MLA scope are given in Annex 7.

2.3 Evaluation of Level 3, 4 and 5 activities

2.3.1 Witnessing

The evaluation team shall consider how to deal with witnessing for the activities and standards ofthe MLA scopes that are being evaluated. Discussion about number and type of assessments tobe witnessed should start as soon as the team has been assigned. The AB should be informed about the evaluation team plans so that they may provide the team with a possible list of assessments to be witnessed and should include both on-site and remote assessments (as applicable).

For planning of the witnessing, six weeks before the evaluation or as agreed with the team leader, the AB shall provide the evaluation team with detailed information about the assessments planned, so that the evaluation team can select the assessments to be witnessed. This gives the evaluation team the opportunity to carefully select and plan the witnessing activities taking into consideration:

- standards for accreditation,
- number of accredited CAB,
- size of the schemes,
- new schemes and complex schemes,
- initial evaluation/ re-evaluation.
- witnessed assessments from the last evaluation.
- assessment techniques applied by the AB (on-site and/or remote),
- flexible scopes of accreditation and for which accreditation schemes they are used,
- crossfrontier accreditation documents and relative arrangements,
- self-declaration of new sub-scopes.
- Results of previous AB evaluations.

It is important to have the opportunity to witness assessments covering all accreditation requirements, particularly in the initial evaluation. It may be necessary to perform more witnessingin initial evaluations than in re-evaluations.



Normally the evaluation team will witness an initial assessment or a reassessment of a CAB or two assessment activities for every level 3 scope. Preferably the evaluation team should witness reassessments instead of initial assessments. In case it is not possible to witness a reassessmentor an initial assessment or two assessment activities, the evaluation team may witness only oneassessment activity that covers all accreditation requirements; this shall be clearly stated in the evaluation plan (FM 004). The key is that the peer evaluation team witness the AB assessment team's performance when assessing the technical activities of the CAB. Table 1 below provides additional instructions for each scope.

Note: For definitions of Levels, please refer to IAAC PR 025, as applicable.

For cases were the process of establishing an MoU is in progress, with certain industry sectors, specific attention may be needed to assure the AB's competence to assess in these schemes. The evaluation team shall consider theneed to witness assessments of CAB accredited for accreditation programs endorsed by IAAC, IAF and ILAC. Even if witnessing is not considered necessary, the evaluation team shall review records (this may be done remotely) of accreditations granted in those schemes and record this information in the evaluation report.

Table 1: Additional Instructions about witnessing

Scope	Specific instructions about witnessing	
Calibration ISO/IEC 17025	Includes witnessing of the assessment by the AB of the CAB performing calibration.	
Testing ISO/IEC 17025	Includes witnessing of the assessment by the AB of the CAB performing testing.	
Clinical/ medical laboratories ISO 15189	Witnessing includes witnessing of the assessment by the AB of the CAB performing testing.	
Inspection ISO/IEC 17020	Includes witnessing of the assessment by the AB of the CAB performing inspection.	



	\$
	Includes witnessing of an office assessment by the AB of the CAB. It may be a remote assessment, as agreed by the team leader with the AB, provided that the AB performs remote evaluations as part of its normal activities.
Management system certification	The peer evaluation team shall carry out at least one witness of an assessment carriedout by the accreditation body to the conformity assessment body regarding its compliance with the requirements of ISO / IEC 17021-1.
	The witnessing will be selected considering: - The risk - The findings and scopes witnessed in the last peer evaluation.
	- The number of accreditations granted for each sub-scope - The experience of the AB in the sub-scope
ISO/IEC 17021-1	- New sub-scopes and more complex sub-scopes - Decisions by the IAAC MLAG.
	- The sub-scope witnessed in the last evaluation
	If a particular sub-scope is not witnessed in a reevaluation, the peer evaluation team shall review assessment records and qualification of the AB evaluators to confirm the AB's competence in that scheme. This evaluation may be performed remotely.
	It is not necessary to witness the AB witnessing the CB perform certification audits. However, the peer evaluation team shall review the AB's procedures for witnessing certification audits as well as assessment records to confirm appropriate implementation.
	When the assessment to be witnessed by IAAC includes different schemes, the peer evaluation team will confirm with the AB's assessment team the witnessing to be performed. The witnessing will be selected considering:
Product certification	 The risk The findings and scopes witnessed in the last peer evaluation. The number of accreditations granted for each scope The experience of the AB in the scope
ISO/IEC 17065	- More complex scopes - Decisions by the IAAC MLAG.
	It is not necessary to witness the AB witnessing the CB perform certification audits. However, the evaluation team shall review the AB's procedures for witnessing certification audits as well as assessment records to confirm appropriate implementation.
	Includes witnessing the office evaluation by the AB of CBs.
	It is not necessary to witness the AB when conducting the candidate evaluation.
Certification of	However, the evaluation Team shall witness when the AB assessment team analyzes compliance with ISO/IEC 17024 requirements 9.2 and 9.3.
persons ISO/IEC 17024	Note: The evaluation team shall review in detail the AB's procedures for assessing the cases where a CB subcontracts the examination services, as well as assessment records to confirm appropriate implementation.
	In case where the CB subcontracts the majority of the examination process, the evaluation team may consider it appropriate to witness how the AB assesses the competence of the CB for that certification.
	Witnessing includes witnessing of the assessment by the AB of the CAB, including assessment of all key activities.
Biobanks ISO 20387	The evaluation team shall review in detail the AB's procedures for: - Acquisition*
	- Collection - Preparation/Preservation



3		
	- Storage* - Testing/Analysis - Distribution	
	*Acquisition and Storage must be a performed activity along with one other activity, per ISO 20387 clause 3.6.	
	Witnessing includes witnessing of the assessment by the AB of the CAB, including assessment of all key activities.	
	Note 1: The evaluation team shall review in detail the AB's procedures for assessing the cases where a PTP uses subcontractors, as well as assessment records so as to confirm appropriate implementation.	
Proficiency Testing Provider (PTP) ISO/IEC 17043	The evaluation team should consider the need for witnessing the AB that assesses how the proficiency testing provider demonstrates that the subcontractors' experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of this International Standard and other appropriate standards.	
	Note 2: ISO/IEC 17025 or ISO 15189 can be used to demonstrate the competence of a proficiency testing provider's laboratory, or the laboratory subcontracted to perform tests or measurements related to the proficiency testing schemes. ISO 17034 can be used to demonstrate the competence of producers of reference materials that provide proficiency test items.	
	Witnessing includes witnessing of the assessment by the AB of the CAB, including assessment of all key activities.	
	The evaluation team shall review in detail the AB's procedures for assessing the cases where a RMP uses subcontractors, as well as assessment records so as to confirm appropriate implementation.	
Reference Material Producer(RMP) ISO 17034	Note 1: The evaluation team should consider the need for witnessing the AB that assesses how the RMP demonstrates that the subcontractors' experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of this International Standard and other appropriate standards. Depending on the risk, number of accredited and the variety of the scopes, IAAC MLAG decisions, it may be necessary to perform more witnessing.	
	Note 2: ISO/IEC 17025 or ISO 15189 can be used to demonstrate the competence of a RMP's laboratory, or the laboratory subcontracted to perform tests or measurements related to the reference material.	
Validation and	The evaluation team shall witness a validation where possible, otherwise a verification shall be witnessed. Validation requires greater judgment and competency and therefore, represents more risk than verification.	
verification ISO/IEC 17029	It is not necessary to witness the AB witnessing the CAB as it performs validation and verification audits. However, the evaluation team shall review the AB's procedures for witnessing those audits as well as assessment records to confirm appropriate implementation.	
Greenhouse Gas Validation	The evaluation team should witness a validator where possible, otherwise the witnessing of a verifier will be performed. The validation process requires a higher judgment of competence and therefore represents a higher risk than verification.	
and Verification ISO 14065 (Version 2013)	It is not necessary to witness the assessing AB to the CAB performing the validation and verification audit. However, the assessment team should review those the AB's procedures for witnessing those audits, as well as the assessment records confirm their proper implementation.	
<u></u>		

Note: Depending on the risk, the number of accredited CABs, the variety of the scopes or sectors and IAAG MLAG decisions, further witnessing may be necessary.



The use of assessment techniques implemented by the AB (on-site and/or remote) shall be evaluated and considered when developing the witnessing plans for each accreditation scheme for which the AB is seeking recognition. This means that, when the AB regularly uses remote evaluation as an evaluation technique, this technique can be witnessed in any accreditation scheme. The acceptability of an assessment technique will differbased on the accreditation scheme and the accreditation activity for which the assessment technique is being used. The TL and evaluation team members must understand and be knowledgeable with the assessment techniques implemented by the AB and evaluate the appropriateness of their use for each accreditation scheme.

If an AB only uses on site assessment techniques for an accreditation scheme, then the peer evaluation must include witnessing of on-site assessment. If an AB uses remote assessment and on-site assessment for the same accreditation scheme, the Lead Evaluator, with the approval of the MLAG Chair, will determine the type of witnessing to be performed, on-site, remote, or a combination of both. This determination will be made based on a risk assessmentthat will include considerations such as the results of previous peer evaluations, complaints received by IAAC, the complexity of the accreditation scheme, etc. The remote and/or on-site evaluation techniques implemented must ensure that all the relevant requirements of ISO/IEC 17011 and IAAC are evaluated for compliance during the witnessing of the evaluated accreditation scheme(s). On-site witnessing will normally be required for extensions to the scope of recognition that include onsite assessment and always be required for initial evaluations, when onsite assessment techniques are utilized by the AB for that accreditation scheme(s).

2.3.2 Additional instructions for Level 4 and 5:

For all level 4 and 5 activities, it must be stressed that despite spending time on witnessing, it is very important to spend ample time to:

- check how an AB selects its assessors and experts for a particular assessment.
 Thoroughchecking of records from assessments is required including matching the assessor's expertise and competence criteria for the scope of the CAB being assessed.
- review assessment records and reports and decision-making records other than those ofthe CAB witnessed.
- review the way an AB expands its accreditation activities for level 4 and 5, according
 to clauses 4.6.3 and 4.6.4 of ISO/IEC 17011, especially the demonstration of
 competence by the AB, in new schemes and how relevant requirements as defined
 by IAF, ILAC or IAAC have been met, when applicable.

2.4 Size of the AB

The influence of the AB's scope on the duration of the evaluation relates primarily to the number of witnessing activities. The AB's management system may not differ too much when the AB hasone activity or several activities.

When there is a large difference in the number of accreditations in the various schemes, the TL may decide to place more emphasis on witnessing in the larger scheme(s).



2.5 Evaluation of Sources of Metrological Traceability and Visit to the NMI

- One of the tasks of the evaluation team is to evaluate the AB's policy on metrological traceability and how the AB ensures traceability of results of their accredited laboratories. The AB is required to provide the following information (see form FM 001, item 20) information about the available sources of metrological traceability and the calibration and measurement capabilities (CMC) available from these sources (see ILAC P10 and ILAC P14);
- a list of recent international comparisons in which the economy's national metrologyinstitute (NMI) or designated institutes have been involved (e.g., BIPM or regional metrology organization) or, when applicable, reference to the NMI's calibration and measurement capabilities as published on the BIPM website:

This information needs to be evaluated in connection with the AB policy for traceability to confirmits compliance with ILAC P10.

2.5.2 Need for a visit to the NMI.

For initial evaluations, a visit to the NMI will be required. For maintenance evaluations, the following applies:

2.5.2.1 The visit to the NMI will not be necessary in the following cases:

- a) When the NMI is a signatory to the CIPM MRA for all quantities for which traceability is neededunder the scopes accredited by the AB.
- b) When the NMI is a signatory to the CIPM MRA for some of quantities for which traceability is needed under the scopes accredited by the AB, and the AB requires traceability for the remaining quantities to acceptable sources of traceability.
- c) When the NMI is accredited by a signatory of the IAAC and/or ILAC Arrangement.

2.5.2.2 The visit to the NMI is needed in the following cases:

- a) When the NMI is not a signatory of the CIPM MRA.
- b) When the NMI is a signatory of the CIPM MRA. but none of its calibration and measurement capabilities (CMC) are listed in Appendix C of the CIPM MRA.
- c) When the NMI is a signatory to the CIPM MRA for some of quantities for which traceability is needed under the scopes accredited by the AB, but is also the source of traceability to quantities which are not yet included in Appendix C of the CIPM MRA.
- Note 1: The NMI may be in one or several organizations. The evaluation team needs to take thatinto account when planning the evaluation.
- Note 2: When deciding whether or not a visit to the NMI is needed, the evaluation team also needsto consider the fact that traceability may be achieved through sources other than the NMI, such as, NMIs from other economies, laboratories accredited by other signatories to the IAAC and/or ILAC Arrangement, in the economy or abroad.

Note 3: In the situation described in clause 2.5.2.2 c), the visit to the NMI may not be needed in case the information provided by the AB about sources of traceability in the country is



sufficient to confirm compliance with ILAC P10.

2.5.2.3 The visit to the NMI, when applicable, aims at:

- a) Confirming the information provided by the AB about the NMI activities, in particular its participation in regional metrology organizations, the BIPM, and regional and international intercomparisons.
- b) Confirming the calibration and measurement capabilities available from the NMI for quantitieswhich are not included in Appendix C of the CIPM MRA and collecting information the NMI's traceability chain and on how the NMI has validated those CMC. Note: The evaluation team is not supposed to carry out an assessment of the NMI.

The information collected in this visit needs to be included in the evaluation report. This information needs to be considered by the evaluation team in connection with the AB's traceability policy and information on its implementation in order to confirm compliance with the requirements in ILAC P10.

2.5.3 Use of non accredited calibration laboratories

2.5.3.1 If the AB's policy for metrological traceability allows for the use of non accredited calibration laboratories, the evaluation team needs to evaluate how the AB ensures metrologicaltraceability. The evaluation team needs to provide Information in the evaluation report about the AB's policy for this case and its implementation, in compliance with ILAC P10.

2.6 Application from an AB that is a signatory of the MLA of another recognized regional body and/or ILAC and IAF

- **2.6.1** If the AB is applying for recognition for a scope for which it is already a signatory of the MLA of a recognized regional body and/or IAF and ILAC, team leader shall also take into account all information provided by the AB with the application in planning the peer evaluation, including:
 - the previous evaluation report;
 - the decision made by the regional body and/or IAF and ILAC;
 - the changes that have taken place since the previous evaluation.

Note: This procedure is also applicable for new MLA scopes that are developed by IAAC. In casethe new MLA scope is not yet implemented by IAF and/or ILAC in their own MLA, any regional cooperation that is recognized by IAF and or ILAC for other scopes of the MLA are considered "recognized cooperations" for the new MLA scopes.

2.7 Other factors

2.7.1 Factors that may influence the duration of the evaluation include:

- a) Need for translators and their effect of slowing down the evaluation
- b) Extensive travel and travel circumstances
- c) Cultural differences
- **2.7.2** This annex cannot provide guidance on all possible cases. It is left to the evaluation



teamand 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.

2.7.3 If the leader in consultation with the AB recommends adjusting the plan or including additional evaluation time. Must notify the MLAG Chair prior to finalizing the plan. The MLAG Chair should review the recommendation, approve the assessment plan, and should inform the MLA Group of the decision.

3 Managing the evaluation

3.1 Preparation and planning

The time that the evaluation team needs to spend on preparation largely depends on the quality ofthe documents that the AB forwards. The documents that are required for both initial evaluations and reevaluations are specified in form FM 001. Accurate translation of the documents into English or Spanish must be done if requested by the TL and /or TMs and agreed with the AB. The self-assessment prepared by the AB using IAF/ILAC A3) and the checklist (see form FM 003) relating the accreditation standard(s) to the AB's procedures/documents must be detailed and accurate (instructions, forms, guides, etc.) indicating the current revision. These two documents will greatly assist the evaluation team in preparation. If the self-assessment document does not provide adequate information to the team, the team leader can request the AB to revise the documentwith the necessary information. The AB shall send all documents listed in form FM 001, at least 90 days in advance of a visit to allow for preparation and for requesting additional information.

If documentation is not received on time, the TL shall inform the Chair of the MLAG who may as a result cancel the evaluation (see also Annex 5 for cancelation of a reevaluation).

The team members must start evaluating the documents directly after receipt. In essence the teamleader should be able to prepare a part of the report with background information before the evaluation. This part of the preparation is the same for all types of evaluations.

When planning the evaluation, the TL shall also consider the need to mentor and supervise trainee evaluators working as team members. Particular care should be taken to ensure that trainee evaluators are supervised by an evaluator or lead evaluator when carrying out evaluationtasks in the AB's office. Trainee evaluators may perform witnessing on their own.

If the applicant has applied for accreditation activities for an industry specific program, then the requirements set by that industry group for accreditation bodies shall also be considered on a sampling basis.

The TL, in cooperation with the TMs, shall prepare an evaluation plan using form FM 004 that contains as a minimum:

- Identification of the AB,
- The purpose and date of the evaluation, including the accreditation programs to be evaluated
- The names of the TL and TMs and the accreditation programs that they are authorized for.
- The requirements to be considered.
- Date and time for the opening meeting and date and estimate time for the final meeting.



- General description of activities and/or requirements to be evaluated by each member ofthe evaluation team each day.
- If necessary, identification of AB personnel that will be involved with particular evaluationactivities.
- Private activities of the evaluation team, such as meetings before the evaluation, at nightor after the evaluation.
- Identification of the assessments to be witnessed and the evaluators assigned to them (This identification should include the type of CAB, accreditation scheme or specific fieldof conformity assessment, number of assessor.)
- Information on the need for a meeting between the IAAC TM and the AB's assessment team after the end of the assessment witnessed.
- Other organizations to be visited (such as the NMI) or Committee meetings to be witnessed and the TM that has been assigned those tasks.
- Any travel or any other arrangements that may interfere with the performance of the evaluation.

The evaluation plan FM 004 should be sent to the AB 30 days in advance of the evaluation.

3.2 On-site evaluation

The evaluation team should be prepared to make long working days during the office evaluation.

An on-site evaluation 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 self-assessment report as per IAF/ILAC A3 (This self-assessment is written by the AB using IAF-ILAC A3):
- Evaluation of the records of CAB whose assessment is to be witnessed and of the preparation for the assessment; if possible witnessing of the accreditation decision makingprocess;
- 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;
- Discussing the results of the witnessing with the AB assessment team and AB staff,
- Preparing the report on the witnessed assessments using IAF-ILAC A3 Annex IV;
- Preparation of the summary section of the report, and writing and classification of findings; and
- Meeting with the AB's Director to review IAF-ILAC A3, Annex I, for comments prior to theclosing meeting;
- Closing meeting, presentation and discussing of findings.

During the evenings the team members should meet to discuss their findings and possibly adjust the focus of their attention. In case meetings are not possible the evaluation team should arrange means of communication with the team leader. 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 evaluation plan shall allow the evaluation team sufficient time for all team members to review the findings before presenting them to the AB so as to make sure that all issues raised by all members of the evaluation team have been covered.



Some timetable examples are:

3.2.1 Full size scope AB

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

3.3 Activities after the on-site or remote evaluation

- **3.3.1** Electronic means of communicating with team members should be sufficient to provide feedback and support as TL prepares the final report for the AB.
- **3.3.2** The assessment team needs to spend time in reviewing the AB corrective actions and in preparing the assessment team's commentary to these corrective actions. The TL should take the lead in preparing this feedback.
- **3.3.3** Finally, the TL shall prepare a recommendation.



Annex 3

Evaluation Reporting on an Accreditation Body

1. Steps in Evaluation Reporting on an Accreditation Body:

1.1. Preparation of summary section of report

This summary section has to be completed and be confirmed by the applicant at the end of the on-site evaluation visit. The content of the summary is described in IAF/ILAC A3. It includes as an annex the nonconformities and comments presented in table format using form IAF/ILAC A3,Annex I (see section 2.1). In addition, it should include a recommendation on the program for the witnessing program to be carried out in the next evaluation, for the scheme of Management System Certification Bodies within the scope of recognition (See Annex 2, Table 1).

The summary report and the findings shall be provided to the MLAG Secretary and MLAG Chair immediately after the evaluation visit.

1.2. Preparation of the Draft Report of the On-site and Remote Evaluation

Visit.(Deadline - within 60 days from the closing meeting in office evaluation). This report is the agreed report of the evaluation team and the Accreditation Body and includes all information described in IAF/ILAC A3, except the responses to the findings, the reaction from the evaluation team, and the recommendation.

The report, that is prepared by the leader with the support of the team members shall include any outstanding disagreement within the evaluation team or between the evaluation team and the accreditation body, with the opinions of all parties.

For any AB appeals of findings or adverse decisions by an evaluation team during the evaluation process, see PR 005, Procedure for Handling Appeals and Complaints

1.3. Formal Response of the Accreditation Body to the Findings.

The accreditation body's response can simply be inserted under each finding in form IAF/ILAC A3, Annex I, with attachments of supporting evidence of corrective action as appropriate. (see what is expected of the AB's response and corrective action described in section 3 of this Annex).

In case the nonconformity is appealed, the response to the finding(s) being appealed is subject to the closure of the appeal. The report should contain information on the process followed and actions taken: acceptance of the appeal, closure of the appeal process, actions proposed by the AB if applicable, and team response if applicable.

For initial evaluations and extensions of scopes:

- Within 90 days from the evaluation the AB shall present an action plan and time schedule for implementation of actions for nonconformities and responses to the comments.
- The AB should provide evidence of effective implementation of actions implemented to address nonconformities within 240 days from the evaluation or as agreed with the TL.



- In case there is a need for a follow up visit to confirm implementation of actions, the AB shall present evidence of implementation of actions at least 60 days before the followup visit, or as agreed with the TL. In this case, if there are any actions pending after the follow up visit, the AB should provide evidence of effective implementation of actions to address nonconformities within 120 days from the follow up visit.

For reevaluations:

- Within 30 days from the reevaluation the AB shall present an action plan and time schedule for implementation of corrective actions for nonconformities and responses to the comments.
- The AB shall present evidence of effective implementation of corrective actions for nonconformities within 90 days from the evaluation.
- In case there is a need for a follow up visit to confirm implementation of actions, the AB shall present evidence of implementation of actions at least 60 days before the followup visit, or as agreed with the TL. In this case, if there are any actions pending after the follow up visit, the AB shall provide evidence of effective implementation of corrective actions for nonconformities within 30 days from the follow up visit.
- 1.4. Formal Reaction of the evaluation team to this Response. The evaluation team's reaction to each response to every finding is submitted in writing to the Accreditation Body for consideration using IAF/ILAC A3, Annex I. (Deadline within 30 days of receipt of the response described in step 1.3.)

1.5. Steps 1.3 and 1.4 may be repeated.

Any problems completing steps 1.3 and 1.4 shall be reported by the TL to the Chair and Secretary of the IAAC MLAG.

Provided that the 180 days indicated in clause 1.6 is not exceeded, the process may include up to four closure proposals from the Accreditation Body. If there is no agreement of closure of the nonconformity(ies) by the evaluation team after the fourth proposal by the AB, the incomplete report shall be submitted to the MLAG for a decision.

1.6. Preparation of a Final Report to the MLA Group.

(Deadline: 30 days from completion of step 1.5.)

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 evaluation team stated as a section of the evaluation team's final report (see section 2.1 in this Annex). Items included in steps 3 and 4 shall be combined into IAF/ILAC A3, Annex I, stating the findings, the formal AB response including corrective actions, and the evaluation team's reaction. The report shall also include information on the follow up visit, if relevant (see clauses 2.2 and 2.3 in this Annex).

For initial evaluations and extensions of scope, the final report shall be provided to the MLAG Secretary and MLAG Chair 30 days after all findings have been closed.

For reevaluations, the final report shall be provided to the MLAG Secretary and the MLAG Chair 180 days from the date of the reevaluation even if some findings are still open unless the MLA Group or the MLAC Chair has authorized a follow up visit, in which case the final report shall be provided to the MLA Secretary and the MLAC Chair 60 days after the follow up visit.



At this stage of the evaluation, if the evaluation team's recommendation includes a follow-up visit verify the corrective actions, this decision shall be made by the MLA Group Chair. If a follow-up visit to be conducted, the evaluation team should be composed of one or more members of the evaluation team that conducted the full evaluation.

2. Typical Structure and Content of a Final Evaluation Report on an Accreditation Body

2.1. Full evaluation report

The report shall be prepared using IAF/ILAC A3.

2.2. Follow up visits done before a final decision by the MLA Group.

The report shall be prepared using IAF/ILAC A3.

The summary section about the follow up visit and the updated IAF/ILAC A3, Annex I, shall be provided to the AB at the end of the visit.

2.3. Follow up visits done after a final decision by the MLA Group.

If the follow up visit aims at checking implementation of corrective actions after IAAC MLA Group makes a decision on granting or maintaining recognition, the information on the activities done in the follow up visit shall be included in a report issued specifically for that follow up visit as follows:

- **2.3.1.** The cover page shall state 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 and team members, specifying the organization to which they belong, and a clear indicationthat the report is confidential.
- 2.3.2. The report shall include a section with a summary of the follow up visit, including the reasons for the follow up visit, reference to the decision authorizing the visit, by the MLA Group, the evaluators participating in the visit, dates of the visit, a summary of the activities performed by the evaluation team, confirmation whether or not all findings have been closed and a recommendation to the MLA Group on the next steps of the process.
- **2.3.3.** An annex with the follow up visit plan.
- 2.3.4. An annex with the report on any assessments witnessed using IAF/ILAC A3, Annex V.
- 2.3.5. IAF/ILAC A3, Annex I, including only the findings and corrective actions of the previous evaluation visit that were checked in the follow up visit, and information about the evidences obtained by the evaluation team for each of the findings, confirmation that the finding is closed or information on the actions that are still pending.
- **2.4** The summary section, the table of findings with information about the actions taken shall be provided to the AB at the end of the visit. The final report shall be sent to the MLA Secretaryand MLAG Chair within 30 days after the visit.



- Content of a final evaluation report for an Accreditation Body that is a signatory of the MLA of another recognized regional body and/or ILAC andIAF.
- **3.1.** When an AB is applying for recognition for a scope for which it is already a signatory of the MLA of a regional body and/or IAF and ILAC, the evaluation activities may be limited to a document review of the current documentation and resolution of any findings observed therein.
- **3.2.** In this case the report shall include:
 - A summary section regarding the application, related documents, and the decision to limitthe evaluation activities to a document review;
 - Description of the outcomes of the document review for all the requirements of ISO/IEC 17011. The team leader can issue the report based on the complete and updated IAF/ILAC A3. If there is an IAAC mandatory document related to the scope under evaluation, it shall be considered in this section of the report;
 - Information regarding the changes in the AB since the evaluation date performed by theregional body and/or IAF and ILAC;
 - Evaluation team recommendation to the MLA Group;
 - An annex using IAF/ILAC A3, Annex I, that includes the nonconformities and comments, and when applicable, it should include the AB's responses;
 - An annex with the full report of the regional body and/or IAF and ILAC; and
 - An annex with documentation of the decision from the other regional body and/or IAF and ILAC.
- 4. Content of a final evaluation report for an accreditation body extending the MLA to level 4 and/or 5.
- **4.1.** For extensions of scope to include new Level 4 and/or Level 5 normative documents theevaluation report shall include:
 - A summary section regarding the application, related documents, the decision to limit theevaluation activities to a document review according to Annex 7 on this document.
 - Description of the outcomes of the document review for clauses, 4.6, 6 and, 7 of ISO/IEC17011 and IAAC, IAF and ILAC mandatory documents applicable to the MLA subscope.

Note: Other requirements may be evaluated if the evaluation team finds it necessary.

- Evaluation team recommendation to the MLAG
- An annex using IAF/ILAC A3, Annex I, with the nonconformities and comments, and whenapplicable, it should include the AB's responses.

5. Guidance on classification of findings

Finding: To be used as a general term



The IAAC MLA structure is defined in procedure PR 025. During an evaluation, findings shall onlybe raised within the scope the IAAC MLA that is being evaluated.

The IAAC MLA for calibration, testing clinical/medical, inspection, product certification, certification of persons, validation and verification of Greenhouse gas (GHG), proficiency testing and reference materials production, management system certifications, biobanks, covers all accreditations granted by the AB under the applicable standards for those activities, and all conformity assessment services accredited by the AB. Therefore, findings can be raised for issues related to all Levels of the IAAC MLA (Levels 1, 2, 3,4 and 5).

The IAAC MLA for management systems certification covers all accreditation granted by AB underISO/IEC 17021-1, therefore, findings can be raised to any issues related to Levels 1, 2 and 3 of the IAAC MLA (main scope). The IAAC MLA for management system covers only conformity assessment services included in the Level 4 and 5 standards specified in PR 025 (sub-scopes), therefore, findings can only be raised for issues related to those specific Level 4 and 5 standards.

The findings are categorized into:

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

The evaluated AB is required to respond to nonconformity by taking appropriate corrective action and providing the evaluation team with evidence of effective implementation.

A nonconformity is considered closed when the evaluation team has accepted the evidence of effective implementation of corrective action provided by the AB.

- **Comment:** Finding about documents or AB's practices with a potential of improvement; but stillfulfilling the requirements.

The evaluated AB is required to respond to comments.

A comment is considered closed when the evaluation team has received the response from the AB.



Annex 4 Decision Making Regarding Evaluations

1. Decision Making Regarding Evaluations

- **1.1** The final evaluation report shall be submitted to the MLAG Secretary and MLAG Chair (seedeadlines in Annex 3, item 1.6).
- **1.2** The MLAG Secretary distributes the final report to the MLA Group, which shall decide:
 - **1.2.1** in the case of an initial evaluation, whether or not the Applicant Body may enter the Cooperation's Arrangement;
 - **1.2.2** in the case of a re-evaluation, whether the applicant Body will maintain, extends, reduces, suspends, lifts the suspension, or withdraws its status as a Signatory to the Arrangement. Positive decisions can be accompanied by conditions (see 2.0 Hierarchy of Decisions).

Note 1 The MLA 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 relevant re-organizations.

Note 2 For voting rules see the document AD 021.

- 1.3 The MLA Group shall review the evaluation report findings to confirm that they are correctly classified and that the report contains the necessary information to have full confidencethat the applicant complies with MLA requirements. The MLA Group may request additional information from the evaluation team and the AB. During this review no new NC will be raised, however the MLAG could identify an improvement opportunities regarding the classification of finding in order to harmonize peer evaluation criteria.
- **1.3.1** Decisions on initial evaluations will normally be made during the MLAG meetings. In case decisions are made by email ballot, this process will be carried out in 3 steps:
- **Step 1)** Review of the evaluation report by the MLA Group and presentation of comments. The MLA Group shall provide written comments to the report within 30 days or as agreed by the MLA Group. All signatories are required to send their comments to the MLA Secretary. If a signatory does not have any comments, the signatory's representative shall state that in writing.

Comments shall clearly identify the section, page of the report and, if relevant, the number of thefinding. Comments should include issues that need to be clarified by the evaluation team and/or the evaluated accreditation body.

Step 2) Clarification on comments

As soon as the comments for a MLAG member are received, the MLA Secretary will forward them to the evaluation team leader and the evaluated accreditation body for their clarification. This step should be completed within 30 days from the end of the comment period or as agreed by the MLAGroup.



Step 3) Email ballot

After getting clarifications on the comments, the MLA Secretary will submit the final report, the comments and the clarifications to the MLAG for a 30-days electronic ballot. In order to avoid conflict of interests, the person representing the signatory in this email ballotshall not have participated in the evaluation.

2. Hierarchy of Decisions

- **2.1** Decisions on New MLA Applicant and Extensions of Scope and re evaluations.
 - 2.1.1 The decision must include the date of the reevaluation, which must not exceed 4 years period from the date of the evaluation, if there was no date extension by the MLAG Chair t, if there was, then it will be 4 years from the original date. Note: In case the Accreditation Body includes in its scope of recognition the Management Systems Certification Bodies scheme, the decision must include the witnessing program to be carried out in the next reassessment.
 - **2.1.2** The MLA group may decide that a follow-up visit by one or more members of the assessment team is necessary to confirm the implementation of corrective actions.
 - **2.1.3** The MLA Group may request additional information before making a decision. This may include submittal of required evidence of corrective actions, or of any other information as determined by the MLA Group.
 - **2.1.4** In case the AB is not able to meet the deadlinesfor responding to and closing findings, the MLA Group may issue warnings and fix a prorogation of the deadline after which a decision will be made.

2.2 Acceptance into the IAAC MLA Group

- **2.2.1** Once the IAAC MLA Group has approved a new signatory of the MLA, it is accepted immediately into the MLA.
- **2.2.2** The MLA Secretary will inform the IAAC General Assembly of new signatories and theirscopes of recognition.
- **2.2.3** The MLA Group may decide reduction of recognition for one or more scopes, the suspension of the IAAC MLA or withdrawal of MLA signatory status.

2.3 Notification of change

- 2.6.1 Each Signatory of the IAAC MLA shall report any significant changes in its status and/orits operating practices, key staff. As well as, other changes that significantly affect the competence or credibility of the accreditation process (e.g. as listed below) including the impact of these changes, without delay to all MLA Group members through the IAAC MLA Secretary.
 - 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;
- Sector specific accreditation programs/schemes endorsed by IAAC, IAF and ILAC with which the AB is involved.
- Other changes that significantly affect the competence or credibility of the accreditation process.
- 2.3.1. The MLA Secretary will update the relevant information about the signatory on the IAACwebsite and inform all IAAC members about the changes. The MLA Group shall review the changes that affect the MLA and decide on the need for any subsequent actions, which may include but are not limited to:
 - Request the signatory to provide additional information,
 - Perform an extraordinary evaluation,
 - Verify the implementation of the changes in the next re-evaluation,
 - Update the name of the organization and sign a new Signature Sheet of the IAAC MLA.

2.4 Suspension and withdrawal of MLA Group

- 2.4.1 It may be that the IAAC MLA Group cannot accept the corrective action taken by an AB with regard to significant changes notified by the AB, or to nonconformities which have beenfound, or to substantiated complaints from interested parties. It may also be that the AB does not provide the documentation required to perform the evaluation, delays reevaluations or follow up visits, or does not appropriately respond to the nonconformities of a peer evaluationin the time frame established in this document. The IAAC MLA Group shall take appropriate action. This action can be suspension for a maximum period of 6 months or withdrawal from the IAAC MLA.
- 2.4.2 Notwithstanding any other clause in this document, an accreditation body member shallnot remain a member of the MLA Group if it is, for any reason, suspended or withdrawn from the MoU. The IAAC Executive Secretariat shall immediately notify the MLA Group when any member of the MLA is suspended or withdrawn from the MoU for any reason, and the MLA Group shall immediately suspend or withdraw the membership of the body in the MLA.
- 2.4.3 Suspension or withdrawal of a signatory shall be decided by the IAAC MLA Group in accordance with the same procedures used for acceptance of MLA signatory. IAAC MLA Secretary shall inform IAAC members, ILAC, IAF, and all recognized Regional Cooperations about any suspension or withdrawal decided by IAAC. That information shall be accompanied by an appropriate explanation stating the reason for suspension or withdrawal to the signatory.



The suspended or withdrawn AB may appeal the decision in accordance with IAAC PR 005.

- **2.4.4** Decisions on suspension shall state:
 - the reasons for suspension;
 - the period of suspension (maximum 6months) and/or the conditions for reacceptance into the IAAC MLA;
 - the consequences of suspension.
- **2.4.5.** The consequences of suspension shall be decided by the IAAC MLA Group on a case by case basis, depending on the reason for suspension. The consequences of suspension may include, for the applicable scope:
 - Not actively promote the fact that they are a signatory to the IAAC MLA;
 - Not be able to participate in any ballots associated with the IAAC MLAG;
 - notify all accredited CABs of the suspension and the consequences of the suspension as it relates to them; and
 - Notify stakeholders in their economies of the suspension.
 - Do not issue any accreditation document bearing the IAF MLA and/or ILAC mark.
- **2.4.6.** The obligations of the accreditation body while suspended are:
 - Continue to comply with the obligations of full membership;
 - Cooperate fully with the IAAC MLA Group to enable a speedy resolution of thesuspension;
 - · Maintain oversight of their accredited CABs.
 - Continue to participate in IAAC, ILAC, IAF or other voting related to the agreement.
- **2.4.7.** 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 IAAC MLA and, if applicable, the IAF/ILAC Arrangement and the CAB shall no longer make reference to the IAAC MLA and to IAF/ILAC Arrangement.
- **2.4.8.** When a withdrawn AB applies to become an IAAC signatory again, the procedure fornew applicants must be followed.



Annex 5 Monitoring and Re-evaluation of a Single Accreditation Body

- **1.** Periodic monitoring and re-evaluation of the Arrangement(s) is necessary.
- **2.** All MLA Signatories shall be formally re-evaluated at maximum intervals of four years from the month when the previous full evaluation was done.
 - 2.1 The procedures for reevaluation are essentially the same as for an initial evaluation. Although an application as per form FM 001 is not required, the AB shall provide the evaluation team all documents required in form FM 001, item 20, 90 days in advance of the evaluation. For planning of the witnessing, the AB shall also provide the evaluation team with a list of assessments that will take place from about 6 weeks before the proposed on-site evaluation date, or as agreed with the team leader. Failure to meet that deadline may lead to the cancelation of the re-evaluation and other action as found appropriate by the MLA Group (see Annex 4, clause 2.7.1).
 - **2.1.1** In addition, as soon as the evaluation team is appointed, the MLAG Secretary shall sendthe evaluation team:
 - a) The final report of the last evaluation or reevaluation;
 - b) Reports on any follow up visits done after the last evaluation/reevaluation;
 - c) The MLA Profile of the AB which includes all of the MLA Group resolutions regardingthe AB, as well as other useful information for the evaluation team;
 - d) A list of the names of the CABs and assessors/experts that were witnessed during the previous evaluation, form FM 022;
 - e) Information on complaints received at IAAC about the Accreditation Body, when applicable.
 - f) Information on changes reported by the AB, according to numeral 2.3 of Annex 4
 - 2.2 Where there are difficulties to agree on a date for the re-evaluation that suits the evaluation team and the accreditation body, the MLAG Chair may authorize the evaluation to be delayed for 30 days. Any delay longer that 30 days shall be consideredby the IAAC MLA Group and may lead to suspension from the MLA or other actions as found appropriate by the IAAC MLA Group.
- **3.** Partial to total re-evaluation may be conducted at an earlier date as directed by the MLA Group, should there be due cause such as notification of significant changes (see Annex 4, clause 2.6).

Note: Re-evaluations may also be conducted earlier than the deadline if that is requested by the accreditation body, for example, in order to carry it out together with an evaluation for extension of the scope of recognition.

4. The changes notified by an MLA signatory shall be appropriately evaluated (see Annex 4, clause 2.6).

The MLA Group shall evaluate the implementation of new versions of standards applicable to the scope of the IAAC MLA, and if necessary other documents mandatory for the MLA, so as to ensure that implementation dates decided by IAAC, IAF and ILAC are met.



Annex 6

Disclosure of Evaluation Reports

- 1. A report on the evaluation of an accreditation body carried out on behalf of the IAAC MLA Group shall not be published in the public domain.
- 2. An accreditation body may, however, choose to disclose the full report to its interested parties with the purpose of promoting the acceptance of the IAAC MLA under the conditions detailedbelow.
- **3.** The evaluation report shall not be disclosed until after it has been formally considered by theIAAC MLA Group.
- 4. The IAAC MLAG Secretary may provide to the accreditation body the documents that may be collectively disclosed to interested parties. Those documents shall include the full evaluation report, including the responses to the findings and all other Annexes, and the IAAC MLA Group resolution arising from the consideration of the report. All references to any specific conformity assessment body and names of assessors shall be removed by the IAAC MLAG Secretary from the documents that may be disclosed. The IAAC MLAG Secretary may provide these documents to the accreditation body, if requested, within 30 days from the date of the MLA Group resolution.
- 5. The documentation provided by the IAAC MLAG Secretary to the AB shall be disclosed by the AB collectively; together with an appropriate statement as to the confidential nature of the information, i.e. the information shall remain confidential to the accreditation body and the recipient except where the law requires such information to be disclosed.
- **6.** Where the evaluation is performed jointly with other regional groups or with ILAC or IAF, the evaluation report shall not be disclosed unless there is agreement among the parties involved in the evaluation and the accreditation body.



Annex 7 Extension of the Accreditation Body's MLA scope

- A signatory of the IAAC MLA may apply to extend its MLA to include new scopes. This
 Annexspecifies the procedures to be followed for those extensions. The IAAC MLA
 structure is documented in PR 025 and includes 5 Levels. Theterm "scope" is used in this
 Annex a generic term for all MLA Levels; the term "sub-scope" issued for Levels 4 and 5
 of the IAAC MLA.
- 2. When an AB applies for an extension it shall have a minimum of one accredited CAB under the scope or sub scope applied for. If the AB does not have the minimum of accredited CABsthe application shall not be considered by the MLA Group.

The AB shall apply for an extension of the IAAC MLA using FM 001.

Note: For the extension for recognition of accreditation of sub-scopes for certification of management systems, the AB shall present to the MLA Secretary a self-declaration using IAF MLA MC 28 "MLA Declaration for sub-scope extensions (AB)" form. The MLA Group will decide on the acceptance of the self-declaration by resolution. This decision/resolution will be communicated to IAF by the IAAC Executive Secretary.

Note: Instructions on how to evaluate the sub-scopes are described in Annex 2 clause 2.3

3. Extensions of scope to include a new Level 3 activity will require a full evaluation of all MLA requirements, similar to an evaluation for initial recognition for the IAAC.



Annex 8 Description of other activities of the AB and the peer evaluation team

1 Introduction:

This Annex defines activities and contains a check list for IAAC evaluation teams to assist them in theplanning and conduct of peer evaluations. It is also an applicable resource for IAAC accreditation bodies that are subject to these evaluations.

For initial evaluations and evaluation for extensions of scope, the AB is responsible for submission of the application for arrangement membership to the IAAC MLAG Secretary who will carry out a review and if the application is complete, will send it to the MLA Group for a ballot. If the application accepted, the Team Leader and Team Members will be appointed by the IAAC MLA Group Chair within 90 days from the acceptance of the application. For a re-evaluation, the evaluation team is usually appointed from 6 to 12 months before the re-evaluation due date.

The MLAG Secretary informs the AB of the composition of the Team, and the AB may object basedon conflict of interest or impartiality.

2 Preparation for the evaluation

- **2.1** The Team Leader must communicate with the AB to, identify any changes occurring since the submittal of the application, and identify potential dates for the evaluation.
- **2.2** For all evaluations all Team Members will receive the relevant documentation from the IAAC MLAG Secretary. The AB must provide the documentation specified in FM 001to the team 90 days in advance of the evaluation.
- **2.3** The Team will begin the document review as soon as they receive the documentation and fill out the FM 003 and send it to the AB up to 30 days prior to the evaluation or 60 days after receiving all documentation.
- **2.4** For initial evaluations, if a Preliminary Visit is done a short written report is submitted by the Team Leader and all corrective actions must be completed. The MLAG will receive the recommendation of the Team Leader and decide if a full evaluation can take place.
- **2.5** If the evaluation is done jointly with another Regional Body, the Team Leader should liaise with the Chair of the IAAC MLAG and the other region's MLA Committee Chair to agree on specific arrangements for the evaluation.
- **2.6** Team Leader must work with AB on agenda of the evaluation visit including:
 - Dates of visit, to include any possible need to stay more than 5 days;
 - Travel considerations including flight issues to/from the evaluation and travel to CABs forwitnessing;
 - Assignment of tasks to Team Members; care should be taken to avoid allocating the evaluation of related requirements to different members of the evaluation team, when there is not enough AB personnel available for interviewing, the purpose is to avoid duplication and restricted access to the appropriate AB staff;
 - Need for interpreters;
 - Ensure sufficient time for team meetings after the evaluation at the AB's office,



especiallyfor the evening before the last day of the evaluation. Inform the AB of any dietary requirements and physical limitations of Team Members;

- Ensure that the AB knows the requirement for arranging travel and accommodations, as well as for covering daily expenses incurred by the each Team Member;
- Need for a meeting room at the hotel the day before the evaluation and each evening during the evaluation;
- Need for a private meeting room during the evaluation at the AB's office;
- Need for Internet access at the AB 's office and at the hotels;
- Identification of AB Staff Members who will be involved in the evaluation and the requirements they will be involved with (This information may be included in FM 004);
- It may be important to document in FM 004 information regarding location, type of assessment and dates of the witnessing activities;
- Complete form FM 004 approximately 30 days prior to the visit and submit to the AB.
- 2.7 TL should consider the AB's directory of accredited CABs, its accreditation scopes and the dates of accreditations renewals, in order to plan the peer evaluation schedule and to select the assessment activities to be witnessed.
- **2.8** Team Leader must communicate with Team Members to:
 - Obtain information about their technical background and experience in accreditation and peer evaluations, and language skills;
 - Ensure Team Members understand the need to complete document review and submitcomments for inclusion in Form FM 003;
 - Verify Form FM 004 is completed and assignments understood;
 - Explain how travel and hotel arrangements will be made and how costs of will bemanaged;
 - Explain expectations at the AB's site or witnessing sites including dress codes and /orsafety issues.
- **2.9** Additional issues to be considered by the Team Leader during preparation:
 - Is there a need to visit the NMI? (see Annex 2, section 2.5)
 - Is the AB applying for recognition for a scope for which it is already a signatory of the MLAor a recognized regional body and /or IAF or ILAC? (see Annex 2, section 2.6)
 - Determine a time for team meeting each day by telephone or some other means communication.
 - Partial preparation of draft report using submitted self-evaluation given in FM 003.
 - Consider the need to mentor and supervise trainee evaluators.

2.10 Evaluation team meeting before the evaluation

The Team Leader shall conduct a meeting with the Team Members the day before the evaluation in which discussions should focus on:

- Identification of key items arising from the documentation review to follow-up on;
- For re-evaluations, identification of any findings from the previous evaluation that need tobe reviewed and any special instructions / resolution from the IAAC MLA Group concerning the evaluation;
- What objective evidence to going to be sought to verify conformity requirements:
- Assignment of any specific task to Team Members;
- Any queries to be clarified during the opening meeting;



- Confirmation of means of communication and issues to be reported, particularly when Team Members need to travel for witnessing;
- Review of witnessing objectives (IAF-ILAC A3, Annex V);
- Confirmation on results on reporting from each Team Member (findings, summary report, IAF-ILAC A3);
- Provide any necessary guidance to trainee evaluators and confirm how they will be mentored / supervised;
- Confirmation of evaluation plan (FM 004) and any need for changes, verify that documentsnot applicable to the evaluations scope are deleted from the plan.

3 During the evaluation

3.1 The Team Leader shall:

- Lead the opening meeting; ensure any queries from team members have been clarified with AB and remind the AB the classification of findings as describe in this document.
- Ensure the evaluation remains on track;
- Ensure team members gather sufficient objective evidence to support their findings;
- Mentor less experienced team members;
- Ensure AB receives feedback, as appropriate, throughout the evaluation;
- Ensure team discussions remain on track:
- Gather information from team members at the end of each day.
- Ensure that meetings and other communications among the team focus on:
 - follow up on issues as decided the day before,
 - findings already confirmed, potential findings and additional evidence to be ought,
 - issues to be followed up and assignment of tasks,
 - confirmation that plans are on track and need for changes of plans,
 - confirmation that reports (IAF-ILAC A3) are being done by each teammember as planned;
- Ensure that the meeting at the end of the day focuses on:
 - confirmation of findings and their classification by all team members
 - drafting the summary report (as far as possible),
 - issues to be finalized the last day,
 - confirmation of the time by which all findings and the summary report willbe completed the next day for review by the AB before the final meeting, remind team members that report on witnessing (IAF-ILAC A3, Annex V) should have been completed before that meeting. If that is not possible, allissues that may result in a finding shall be reported during the meeting and IAF-ILAC A3, Annex V shall be delivered to the Team Leader shortly thereafter in the week following the evaluation.
- Ensure findings are based on clear and objective evidence, are correctly classified and assigned to clauses of ISO/IEC 17011 and other MLA requirements;
- IAF-ILAC A3, Annex I, shall be reviewed for comment by the AB prior to the closingmeeting:
- Prepare summary report and list of Nonconformities and Comments (IAF-ILAC A3 AnnexI) for presentation to AB at closing meeting;
- Recommendations for follow up visits should be made based on:
 - the need of confirming implementation of actions,



- AB has not demonstrated enough experience due to a limited number of accredited CABs or limited number of evaluators,
- Or the peer evaluation team may indicate that the recommendation for follow up will be made after they received the AB's response for the findings. The summary report should highlight any findings that are recurrences of findings from the previous evaluations;
- Ensure, during closing meeting, that any differences are clarified, disagreements resolved;

3.2 Team Members should:

- Follow the evaluation plan and instructions given by the Team Leader;
- Make sure enough evidence is collected to confirm compliance and competence, or sufficient evidence for any finding;
- Keep notes of evidence collected for reference (document number, forms, identification and dates of records, details observed in records, persons interviewed, etc.);
- Make sure the AB understands any finding and is given opportunity to clarify the issue;
- Make sure the person that provides information is the appropriate responsible person inthe AB and, if necessary double check and reconfirm the information given;
- Not interfere with the work of AB assessors during witness;
- Provide feedback after the conclusion of the witnessing and clarify any outstanding issueswith the AB assessors
- Make notes of discussion, records and documents during witnessing so that informationmay be recollected and confirmed with assessors after the end of the witnessing;
- Confirm facts with assessors and AB representative after the end of witnessing;
- Report to the Team Leader any issues that may need to be confirmed by other teammembers:
- Complete reports on time.

4 After the evaluation

4.1 The Team Leader shall:

- Provide the draft report, agreed among the team members, to the AB for comment and correction of errors (if necessary) within 60 days of the evaluation visit (see Annex 3. section 1.2):
- Review the AB 's corrective action and response report (IAF-ILAC A3 Annex I), assigningparts to team members, as applicable;
- Ensure AB provides evidence of identification of and correction of the root cause(s) of non-conformities, as well as a response to comments (see Annex 3, section 5);
- Advise the AB if the response is acceptable within 30 days of receipt;
- Ensure the deadlines for responses from the AB and the team for delivering the report to the MLAG Chair is met (see Annex 3, section 1.3, 1.4 and 1.6);
- Once the team is state that the AB 's response is satisfactory and all necessary corrective action has been taken, prepare a recommendation to the IAAC MLA Group andinclude it in the Final Report (IAF-ILAC A3), this recommendation shall include the recommendations of the witnessing plan, where applicable.
- Send the Final Report (IAF-ILAC A3) (findings, AB 's response, evaluation team 's reaction to that response), and any relevant annexes to the MLA Secretary and the



- MLAC Chair, together with Lists of Witnessed Assessment (FM 022);
- complete evaluator performance log for each team member (FM 007) and send it to the IAAC MLA Secretary;
- In case the Final Report is distributed to the MLA Group for written comments, respond tocomments as requested and amend the Final Report, if necessary (see Annex 4); within 30 days
- Inform the MLAG Secretary if you will be present in the next MLAG meeting or whether you may be available via Internet. In case attendance of the meeting is not possible, inform the MLAG Secretary who may represent the evaluation team during the meeting.

4.2 Team Members shall:

- Provide the Team Leader their complete report on assessments witnessed (IAF-ILAC A3Annex V) immediately after the evaluation (if not complete during the evaluation);
- Provide the Team Leader their assigned part of the Final Report (IAF-ILAC A3) immediately after the evaluation;
- Review AB 's response for the findings assigned to him/her as soon as they are received;
- Complete evaluator performance log for the Team Leader (FM 008) and send it to theIAAC MLAG Secretary.