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Reference***

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**EA Procedure  
for the evaluation  
of a National Accreditation Body**

***PURPOSE***

This document defines the procedure of EA to peer evaluate EA members that are or wish to be signatories to the EA MLA.

### *Authorship*

This document has been prepared by the EA MLA Council (MAC).

### *Official language*

The text may be translated into other languages as required. The English language version remains the definitive version.

### *Copyright*

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### *Further information*

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Note: The term Bilateral Agreement (BLA) has been removed from EA-1/06, therefore all the references made to BLA within EA-2/02 shall be read as MLA.

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## **CONTENTS**

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<b>PREAMBLE .....</b>	<b>4</b>
<b>PURPOSE .....</b>	<b>4</b>
<b>INSTRUCTION FOR USE .....</b>	<b>4</b>
<b>Section 1: Introduction.....</b>	<b>5</b>
<b>Section 2: Requirements for a National Accreditation Body .....</b>	<b>5</b>
<b>Section 3: Flow Chart for the Evaluation Process.....</b>	<b>9</b>
<b>ANNEX 1: PROCESS AND PROCEDURES FOR SELECTION, QUALIFICATION AND MONITORING OF EVALUATORS AND THE APPOINTMENT AND COMPOSITION OF THE EVALUATION TEAM.....</b>	<b>15</b>
<b>ANNEX 2: TYPICAL EVALUATION PROGRAM OF A SINGLE NATIONAL ACCREDITATION BODY.....</b>	<b>27</b>
<b>ANNEX 3: CONTENT OF THE EVALUATION SUMMARY REPORT ON A NAB.....</b>	<b>37</b>
<b>ANNEX 4: PROCEDURE FOR DECISION MAKING REGARDING EVALUATIONS OF A NATIONAL ACCREDITATION BODY.....</b>	<b>38</b>
<b>ANNEX 5: EA PROCEDURE FOR HANDLING APPEALS.....</b>	<b>43</b>
<b>ANNEX 6: PROCEDURE FOR RE-EVALUATION OF AN EA MLA SIGNATORY AND ON-GOING CONFIDENCE BUILDING ACTIVITIES .....</b>	<b>44</b>
<b>ANNEX 7: PROCEDURES FOR MAINTENANCE, SUSPENSION AND WITHDRAWAL OF EA MLA SIGNATORIES.....</b>	<b>45</b>
<b>ANNEX 8: DISCLOSURE OF PEER EVALUATION REPORTS.....</b>	<b>48</b>
<b>ANNEX 9: EXTRAORDINARY EVALUATIONS .....</b>	<b>49</b>
<b>ANNEX 10: EVALUATION REPORTING.....</b>	<b>50</b>
<b>ANNEX 11: SUPPLEMENTS TO EA-2/02 .....</b>	<b>51</b>

## **PREAMBLE**

The EA Multilateral Agreement (EA MLA) is a signed agreement between the EA Full Members whereby the signatories recognise and accept the equivalence of the accreditation systems operated by the signing members, and also the reliability of the conformity assessment results provided by conformity assessment bodies accredited by the signing members.

A Bilateral Agreement (BLA) between an EA Associate Member and EA has the same purpose and bilateral signatories to the EA MLA shall meet the same requirements as EA Full Members.

The strength of the EA MLA is maintained through a robust peer evaluation process. The main objective of the peer evaluation activities is to evaluate the on-going compliance of the national accreditation bodies to the internationally agreed requirements and to ensure that regulators, stakeholders and the business community can have confidence in certificates and reports issued by conformity assessment bodies under the EA MLA.

EA has been recognised by the European Commission according to Article 14 of Regulation (EC) No 765/2008 "Setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) 339/93" to operate the peer evaluation system of national accreditation bodies in Europe.

National accreditation bodies are evaluated against the international standard ISO/IEC 17011, Regulation (EC) No 765/2008 and other relevant standards and related criteria such as application documents from EA, ILAC or IAF, and applicable criteria on behalf of European or National Regulators and industrial schemes. The EA MLA process is overseen by the European Commission, the EA Advisory Board and the national authorities.

## **PURPOSE**

This document describes the procedure for the evaluation of National Accreditation Bodies.

## **INSTRUCTION FOR USE**

This document is based on IAF/ILAC-A2:01/2018 *Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Single Accreditation Body*.

In general, the text of IAF/ILAC-A2 section 2 and the annexes have just been reproduced. The names/acronyms IAF/ILAC and their committees/groups have been replaced by EA and its committees/groups. Clauses which are not relevant for EA have been marked in grey or with the information "not relevant for EA".

EA specific procedures and processes, different from those in or in addition to the original text, have been added and clearly marked (blue letters).

Furthermore, the term (single) accreditation body has been replaced by National Accreditation Body (NAB) in compliance with Regulation (EC) No 765/2008 and the European Accreditation system.

## Section 1: Introduction

### 1.1 Scope

According to Regulation (EC) No 765/2008 on accreditation and market surveillance and EA-1/17 *Rules of Procedure*, EA manages the peer evaluation system operated by National Accreditation Bodies (NABs) and provides EA members with peer evaluation services.

This document describes the procedures that EA has adopted for the peer evaluation of the operation and effectiveness of the accreditation activities of the National Accreditation Bodies (NABs), when these NABs are or wish to be signatories to EA Multilateral Agreement (EA MLA).

It complements the document EA-1/06 that provides general information on the purpose, operation and management of the EA MLA as well as on its scope and structure and all requirements applicable to the NABs.

The document shall be used by (applicant) signatories, by evaluators, by Task Force Group (TFG) members and MAC members.

### 1.2 Definitions

- **Evaluation Deputy Team Leader (Deputy TL):** a Team Leader (TL) or (experienced) Team member (TM) taking over tasks assigned by the TL in preparation and managing the evaluation, can also replace the TL in case of illness or similar circumstances.
- **Scope:** Set of accreditation activities, performed according to a set of criteria specified in a standard or normative document used for the accreditation of conformity assessment bodies, evaluated through the peer-evaluation process and in which the NAB has demonstrated competence to perform accreditation.
- **Signatory:** A NAB which is a full member of EA and has signed the EA Multilateral Agreement (MLA), or an associate member which has signed a bilateral agreement (BLA).
- **Secretariat:** Persons within EA Secretariat carrying out tasks described in this document who fulfil the competence requirements foreseen in EA-2/02 S1.

For further definitions see IAF/ILAC-A2.

## Section 2: Requirements for a National Accreditation Body

### 2.1 Requirements

EA-1/06 *EA Multilateral Agreement. Criteria for signing. Policy and procedures for development* defines the requirements for signing the EA MLA.

Clause 2.2 of this document includes some additional requirements, which are (partly) not included in EA-1/06.

**2.1.1** A NAB shall comply with the provisions of ISO/IEC 17011 requirements, [Regulation \(EC\) No 765/2008](#) and mandatory documents in EA, IAF and ILAC where applicable.

**2.1.2** not relevant for EA

## 2.2 Supplementary requirements

### 2.2.1 A NAB shall:

- 2.2.1.1 Have demonstrated experience in the assessment of its accredited conformity assessment bodies (CAB) and have carried out and granted at least one accreditation that is valid at the time of the evaluation in each of the scopes of the Arrangement for which it applies;

For IAF additional level 4 and/or 5 extensions under the same level 3 scope will be granted on the basis of NAB self-declaration that the level 4/5 scope has been introduced and relevant requirements as defined by IAF have been met. The additional level 4 and/or 5 scope will be evaluated at the next peer evaluation. In exceptional cases, inclusion of a level 4/5 scope may need evaluation as specifically defined by IAF for the particular level 4/5 scope.

Note: For definitions of Levels, please refer to [EA-1/06](#), IAF PR 4 or ILAC R6, as applicable.

- 2.2.1.2 Have demonstrated experience in operating a NAB and have access to technical expertise in all aspects of its accreditation activities.  
Where the number of accredited CABs is less than 4 at the time of evaluation, the need for a follow-up evaluation before the normal 4-year period shall be considered by the [MAC](#).
- 2.2.1.3 Specify the acceptable routes for traceability, and assess its implementation by CABs (EA and ILAC applicant and signatory NABs: see ILAC P10);
- 2.2.1.4 Ensure that it meets the relevant requirements for proficiency testing activity (EA and ILAC applicant and signatory NABs: see ILAC P9);
- 2.2.1.5 Abide by the requirements and obligations of the EA MLA and international Arrangement(s);
- 2.2.1.6 Have evidence of promoting the [EA, IAF and ILAC](#) Arrangements with major stakeholders;
- 2.2.1.7 Contribute its fair share of personnel resources for carrying out peer evaluations at the regional and/or global level; and
- 2.2.1.8 Have implemented a cross frontier accreditation policy in accordance with [EA-2/13 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members](#) and with the relevant IAF document(s) (for IAF signatories) or taking into account ILAC Guide 21 (for ILAC signatories).

### 2.2.2 Notification of change

Each NAB signatory to the EA MLA shall report any significant changes in its status and/or its operating practices (e.g. as listed below) including the impact of these changes without delay to the MAC. For possible consequences associated with changes see Annex 7.

- Legal status;
- [Top management of the NAB](#);
- Senior accreditation program personnel;
- Contact person or liaison officer for the EA MLA;
- Accreditation criteria and procedures for its accreditation programs, related to the EA MLA;
- Office address (and postal address, if different), including head office and any offices;
- Relationship with Government;
- Other changes that significantly affect the competence or credibility of the accreditation process.

[A notification on the significant changes shall be sent by the NAB without delay to the Secretariat within maximum 1 month since the changes occurred.](#)

[According to EA-1/06 clause 5 \(l\) the notification shall be accompanied by an impact analysis. The impact analysis prepared by the NAB shall be a self-evaluation report addressing the relevant clauses of ISO/IEC 17011 and the Regulation \(EC\) No 765/2008.](#)

[In case of changes of persons in key management functions, NAB shall send to the Secretariat a brief CV accompanied by a justification for being the right candidate and his/her involvement in the daily practice and management of the NAB and an “introduction plan”. Evidence should be provided that the new person fulfils the tasks in an appropriate way, giving the same level of confidence.](#)

[EA MAC Management Group \(MAC MG\) shall review the impact analysis provided by the NAB in order to evaluate whether compliance with the Regulation \(EC\) No 765/2008 and the standard ISO/IEC 17011 is still met.](#)

[If the MAC MG concludes that the impact of the changes does not justify further action, the MAC members shall be informed at the following MAC meeting about the respective notification of changes accepted by the MAC MG.](#)

[If the MAC MG considers that the impact of the changes introduces a significant risk, or if the compliance of the changes to the Regulation \(EC\) No 765/2008 and the standard ISO/IEC 17011 cannot be determined after the document review, resulting in a recommendation for further action \(e.g. extraordinary evaluation, anticipation of the next evaluation, sanction\), the proposal shall be presented to the MAC for final decision.](#)

[In such a case, the Secretariat shall:](#)

- [send the notification and impact analysis supplied by NAB, including any additional information requested by the MAC MG in the previous review stage, to all MAC members;](#)
- [table the item on the MAC meeting agenda for discussion and decision.](#)



### 2.2.3 Confidentiality

- 2.2.3.1 All oral and written information received about the NAB through the operation of the MAC relating to evaluations, re-evaluations, notification of changes, appeals and complaints (except that information which is already publicly accessible) shall be treated confidentially by all parties and persons concerned, [such as members and observers of the evaluation teams, all members, observers and Secretariat personnel of the MAC and the MAC MG as well as the Appeals Review Panel](#). This includes information relating to applicants and/or signatories of the EA MLA. All individuals having access to confidential information shall provide a signed declaration of confidentiality to the [Secretariat](#) before being given access.
- 2.2.3.2 The NAB under evaluation and team leader shall agree about how to treat the documents it has provided. This may require the team members to:
- ◆ return all documents to the NAB; or
  - ◆ destroy the documentation, when it is determined there is no further need to maintain the documents.
- 2.2.3.3 EA shall remain the owner of the evaluation report. The report shall not be made publicly available except as detailed in Annex 8.

### 2.3 Conditions for application

- 2.3.1 The NAB agrees to pay for the hotel costs, meals and all travel costs of the evaluation team.
- 2.3.2 Travel shall be done in economy class unless the applicant NAB agrees to pay business class. If the NAB does not agree, then economy travel is mandated unless the evaluators wish to pay for their own airlines upgrades.
- 2.3.3 Observers/trainees pay all of their own costs.
- 2.3.4 [The peer evaluations shall be performed in the English language. If needed, the NAB shall provide sufficient translators to assist the team during the evaluation process. Expenses for translators shall be covered by the NAB under evaluation \(see also 1.6.1.2 of Annex 1\).](#)

### 2.4 Requirements relating to the Safety and Security of Peer Evaluation Teams

[The NAB under peer evaluation shall take all appropriate precautions to ensure the safety and security of all members of the peer evaluation team whilst operating within its national boundaries. The ultimate responsibility for the safety and security of these staff rests with their own Accreditation Body, i.e. the body with which they are contracted, although the NAB under peer evaluation shall fully cooperate and coordinate with the AB of each Team Member over safety and security matters should the need arise. Should the NAB of a team member not be satisfied that the NAB under peer evaluation is taking appropriate precautions then the team](#)



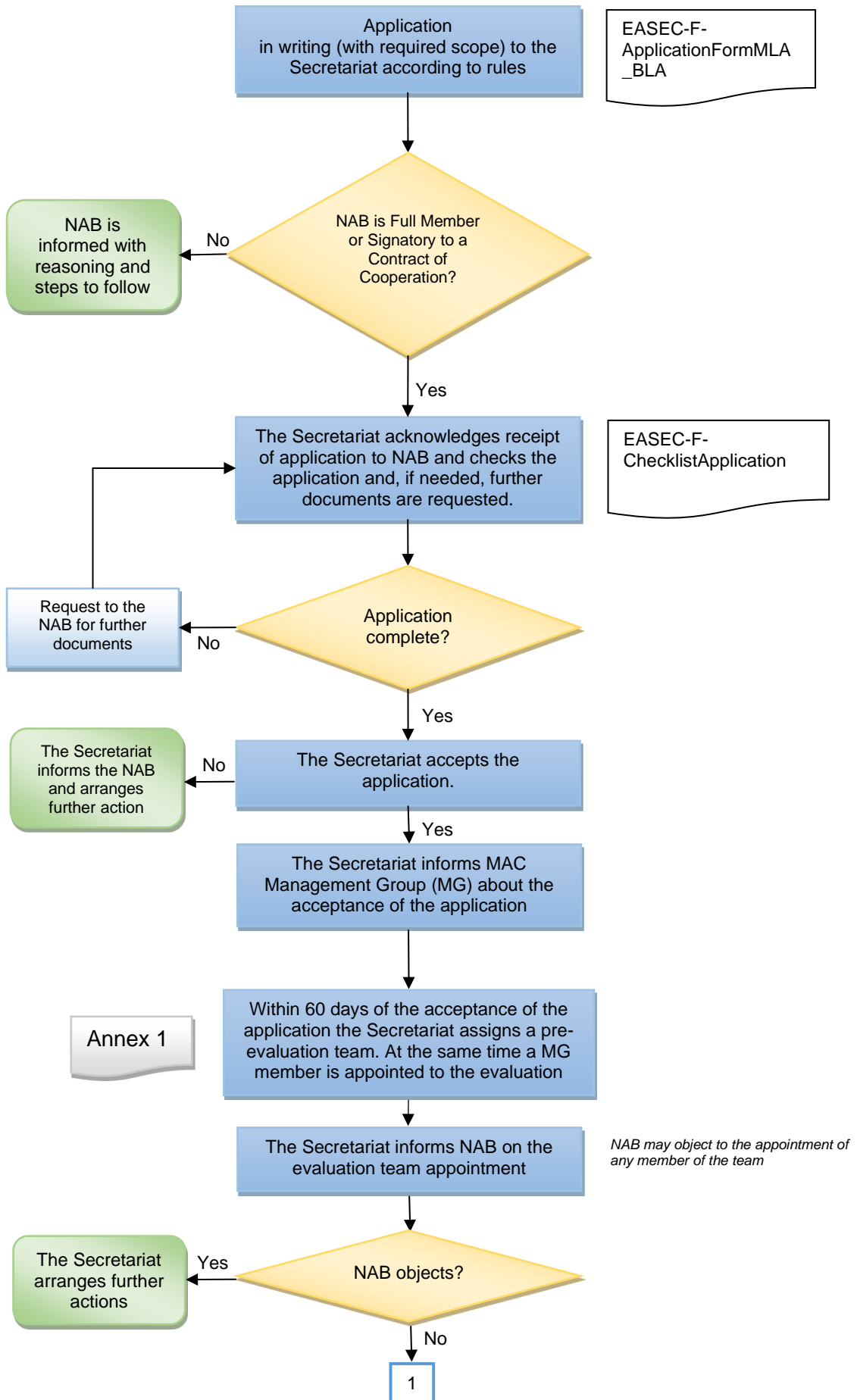
member's NAB can withdraw their member of staff from the peer evaluation team until such time that the safety and/or security concerns have been satisfactorily resolved.

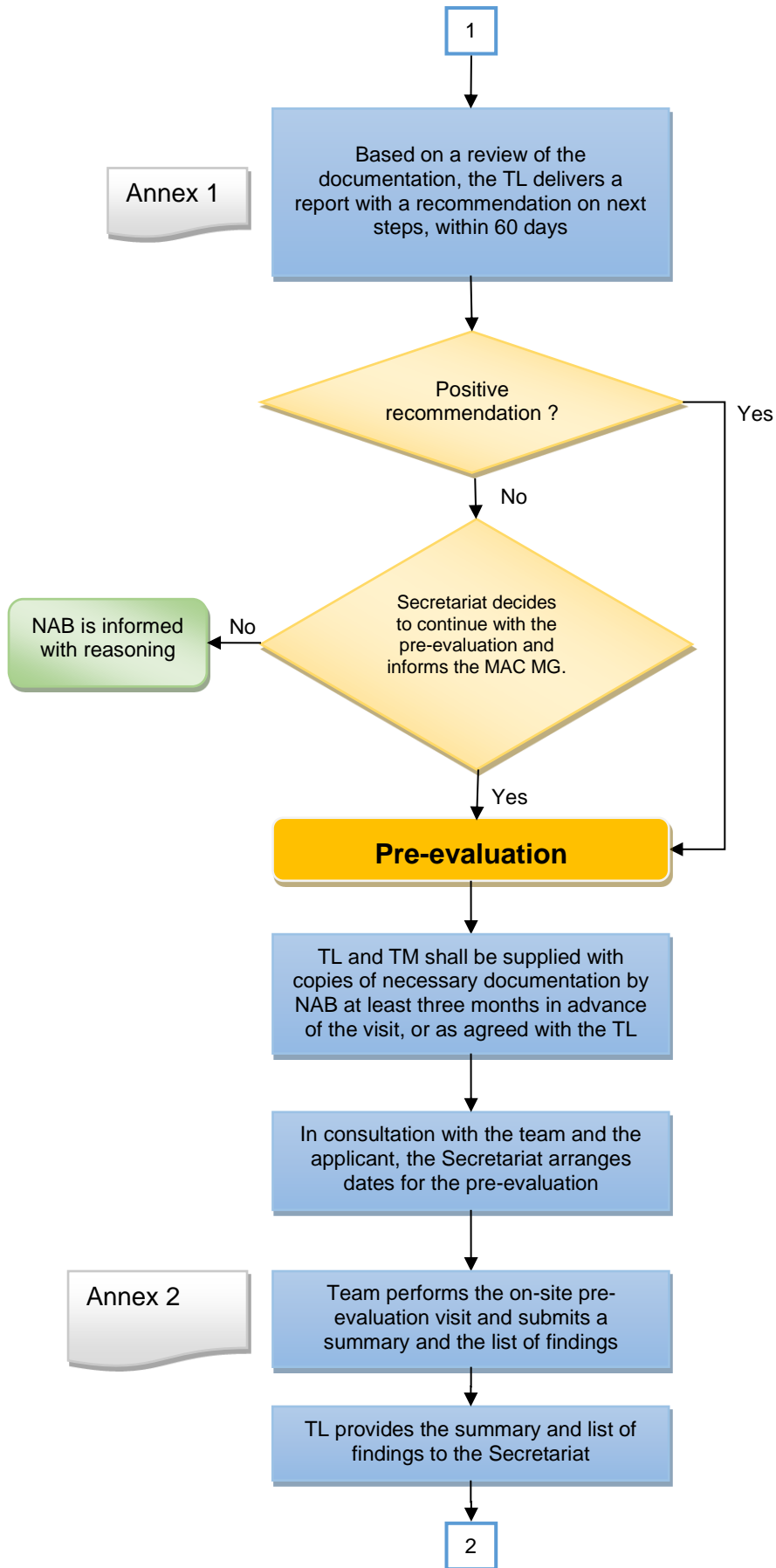
### **Section 3: Flow Chart for the Evaluation Process**

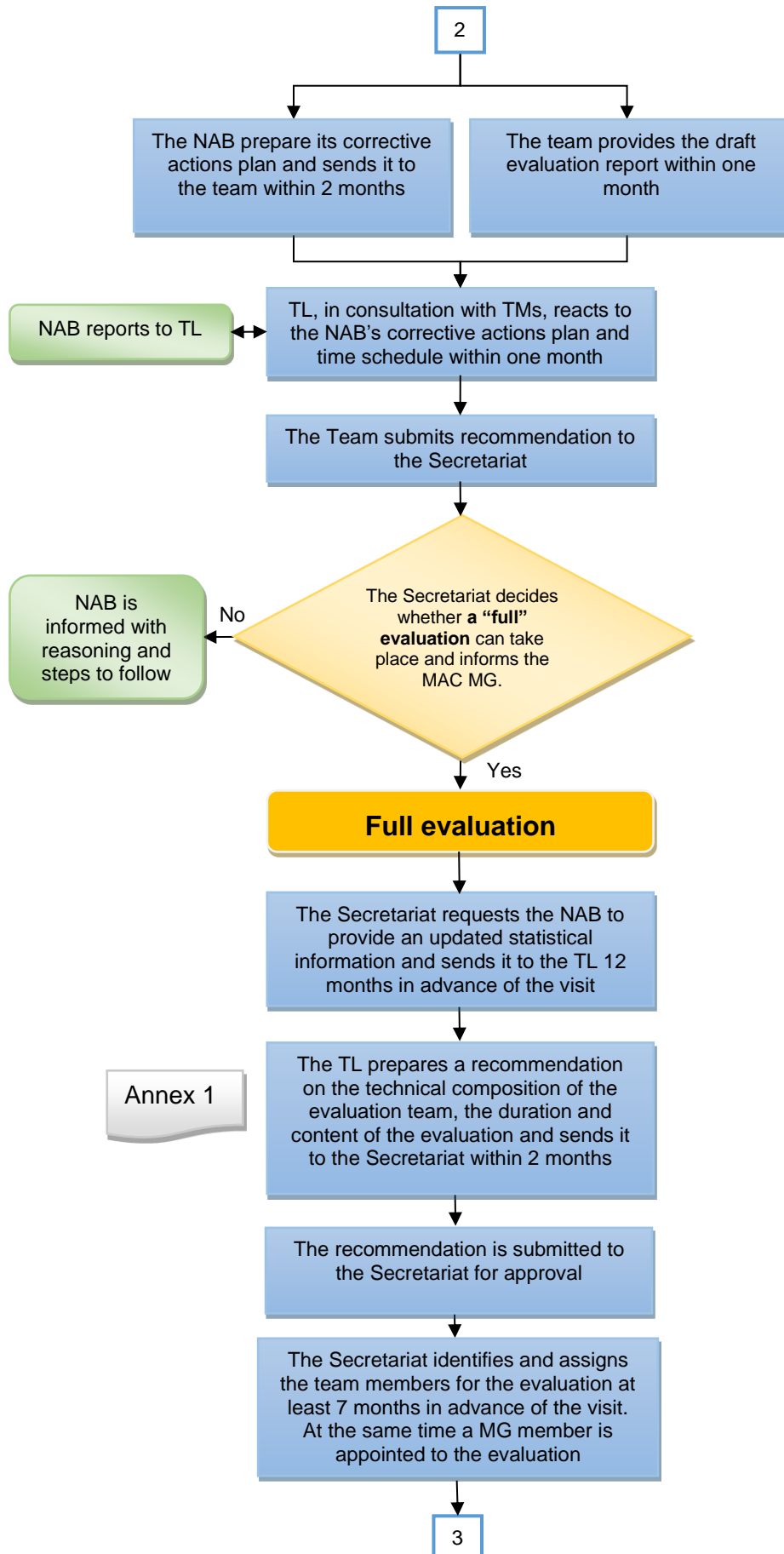
Details on the evaluation process including the application are provided in the following flowchart.

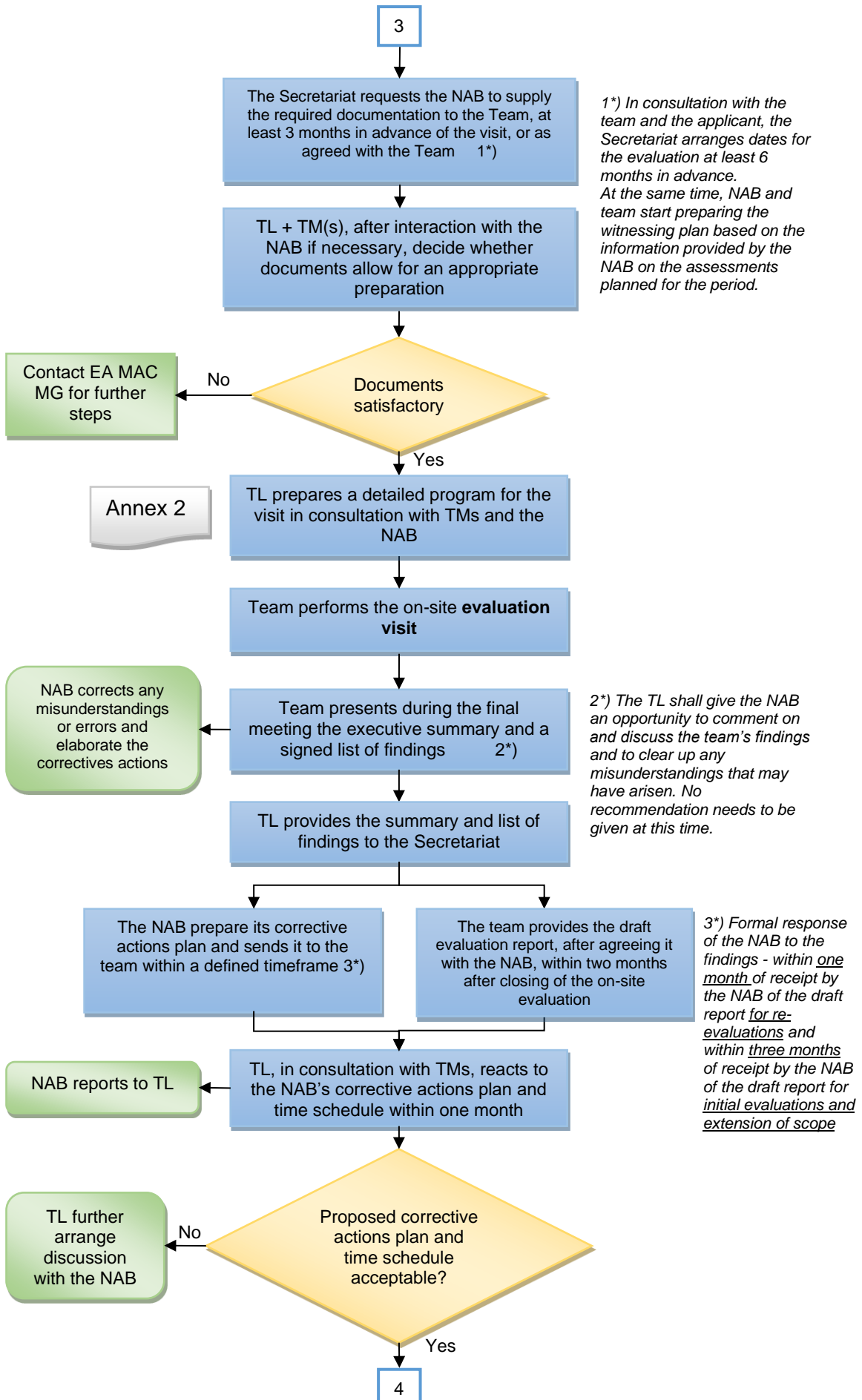
Note 1: In some parts of the flowchart a double arrow (↔) is used to indicate an interactive process.

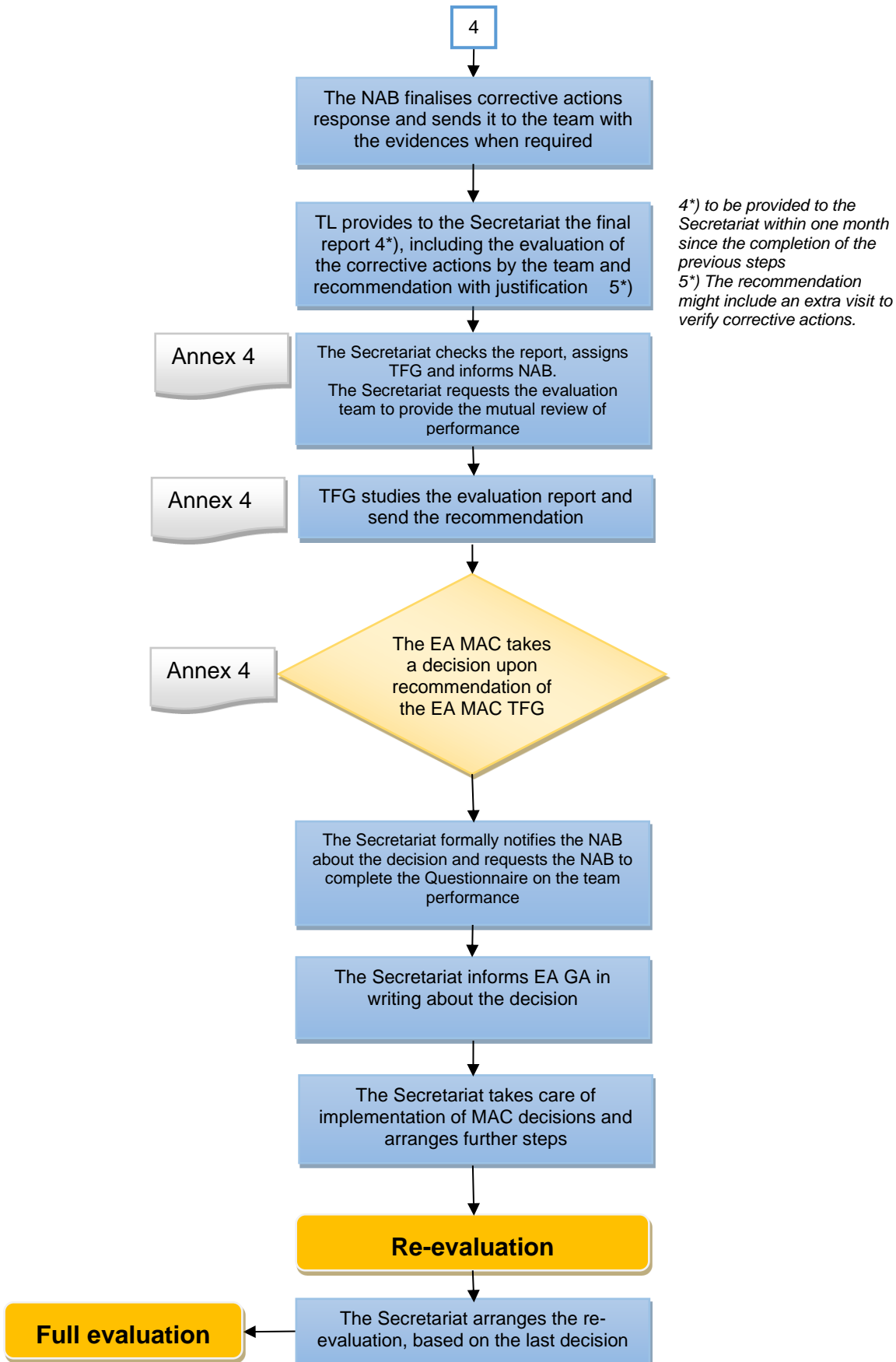
Note 2: The following flow chart reflects the EA process and may deviate from the flow chart in IAF/ILAC-A2.











## **ANNEX 1: PROCESS AND PROCEDURES FOR SELECTION, QUALIFICATION AND MONITORING OF EVALUATORS AND THE APPOINTMENT AND COMPOSITION OF THE EVALUATION TEAM**

### **1.1 Process for selection and qualification (authorization) of evaluators**

**1.1.1** Initial selection and training of Evaluators:

**1.1.2** When proposing a candidate peer evaluator, the NAB shall provide the Secretariat with information about the person's competence to confirm that the criteria stated in 1.5 are met.

The EA members shall nominate candidate evaluators in writing, including a description of the experience and competence to the Secretariat, by way of the MAC standard evaluator CV form. This shall be signed by an appropriate Director of the NAB assuring the correctness of the data and suitability of the candidate evaluator. The NAB nominating a candidate evaluator is responsible for ensuring that the nominee complies with the criteria stated in 1.5.

**1.1.3** The Secretariat shall review the information and shall either deny the application or invite the person for the training for new team members.

The Secretariat may give priority to specific candidate evaluators in order to fulfil the needs of the peer evaluation system and to ensure a balanced contribution of all EA members.

**1.1.4** Training for new team members (TMs) shall be designed to ensure and confirm that the evaluators meet the competence criteria stated in 1.5.

**1.1.4.1** EA newcomer's trainings will cover the following topics:

- requirements of EN ISO/IEC 17011 and other applicable documents,
- harmonisation of interpretation of requirements applicable to NABs,
- evaluating NABs competencies with regard to EU harmonization legislation and the appropriate requirements of Regulation (EC) 765/2008,
- EA evaluation procedures (EA-2/02),
- EA evaluation documents (checklists, self-assessment tools),
- harmonisation in the evaluation of critical findings.

**1.1.4.2** The training team will include at least one representative of the MAC MG and one or more MAC members and/or authorized EA evaluators, depending on the specific objectives of the training. A member of the training team shall act as coordinator.

**1.1.4.3** The training team shall evaluate each participant taking into account:

- understanding of requirements and procedures: Demonstration by the participants of their understanding and awareness of the evaluation process and the evaluation requirements;



- demonstrated ability to work as an evaluator (dedication, open minded, team work, communication skills, in particular communication in English).

#### 1.1.4.4 The outcome of the training evaluation may be:

- the trainers consider the candidate evaluator ready to participate in evaluations. Based on his/her excellent performance and his/her experience they recommend to skip the trainee team member stage and recommend to invite the candidate evaluator to act as a Team member in an evaluation, or
- the trainers consider the candidate evaluator ready to participate in evaluations and recommend to invite him/her to act as a trainee in an evaluation (see 1.5.5 for the tasks of a trainee), or
- the trainers are not convinced that the candidate evaluator has reached the necessary level required of a team member and recommend that the candidate evaluator first takes part as an Observer in an evaluation, in order to develop his/her experience before being appointed as a trainee, or
- the trainers do not consider the candidate evaluator meets the required competence of a team member and is not ready to participate in evaluations. They shall state the reason(s) why the candidate evaluator has not yet been accepted and where he/she needs to improve in order to get a positive recommendation to become a trainee.

The Secretariat shall inform the candidate evaluator and the nominating NAB of the outcome of the training evaluation.

#### 1.1.4.5 The Secretariat shall approve the relevant scopes of the trainee/TM, including for his/her scope extensions.

#### 1.1.4.6 After authorization as a TM, trainee or observer, candidate evaluators shall sign a declaration of confidentiality with permanent validity. This shall be submitted to the Secretariat for inclusion in their evaluator records.

#### 1.1.5 After a minimum of one positive feedback from the TL or TM and the NAB the trainee team member will be authorized by the Secretariat as a team member peer evaluator.

#### 1.1.6 For each team member the Secretariat shall state the main scopes, and sub-scopes if relevant for which the person is considered competent.

## 1.2 Selection of team leaders

#### 1.2.1 After a defined minimum number of evaluations as TM and positive feedback from the participating team leaders and NABs (see 1.5.3.8), the Secretariat may invite a TM to become a team leader.

#### 1.2.2 To demonstrate fulfilment of the competence criteria as stated in Clause 1.5.3, a TM may first act as a deputy TL (assisting the TL in planning, preparing, managing the evaluation) or as a TL supervised by an authorized TL.

### 1.3 Monitoring and evaluation of performance

- 1.3.1 The Secretariat shall monitor the performance of evaluators in accordance with the criteria in the following sections on an on-going basis.
- 1.3.2 Monitoring of team leaders and team members shall consist of collecting and evaluating feedback from the evaluated NAB, using the related EA form sheet.
- 1.3.3 Monitoring of evaluation team members shall also include evaluation by each team leader of the teams in which a team member is participating, completing the relevant EA form sheet.
- 1.3.4 Monitoring of evaluation team leaders shall include feedback from the team members by using the relevant EA form sheet.
- 1.3.5 At least once every three years the performance shall be re-evaluated [based on the monitoring, updated CV and participation in refresher training](#) and the authorization (see Clause 1.5) of an evaluator shall be re-confirmed by the Secretariat.

The Secretariat shall refer to the MAC MG on critical cases. Evaluators and their NABs are notified of the outcome of the re-approval process.

- 1.3.6 Evaluators are notified of the feedback received at least once every three years or in case of negative results.
- 1.3.7 Evaluators are responsible for submitting their updated CV to the Secretariat each time there is a significant change.

### 1.4 Improving and harmonisation

- 1.4.1 There shall be implemented procedures for improving the performance of evaluators (team leaders and team members) and to harmonise the evaluations by:
- Exchange of experience by regular meetings of evaluators, or by other means.
  - Informing the evaluators about new requirements and changes in peer evaluation procedures.
  - Feedback to evaluators on their performance as received from the NAB and/or team leader/member(s) and/or decision makers.
  - Informing the evaluators of areas for improvement

#### 1.4.2 Refresher training courses

The MAC MG shall plan and organise refresher training courses for TLs and TMs in order to improve and harmonise the outcome of evaluations. The training activities shall consider, but not be limited to, issues such as:

- [changes in peer evaluation procedures or requirements,](#)
- [result of monitoring of the performance of evaluators,](#)

- feedback from MAC about evaluation reports,
- complaints about EA peer evaluation process.

TMs are normally expected to attend refresher training 3 years after their initial training or after their first 2 evaluations as a TM, whichever is soonest. Thereafter TLs and TMs are normally expected to attend refresher training every 5 years.

### 1.4.3 Regular information of evaluators

EA evaluators are regularly updated by the Secretariat on any new requirements and changes in peer evaluation procedures.

EA Evaluators are given access to a dedicated folder on the EA intranet.

Note: In certain circumstances, for instance when planning to extend the scope of the EA MLA to include a new conformity assessment activity, evaluators may need to have their general evaluator training supplemented by technical training in the relevant conformity assessment activity/standard(s): This is to ensure a harmonized approach is taken by the pool of evaluators seeking authorization in this activity. Although the MAC MG will identify evaluators with the necessary experience for this new area, responsibility for this technical training does not rest with the MAC but is the responsibility of the EA technical committee that has been given responsibility for this area. The chair of the relevant technical committee will liaise with the MAC Secretariat to ensure that this is planned and implemented appropriately. Records of this technical training shall be sent to the MAC Secretariat for inclusion in the evaluators records.

## 1.5 Competence criteria

### 1.5.1 Candidate peer evaluator team member

1.5.1.1 A candidate team member shall possess the qualities to enable him/her to evaluate or assess organisations. In particular a candidate team member shall have the following personal attributes and skills:

- ◆ Be open-minded and mature;
- ◆ Have sound judgment and analytical skills;
- ◆ Be able to perceive situations in a realistic way, to understand complex operations from a broad perspective, and to understand the role of individual units within an organization;
- ◆ Be decisive and diplomatic;
- ◆ Be versatile and culture sensitive;
- ◆ Be persistent and able to focus;
- ◆ Be a team player;

- ◆ Have interviewing, presentation, note-taking and report writing skills;
- ◆ Have appropriate [English](#) language skills to enable effective communication (orally and in writing).

1.5.1.2 A candidate team member shall be able to determine whether the bodies accredited by the NAB under evaluation comply with the requirements of the appropriate standard(s) [listed as level 3 and 4 of the EA MLA](#) and corresponding EA/IAF/ILAC documents, by having:

- ◆ knowledge of the relevant standards for accreditation of conformity assessment bodies and other documents; and
- ◆ understanding of the applicable sector/scheme.

1.5.1.2.1 A candidate team member shall be able to understand the management practices and processes of accreditation bodies based on his/her knowledge and experience in accreditation.

1.5.1.3 A candidate team member shall have knowledge of EN ISO/IEC 17011, [Regulation \(EC\) No 765/2008](#) and the EA MLA requirements.

## **1.5.2 Peer evaluator team member**

1.5.2.1 In addition to the attributes and competencies described above for candidate evaluators the team member in particular shall be able to evaluate whether a NAB complies with the requirements of [Regulation \(EC\) No 765/2008](#), EN ISO/IEC 17011, IAF/ILAC A5 and other relevant requirements, based on:

- ◆ Understanding of the application of EN ISO/IEC 17011 [and Regulation \(EC\) No 765/2008](#) in a peer evaluation context;
- ◆ knowledge of IAF/ILAC A5 and other relevant requirements;
- ◆ knowledge of evaluation principles, procedures, practices and techniques; and
- ◆ skills to effectively plan and organize the assigned evaluator tasks.

1.5.2.2 A team member shall be able to:

- ◆ decide from the submitted documentation any features requiring special study during the evaluation;
- ◆ 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 EA MLA;
- ◆ evaluate constantly the effects of evaluation observations and personal interactions during an evaluation;
- ◆ treat concerned personnel in a way that will best achieve the evaluation objective;
- ◆ react with sensitivity to the local conventions of the area in which the evaluation is performed;

- ◆ perform the evaluation process without deviating due to distractions;
- ◆ react effectively in stressful situations;
- ◆ commit full attention and support to the evaluation process.

1.5.2.3 A team member shall be able to obtain and evaluate objective evidence fairly and to report on his/her findings according to the applicable reporting procedures.

1.5.2.4 A team member shall be able to understand quickly and easily cultural differences, as far as essential in the evaluation process.

1.5.2.5 A team member shall be able to:

- ◆ determine the criticality of the findings and to evaluate whether the corrective actions decided by the AB are likely to be effective and to evaluate the corrective actions carried out;
- ◆ arrive at generally acceptable conclusions based on evaluation observations;
- ◆ remain true to a conclusion that is based on objective evidence, despite pressure to change.

1.5.2.6 Be able to act impartially and remain true to the purpose of the evaluation without fear or favour also based on the absence of any conflicting interests.

#### 1.5.2.7 Preconditions

A team member shall:

- a) have at least appropriate technical background and at least 3 years' experience as accreditation assessor,
- b) have successfully completed relevant training course(s) and should have experience as a trainee in peer evaluation of NABs (if required),
- c) have appropriate experience in at least one standard that is applicable to the accreditation of a CAB and be authorized by their NAB to assess against this standard,
- d) have preferably participated in an EA/ILAC/IAF working group/committee,
- e) be preferably a staff member of a NAB.

### 1.5.3 Peer evaluator team leader

1.5.3.1 In addition to the attributes and competencies described above for evaluator team members the team leader shall be able to manage an evaluation, lead an evaluation team in an efficient and effective way, plan and control the contribution of the individual team members and report clearly and succinctly the results of the evaluation.

1.5.3.2 A team leader shall be able to discuss the objectives and impact of accreditation services with the management and staff of a NAB, based on his/her knowledge of the

accreditation body's services, the (business and regulatory) context thereof and the associated risks.

- 1.5.3.3 The team leader shall be able to understand issues raised by the other members in the team on the accreditation fields which are outside his/her area of expertise.
- 1.5.3.4 Based on his/her interpersonal skills a team leader shall be able to optimize the performance of an evaluation team taking into account the strengths and weaknesses of the individual team members.
- 1.5.3.5 The team leader shall be able to take decisions on the classification of findings and on the closing of findings based on the recommendation of the team members.
- 1.5.3.6 The team leader shall be able to chair meetings and to reach consensus on delicate points.
- 1.5.3.7 The team leader shall be able to report to the decision-making committee, and to present a recommendation, taking into account the findings of all team members, in conformity with the MLA requirements.

#### 1.5.3.8 Preconditions

A team leader shall:

- a) be a permanent staff member of a NAB or a former staff member of a NAB who retired or left the NAB no more than 5 years previously. For ex-NAB staff, a working contract shall be established with a NAB to allow for the compensation of man days through the operating grant,
- b) have at least 3 years' experience in the operation of a NAB and have appropriate technical background and experience in assessment,
- c) have enough working experience in a NAB to be able to understand requirements of any of the relevant standards that are applicable to the accreditation of CABs,
- d) have participated successfully in at least three evaluations of NABs as a TM or as a deputy TL (DTL).

#### 1.5.4 Peer evaluator deputy team leader (see also 1.6.3)

1.5.4.1 A DTL shall be a team leader or an experienced team member capable of acting as a team leader and shall be a permanent staff member of a NAB.

1.5.4.2 The role of DTL may be used as training for development of future TL.

#### 1.5.5 Trainees

1.5.5.1 A Trainee Team Member acts as a team member in his/her field of expertise. However, during the first evaluation activity, a member of the team (team leader,

deputy team leader or experienced team member) with competence in the same scope is assigned to mentor the trainee and assist where needed.

1.5.5.2 The tasks assigned to the trainee are decided by the mentor, considering the experience of the trainee on the basis of the feedback sent by the Secretariat based on the trainee's CV, and the appraisal of his/her performance by the trainers following his/her participation to the training of newcomers.

1.5.5.3 A trainee team member shall have participated in a "newcomers" training session and have been recommended as a trainee.

1.5.5.4 The trainee's NAB shall pay all expenses (travel and accommodation), including for witnessing purposes (see also 2.3.3).

### **1.5.6 Observers**

Note: This clause is related to observers, who shall be authorized as peer evaluators, if the requirements in this section are met (see also 1.1.4.4).

#### 1.5.6.1 Duties

An observer takes part in an evaluation as an additional person added to the regular team. The observer is 'linked' to a team member with competence in the same field, who has been involved before in at least 2 evaluations. The observer is expected to observe the team and not actively take part in the evaluation. In particular after the evaluation the observer shall:

1. summarise the activities of the team member in the field of expertise of the observer;
2. summarise the rationale in terms of the requirements (EN ISO/IEC 17011, Regulation (EC) No 765/2008, etc.) and EA procedures (EA-2/02) for the selection of files and witnessing that was made by the team member observed;
3. summarise in his/her own words the rationale for the findings raised which are related to the field in question and to the general management system of the NAB;
4. explain what the observer learned from this observation;
5. the summary will consist of 750-1000 words and will be provided to the Secretariat and to the team leader of the evaluation team.

#### 1.5.6.2 Preconditions

- a) after having participated in a training for 'newcomers' be recommended as an observer,
- b) the observer's NAB pays all expenses (travel and accommodation), including for witnessing purposes (see also 2.3.3 of Section 1);
- c) the observer shall be provided with the same documents from the NAB as the rest of the team.



### 1.5.6.3 Procedure

The summary will be provided to the trainers who were responsible for the appraisal of the person after the training. They will review the summary, discuss with the team leader and team member observed and decide whether the observer will be recommended as a trainee or will have a negative recommendation. The observer and the Secretariat are informed about this recommendation.

## 1.5.7 Records

### 1.5.7.1 Records on evaluators

The Secretariat shall maintain the following records for each evaluator:

- CVs,
- Signed declaration of confidentiality,
- Evaluation for participation in a Peer Evaluator Training Course / Authorization letter (including competence),
- Reviews of performance,
- Any action taken by the MAC in relation to the performance of the evaluator.

### 1.5.7.2 Records on training activities

The EA Secretariat shall maintain the following records of Newcomer Training and other training activities:

- Course program, including date, venue and trainers
- Course material, including presentations, tests and exercises.
- Attendance list.
- Evaluation of participants on “newcomers” training courses.

## 1.6 Procedure for the Appointment and Composition of the Evaluation Team

### 1.6.1 Composition of the evaluation team

1.6.1.1 For the full evaluation visit, members of the evaluation team shall be chosen as needed to cover the types of accreditation, the technical scopes, and the size and complexity of the accreditation system under evaluation.

An evaluation team shall be composed of a TL and at least one TM to ensure the “four eyes principles” for each evaluation.

For pre-evaluations, the team shall be composed of a TL and one TM, each of them having competence to cover at least one of the EA MLA scopes to be covered by the evaluation.

- 1.6.1.2 Team members shall be chosen, in consultation with the TL, from a list of team members authorized according to the process described in 1.1 and kept up-to-date by the Secretariat. This list should record the scopes and sub-scopes for which the evaluator is considered competent and experienced in evaluations.

**Note:** In case no evaluator in the team has knowledge of the local language of the country where the evaluation takes place and if considered useful by the Secretariat to ensure an efficient communication an independent translator will be added to the team.

- 1.6.1.3 The evaluation team chosen shall consist of representatives from a cross-section of Member National Accreditation Bodies. The evaluation team shall be chosen to provide a balanced set of skills so as to be able to conduct an effective evaluation of the key components of the system under examination.

- 1.6.1.4 No team member shall be associated with any accreditation body that has provided consultancy service to the accreditation body being evaluated within three years prior to the evaluation (see also 1.6.1.7).

- 1.6.1.5 A team should not have more than two evaluators participating in their first evaluation (trainees). For the trainee evaluators on the team, an authorized mentor (an evaluator with experience in more than two evaluations) will be appointed.

- 1.6.1.6 A team member may, in addition to his/her evaluation tasks, mentor any "trainee peer evaluator" (those performing their first evaluation) assigned to the evaluation team. Mentoring trainees includes allocating him/her such task as he/she is capable of performing, supervising and providing a report to the Secretariat about the performance of the trainee.

*NOTE 1: It is normal practice that evaluators from as many members as possible are appointed in a team.*

*NOTE 2: A team leader should normally be accompanied by at least one other team member for a pre-evaluation visit to ensure more than one person is involved in establishing an applicant's readiness for a full evaluation visit (see also 1.6.1.1).*

*NOTE 3: There should be no more than one team member from each 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 than the rest of the evaluation team.*

- 1.6.1.7 Situations where a member of the evaluation team or the NAB he/she belongs to has provided services to the NAB under evaluation may represent a threat to the impartiality and shall be clearly described in the declaration of Conflict of interest. In particular no member of the evaluation team or the NAB he/she belongs to can have provided specific advice or training to the NAB under evaluation on the operational or management procedures in the 3 years in all cases prior to the evaluation.

Note: A Declaration 'Conflict of Interest' shall be signed by each member of the team prior to the evaluation visit.

### **1.6.2 Appointment and duties of the evaluation team leader:**

1.6.2.1 In appointing an evaluation team leader for a specific evaluation, the Secretariat should not appoint the same team leader for two successive evaluations of the same applicant.

Note: For extraordinary evaluations and evaluations for scope extensions (see 2.2) it may be useful to appoint the same team leader as in the previous evaluation.

A team leader who was appointed for a follow up, an extraordinary or an extension evaluation, may also be appointed for the next re-evaluation, if he was not the TL of the previous re-evaluation of the NAB.

1.6.2.2 Team leaders shall be chosen from a list of team leaders prepared based on the process described in 1.2 and kept up-to-date by the Secretariat. This list should record the scopes and sub-scopes for which the team leader is considered competent and experienced in evaluations.

1.6.2.3 The team leader shall have ultimate responsibilities for all phases of evaluation and is delegated authority by the MAC to make final decisions regarding the conduct of evaluation.

### **1.6.3 Appointment and duties of the evaluation deputy team leader (see also 1.5.4):**

1.6.3.1 A Deputy Team Leader (DTL) may be assigned. 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.

1.6.3.2 A DTL can be identified one of two ways:

a) After a minimum of 3 peer evaluations (pre-evaluations can be considered) as a TM with positive feedback from the participating TLs and NABs, the Secretariat may invite a TM to become a TL/DTL if he/she has also demonstrated that he/she fulfils the conditions referred to in section 1.5.3 and 1.5.4 above.

Note: To demonstrate fulfilment of the competence criteria as stated in section 1.5.3, a TM may first act as a DTL (assisting the TL in planning, preparing, managing the evaluation) or as a TL supervised by an authorized TL.

b) Alternately, a deputy team leader may be an approved team leader but if assigned to a team, the DTL shall have different competences than the TL to cover as much as possible of the accreditation activities of the NAB under evaluation.

### **1.6.4 Operation of the appointment of the evaluation team**

1.6.4.1 The appointed TL prepares a recommendation on the technical composition of the evaluation team, the duration and content of the evaluation, taking into account the

following information:

- the statistical information provided by the NAB;
- the information included in the previous evaluation report;
- any decision of the MAC with respect to the objectives of the evaluation;
- any other available information (notification of changes, complaints ...)

The TL's recommendation shall identify on a sampling basis the activities (or groups of activities) at level 4 and 5 of the EA MLA that should be given specific attention during the evaluation process and shall agree them with the Secretariat.

- 1.6.4.2 The Secretariat reviews the TL's recommendation and if acceptable proceeds with the assignment of the team members. If any issues are identified those shall be raised and resolved with the TL.

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

Each evaluation team shall include a team member with the competence necessary to evaluate each of the activities listed under level 2 and 3 of the EA MLA.

The team shall include general competence with the requirements coming from the EC harmonized legislation and sector schemes, where applicable.

If an extraordinary visit is to be conducted the evaluation team is composed of one or more members of the evaluation team that conducted the full evaluation.

- 1.6.4.3 Document review and preparation of the evaluation

The TL will conduct the document review considering the contributions from the TM(s) before each evaluation visit. There is no prescribed format for the document review. Normally the document review outcome is exclusively to be used by the team. When the document review gives an indication that proceeding with the on-site evaluation is not useful, a brief written report shall be prepared for the MAC/MG stating the reasons.

## **ANNEX 2: TYPICAL EVALUATION PROGRAM OF A SINGLE NATIONAL ACCREDITATION BODY**

### **A. Pre-evaluation program**

If it is determined by EA that a pre-evaluation of the NAB is needed before the full evaluation can take place, a pre-evaluation program shall be prepared. Based on the results of the document review, the pre-evaluation team may consider reviewing the following in the context of the pre-evaluation:

- ◆ Management system policies and procedures (as part of a document review prior to the pre-evaluation visit);
- ◆ Legal identification of the NAB;
- ◆ Relationships with the regulators and other specifiers (e.g. 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, and inspection bodies where relevant);
- ◆ Measurement traceability routes (for testing and calibration accreditation, and inspection bodies where relevant). In some cases it may be necessary to visit the NMI;
- ◆ Witnessing one or more assessments, if possible.

It is sufficient if the report provides information related to the context given above.

In addition, all non-conformities and comments should be documented in a list of findings. The NAB will give its response to these findings.

The report of the pre-evaluation shall be drafted following the reporting template for evaluation reports.

A recommendation for the Secretariat on when and how to proceed shall be included.

At a later stage some of these issues can be used in the report of the full initial visit as well.

Note: Normally, a pre-evaluation shall take place before the first full evaluation.

A pre-evaluation may be skipped e.g. based on a justified recommendation by the TL to be accepted by the Secretariat, provided the applicant NAB replaces a NAB in the Member State already signatory to the EA MLA, and the changes are such that a continuity is demonstrated in Functioning and Personnel resources.

A typical plan for a pre-evaluation is illustrated in the next table.

Days	Actions	Evaluators
2,5 to 3 days	Team meeting	TL + 1 TM
	Opening meeting	
	Evaluate key processes and policies	
	Interview key persons	
	Sample records	
	Witnessing one assessment (entirely or partly)	
	Preparing the list of findings	
Closing meeting		

## B. Full evaluation program

### 1. Introduction

The task of an evaluation of a NAB is to collect sufficient information about the assessments and decision-making process of the NAB to have confidence in the conformity assessment results from CABs accredited by the NAB such that the signatories to the EA [MLA](#) can promote acceptance of these results.

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.

Because there exists a large variety of circumstances under which an evaluation will take place, it is the prerogative of the TL to deviate from the examples shown in 3.2 of this annex. The TL should agree with the team members on the duration. Consultation with the NAB under evaluation is essential. When the proposed timetable largely differs from the examples of 3.2.2 of this annex or when additional evaluation team capacity is required, the Chair of the [MAC and the Secretariat](#) should also be consulted at an early stage.

### 2. Considerations

#### 2.1 Maximum Duration

The TL should arrange the evaluation to take place in the shortest possible time, 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, together with the [NAB](#), should schedule witnessing to be performed before the [Head Office](#) evaluation (see 2.3 below). This will allow for a well-founded closing meeting in which all fact finding can be reviewed and discussed. It is additionally advised to use only experienced team members for such parts of the evaluation.

However, in some cases it is preferable or necessary to perform a staggered on-site evaluation. If the team and the NAB agree on a staggered on-site evaluation the time between the beginning and end of the on-site evaluation should not exceed 6 months.

The TL may decide that not all TMs are required to attend all staggered on-site evaluation visits. The TL may not be required to participate to all staggered evaluation activities but can participate when necessary through remote means.

If the staggered evaluation activity is focused on witnessing only, the TM can perform alone, subject to approval by the Secretariat and provided that the TL is available for interaction with the TM in a timely manner.

## 2.2 Types of Evaluation

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

Given the long interval (approximately 4 years) between evaluations, the duration of a re-evaluation is comparable to that of an initial evaluation. A shorter duration applies for pre-evaluations, for follow-up evaluations and for scope extensions that are conducted separately from a re-evaluation.

Extension of scope: the general provisions applicable for a peer evaluation remain valid but the team will normally be limited to a TL and TM(s) with the required competence to cover the scope(s) of the extension.

The Secretariat will preferably assign as TL for the extension of scope the TL appointed for the previous peer evaluation, or the TL planned for the next re-evaluation.

Where a NAB has an evaluation to extend the scope of its EA MLA within 12 months of when its regular peer evaluation is due, then that level 3 activity will not be evaluated again at the next regular evaluation, unless the regular evaluation is significantly delayed or otherwise justified by the Secretariat.

Extraordinary evaluations: The duration and the tasks of the extraordinary evaluations shall be determined by the MAC (see below clause 4).

## 2.3 Witnessing

The evaluation team shall consider how to deal with witnessing. For every level 3 there shall be:

- One witness of an initial assessment or reassessment of a CAB.
  - While full assessments are preferred, other on-site assessment activities may be considered. When the witnessing of other on-site assessment activities takes the place of the witnessing of a full assessment or re-assessment, then those activities shall include all of the accreditation requirements and assessment of a portion of the scope of accreditation. The key is that the evaluation team witness the performance of technical activities of the CAB as much as possible;
- or two other on-site assessment activities, including a portion of the scope of accreditation which may each only include parts of the accreditation requirements.

The evaluation team shall also witness other reassessments and assessments activities as determined by the team leader or the MAC MG.



For certification and validation/ verification, the evaluation team should witness the NAB assessment team performing the assessment of the body only at the office location.

**Note:** For definitions of Level 2 and Level 3, please refer to EA-1/06 or IAF PR 4 / ILAC R6, as applicable.

For planning of the witnessing, the NAB shall provide the assessment planning six months prior to the planned evaluation. This gives the evaluation team the opportunity to carefully select and plan the witnessing activities taking into consideration the following:

- standards for accreditation,
- number of accredited CAB,
- size of the fields,
- initial evaluation/re-evaluation,
- witnessed assessments from the last evaluation,
- cross frontier accreditation policy and relative procedures.

The Team Leader makes the selection of witnessing in consultation with the team members. If the witnesses are not satisfactory, or in case of unforeseen events, their number might be increased.

The decision on the assessments to be witnessed shall be based on the technical coverage (considering risk), rather than simply convenience.

Once the choice of activities to be witnessed has been made by the PE team, the NAB can look at the planning of upcoming assessments and highlight all the possibilities to perform the witnessing in advance or during the Head office visit.

The format of the evaluation should be agreed between the Secretariat, TL and NAB at the beginning of the process - in particular, it should be determined whether witnessing can best be conducted during the Head Office visit, in advance, or a combination of both. The TL will inform Team Members and the Secretariat.

If witnessing performed in advance, then it should be relatively close to the Head Office visit, normally within 3-4 months. If, in exceptional circumstances (e.g. a MAC decision that a witnessing in a specific scope shall be carried out earlier than the re-evaluation etc.), the evaluation team determine that they need to witness an assessment type where the NAB has few CABs and hence there are limited opportunities then the witnessing can be conducted further in advance, up to a maximum of 12 months.

If witnessing shall be performed 3-4 months in advance, then submission of the documents by the NAB in advance should not be affected, however if considering up to 12 months in advance then the Secretariat will need the statistics information at least 15 months in advance.

The form of the witness report contains the elements to be observed during the witness. During internal meetings, the team shall discuss whether the observations made during the witness are consistent and which questions have to be asked at the NAB's office.

## 2.4 Size of the National Accreditation Body

The influence of the NAB's scope on the duration of the evaluation (on-site part) relates primarily to the number of witnessing activities. The NAB's management system may not differ (see ISO/IEC 17011) too much when the NAB has one activity or several activities. When there is a large difference in the number of accreditations in the various fields, the TL may decide to place more emphasis on witnessing in the larger field(s).

Since Memoranda of Understanding (e.g. with regulators or specifiers of the NAB's economy) are being concluded with certain industry sectors, specific attention may be needed to assure the NAB's competence to assess in these fields.

It shall be stressed that, despite spending time on witnessing, it is very important to spend ample time to check on how a NAB selects its assessors and 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.

## 2.5 Other Factors

Factors that may influence the duration of the evaluation include:

- Need for translators;
- Extensive travel and travel circumstance; and
- Cultural differences.

This annex cannot provide guidance on all these items. It is left to the team members and their experience to judge these effects and to cater to them in such a way that there is no compromise to the principle stated in the introduction to this annex.

## 3. Managing the evaluation

An evaluation visit needs advanced planning, so that efficient use of resources is implemented –

Note: To enable the Secretariat to assign an evaluation team in line with the NAB's accreditation activities and with the appropriate requirements of the Regulation (EC) 765/2008 the NAB is requested to provide the statistical information one year before the scheduled evaluation period.

The evaluation visit has to be carefully prepared in close interaction between TL, TMs and the NAB. The TL has the lead and the obligation to ensure that all necessary documents are provided to him and to the team in due time or as specified in the rules. The content and extent of the documents have to be in such a condition that the evaluation can be prepared and carried out in good manner and successfully, and this way the time on site can be used for the verification and witnessing. In case the extent or the content of the documents are not enough, further documents or revisions have to be demanded by interaction with the NAB and the Secretariat. The evaluation visit can be postponed if the documents are not satisfactory, at the request of the TL.

The TL shall send to the NAB the final agenda of the evaluation at least 1 month prior to the evaluation.

### **3.1 Preparation and Planning**

**3.1.1** The time for the evaluators to spend on preparation largely depends on the quality of the documents that the NAB forwards. The documents that are required are specified in the *Application form*. Accurate translation of the documents into English by the NAB is essential.

**3.1.2** The self-assessment document (EA-2/02 T1) shall be detailed and accurate. This document 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 ask the NAB to revise the document with the necessary information.

**3.1.3** The NAB shall send all documents to the evaluation team, at least 3 months in advance of a visit to allow for preparation and for requesting additional information.

**3.1.4** The team members should start reviewing the documents directly after receipt. In essence the team leader should be able to prepare a part of the report with background information before the on-site evaluation. This part of the preparation is the same for all types of evaluations. The total time involved in studying the documentation may take an average of 3 to 5 days for the TL and 2 to 4 days for the team members.

**3.1.5** For planning of the witnessing, the NAB shall provide the assessment planning. This gives the evaluation team the opportunity to carefully select and plan the witnessing activities taking into consideration the following (see also 2.3):

- standards for accreditation,
- number of accredited CAB,
- size of the fields,
- initial evaluation/re-evaluation,
- witnessed assessments from the last evaluation,
- cross frontier accreditation policy and relative procedures.

If the applicant or signatory is active in the framework of an industry or regulator specific scheme, then the fulfilling of the requirements set by that industry group or by regulators for accreditation bodies shall also be considered on a sampling basis.

### **3.2 On-site Evaluation**

The standard evaluation program for each TM shall generally include at least 1 full day office evaluation and 2 full days for witness assessment for each of the activities at level 2 and 3 of the EA MLA. The TL's recommendation shall identify, based on a risk analysis, whether the duration for the evaluation for each activity should be limited or increased.

Note: The risk analysis shall take into account amongst others the number of accredited CAB's for the concerned activity and the evolution of the volume of work, the results of previous peer evaluations, recent changes in the operation of the NAB, specific circumstances such as the NAB operating from different sites, the need to consider split evaluation

### 3.2.1 The evaluation team should be prepared to undertake long working days during the on-site evaluation.

An on-site visit typically consists of:

- Preliminary meeting of the evaluation team for exchange of views, review of key issues identified during the document review and further discussion of the evaluation plan and distribution of tasks,
- Opening meeting, presentation by team leader outlining aims, objectives and procedure to be used by evaluation team,
- Evaluation of the NAB's offices and management system, review of files and records,
- Discussing of the results of the self-assessment document ([EA-2/02 T1](#)),
- Evaluation of the assessment reports, including preparation of the assessment and decision-making records (and possible witnessing of the accreditation decision making process.),
- Splitting of the team in accordance with their experiences for the purpose of witness including the on-site preparation of the draft evaluation report with a list of findings,
- Witness of a CAB for every scope (see Clause 2.3 of this annex),
- Discussion of the results of the witnessing with the evaluation team and NAB,
- Closing meeting, presentation and discussion of findings.

Some timetable examples are shown below.

### 3.2.2 NABs with single scope

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 evaluation team)	TL + 2 TM
Day 3	Office + witnessing staff + preparation final report + closing meeting	TL + 2 TM
Day 4 morning	Discussing further actions for TMs + departure	TL + 2 TM

**3.2.3 NABs with 2 scopes**

<b>Day</b>	<b>Actions</b>	<b>Evaluators</b>
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 + preparation for witnessing assessments	TL + 2 TM
Day 3	Office + witnessing staff + witnessing assessments (split evaluation team)	TL + 2 TM
Day 4	Same + preparation final report + closing meeting	TL + 2 TM
Day 5 morning	Discussing further actions for TMs + departure	TL + 2 TM

**3.2.4 NABs with 3 scopes**

<b>Day</b>	<b>Actions</b>	<b>Evaluators</b>
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 evaluation team)	TL + 3 TM
Wednesday	Office + witnessing staff + vertical audits + witnessing assessments (split evaluation team)	TL + 3 TM
Thursday	Office + witnessing staff + vertical audits (specially directed for confirmation of previous findings) + witnessing assessments (split evaluation team)	TL + 3 TM
Friday	Preparation final Report + closing meeting + Discussing further actions for TMs + departure	TL + 3 TM

**3.2.5 NABs with full scope**

<b>Day</b>	<b>Actions</b>	<b>Evaluators</b>
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 evaluation team)	TL + 4 TM
Wednesday	Office + witnessing staff + vertical audits + witnessing assessments (split evaluation team)	TL + 4 TM
Thursday	Office + witnessing staff + vertical audits (specially directed for confirmation of previous findings) + witnessing assessments (split evaluation team)	TL + 4 TM
Friday	Same + preparation final report + closing meeting	TL + 4 TM
Saturday	Discussing further actions for TMs + departure	TL + 4 TM

NOTE: This is guidance only. In some regions it is common for a four person (laboratory accreditation evaluation) team to witness up to 10 different laboratories, during a five day evaluation. Where the NMI is not a signatory to the CIPM MRA or where the NMI's

CMCs are not listed in the BIPM database, the evaluation team should consider the need to visit the NMI and any designated institute so as to evaluate the traceability routes available to accredited laboratories. 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 accredited bodies.

**3.2.6** 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 the studying of the documentation and discuss such changes during the week with the team members. The TL may also require the NAB to provide a general description of the NAB to be used in the report.

### **3.3 Activities after the On-site Evaluation**

**3.3.1** Electronic means to communicate with the team members should be sufficient to provide feedback and support as the TL prepares the final report for the NAB.

**3.3.2** The evaluation team needs to spend time on reviewing the NAB's corrective actions and on the preparation of the evaluation team's comment to these corrective actions. The TL should take the lead in preparing this reaction.

**3.3.3** Finally the TL shall prepare a recommendation to the MAC.

**3.3.4** Typically these activities may take 2-3 days for the TL. For TMs, the time involved may be limited to 0.5 days.

**3.3.5** Writing the Evaluation Report: [EA-2/02 T1](#) contains information concerning the structure and timeline for writing and presenting a report.

### **3.4 Elements extending the duration of evaluation**

- Size of the NAB,
- Extensive travel and travel circumstances,
- Need of translation,
- Multi-site NAB-offices,
- Possibilities for witnessing,
- Cultural differences,
- Requirements from regulators,
- Requirements from special schemes (Bluetooth, etc.),
- The additional time should be agreed among all and should be guided by common sense.

## **4. Procedure in case of serious issues during evaluations**

When an evaluation team detects a situation at a NAB that results in a total lack of confidence in the NAB's operations and in the issued accreditations, the team will have to deviate from the normal reporting procedure as described in the section 3 flowchart.

In this case they will immediately send to the MAC MG a draft report containing at least the Executive Summary and the list of findings without awaiting the corrective actions of the NAB.

During the evaluation the NAB's management shall be informed that serious problems are detected. In other words the outcome reported at the closing meeting cannot be unexpected.

The MAC MG will decide on immediate steps to be taken and will decide if an extra meeting or electronic consultation/ballot of the MAC is required.

## **5. Delay in the evaluation process**

### **5.1 Delay Caused by the NAB**

If the NAB does not cooperate with the evaluation team within the timeframes specified in this document, the Team Leader should, at any stage, inform Secretariat on the situation, in order to make a decision on a possible suspension of the evaluation process.

The MAC in consultation with the MAC MG shall decide on the evaluation process and the signatory status of the NAB.

### **5.2 Caused by Adverse Travel Advisory**

If adverse travel advice for the NAB's economy occurs the team leader shall, in consultation with the Evaluation Team, propose Secretariat to postpone the evaluation.

MAC MG shall decide on the basis of advice from the team leader appointed for the evaluation, on the postponement of the evaluation.

After the postponement, MAC shall decide the impact on the maintenance of the EA MLA signatory status.



### **ANNEX 3: CONTENT OF THE EVALUATION SUMMARY REPORT ON A NAB**

(This report is prepared by [nominated EA TFG's](#) for presentation to the MAC. [It deviates from the content set out in IAF/ILAC-A2 Annex 3](#))

**Applicant:**

**Scope of evaluation:**

**Evaluation team:**

**TFG composition:**

**Identification of the full evaluation report:**

**TFG conclusions**

Short summary:

Statements on findings observed by the evaluation team:

Interaction by TFG with team and/or AB:

**Recommendation with justification**

Recommendation of the EA evaluation team:

Recommendation and the justification of TFG:

The TFG report should consider the following:

- Were EA procedures followed?
- Were the appropriate normative documents applied?
- Does the report contain sufficient information to support a decision?
- Are the conclusions and recommendations supported by the report?
- Are the findings appropriately classified, clear and concise?
- Is the proposed/implemented corrective action appropriate to the finding?
- Were the findings appropriately closed?
- Were there any issues raised by the TFG that required a response from the team?

## **ANNEX 4: PROCEDURE FOR DECISION MAKING REGARDING EVALUATIONS OF A NATIONAL ACCREDITATION BODY**

### **1. Decision making regarding EA evaluations**

**1.1** The evaluation report, the corrective actions and the recommendations of the team leader shall be submitted as the final report **together with the TFG report** to listed members of the MAC.

**1.1.1** Reports on all evaluation visits may be copied to the representatives of **EA MLA<sup>1</sup>** signatories who have a role to play in decision making.

**1.1.2** Regulators or other observers who are allowed to attend the decision-making meetings, may also be provided with the evaluation/re-evaluation report for a given NAB, with that decision-making group's and NAB's written permission.

Note: Restriction to participate in a MAC meeting during voting may happen due to conflict of interest (see Annex 1, clause 1.6.1.7).

A Member under evaluation may invite one representative from the Member State to observe the EA MAC meeting when their evaluation report is discussed.

Two observers, one designated by the European Commission and one designated by the EA Advisory Board, will be entitled to attend the MAC meetings and discussions and they receive the MAC documents, including PE reports. The MAC Chair may invite other observers as appropriate.

**1.2** **Before making the evaluation report available to the TFG, the Secretariat reviews the report and gives feedback of this review to the TFG as follows:**

- whether the evaluation was carried out as originally planned (all evaluators carried out their part and all the planned witnesses have taken place);
- the completeness of the final report from a procedural point of view (templates were used appropriately, all clauses have been addressed, list of findings included, information related to witness/file review enclosed). The Secretariat should interact with TL where the report is incomplete or does not meet EA-2/02 requirements;
- any specific issues, if necessary.

**1.3** The role of the TFG is to focus on the technical aspects of the report/evaluation so as to ensure that the MAC can make a sound decision. Therefore, the TFG is required to:

- a) examine the content of the report from a technical point of view and appraise the content:

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<sup>1</sup> MLA signatories include EA BLA signatories (see EA-1/06)

- the self-evaluation document is detailed and accurate to provide adequate information;
  - the report should contain all relevant information and sufficient evidence to make a decision on compliance/non-compliance;
  - traceability.
- b) check whether all clauses and criteria have been evaluated in sufficient depth;
- c) check the findings to ensure;
- technical correctness;
  - clear wording and traceability;
  - reasonable grading.
- d) check whether all findings were correctly closed (cause analysis was appropriately considered, the proposed actions give confidence that the findings have been (or will be) sufficiently resolved, evidence provided when requested by the peer evaluation team etc.);
- e) request for clarification from team Leader where issues remain open or unsolved and take a position on it;
- f) identify any issues requiring discussion at the MAC level;
- g) formulate a recommendation on suitability for submission to the MAC;
- h) make an overall statement on the evaluation process (taking into account the review made by the secretariat) and formulate a recommendation on the decision of the MAC.

**1.4** The MAC TFG prepares a summary report (see Annex 3) for the MAC which shall decide:

- in the case of an initial evaluation, whether or not the applicant may enter the Agreement;
- in the case of a re-evaluation, whether or not the accreditation body will remain a signatory to the Agreement. Positive decisions can be accompanied by conditions (see Clause 2 of this Annex).

NOTE 1: The MAC 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 fundamental re-organizations.

NOTE 2: For voting rules see [EA-1/17 EA Rules of Procedure](#).

**1.5** Any representative of the NAB under evaluation, the Team Leader or Team Member involved in the respective evaluation cannot cast the vote when that evaluation decision is made.

## 2. EA MAC Task Force Group for studying evaluation reports

Note: This clause deviates from IAF/ILAC-A2, which describes the decision making regarding joint IAF/ILAC evaluations. Relevant clauses for the work and competencies of TFGs and/or the MAC, involved in the decision-making process, have been incorporated.

**2.1** A Task Force Group (TFG), composed of four members, is assigned by Secretariat to study the evaluation report, as follows:

- 3 members, out of which one is the reporter;
- 1 member representing MAC Management Group.

**2.2** Criteria to be a TFG member:

- represent a signatory;
  - three (out of four members) have at least one-year experience in the MAC.
- The MAC MG member shall ensure that sufficient discussions, when relevant, have taken place between the NAB, the EA evaluation team and the TFG.

**2.3** MAC members are informed on the composition of the TFG(s), well in advance of the meetings, to anticipate on a specific situation in a NAB.

**2.4** The task of the TFG is to evaluate the report on completeness and good understanding, to study the evaluation report and to make a recommendation on decision to MAC MG.

The TFG is requested to comment on the general impression of the performance of the evaluation team, the reporting and the classification of findings (see also Annex 3). The TFG is expected to communicate with the evaluation team and, in exceptional cases, with the NAB under evaluation when there are open, missing or unclear issues in the report in order to solve or clarify the situation.

Unless serious issues are identified which require additional consideration, the review report of the TFG has to be provided to the Secretariat within 3 weeks after receiving the evaluation report.”

### 2.5 TFG Competencies

2.5.1. To appreciate comprehensiveness the TFG will need to have an understanding of what should be in a report from a generic and specific perspective. The TFG shall have collective expertise at levels 1, 2 and 3 of the EA MLA.

Note: If a specific TFG is not appointed as part of a region’s review and decision-making process, then demonstration of compliance with these competency requirements will be considered as part of the evaluation of the region’s nominated review and decision-making body(ies).

2.5.2 The TFG needs to understand; the planning and conduct of the evaluation, its breadth and depth, the findings and their classification, and the adequacy of the conclusions,

and recommendations. The competencies required would be consistent with that of an individual with experience as a CB auditor or a NAB assessor, and exposure to the [EA peer evaluation and policy documents](#), IAF MLA P&P, ILAC P-Series as well as practical experience in the peer evaluation process.

- 2.5.3 To be able to effectively correspond with the team, the TFG convener requires good communication skills and an understanding of the criteria and process. The competencies would be similar to those listed in point 2.5.2 above.
- 2.5.4 At least one member appointed to the TFG, shall be an authorized peer evaluator.
- 2.5.5 There should be a balance of members with competencies on the different level 3 activities.

### 3. Hierarchy of decisions

3.1 Decisions made as a result of peer evaluations can take many forms. Implicit in these decisions is the possibility of a variety of "conditions". This guidance outlines a hierarchy of the major types of decisions from the most positive decision to the least positive decision; conditions of increasing severity are imposed.

3.2 not relevant for EA

3.3 The MAC makes all decisions on NABs and the decisions [should](#) be made in a period of 30 days after the review made by the MAC TFGs. The persons participating in the decision making shall have an understanding of: objective and purpose of the EA MLA; criteria used for the evaluation; the evaluation process and the EA MLA structure. There are primarily two situations to address: new applicant NABs and signatory NABs. A third situation that is not addressed below is the possibility of adverse decisions or sanctions imposed on an EA MLA signatory which fails to abide by its obligations under the EA MLA itself.

3.4 Decisions on new applicant NABs:

- ◆ Approval without conditions ([and the period of the first re-evaluation, normally a 2-year period is used for initial evaluations after entering into the EA MLA. This procedure does not apply to 'extension\(s\) of scope](#));
- ◆ Approval with conditions (e.g., shortened interval for re-evaluation);
- ◆ Defer approval pending submittal of required evidence of corrective actions [and/or progress reports for non-conformities](#) and/or re-visit by one or more members of the evaluation team to confirm implementation of corrective actions;
- ◆ Disapproval with a new evaluation required.

Note: Disapproval should rarely happen for new applicant unaffiliated single accreditation bodies since an evaluation report is normally only submitted for a decision once a consensus of the evaluation team and the IAF MLA MC or ILAC Arrangement Management Committee has concluded that all requirements have been met.

### 3.5 Decisions on signatory NABs:

- ◆ Continuation without condition (re-evaluation in 4 years after the originally planned date for the previous re-evaluation)
- ◆ Continuation with conditions (e.g. extraordinary evaluations, shortened re-evaluation interval, additional information or progress reports)

The MAC shall decide on:

- The applicable action to confirm implementation of corrective actions.
- The maximum time span for the subsequent decision by the MAC.

**ANNEX 5: EA PROCEDURE FOR HANDLING APPEALS.**

EA's procedure for handling appeals is set out in EA-1/17 S3 *EA Procedure for the investigation and resolution of Complaints and Appeals*.

**ANNEX 6: PROCEDURE FOR RE-EVALUATION OF AN EA MLA SIGNATORY  
AND ON-GOING CONFIDENCE BUILDING ACTIVITIES**

1. Periodic monitoring and re-evaluation of the MLA signatories is necessary (see also Annex 1).
2. All MLA signatories shall be formally re-evaluated at maximum intervals of four years from the last day of the previous evaluation (**-3 to +6 months**).

Note: The four years interval shall be calculated each time from the “reference date”. The reference date is the month/year of the initial (on-site) peer evaluation. The month/year of the next peer evaluation, based on the reference date, shall be noted with each MAC decision on peer evaluations.

3. The Signatory under re-evaluation shall provide the evaluation team with all the documents which are required for an initial evaluation (see Application from a NAB to join the MLA). In addition, the evaluation team shall get the full evaluation report from the last evaluation/re-evaluation or any special evaluation.
4. Partial to total re-evaluation may be conducted at an earlier date as directed by the MAC, should there be due cause such as notification of significant changes in administration, finances, operational practices or an extension of the scope of accreditation available.
5. The impact of changes notified by an MLA signatory shall be evaluated (see Section 2, Clause 2.2.2).
6. Re-evaluation visits should be led by an evaluation team, in which the majority of members will not have been in the evaluation team that undertook the previous evaluation.



## **ANNEX 7: PROCEDURES FOR MAINTENANCE, SUSPENSION AND WITHDRAWAL OF EA MLA SIGNATORIES**

### **1. Maintenance, suspension and withdrawal**

- 1.1** It may be that the MAC cannot accept the significant changes notified by the NAB, the corrective action taken by this NAB, major non-conformities which have been found or substantiated complaints from interested parties. The MAC shall take appropriate action. This action can be suspension for a maximum period of 6 months or withdrawal from the EA MLA.
- 1.2** Maintenance, suspension or withdrawal of a signatory NAB shall be decided by the MAC after receipt of the recommendation by the MAC TFG. Any suspension or withdrawal decided by the MAC shall be accompanied by an appropriate explanation stating the reason for suspension or withdrawal.
- 1.3** not relevant for EA
- 1.4** A NAB shall not remain a signatory of the MLA if it is, for any reason, suspended or withdrawn as a member of EA. The Secretariat shall immediately notify the MAC when any signatory is suspended or withdrawn from the organization for any reason, and the MAC shall immediately suspend or withdraw the accreditation body from the Agreement.
- 1.5** In the event of a decision to suspend, EA shall:
- a) Officially notify the NAB of the decision to suspend, the reasons for the decision to suspend, the 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 NAB of their right to Appeal the decision (see Annex 4);
  - c) If the appeal is not upheld, amend the list of EAMLA signatories to identify that the body is suspended;
  - d) notify all MLA signatories of the suspension; and
  - e) remind the NAB of the consequences of suspension.
- 1.6** The consequences of suspension shall be decided by the MAC on a case-by-case basis, depending on the reason for suspension. The consequences of suspension may include, for the applicable main scope and/or sub-scope that the NAB shall:
- a) not actively promote the fact that they are a signatory to the MLA;
  - b) not issue any accreditation documents that bear the IAF MLA Mark and/or the ILAC MRA Mark, as applicable;
  - c) not participate in any ballots associated with the MLA;
  - d) notify all 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.

Note: Accreditations granted during the suspension period are not covered by the MLA and are not internationally recognised.

There is no consequence for the CABs accredited before the suspension.

The MAC will inform the NAB's Top Management and the responsible body who, on behalf of the Member State, has assigned the National Accreditation Body, about the suspension and the serious possibility of withdrawal of the signatory status to the MLA. A note will be published on the EA website and ILAC and IAF MRA/MLA committees will be informed.

As a general rule a suspension can last for a maximum of six months with the possibility to be extended for another six months. Within the first six months an extraordinary visit will normally be conducted.

Based on the result of the extraordinary evaluation, the MAC will decide as follows:

- to lift the suspension and reinstate the signatory status with or without conditions
- to withdraw the signatory status
- to extend the suspension for another six months, for instance in case of an appeal procedure not yet finalised.

Because of the limited time frame a 'quick decision making' (based on the summary evaluation report with recommendation and the closure of non-conformities with enough justification) will be applied. A Task Force Group report is not mandatory. In this case, the MAC MG will review the summary evaluation report and prepare the recommendation to be voted by MAC.

**1.7** The obligations of the NAB while suspended are:

- a) continue to comply with the obligations of full membership;
- b) cooperate fully with the MAC to enable a speedy resolution of the suspension;
- c) maintain oversight of their accredited CABs; and
- d) continue to vote on EA ballots, other than those associated with the MLA.

**1.8** In the event of withdrawal, EA shall:

- a) officially notify the NAB of the withdrawal and the reasons for the withdrawal;
- b) prior to taking action on the decision to withdraw, notify the NAB of their right to Appeal the decision;
- c) if the appeal is not upheld, amend the list of MLA signatories to withdraw the signatory;
- d) notify all MLA signatories of the withdrawal;
- e) not relevant for EA;
- f) remind the NAB of the consequences of withdrawal.

- 1.9** The consequences of withdrawal are, for the applicable main scope or sub-scope of the MLA are that the NAB shall:
- a) immediately stop promoting the fact that they are a signatory to the MLA;
  - b) immediately stop issuing any accreditation documents that bear the IAF MLA Mark and/or the ILAC MRA Mark, as applicable; and
  - c) notify all accredited CABs of the withdrawal and terminate all relevant Agreements for the use of the IAF MLA Mark and/or the ILAC MRA Mark, as applicable.

A withdrawn signatory must inform (with a copy to the MAC) all applicant and accredited CABs within 1 month that their reports/certificates are no longer accepted under the MLA and they may no longer make reference to the MLA.

Certificates and reports issued by accredited CABs before withdrawal of MLA signatory status are considered to be covered by the EA MLA. For Certification Bodies, certificates issued before withdrawal, MLA coverage will apply until 6 months after withdrawal of MLA signatory status.

Certificates/reports issued after withdrawal are not covered by the EA MLA.

As soon as MLA signatory status has been withdrawn, all EA MLA/BLA signatories shall make information available to their accredited CABs about the consequences as described above.

Withdrawal means removal from the list of signatory members, publishing of the withdrawal on the EA website, informing the ILAC and IAF MLA committees and the responsible body who, on behalf of the Member State, has assigned the National Accreditation Body.

- 1.10** When a withdrawn NAB applies to become an MLA member again, the procedure for new applicants shall be followed.

## **ANNEX 8: DISCLOSURE OF PEER EVALUATION REPORTS**

Reports from peer evaluations managed by EA shall not in general be made available in the public domain.

A peer evaluated NAB may, however, choose to make the full report available to its interested parties with the purpose of promoting the acceptance of the MLA under the conditions detailed below:

1. The peer evaluation report shall not be disclosed until it has been formally considered by the MAC and a decision has been confirmed.
2. The EA Secretariat shall provide to the peer-evaluated NAB on request the documents that may be collectively disclosed to the relevant interested parties. The documents shall include the full evaluation report, including the responses to the findings and all other annexes, and the MAC resolution(s) related to the peer-evaluation. All references to any specific conformity assessment body and assessors, as applicable, shall be removed by the EA Secretariat from the documents.
3. The documentation provided by the Secretariat to the NAB 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 body and the recipient.

## **ANNEX 9: EXTRAORDINARY EVALUATIONS**

Irrespective of situations where suspension has been decided, additional evaluation visits are sometimes necessary. A decision to conduct such extraordinary evaluations will be taken by the MAC and will consider but not be limited to the following criteria:

- The NAB has not offered the evaluation team an acceptable choice in witnessing activities or has not provided all needed documentation preventing the evaluation team to prepare correctly in the required timeframe.
- A NAB fails to respond within the required timeframe on NCs and CNs
- The nature of the corrective actions is such that their effectiveness can only be proven adequately through an additional evaluation visit.
- The evaluation report does not provide evidence of effective implementation of the corrective actions.
- There are major changes in the structure or processes of the NAB, which could affect issues such as competence, impartiality and operational ability.
- Any complaint as referred to in EA-1/17 S3 *EA Procedure for the investigation and resolution of Complaints and Appeals*. In this case and depending on the results of the examination of the complaint, the Executive Board shall in addition decide whoever has to pay the costs for the extraordinary visit and what should be included in those costs.
- When an NAB does not respond to an EA survey seeking confirmation that the transition of CABs to a revised standard was completed by an internationally agreed deadline.

**ANNEX 10: EVALUATION REPORTING**

Template EA-2/02 T1 (reproduced by IAF/ILAC A3) shall be used for the reporting of all evaluations.

**ANNEX 11: SUPPLEMENTS TO EA-2/02**

The supplements to EA-2/02 are listed in [EA-INF/01](#) and are published on the EA website.