

# IAF/ILAC Multilateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of an Accreditation Body

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IAF-ILAC Multilateral Mutual Recognition Arrangements (Arrangements): Requirements for Evaluation of an Accreditation Body

# **PREAMBLE**

The international accreditation community is comprised of Regional Groups, Accreditation Bodies and stakeholders which cooperate through the International Accreditation Forum, Inc. (IAF) and the International Laboratory Accreditation Cooperation (ILAC). A principal objective of IAF and ILAC is to put in place worldwide, Multilateral Arrangements/Mutual Recognition Arrangements (Arrangements). Both IAF and ILAC aim to demonstrate the equivalence of the outcomes of their recognised Member Accreditation Bodies through these Arrangements. As a consequence, the equivalent competence of Conformity Assessment Bodies accredited by these Accreditation Bodies is demonstrated. The market can then be more confident in accepting certificates, reports and services provided by the accredited Conformity Assessment Bodies.

IAF and ILAC link the existing Arrangements of the Regional Groups (also called: regional accreditation cooperations or regional accreditation groups). For the purposes of their Arrangements, both IAF and ILAC recognize Regional Groups for the evaluation and re-evaluation of Applicant and Full Member Accreditation Bodies within their defined territory and associated decision-making relating to the membership of the IAF and ILAC Arrangements in that territory. Formal "Recognition" of a Regional Group with respect to the IAF and ILAC Arrangements is based on an external evaluation of the Regional Group's competence in Arrangement management, practice and procedures by an evaluation team composed of Evaluators from other IAF and ILAC Member Regional Groups and Accreditation Bodies.

Evaluations relating to the development and maintenance of the IAF and ILAC Arrangements operate at two Levels:

- ♦ the evaluation of the competence of Accreditation Bodies to perform accreditation of Conformity Assessment Bodies;
- ♦ the evaluation of a Regional Group's competence in managing the operations of regional Arrangements (see IAF/ILAC A1).

The general requirements to be used by IAF and ILAC and their recognised Regional Groups, when evaluating the competence of an Accreditation Body for the purpose of qualifying to sign the applicable Arrangement(s) are set out in this document.

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

Arrangement Groups are encouraged to share information on the practical use and improvement of their peer evaluation systems.

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IAF-ILAC Multilateral Mutual Recognition Arrangements (Arrangements): Requirements for Evaluation of an Accreditation Body

# **PURPOSE**

To provide the Regional Groups, ILAC and IAF with general requirements for evaluating single Accreditation Bodies for the purpose of signing applicable Arrangement(s). Regional Groups, ILAC and IAF shall follow these requirements and their procedures shall be consistent with those specified in this document.

# **AUTHORSHIP**

This publication was prepared by a joint IAF/ILAC working group on Harmonization of Peer Evaluation Processes and endorsed for publication by the respective General Assemblies of IAF and ILAC in 2004. It was reviewed by the joint IAF/ILAC working group on maintenance of A-series documents in 2006, 2009, 2013, 2015, 2016, 2017 and 2025.

# 1 Introduction

# 1.1 Scope

This document identifies requirements for the evaluation of an Accreditation Body. IAF/ILAC A1 requires the Arrangement Groups to adopt the requirements and develop procedures consistent with those requirements described in this document.

#### 1.2 Definitions

For the purpose of this document the following definitions apply:

- 1.2.1 Accreditation Body (single or multi economy AB): An organisation that operates an accreditation system for one or more types of Conformity Assessment Bodies and is a member of ILAC/IAF and/or a Regional Group.
- 1.2.2 Accreditation Scheme: Rules and procedures specified in a standard or normative document included in IAF and/or ILAC Arrangements that address the process for the accreditation of Conformity Assessment Bodies (Level 3).
- 1.2.3 Arrangement: The Multilateral or Mutual Recognition Arrangement (MLA/MRA) of a recognised Regional Group or of IAF or ILAC.
- 1.2.4 Arrangement Group: All signatories to an Arrangement.
  - NOTE: Currently IAF, ILAC and the Regional Groups are considered as relevant Arrangement Groups.
- 1.2.5 *Decision Making Group:* A body within the Arrangement Group structure that decides on the status of membership of an Arrangement.
- 1.2.6 Evaluation Deputy Team Leader: A person supporting the Evaluation Team Leader.
- 1.2.7 Evaluation Team Leader: A person responsible for leading a team in the evaluation of an accreditation body.
- 1.2.8 Evaluation Team Member: A person serving on a team in the evaluation of an accreditation body with a specific task (usually at Level 3 of the MLA/MRA).
- 1.2.9 Extraordinary situations: Unforeseeable situations beyond the control of the organisation that may negatively impact the ability to continue work, commonly referred to as "Force Majeure" or "act of God". Examples include war, strike, riot, political instability, geopolitical tension, terrorism, crime, pandemic, flooding, earthquake, malicious computer hacking, other natural or man-made disasters.
- 1.2.10 *Full Evaluation:* Initial Evaluation, Re-Evaluation, Extension of Level 3 Scope Evaluation.
- 1.2.11 *Management Committee:* A small member group responsible for the everyday management of the Arrangement.

- 1.2.12 *Peer Evaluator:* A person authorized as an Evaluation Team Leader, Deputy Team Leader, Team-Member or Trainee Team Member.
- 1.2.13 *Peer Evaluation:* A structured process of evaluation of a Regional Group or Accreditation Body by representatives of Accreditation Body Peer Evaluators against specified requirements in an Arrangement Group.
- 1.2.14 Regional Group (also Regional Accreditation Group or Regional Accreditation Cooperation): A Regional Group consisting of accreditation body members representing different economies (possibly involving other stakeholders) whose purpose is to develop and maintain a Mutual Recognition Arrangement and be a member of ILAC and/or IAF.
- 1.2.15 Review Group: A person or group of persons with the required competencies who reviews a Peer Evaluation report, other supporting documents and the procedure of the Peer Evaluation and provides a summary report and recommendation to the decision-making group(s).
- 1.2.16 *Signatory:* A Member who has signed one or more of the Arrangements.
- 1.2.17 *Split-Evaluation*: A Full Peer-Evaluation, where different Level 3 activities are evaluated on different dates from the commencement of the office Peer Evaluation.
- 1.2.18 *Standard:* A standard or other normative documents related to Accreditation and Conformity Assessment Bodies.
- 1.2.19 Trainee Evaluation Team Member: A person serving on a team in the evaluation of an accreditation body directly supervised by an experienced team member in order to achieve the practical competencies to become an Evaluation Team Member.
- 1.2.20 *Technical Expert:* A person with specific technical competencies assigned to participate in a Peer Evaluation, who does not fulfil the requirements of an Evaluation Team Member.
- 1.2.21 *Witnessing:* Observation of an Accreditation Body carrying out an assessment of a Conformity Assessment Body.
  - NOTE: Regional Groups as well as ILAC and IAF may use different names for the terms defined above.

# 1.3 Abbreviations

abbreviation		Defined under
AB	Accreditation Body	1.2.1
AG	Arrangement Group	1.2.4
CAB	Conformity Assessment Body	ISO/IEC 17011:
		Clause 3.4
DMG	Decision Making Group	1.2.5
DTL	Evaluation Deputy Team Leader	1.2.6
MC	Management Committee	1.2.11
MLA	Multilateral Arrangement / Agreement	1.2.3
MRA	Multilateral Recognition Arrangement / Agreement	1.2.3
PE	Peer Evaluation	1.2.13
RG	Regional Group	1.2.14
RevG	Review Group	1.2.15
TE	Technical Expert	1.2.20
TM	Evaluation Team Member	1.2.8
TL	Evaluation Team Leader	1.2.7
TTM	Trainee Evaluation Team Member	1.2.19

# 2. Requirements

# 2.1 Confidentiality

- 2.1.1 All oral and written information and data received about the AB relating to evaluations (including the information created during the evaluation process), appeals and complaints (except that information which is already publicly accessible) shall be treated confidentially by all parties and persons concerned. This includes information relating to applicants and/or Signatories to the Arrangement. All individuals having access to confidential information shall provide a signed declaration of confidentiality to the relevant MC Secretary(s) before being given access to the information.
- 2.1.2 The AB under evaluation and the evaluation team shall agree on how all access and information provided by the AB shall be dealt with following the completion of the evaluation and decision-making process.
- 2.1.3 The AG shall remain the owner of the evaluation report. The report shall not be made publicly available except as detailed in Chapter 9. In a joint peer-evaluation of an AB, the AGs conducting the Peer Evaluation are considered as owners of the evaluation report.

# 2.2 General Requirements for Arrangement Groups

- 2.2.1 AGs shall develop and maintain policies, procedures, and processes consistent with the requirements of this document covering all aspects of the operation, maintenance and ongoing development of their Arrangements.
- 2.2.2 AGs shall maintain records sufficient to demonstrate their compliance with the requirements of this document and with their own policies and procedures.

# 2.3 General Requirements for an Accreditation Body

- 2.3.1 An AB shall comply with the requirements of ISO/IEC 17011 and mandatory documents of IAF and ILAC, as applicable.
- 2.3.2 An AB shall also comply with relevant supplementary requirements (see Clause 2.5) and any applicable requirements of the RG to which it has applied or belongs as a member.
- 2.3.3 An AB shall have demonstrated experience in the assessment of its CABs and have carried out at least one accreditation procedure (one file, independent on the outcome of the accreditation process) when applying for Peer Evaluation in each of the scopes of the Arrangement for which it applies.
- 2.3.4 The AG may decide to include supplementary requirements for the inclusion of additional Level 4 and/or 5 sub-scopes under the same Level 3 scope, which will apply to all Signatories.
  - NOTE: For definitions of Levels, please refer to IAF PL3 or ILAC R6, as applicable.
- 2.3.5 An AB shall have demonstrated experience in operating an AB and have access to technical expertise in all aspects of its accreditation activities.

- 2.3.6 An AB shall abide by the requirements and obligations of the applicable regional and international Arrangement(s).
- 2.3.7 An AB shall have evidence of promoting the RGs Arrangement(s) as well as the IAF and ILAC Arrangements, as applicable.
- 2.3.8 An AB shall contribute its fair share of personnel resources for carrying out peer evaluations at regional and/or international level.
- 2.3.9 An AB shall have implemented a policy on cooperation with other ABs (including cross-frontier accreditation) in accordance with the Arrangement requirements.

# 2.4 Conditions for application from an Accreditation Body to an Arrangement Group for MLA / MRA recognition

- 2.4.1 An AB must adhere to the policies that the AG shall define on travel, visa, accommodation and meals for Evaluators and observers.
- 2.4.2 If an RG is not recognised for a specific scope an AB of this RG can apply to another RG or IAF and/or ILAC for evaluation of this scope (with prior notification to the RG it is a member of).

# 2.5 Other Accreditation Body obligations in relation to peer evaluation activities

2.5.1 The AB providing Peer Evaluators as members to a specific Peer Evaluation team in liaison with the MC and AB under evaluation is responsible for those Peer Evaluators.

## This includes:

- a) any emergency medical repatriation, search-and rescue operations or similar support services (in liaison with the MC) and other measures safeguarding its staff performing Peer Evaluation activities outside of its territory (e.g. travel and related insurances); and
- b) ensuring that the assigned Evaluator follows the AG time-requirements for Peer Evaluations, including reporting and review of submitted evidence.

# 2.6 Notification requirements for an Accreditation Body

- 2.6.1 Each AB Signatory to an Arrangement shall report changes, which may significantly affect its status and/or its operating practices, including the impact of these changes, without delay to the relevant AG(s).
- 2.6.2 Significant changes include changes which significantly affect the competence, impartiality, and credibility of the accreditation process / body.
- 2.6.3 A deviation by an AB from decisions by ILAC/IAF/RG Technical Committees on best practices and the understanding of accreditation requirements should be notified to the relevant AG(s) for their consideration of any further action.
- 2.6.4 For possible consequences associated with changes having an adverse impact see Clause 8 below.

# 2.7 Information requirements for an Accreditation Body on hazards

The AB under evaluation is obliged to inform the evaluation team of any specific hazards or local requirements/conditions.

# 3. Procedures for Selection, Qualification and Monitoring of Evaluators

The AGs shall establish and implement procedures covering the requirements below:

# 3.1 Procedure for selection and qualification of Evaluators - Initial selection and training of Evaluators

- 3.1.1 When proposing a candidate to become a Peer Evaluator the AB shall provide the relevant committee (e.g. MC) with information supporting the candidate's knowledge, experience and competence in meeting the criteria stated in Clause 3.7.
- 3.1.2 The relevant committee shall review the information either denying the application or inviting the candidate for Evaluator training. Training for candidates shall be designed to make them aware of the evaluation procedure, what is expected of them, and to teach them evaluation techniques and how to provide effective feedback as well as to ensure and confirm that the candidates meet the competence criteria stated in Clause 3.7.
- 3.1.3 A candidate, trained in accordance with Clause 3.1.2, shall be observed and evaluated on the job by appointing the person as a TTM in an evaluation.
- 3.1.4 For each team member the AG shall state the arrangement main scopes and sub-scopes, if relevant, for which the person is considered competent.

# 3.2 Procedure for selection and qualification of Evaluators - Qualification as a Team Member

After at least 1 peer evaluation as a TTM (pre-evaluations can be considered subject to the pre-evaluation being performed in the same way as a full Evaluation) with positive feedback from the experienced TM assigned to mentor / supervise the TTM in the PE team, the participating TL and the evaluated AB and evaluation by the MC, a TTM may be qualified as a TM.

# 3.3 Procedure for selection and qualification of Evaluators - Qualification as a Deputy Team Leader

After at least 2 peer evaluations (pre-evaluations can be considered subject to the pre-evaluation being performed in the same way as a full Evaluation) as a TM with positive feedback from the participating TLs and the evaluated ABs and evaluation by the MC, a TM may be qualified as a DTL.

*NOTE:* The role of the DTL may be used as a training for future TL.

# 3.4 Procedure for selection and qualification of Evaluators - Qualification as a Team Leader

After at least 1 peer evaluation as a DTL with positive feedback from the participating TL and the evaluated AB(s) and evaluation by the MC, a DTL may be qualified as a TL.

# 3.5 Monitoring and evaluation of performance

- 3.5.1 The MC shall monitor the performance of Evaluators in accordance with the criteria in the following sections on an on-going basis.
- 3.5.2 Monitoring of TLs, DTLs, TMs and TTMs shall consist of collecting and evaluating feedback from the evaluated AB and feedback from the TLs, DTLs and TMs participating in the evaluations.
- 3.5.3 At least once every five years the competency of an Evaluator shall be re-evaluated and reconfirmed.
- In the event that negative feedback is received, the MC will review the reasons and decide on an appropriate way forward.

# 3.6 Improving and harmonisation

Consistency and overall performance of Evaluators (TLs, DTLs, TMs and TTMs) and harmonisation of the evaluation process shall be achieved by:

- a. Exchange of experience by regular meetings / workshops of Evaluators, or by other means;
- b. Informing the Evaluators about new requirements, improvement and changes in peer evaluation procedures;
- c. Feedback to Evaluators on their performance as received from the AB and/or team leader/member(s) and/or decision makers; and
- d. Informing the Evaluators of areas for improvement and any corrective measures required.

# 3.7 Competence criteria

# 3.7.1 Trainee Evaluation Team Member

- 3.7.1.1 A TTM shall possess the qualities to enable him/her to evaluate or assess organisations. In particular a TTM shall have the following personal attributes and skills:
  - a. open-minded and mature;
  - b. sound judgment and analytical skills;
  - c. perceive situations in a realistic way, to understand complex operations from a broad perspective, and to understand the role of individual units within an organisation;
  - d. decisive and diplomatic;
  - e. versatile and culturally sensitive;
  - f. persistent and able to focus;
  - g. able to consider alternative points of view;
  - h. able to effectively work in a team;

- i. interviewing, presentation, note-taking and report writing skills;
- j. appropriate language skills to enable effective communication (orally and in writing); and
- k. effective time-management skills.
- 3.7.1.2 A TTM shall be able to determine whether the bodies accredited by the AB under evaluation comply with the requirements of the appropriate International standard(s) used for accreditation and corresponding IAF/ILAC and, where applicable, RG documents, by:
  - a. having knowledge of ISO/IEC 17011 and the applicable RG MLA/MRA, IAF MLA and/or ILAC MRA requirements;
  - b. being able to understand the management practices and processes of ABs based on his/her knowledge and experience in accreditation;
  - c. having knowledge of and skills in the relevant standards and other requirements for accreditation of CABs;
  - d. understanding of the applicable field/sector/scheme (Level 4/5);
  - e. having auditing and/or assessment skills;
  - f. understanding of application of risk-based principles;
  - g. being able to recognise that there are different ways of achieving the same goal and not to judge based on their own AB processes; and
  - h. being proficient in the English language or other language(s) as decided by the AG as long as all the relevant documents both from the evaluating AG(s) as well as other documents applicable from other AGs are available in a translated version to those languages.

#### 3.7.2 Evaluation Team Member

In addition to the attributes and competencies described above for TTM the TM in particular shall be able to:

- a. evaluate whether an AB complies with the requirements of ISO/IEC 17011 and other relevant RG, ILAC and/or IAF requirements;
- b. decide from the submitted documentation whether there are any features requiring additional scrutiny during the evaluation;
- c. decide on sampling of activities and files to be selected and persons to be interviewed based on the analysis of risks and related to the scope of work and the scope of the MLA/MRA;
- d. obtain and evaluate objective evidence fairly and to report on his/her findings clearly and according to the applicable reporting procedure;

- e. understand quickly and easily cultural differences, as far as essential in the evaluation process;
- f. determine the criticality of the findings and to evaluate whether the root cause analysis, analysis of the extent and impact of the finding as well as corrections and corrective actions decided by the AB are likely to be effective and to evaluate the suitability of corrections and corrective actions carried out;
- g. arrive at generally acceptable conclusions based on evaluation observations;
- h. remain true to a conclusion that is based on objective evidence, despite pressure to change; and
- i. act impartially and remain true to the purpose of the evaluation without fear or favour and based on the absence of any conflicting interests.

#### 3.7.3 Evaluation Team Leader

In addition to the attributes and competencies described above for TMs the TL shall be able to:

- a. manage an evaluation, lead an evaluation team in an efficient and effective way, plan and control the contribution of the individual TMs and report clearly and succinctly the results of the evaluation;
- b. discuss the objectives and impact of accreditation services with the management and staff of an AB, based on his/her knowledge of the accreditation body's services, the (business and regulatory) context thereof and the associated risks;
- c. understand issues raised by the other TMs on the accreditation programs and schemes which are outside his/her area of expertise;
- d. based on his/her interpersonal skills, optimize the performance of an evaluation team taking into account the strengths and weaknesses of the individual TMs:
- e. take decisions on the classification of findings and on the closing of findings based on the recommendation of the team members;
- f. chair meetings, facilitate discussions and to reach consensus on delicate points; and
- g. report to the DMG, and to present a recommendation, taking into account the findings of all TMs, in conformity with the Arrangement requirement.

# 3.7.4 Evaluation Deputy Team Leader:

A DTL shall have the same attributes and competencies as a TL but may not yet possess the required experience to be approved as a TL.

# 3.8 Appointment and Composition of the Evaluation Team

# 3.8.1 Composition of the evaluation team

Evaluation team(s)

- a. members with appropriate competencies shall be chosen to cover the types of accreditation, the scopes and sub-scopes, and the size and complexity of the accreditation system under evaluation;
- b. members shall be chosen from a register of Peer Evaluators qualified according to the procedure described in Clause 3.1 and kept up-to-date by the MC. This register should record the arrangement scopes and sub-scopes, if applicable, for which the Evaluator is considered competent and experienced;
- c. members shall consist of representatives from a cross-section of Member ABs as far as possible. The evaluation team shall be chosen to provide a balanced set of skills so as to be able to conduct an effective evaluation:
- d. members shall not have been employed at or provided consultancy service to the AB being evaluated within three years prior to the evaluation;
- e. should not include more than two evaluators participating in their first evaluation (TTMs).

For the TTMs on the team, a qualified TM will be appointed to mentor and/or supervise the TTM. The level of supervision may vary, based on the TTM's attributes and skills.

f. may only include Technical Experts for the evaluation of recently extended MLA/MRA scopes for as long as the AG has not authorized a TM in this MLA/MRA scope.

An assigned Technical Expert has to be directly supervised by an experienced TM appointed specifically to the role of monitoring the Technical Expert.

# NOTE 1:

It is good practice that Evaluators from as many member ABs as possible are appointed in a team.

## NOTE 2:

In the case of a pre-evaluation visit, a TL should normally be accompanied by at least one other team member to ensure more than one person is involved in establishing an applicant's readiness for an initial evaluation visit.

# NOTE 3:

There should preferably be no more than two Evaluators (TL, DTL, TM) from any economy.

#### NOTE 4:

Some of the evaluation team members may have as their only task to

perform witnessing at different geographical places or at different times to the rest of the evaluation team.

# 3.8.2 Appointment and duties of the TL

The MC should not appoint the same TL for two successive full evaluations of the same AB.

The TL shall have ultimate responsibility for all phases of the evaluation and is delegated authority by the MC to make final decisions regarding the conduct of an evaluation, however the MC can give instructions to the TL on any specific aspect of the evaluation, as relevant.

# 3.8.3 Appointment and duties of the DTL

The role of the DTL is to assist the TL in planning, preparation, and management of the evaluation. The DTL can replace the TL in case of illness or unforeseen circumstances. A DTL may be an approved TL.

A DTL can be assigned TL-tasks by the TL to allow development of the appropriate competencies. In this case the DTL is supervised by the TL.

Usually, a DTL can be assigned a technical scope to evaluate as a TM simultaneously to the DTL tasks.

In the case of a split evaluation the DTL can act as TL for part of that split activity.

# 4 Typical Evaluation Program of an Accreditation Body - Pre-evaluation

If it is determined by the AG or the applicant AB that a pre-evaluation of the AB is needed before the initial evaluation can take place, a pre-evaluation program shall be prepared. The pre-evaluation will only take place subject to the supply of the required documentation at least one month before the agreed date.

Based on the results of the document review, the pre-evaluation team may consider reviewing the following in the context of the pre-evaluation:

- a. Management system policies and procedures (as part of a document review prior to the pre-evaluation visit);
- b. Legal identification of the AB;
- c. Relationships with the regulators and other specifiers (e.g. recognition; possible competition);
- d. Job descriptions and backgrounds of top management, organisation chart;
- e. Impartiality and conflict of interest; related bodies;
- f. Access to technical expertise;
- g. Application documents;
- h. Assessor records and documents;
- i. Sampling of CAB assessment records, in the various scopes applied for, including the decision making process;
- j. Metrological traceability routes, where relevant; and

NOTE: If Calibration is not included as an evaluation scope in the application but the scope of Testing (including medical) laboratories is, then specific focus must be given on how the appropriate traceability is ensured.

k. Witnessing one or more assessments, if possible.

The results of the pre-evaluation shall be documented in a report including a list of findings and provided to the applicant AB after the Pre-Evaluation, within timelines defined by the AG to allow the AB to address any identified gaps.

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

# 5 Typical Evaluation Program of an Accreditation Body - Full evaluation

#### 5.1 Introduction

The task of an evaluation of an AB is to collect sufficient information about all aspects of the accreditation process including assessments and decision-making process of the AB to have confidence in the conformity assessment activities and results of the CABs accredited by the AB such that the Signatories to the Arrangements can promote acceptance of these results and services.

It is the task of the TL to create a timetable in a timely manner prior to the evaluation of the AB that allows sufficient time to collect information for obtaining such confidence.

Coordination with the AB under evaluation is essential.

The TL should agree with the team members on the duration of the evaluation and on the technical sectors to be evaluated including witnessing choices.

The MC and/or MC Secretary shall have the opportunity to comment on the TLs proposed duration, timetable and technical sectors to be evaluated including witnessing choices.

# **5.2** Types of Evaluation

There are different types of evaluation: e.g. initial evaluations, follow-up evaluations, evaluation for scope extensions and re-evaluations.

## 5.3 General

If a pre-evaluation has taken place, the full evaluation visit will not be carried out before the AB has taken actions to address the report and findings from the pre-evaluation visit.

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

All members of the evaluation team shall have access to the necessary documentation at least 3 months in advance of the visit, or as agreed with the TL.

# 5.4 Evaluation planning using a risk-based approach

The framework conditions of a peer evaluation shall be determined by the individual complexity, stability, and maturity of the AB under evaluation. The experience gained with the individual AB during previous evaluations shall also be taken into account. AGs need to establish their own written procedures on how the consideration of risk is performed. Those procedures may include supplementary considerations not covered in this document.

5.4.1 Input for consideration in the risk-based approach.

In planning a peer evaluation of an AB, AGs shall take at least the following risk indicators into account:

- a. Number of sites of the AB, if relevant;
- b. Size and complexity of the AB's organisation;

- c. Overall number of internal technical staff and ratio to the number of accredited CABs per Level 3 accreditation standard;
- d. Extensions applied for at Level 2, 3 or Level 4;
- e. Number of sector schemes;
- f. Significant changes in the AB (e.g. sudden increase or decrease in the number of accreditations of CABs, structural changes, changes in key persons, high staff-turnover, deviations from decisions by ILAC/IAF Technical Committees, etc);
- g. Increase or decrease of the number of CABs per Level 3 standard since the previous peer evaluation;
- h. Potential challenges for communication between the evaluation team and AB staff (e.g. need for interpreters) and during witnessing;
- i. Challenges to record access (e.g. paper files instead of easily accessible electronic files and the language that AB records are retained in);
- j. Stability, maturity, and experience gained by the AB during previous Peer Evaluations;
- k. If applicable, specifics that need to be considered as an additional risk (e.g. amount of cross frontier activities, economic stability, etc.);
- 1. The AB operating in a region or country that the Regional Group has identified as representing a significant risk in terms of maintaining accreditation requirements for political or safety reasons;
- m. The AB is subject to a formal complaint under investigation by the Regional Group; and
- n. The AB has a history of poorly managed compliance to requirements and/or weak implementation of corrective actions within the AB.

# 5.4.2 Impact of the risk analysis on planning of a peer evaluation

The risk analysis may have an impact on one or more of the following framework conditions in the planning of a peer evaluation of an AB:

- a. Team composition (more or fewer team members in relation to the standard approach of one TM for each Level 2/3 combination;
- b. Duration of the evaluation;
- c. Split evaluation (e.g. if there is a limited number of staff available for interview by the TMs or if the complexity of the AB is exceptionally high);
- d. Evaluation technique (amount of e.g. on-site and remote evaluation activities);
- e. Witnessing (amount of witnessing, witnessing in advance, witnessing remotely); and

f. File review (amount and kind of files to be reviewed, file reviewing in advance).

#### 5.4.3 Duration of the evaluation

The evaluation should take place preferably within one full (7 days) week.

# 5.4.4 Witnessing

In general, each Level 3 accreditation standard should be witnessed in every regular peer evaluation.

The AG may however, based on the outcome of the risk analysis, decide to not witness some Level 3 activities under the condition, that:

- a. every Level 3 scope will be witnessed within 2 consecutive regular peer evaluations; and
- b. at least 50% of all Level 3 activities covered by the Signatory status of the AB must be covered by witnessing in every re-evaluation.

When selecting the witnessing of the assessment(s), each witnessed assessment shall cover:

- o all of the accreditation requirements of the Level 3 standard and
- o assessment of a portion of the accredited sub-scope (Level 4 and/or 5).

The evaluation team shall also witness other assessment activities as determined by the TL or the MC.

For certification and validation/verification, the evaluation team should witness the AB assessment team performing only the office assessment of the CAB.

It is acceptable to perform witnessing within a period of 12 months in advance of the due date of an office peer evaluation, however the TM will need to participate (for a reduced period) in the office evaluation during the normal scheduled evaluation time as well.

The AB under evaluation shall provide a list of possible witnessing assessments based on criteria provided by the TL sufficiently in advance of the due date of the witnessing component of the peer evaluation.

Repeated witnessing of assessments of the same CAB and the same team of assessors in successive peer evaluations should be avoided as far as possible.

NOTE: For the structure of the Arrangements please refer to the AGs as applicable.

## 5.4.5 File review

Irrespective of the outcome of the risk analysis a representative sample of files shall be reviewed during the peer evaluation for every level 3 scope and a representative sample of files of the sub-scopes covered by the AB's Signatory status, if not already considered by a witness. The files reviewed during a peer

evaluation should give a representative picture of the AB's activities covered by the Signatory (or applicant) status to the Arrangement(s).

It must be stressed that, in addition to spending time on witnessing, it is very important to allow sufficient time to check on how an AB selects its assessors and Technical Experts for a particular assessment. Thorough checking of records from assessments is required including matching the assessor's expertise to the scope of the CAB being assessed.

## 5.4.6 Splitting of a peer evaluation

If a split peer evaluation is necessary (e.g. based on organisational circumstances or as an outcome of the risk-based approach), all office activities of the peer evaluation, On-site or remote, shall be performed within a period of 6 months from commencement of the peer evaluation.

In the case

- of splitting the peer-evaluation, any non-conformities provided in writing during the closing-meeting of each part of the split-evaluation must be treated within the same timelines as defined by the AG
- o where witnessing is performed prior to the office-peer evaluation activities, the non-conformities from the witnessing have to be included in the relevant Level 3 part of the split-evaluation.

# 5.4.7 Use of remote evaluation techniques

The standard approach for a peer evaluation is for the evaluation activities to be conducted On-site.

An Initial Peer Evaluation or extension of a main scope (Level 2 and 3) shall be performed On-site.

Remote evaluation techniques may be used to some extent (subject to agreement by the MC) as an outcome of the risk-based approach or under exceptional circumstances on condition the AG is able to demonstrate that a result similar in outcome to an On-site evaluation can be achieved.

Remote evaluation techniques shall not be used on the same Level 3 scope in 2 consecutive Peer Evaluations.

After a peer evaluation, that included activities conducted using remote techniques, the use of these techniques must be reviewed and considered by the MC and DMG to determine, if the evaluation objectives have been met for that component of the evaluation. The outcomes from these reviews should be used to further develop the risk-based approach.

# 5.5 Managing the evaluation

# 5.5.1 Preparation and Planning

5.5.1.1 Accurate translation of documentation by the AB into the agreed language for conducting the evaluation is essential.

- 5.5.1.2 The self-assessment document completed by the AB under evaluation (IAF/ILAC A3 template) shall be detailed and accurate.
- 5.5.1.3 The AB shall make available all documents to the evaluation team, at least 3 months in advance of the evaluation to allow for preparation and for requesting additional information.
- 5.5.1.4 For planning of the witnessing, the TM assigned to evaluate a scope shall, in consultation with the TL, consider the assessment(s) to be witnessed. Also refer to Clause 5.4.4 for witnessing. The AB shall provide possible assessments to be witnessed for the requested scope. The evaluation team should carefully select and plan the witnessing activities based on risk.

If the applicant or Signatory is active in an industry or regulator specific scheme, then the fulfilling of the requirements set by the scheme owner for Accreditation Bodies shall also be considered on a sampling basis.

# 5.5.2 Performing the Evaluation

- 5.5.2.1 An evaluation visit typically consists of:
  - a. Team briefing meeting prior to the evaluation;
  - b. Opening meeting, presentation by TL outlining aims, objectives, and procedure to be used by evaluation team;
  - c. Evaluation of the AB's offices and management system, review of files and records:
  - d. Discussion of the results of the self-assessment document (IAF/ILAC A3);
  - e. Evaluation of assessment reports, including preparation of assessment and decision-making records (and possible witnessing of the accreditation decision-making process);
  - f. Splitting of the team in accordance with their experience for the purpose of witnessing;
  - g. Witness of a requisite sampling of onsite CAB assessments (see Clause 5.4.4);
  - h. Discussion of the results of the witnessing with the evaluation team and AB;
  - i. Preparation of the draft evaluation report with a list of findings; and
  - j. Closing meeting, presentation, and discussion of findings.

The emphasis should be on witnessing enough to have confidence in the accreditation process, and a high level of confidence in the competence of the CABs.

- 5.5.2.2 The team members should meet to discuss their findings and possibly adjust the focus of their attention. The TL will need to add/modify/enhance the preliminary report that resulted from studying the documentation and discuss such changes during the week with the team members.
- 5.5.2.3 Unless defined in IAF/ILAC A3 reporting timelines have to be specified by the AGs.
- 5.5.2.4 The AG must specify actions to be taken in the event that an AB does not address findings within the timeframe specified by the AG.

# 5.5.3 Activities after the Evaluation

5.5.3.1 The ABs response(s) to any findings, including the root-cause analysis, extent-analysis, corrections/corrective actions and supporting evidence, must be reviewed by the evaluation team. The TL should take the lead in preparing this reaction.

If issues arise with regard to delays in closing out the findings from an evaluation the TL should contact the relevant MC and/or MC Secretary. The MC or MC Secretary will provide guidance on addressing the issue causing the delay.

- 5.5.3.2 The TL together with the DTL and team shall prepare a recommendation to the DMG.
- 5.5.3.3 Writing the Evaluation Report: IAF/ILAC A3 contains information concerning the structure for writing and presenting a report.
- 5.5.3.4 The AB shall be given the opportunity to comment on any factual errors in the report.

# 6 Procedure for Decision Making Regarding Evaluations of an Accreditation Body

# 6.1 Receipt of the required documents

- 6.1.1 The final evaluation report, the corrective actions and the recommendations of the PE team shall be submitted in a single report by the TL to the MC Secretary.
- 6.1.2 The MC Secretary shall ensure that all required documents are available.

# 6.2 Decision making process

- 6.2.1 Prior to decision-making, a review of the PE report and process shall be undertaken by a RevG consisting of independent and impartial individual(s) with the required competencies (refer to Clause 6.2.6 below).
- 6.2.2 The evaluated AB and the TL are informed of the member(s) and convenor, if applicable, of the RevG.
- 6.2.3 Members and observers of the MC should be provided access to the evaluation report and may send their comments to the RevG convenor for consideration within the RevG.
- 6.2.4 The RevG is responsible for the drafting of an Evaluation Summary Report.

  The AG shall define the minimum-content of the Evaluation Summary report in order to facilitate an informed decision by the DMG.

The RevG convenor is expected to communicate with the evaluation Team-Leader and, if necessary, with the AB under evaluation in cases where there are open, missing, or unclear issues in the report, in order to resolve or clarify them. The MC Secretary should be copied on such communication.

- 6.2.5 The RevG shall provide the summary-report and recommendation to the DMG within the AG's timelines after receipt of the evaluation report.
- 6.2.6 RevG Competencies

All members of the RevG shall be competent at Level 1 of the Arrangement with collective expertise at Levels 2 and 3 of the Arrangements as well as applicable AG requirements.

# 6.3 Decision Making

- 6.3.1 Decisions on AB peer evaluations are taken by the DMG of their respective AG on the basis of at least the full Peer Evaluation report, the Evaluation Summary report and a recommendation for the decision to be taken by the DMG.
- 6.3.2 No AB personnel or any person involved in the Peer Evaluation as a Peer Evaluator shall be involved when the decision is taken by the DMG.
- 6.3.3 The persons participating in the decision making shall have an understanding of objective and purpose of the Arrangement; criteria used for the evaluation; the evaluation process and the Arrangement structure.

#### 6.4 Decisions as a result of evaluations

- a. Approval without conditions (re-evaluation to occur according to the 4-year peer-evaluation cycle);
- b. Approval with conditions (e.g., shortened interval for re-evaluation);

## NOTE 1:

Where the total number of accredited CABs is less than 3 at the time of evaluation, the need for a follow-up evaluation before the normal 4-year period should be considered by the DMG.

# NOTE 2:

The recommendation might include a follow-up visit to verify corrective actions. The MC decides on the follow-up visit, if necessary. If a follow-up visit is to be conducted the evaluation team is composed of one or more members of the evaluation team, that conducted the full evaluation.

- c. Defer approval pending submittal of required evidence of corrective actions and/or re-visit by one or more members of the evaluation team to confirm implementation of corrective actions;
- d. A new evaluation required for an applicant AB; and

#### *NOTE:*

The requirement for a new evaluation should rarely happen for applicant Accreditation Bodies since an evaluation report is normally only submitted for a decision once a consensus of the evaluation team and the MC has concluded that all requirements have been met.

e. Suspension or withdrawal of the Signatory status to the Arrangement (refer to Clause 8. below).

# 7 Procedure for Re-evaluation of a Signatory to an Arrangement and Ongoing Confidence Building Activities

- 7.1 Periodic monitoring and re-evaluation of the Arrangement(s) Signatories is necessary.
- 7.2 A re-evaluation On-site shall commence before the end of the 4-year peer-evaluation cycle (+/- 3 months) based on the initial peer-evaluation date.

Partial to total re-evaluation may be conducted at an earlier date as directed by the DMG and should there be due cause such as notification of significant changes in administration, finances, operational practices, or a request for an extension of the scope of Signatory status be received.

- 7.3 The evaluation process from the first On-site / remote activity (not including the preparation by the Peer Evaluation Team members or earlier witnessing) until decision-making should be performed within 6 months.
- 7.4 The impact of changes notified by an Arrangement Signatory shall be evaluated (refer to clause 2.6 above for further details on notification requirements by ABs).
  - In case of an AB not being able to provide evidence of having performed accreditation processes for a Level 3 scope since the date of the last re-evaluation the AG shall consider actions to be taken for the inactive scope.
- 7.5 Re-evaluation visits should be conducted by an evaluation team, in which the majority of members must not have been part of the evaluation team that undertook the previous full evaluation.
- 7.6 The Re-Evaluation follows the process described in Chapter 5. The Signatory under reevaluation shall provide the evaluation team with all the documents which are required for an evaluation. In addition, the evaluation team shall get the full evaluation report from the last evaluation/re-evaluation, or any follow up evaluation and any conditions imposed by the DMG from the last evaluation.

# 8 Procedures for Suspension and Withdrawal of Signatories as an outcome of Peer Evaluation activities

# 8.1 Suspension and Withdrawal

It may be that the MC cannot accept the significant changes notified by the accreditation body, findings not appropriately addressed or not addressed with specified timelines or reasonably extended timelines by this accreditation body, critical non-conformities which have been found or substantiated complaints from interested parties. The MC shall report the situation to the DMG with a recommendation and request to take appropriate action. This action can either for the whole or specific MLA/MRA scope(s) be suspension for a maximum period of 6 months or withdrawal from the AG.

### NOTE:

Reasons for suspension or withdrawal of a Signatory-status other than that stemming from the outcome of a Peer Evaluation can be defined by the AGs.

# 8.2 Suspension

- 8.2.1 In the event of a DMG decision to suspend, the DMG shall:
  - a. officially notify the AB of the decision to suspend, the reasons for the decision to suspend, the maximum period of the suspension, and the conditions for lifting of the suspension;
  - b. Prior to taking further action on the decision to suspend, notify the accreditation body of their right to appeal the decision;
  - c. If the appeal is not upheld, amend the list of Arrangement Signatories to identify that the body is suspended;
  - d. notify all Arrangement Signatories (as well as ILAC and/or IAF, as applicable) of the suspension; and
  - e. remind the AB of the consequences of suspension.
- 8.2.2 The consequences of suspension shall be decided by the DMG on a case-bycase basis, depending on the reason for suspension. The consequences of suspension may include, for the applicable main scope and/or sub-scope, that the AB shall:
  - a. not actively promote the fact that they are a Signatory to the RG, ILAC and/or IAF Arrangement;
  - b. not issue any accreditation documents that bear references to the Arrangement / Agreement or Combined Marks, as applicable;
  - c. not participate in any ballots associated with the RG, ILAC and/or IAF Arrangement;
  - d. notify all applicant and accredited CABs of the suspension and the consequences of the suspension as it relates to them; and
  - e. notify stakeholders in their economies of the suspension.
- 8.2.3 The obligations of the accreditation body while suspended are:

- a. continue to comply with the obligations of full membership;
- b. cooperate fully with the MC and the DMG to enable effective and efficient resolution of the suspension;
- c. maintain oversight of their accredited CABs; and
- d. continue to vote on ballots, other than those associated with the RG, ILAC and/or IAF Arrangement, as applicable.

#### 8.3 Withdrawal

- 8.3.1 In the event of a DMG decision of a withdrawal, the DMG shall:
  - a. officially notify the AB of the withdrawal and the reasons for the withdrawal;
  - b. prior to taking action on the decision to withdraw, notify the AB of their right to appeal the decision;
  - c. if the appeal is not upheld, amend the list of Arrangement Signatories to withdraw the Signatory;
  - d. notify all Arrangement Signatories as well as ILAC and/or IAF as applicable of the withdrawal;
  - e. terminate the agreement for use of any Combined Marks, as applicable; and
  - f. remind the AB of the consequences of withdrawal.
- 8.3.2 The consequences of withdrawal, for the applicable main scope or sub-scope of the Arrangement are that the AB shall:
  - a. immediately stop promoting the fact that they are a Signatory to the RG, ILAC and/or IAF Arrangement, as applicable;
  - b. not issue any accreditation documents that bear references to the Arrangement / Agreement or Combined Marks, as applicable; and
  - c. notify all applicant and accredited CABs of the withdrawal and terminate all relevant Agreements for the use of the Combined Marks, as applicable.
- 8.3.3 When a withdrawn accreditation body applies to become an Arrangement member again, the procedure for applicants shall be followed (see clause 4, 5.).

# 9 Disclosure of Peer Evaluation Reports

Reports from peer evaluations are confidential and shall not be made available in the public domain. A peer evaluated AB may, however, request the MC to make the full report available to specific interested parties with a reasoning. In the case the MC(s) supports the AB's request:

- a. all references to any specific person shall be removed from the documents;
- b. the peer evaluation report shall only be disclosed after it has been formally considered by the DMG(s) and a decision has been confirmed;
- c. then the MC shall provide to the peer-evaluated AB the documents that may be collectively disclosed to the specific interested parties. The documents shall include the full evaluation report, including the responses to the findings and all other annexes and the DMG resolution(s) related to the peer-evaluation;
- d. the documentation shall be disclosed collectively together with an appropriate statement as to the confidential nature of the information, i.e. the information shall remain confidential to the peer evaluated AB and the recipient.

# 10 Extraordinary Situations

In case of extraordinary situations, the AG may deviate from the requirements of this document if required.

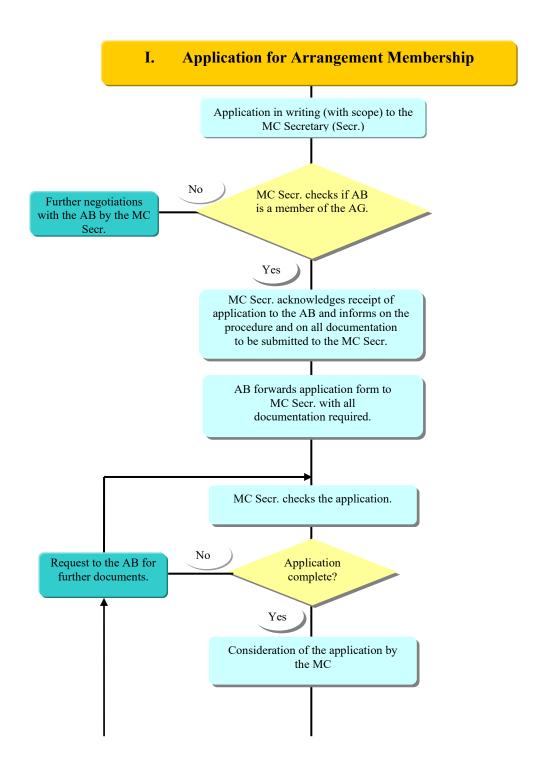
AGs shall have policies/procedures on how to deal with extraordinary situations that may impact the capabilities of the AG to perform peer evaluations according to this document or as originally planned.

These policies/procedures shall include, but not be limited to, considerations on at least the following topics:

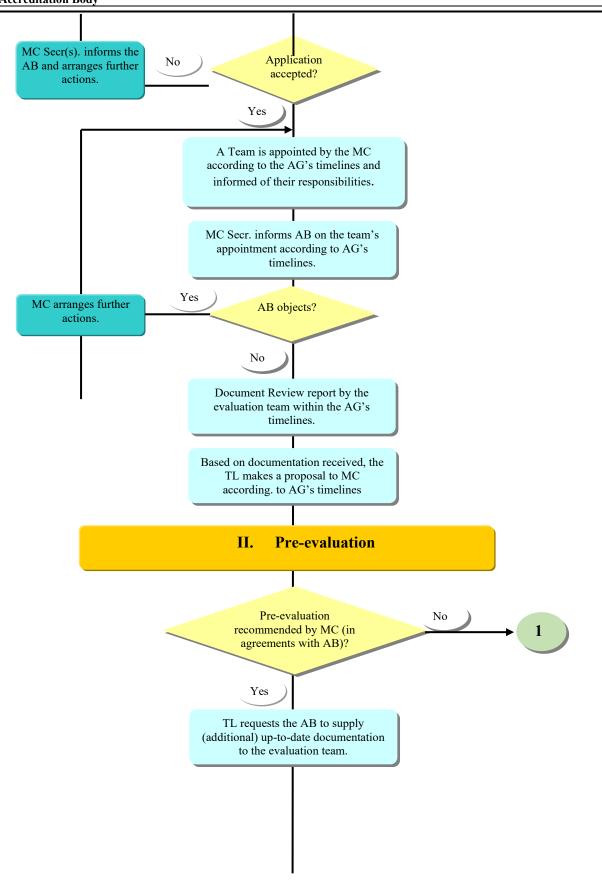
- a. structure within the AGs MLA/MRA process entitled to allow a rapid response to extraordinary situations until the DMG formalises a decision. The delegation of decisions to the MC in such circumstances may be appropriate;
- b. set of actions to be taken based on a risk-based analysis including the possible evaluation methodologies (e.g. use of remote assessment techniques, reduction of the amount or no witnessing and increasing file-review activities, etc);
- c. actions, if travel advice/warnings are imposed;
- d. accidents/incidents involving evaluation team members whilst On-site.

If changes to ongoing or planned peer evaluations are required, the AG's structure entitled to take decisions in extraordinary situations (see a. above) shall review and amend the risk-based analysis for the specific peer evaluation and event. The goal should be achieving as close as possible an outcome, given the circumstances, to the originally planned peer evaluation.

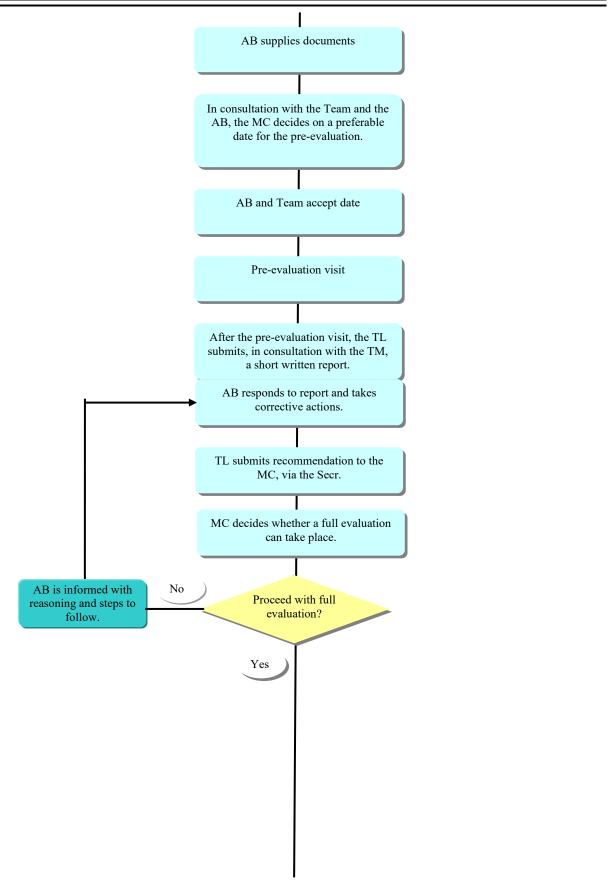
# **ANNEX 1: Flow Chart for the Evaluation Process (informative)**

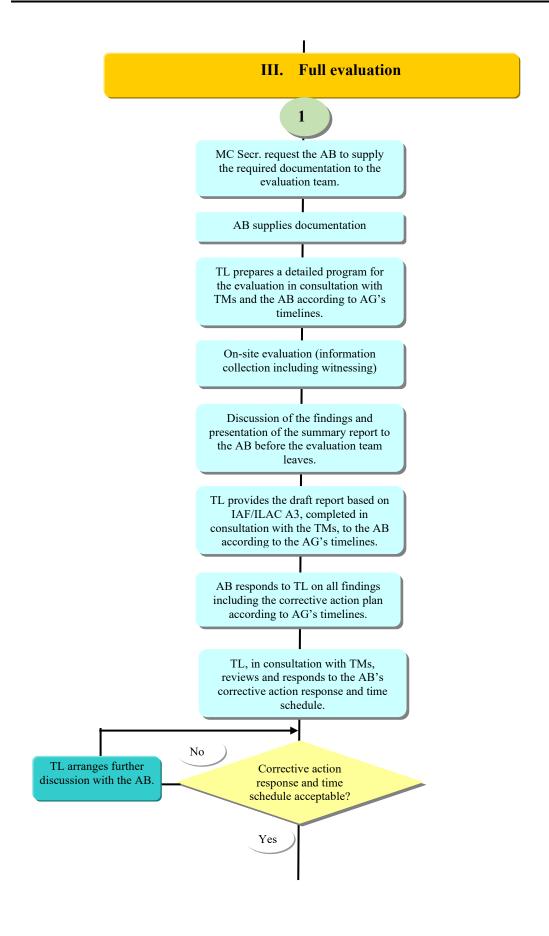


IAF-ILAC Multilateral Mutual Recognition Arrangements (Arrangements): Requirements for Evaluation of an Accreditation Body



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