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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.

Note: The annexes may be revised independent of the core document. The valid version is the version available on the internet.

*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.

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## 1. INTRODUCTION

### 1.1 Scope

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).

This document

- complements the document EA-1/06 that provide 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;
- includes a flow-chart and 7 annexes to describe in more details the major steps of the process;
- is to be used by (potential) signatories, by evaluators, by Task Force Group (TFG) members and MAC members;
- is based on the common IAF/ILAC document for the evaluation of single NABs (IAF/ILAC A2:2014) and supports consistent implementation of the common IAF/ILAC document for the evaluation of a Regional Group (IAF/ILAC A1).

### 1.2 Definitions

The following definitions are applicable only for this document.

- **Evaluation Team Leader (TL):** an evaluator responsible for leading an MLA peer evaluation team.
- **Evaluation Deputy Team Leader (Deputy TL):** a TL or (experienced) 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.
- **Evaluation Team Member (TM):** an evaluator serving on an MLA peer evaluation team.
- **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:** An 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).
- **Witnessing:** Observation of an NAB carrying out assessment at the premises of the conformity assessment body (CAB) and evaluation of the NAB's management system and records by an evaluation team. (It may also include observing the NAB's staff preparing for an assessment and dealing with assessment reports).

### 1.3 References

- EA-1/06 EA Multilateral Agreement – Criteria for signing – Policy and procedures for development
- ILAC/IAF A2 ILAC/IAF MRAs: Requirements and procedures for the evaluation of a regional group
- EA-2/02 S1 Supplement S1 to EA-2/02 : Selection, Training and Monitoring of Evaluators

## 2. CONFIDENTIALITY RULES LINKED TO THE PEER EVALUATION PROCESS

**2.1** All oral and written information received relating to pre- and initial evaluations, re-evaluations and extraordinary evaluations, 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 members of the EA MAC. All members and observers of the evaluation teams, all members, observers and secretariat personnel of the EA MAC Management Group and the Appeals Review Panel, other persons having access to confidential information and all applicants and members of the EA MAC which request access to any report on pre-evaluation, initial evaluation and re-evaluation of other applicants and members must have signed a declaration of confidentiality before being given access.

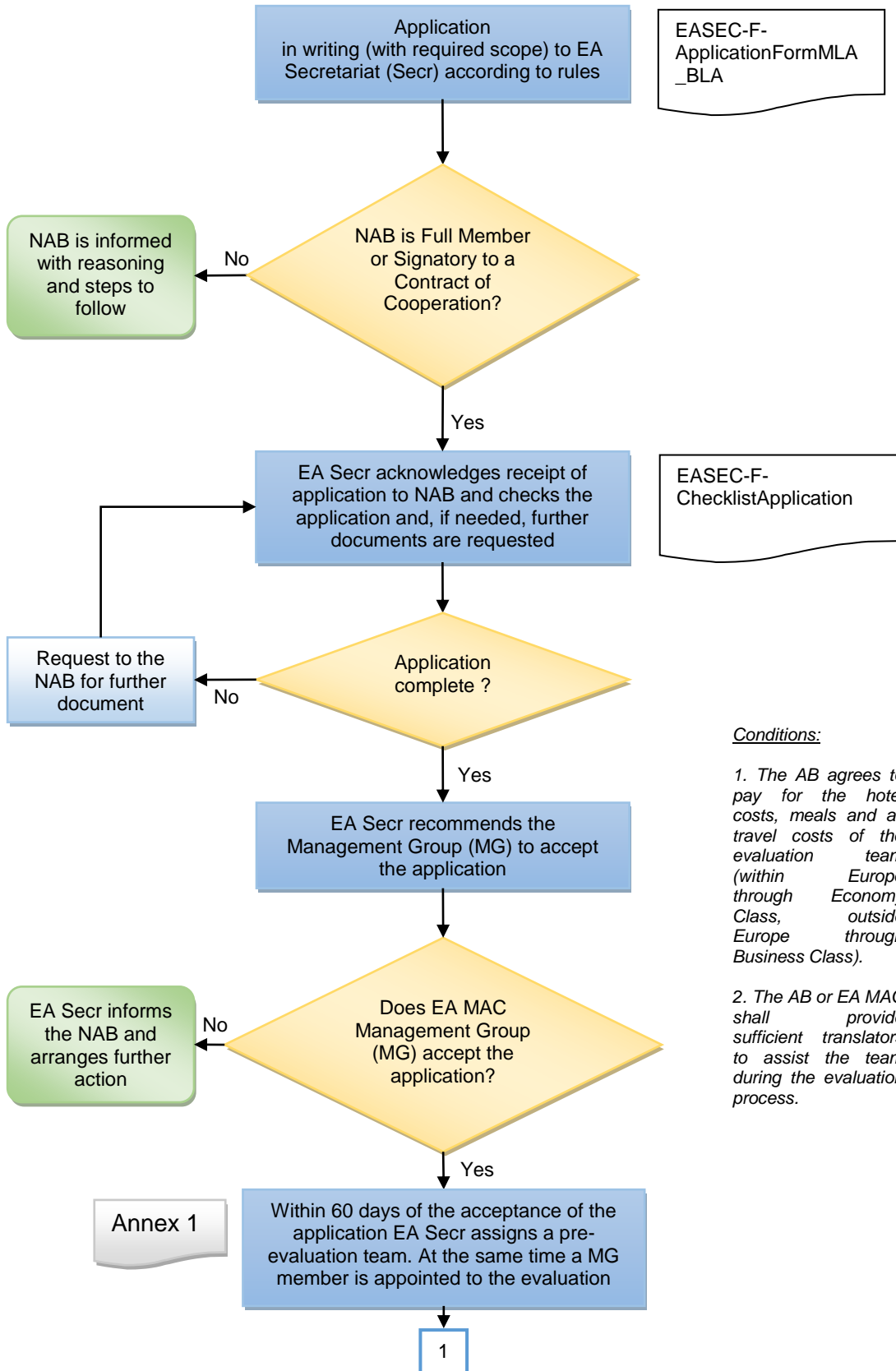
**2.2** Reports on pre- and initial evaluations, re-evaluations and extraordinary evaluation visits may be copied to the representatives of members who have a role to play in decision making. Any such representative must have signed a declaration of confidentiality before being given access.

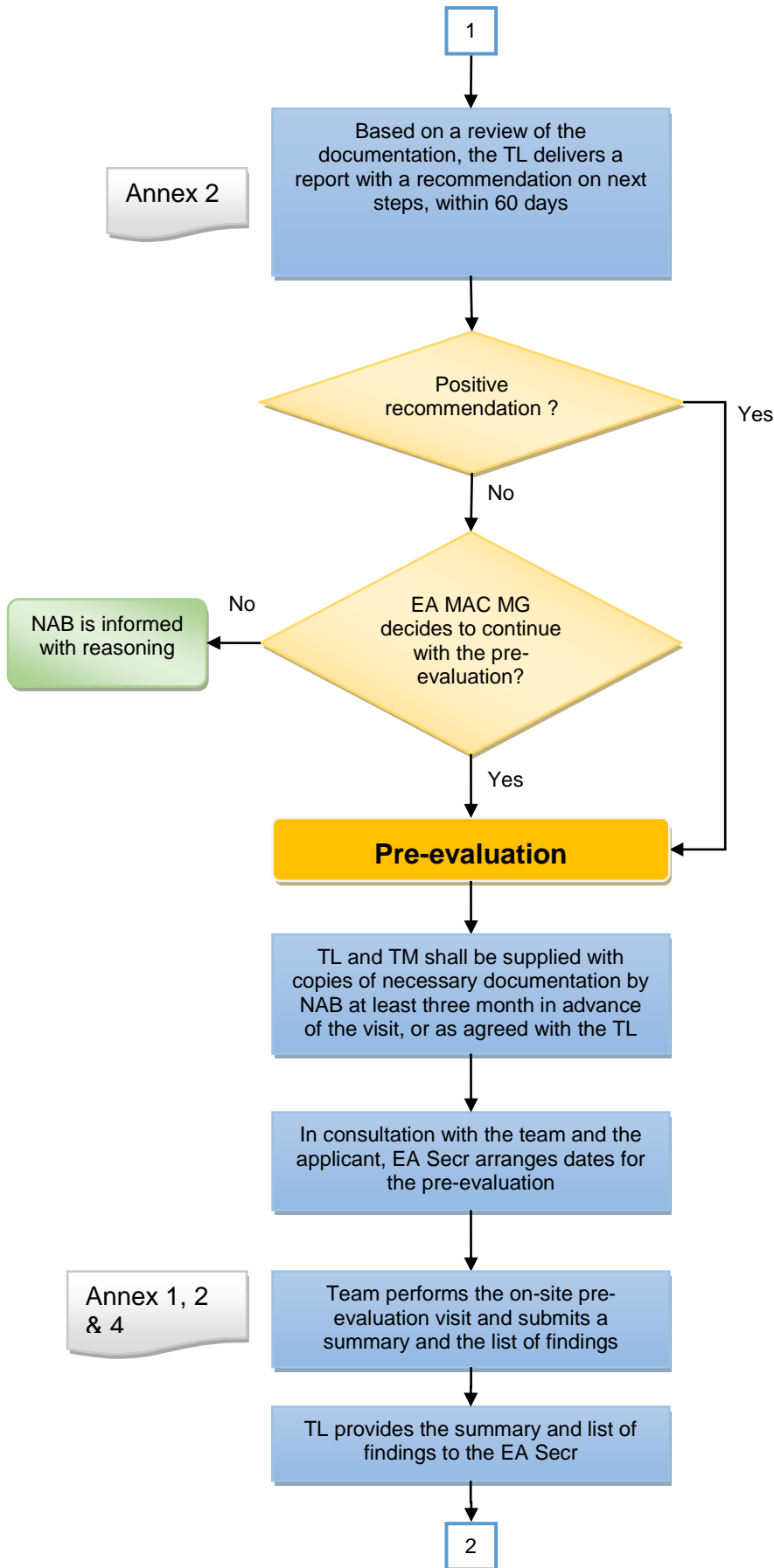
## 3. EVALUATION PROCESS

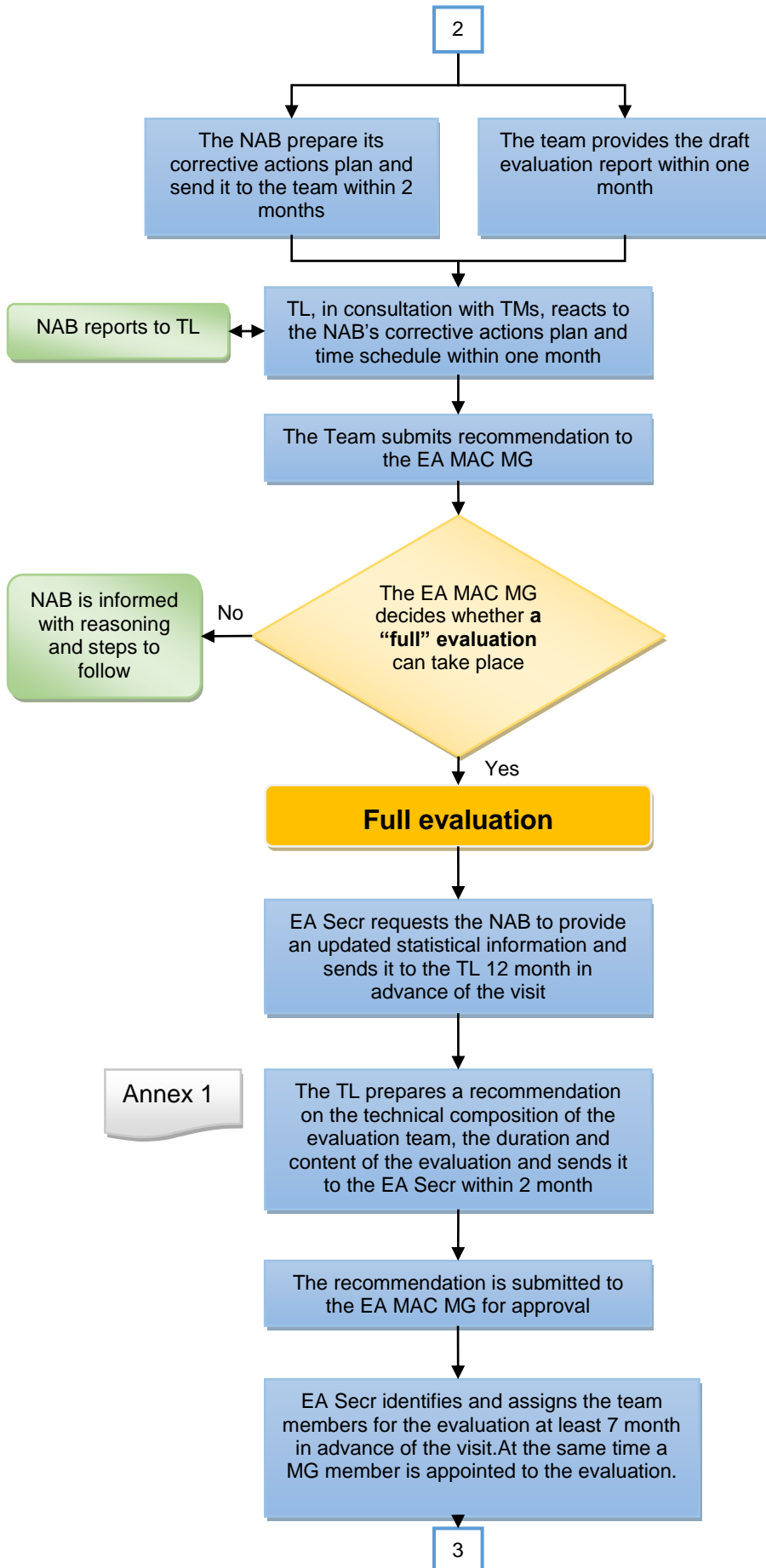
Details on the evaluation process including the application are provided in the following flowchart with annexes.

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

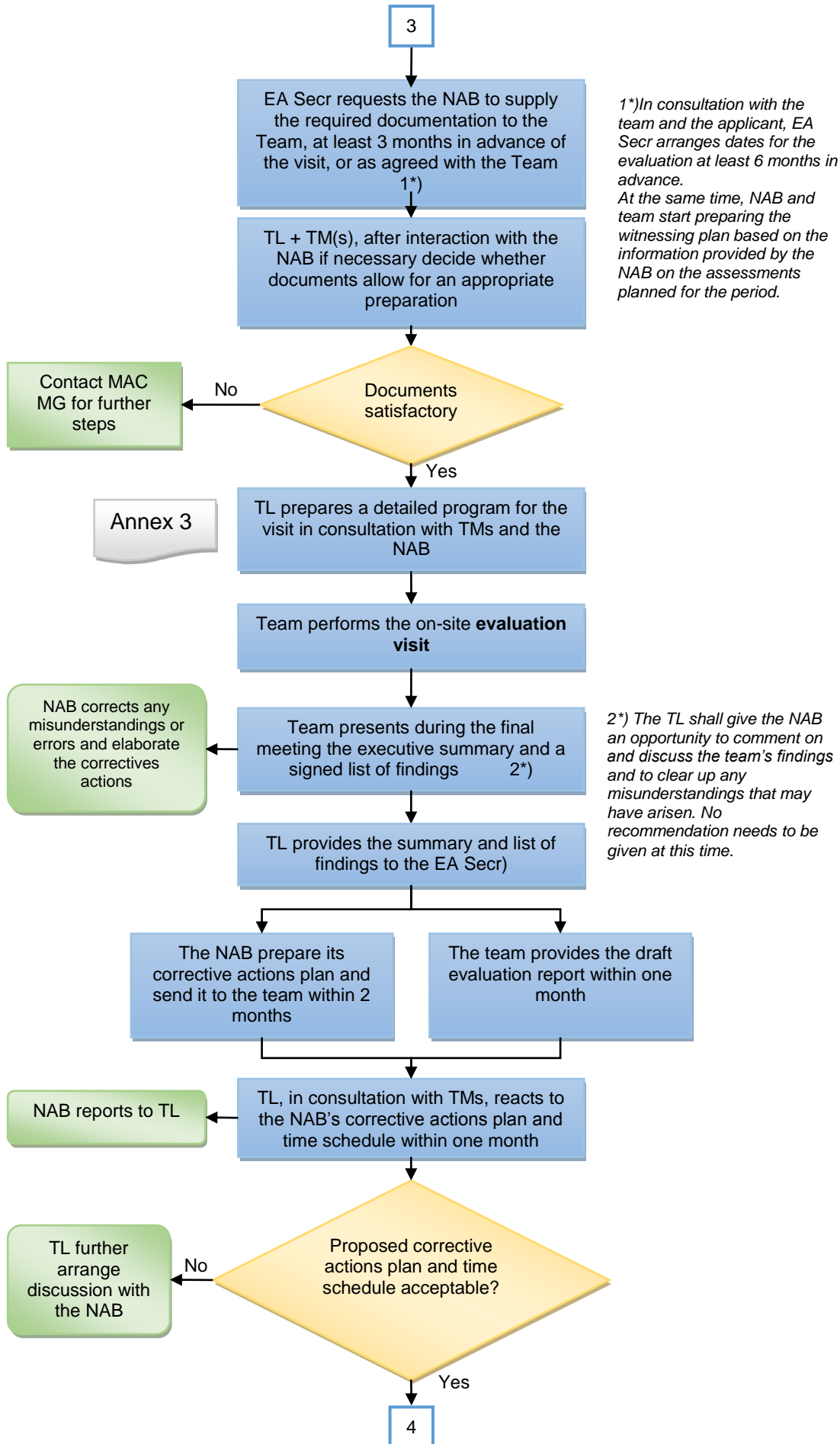
Editorial change (25/01/2017): New paragraph on fees and translation needs added due to an oversight.

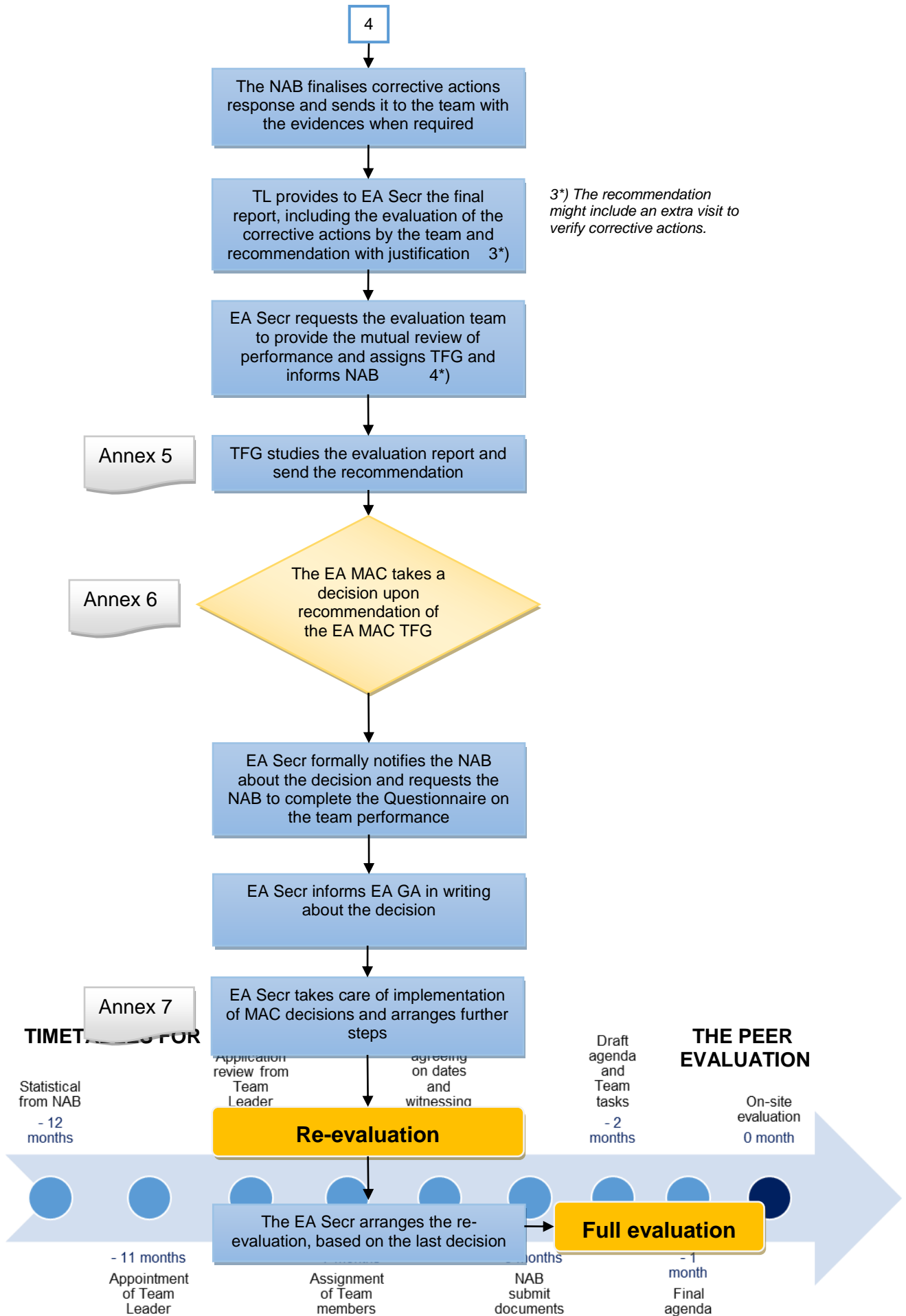












## PROCESS



## **ANNEX 1 APPOINTING AN EVALUATION TEAM AND PREPARING FOR THE EVALUATION**

### **1. THE EVALUATION TEAM: GENERAL PRINCIPLES**

- 1.1** The evaluation team shall be chosen as needed to cover the types of accreditation and the size and complexity of the accreditation system under evaluation.
- 1.2** An evaluation team shall be composed of a TL and at least one TM to ensure the “four eyes principles” for each evaluation.
- 1.3** The team shall consist of representatives from a cross-section of members of EA and/or of other regions if relevant.
- 1.4** A deputy team leader DTL will normally be appointed.
- 1.5** For a full evaluation, the team shall preferably include at least one but not more than two Trainee(s) or Observer(s). For the trainee evaluators on the team, a qualified mentor (an evaluator with experience in more than two evaluations and authorised preferably for the same level2/level 3 scope) will be appointed.

Note 1: Only one evaluator per accreditation body should take part in a team.

Note 2: 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 EA Secretariat to ensure an efficient communication an independent translator will be added to the team.

- 1.6** Evaluators are chosen from the formal lists of evaluators qualified according to the process described in EA-2/02 S1. The lists of evaluators (TL list and TM list) are prepared and kept up-to-date by the EA Secretariat. These lists record their competence and experience. The team will include a maximum of 2 TM's not having participated already in an evaluation with positive feedback (without grades 1 or 2 in the feedback on a scale from 1 to 5, 5 being the highest grading).
- 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 must 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 2 years in all cases prior to the evaluation.

Note 3: A Declaration 'Conflict of Interest' (EASEC-F-DeclaConflictInterestMembers) must be signed by each member of the team prior to the evaluation visit.

- 1.8** In appointing TLs and TMs for a specific evaluation, the EA Secretariat should:
  - avoid appointing TLs and TMs that may give rise to mutual evaluation of their parent organizations in a three year time;
  - not appoint the same TL for two successive full evaluations of the same NAB;
  - have the agreement of the EA MAC MG;
  - have the agreement of the TL/TM and their employers;
  - have the agreement of the NAB under evaluation.

- 1.9** The chosen evaluators, trainees and observers (aiming to be promoted to trainees) will receive a written notice of the appointment including a description of their task from the EA Secretariat.

## **2. PRE-EVALUATION TEAM**

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

## **3. FULL EVALUATION TEAM**

- 3.1** 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 EA 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 base the activities (or groups of activities) at level 4 and 5 of the MLA that should be given specific attention during the evaluation process.

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** Based on review and approval of the TL's proposal by EA MAC MG, the EA secretariat proceeds with the assignment of the team members.

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.

#### **4. 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 PREPARATION AND PLANNING OF THE PRE-EVALUATION**

The purpose of a pre-evaluation is to determine whether the NAB is ready for the initial evaluation.

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

<b>Days</b>	<b>Actions</b>	<b>Evaluators</b>
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	

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;
- cross frontier accreditation activity;
- 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);
- witnessing one or more assessments (entire or partly), if possible.

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

In addition all non-conformities, concerns 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 EA/MAC/MG on when and how to proceed must be included.

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

A pre evaluation may be skipped based on a justified recommendation by the TL to be accepted by the MAC MG, 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

## **ANNEX 3 TIMETABLE FOR AN EVALUATION**

### **1 PRINCIPLES OF PERFORMANCE OF A PEER EVALUATION**

It is a task of the team to collect such information based on objective evidence that confidence can be obtained in the operation of the NAB to such an extent that the signatories to the MLA can promote acceptance of results from the CABs accredited by the NAB.

The TL might adapt the guidance in this annex in agreement with the NAB or with the MAC MG if the circumstances require.

Normally the on-site evaluation visit, including witnessing, is performed during one week. 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. At least one of the witnessing visit should be performed in connection with the evaluation at the NAB office.

The TL may decide that not all TMs are required to participate in all staggered on-site evaluation visits. The TL may not be required to participate to all staggered evaluation activities.

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

Appropriate evaluation techniques include:

- studying the NAB's documents including policies, procedures, accreditation scopes, accreditation activities and cross frontier policies and practices;
- interviews with the NABs management, staff, experts, assessors;
- review of files including vertical audits;
- analysis of minutes from NAB's committees and other structures;
- witnessing.

To achieve the aim of the evaluation the team has to respect the mandates given in the team's assignment and according to the requirements stated above.

Especially the team has to:

- develop a timetable;
- be highly interactive with the NAB and among themselves;
- communicate with the EA Secretariat if major deviations seem necessary
- set out requirements in order to fulfil their duties as early as possible.

### **2 TYPES OF EVALUATION**

- **Pre-evaluation:** see Annex 2;
- **Full evaluation:** The course of events for a full evaluation is given in the flowchart and timetables above;
- **Extension of scope:** the general provisions applicable for a peer evaluation remain valid but the team will normally be limited to a TL (preferably the TL involved in the previous regular PE) and TM(s) with the required competence to cover the scope of the extension.
- **Extraordinary evaluations:** The duration and the tasks of the extraordinary evaluations are basically determined by the MAC;



- **Re-evaluation:** Given the long interval (approximately 4 years) between 2 re-evaluations, the duration of a re-evaluation is comparable to that of a full evaluation.

### **3 PREPARATION OF THE PEER EVALUATION VISIT**

An evaluation visit needs advanced planning, so that efficient use of resources is implemented. – The provisions of the time table presented under clause 3 of this document, at the end of the flow chart with description of the peer evaluation process should be followed.

Note: To enable the EA 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.

The NAB must send all necessary documents (as referred to EASEC-F-ApplicationFormMLA\_BLA) translated at least 3 months in advance of a visit to allow for preparation and for requesting additional information. The Team members must start reviewing the documents directly after receipt. In essence the team leader should be able to prepare a substantial part of the report before the on-site evaluation. This part of the preparation is the same for all types of evaluations. The total time involved in studying of the documentation may take on average 3 to 5 days for the TL and 2 to 4 days for the team members. The TL must send to the NAB the final agenda of the evaluation at least 1 month prior to the evaluation.

### **4. WITNESSING**

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.

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.

Normally there shall be one witness of an initial assessment or reassessment of a CAB for every scope (level 2 and 3), or two on-site surveillances<sup>1</sup>.

For certification, the evaluation team should witness the NAB assessment team performing the assessment of the certification body preferably at the office location.

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. In no case the number should be less than two (for a single scope NAB and/or for initial evaluation in each scope).

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).

The form of the witness report (EAMAC-F-WitnessReport) contains the elements to be observed during the witness. In the evening, 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.

## **5. ON-SITE EVALUATION**

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 (based on the template provided by the EA peer evaluation report template);
- 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
- witnessing;
- discussion of the results of the witnessing with the evaluation team and NAB;
- closing meeting, presentation and discussion of findings.

## **6. PROGRAM OF PEER EVALUATION**

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<sup>1</sup> This presumes that the specific NAB on-site surveillance activities normally includes a representative sample of the Level 3 standard and that it includes technical assessment of conformity assessment activities. Surveillance on-site activities that are limited to a lead assessor visit to check horizontal aspects (e.g. management review, structural changes) or limited to a technical assessor visit to witness the conformity assessment activity being done are not considered enough for peer evaluation witnessing. The peer evaluation team should investigate carefully the kind of surveillance on-site activities performed by the NAB before accepting them for witnessing purposes.

A typical example of the evaluation of an NAB is given in the following table:

<b>Day</b>	<b>Action</b>
Sunday	Preparation: key issues and evaluation plan
Monday	Office ( the whole team) and preparation of the witnessing assessments
Tuesday (full day of witnessing)	Office and witnessing preferable vertical audits together with the NAB staff and technical experts, flexible split between TL and TM
Wednesday (full day of witnessing)	Office and witnessing preferable vertical audits together with the NAB staff and technical experts, flexible split between TL and TM
Thursday	Office and witnessing preferable vertical audits (specially directed for confirmation of previous findings) together with the NAB staff and technical experts, flexible split between TL and TM and preparation of the list of findings. TL shall ensure that all elements necessary for the report have been collected.
Friday	Office for presenting to the NAB the Executive summary and list of findings at closing meeting

Note 1: On agreement with the NAB, the team might spend a full supplementary day without interactions with the NAB in order to get the report ready,

Note 2: A continuous interaction with the management of the NAB is necessary in order to avoid as much as possible misunderstanding or surprises at the end of the evaluation visit.

Note 3: The duration of the evaluation must be adapted according to the circumstances described under paragraph 6 and the following remarks.

Note 4: Friday is a full working day.

For a one scope AB the typical evaluation duration is given in table 2.

Table 2: Typical duration and content of an evaluation of a single scope AB

<b>Day</b>	<b>Action</b>	<b>Evaluator</b>
Day 1	Preparation: key issues and evaluation plan office, opening meeting, records etc.	TL + 1 TM
Day 2	Office and witnessing/observing (split team)	TL + 1 TM
Day 3	Office and witnessing/observing + preparation list of findings + closing meeting	TL + 1 TM
Day 4 morning	Discussing further actions for TMs + departure	TL + 1 TM

Table 3 gives the minimum time to be spent at the AB without detailing the days. The course of actions should be followed as proposed above.

Table 3: Minimum time spent at the AB

	Initial evaluation			Later extension of scope after initial evaluation	
Number of scopes	1	2	full	1	2
Minimum of man-days on site	<p><b>8</b></p> <p>1 TL, 1 TM 4 days</p> <ul style="list-style-type: none"> <li>•office</li> <li>•two witnesses</li> </ul> <p>+</p> <p>observations</p> <ul style="list-style-type: none"> <li>•follow-up and preparation of list of findings</li> </ul> <p>•presentation</p>	<p><b>10-12</b></p> <p>1 TL, 1 TM 5 days (preferred option)</p> <p>or</p> <p>1 TL, 2 TM 4 days</p>	<p><b>25</b></p>	<p><b>6</b></p> <p>1 TL, 1 TM 3 days</p>	<p><b>9</b></p> <p>1TL, 2 TM 3 days</p>

**7. 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.

**8. ACTIVITIES AFTER THE ON-SITE EVALUATION**

- 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.
- 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.
- The TL shall prepare the final report including a recommendation to the EA MAC.

## **ANNEX 4 EVALUATION REPORTING**

### **1 DESCRIPTIONS**

#### **1.1 The evaluation report**

In the evaluations EAMAC-F-EvaluationReport shall be used.

#### **1.2 The final evaluation report**

The final evaluation report is identical with the draft of evaluation report provided to the NAB one month after the visit but the list of findings (element 5 of the evaluation report) extended by the proposed response according to the classification of findings and as agreed between the team and the NAB and will be supported as far as possible by documents giving evidence of their implementation. The list may contain not agreed elements and /or issues to be discussed by the MAC.

The Executive Summary is complemented with a recommendation of the team to the MAC, including justification.

#### **1.3 Classification of findings**

Finding: To be used as a general term

Non-conformity (NC): Finding where the NAB does not meet a requirement of the applicable standard (ISO/IEC 17011), its own management system and the EA-MLA requirements. The evaluated NAB is expected to respond to a NC by taking immediate corrective action and providing the team with evidence of implementation. The response shall include an analysis of root cause and extent and explanation of remedial and corrective actions and objective evidence of implementation.

Concern (CN): Finding where the NAB's practice may develop into a NC. The evaluated NAB is expected to respond to a CN by providing the team with an appropriate action plan and time schedule for implementation. The response shall include an analysis of root cause and extent and a corrective action plan.

Comment (Cm): Finding about documents or NAB's practices with a potential of improvement; but still fulfilling the requirements. The evaluated NAB is encouraged to respond to comments.

## **2 STEPS IN EVALUATION REPORTING ON AN NAB**

### **2.1 Presentation of the draft evaluation report to the NAB**

In an ideal case, the team prepares the evaluation report completely during the time spent at the NAB, maybe -upon agreement with the NAB- using an additional day. If this is not possible, the team will present at least an Executive Summary and the complete list of findings according to the given format at the final meeting. Findings have to be explained to the NAB and be understood by the NAB (understanding does not necessarily mean agreement). If the evaluation report is not completely ready, the TL shall finalize the report in co-operation with the team within one month and forward it to the NAB (the report may not contain additional findings).

## **2.2 Response of the NAB to the draft report, including the list of findings**

The NAB propose corrections to the team for any misunderstandings in the draft report and shall provide a corrective actions plan within one month after reception of the draft report to which the team reacts also within one month by submitting the final report including comments on the proposed corrective actions and the final recommendation.

Ideally, the NAB's response can simply be inserted into the text under each finding according to the report template. Supporting evidence of corrective actions as appropriate may already be attached at that stage of the process but the final set of corrective actions, including evidence shall be available at the latest 4 months after the final meeting. The team's reaction to each response is submitted to the NAB for consideration. If the NAB does not agree with the team's reaction, the TL and the NAB can try to achieve consensus. If this is not possible within a short timeframe the report will have to identify open issues.

Under all circumstances the final report has to be submitted to the EA Secretariat within one month after the NAB has submitted the final set of corrective actions (including evidence of effective implementation, where required), i.e. within 5 months of the final meeting.

## **2.3 Studying of the final report**

The final report will be studied according to Annex 5.

## **ANNEX 5 EA-MAC TASK FORCE GROUP FOR STUDYING EVALUATION REPORTS**

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

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

Criteria to be a TFG member:

- represent a signatory;
- three (out of four members) have at least one year experience in the EA-MAC.

*The MG member must ensure that sufficient discussions, when relevant, have taken place between the NAB, the EA evaluation team and the TFG.*

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

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 EAMAC 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. 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.

The review report of the TFG, according to form EAMAC-F-ReportTFG, has to be provided to the EA Secretariat within 3 weeks after receiving the evaluation report.

## **ANNEX 6 DECISION MAKING**

The MAC is responsible for the decision-taking regarding peer evaluations. Every MLA signatory is entitled to nominate a representative to vote in the MAC meetings, ensuring that the representative is knowledgeable of the MAC procedures and EA MLA criteria and requirements. A maximum of two representatives per Member may be accepted, depending on the logistics and justification.

Restriction to participate in a MAC meeting during voting may happen due to conflict of interest (See Annex 1, clause 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.

An observer designated by the EC will be entitled to attend the MAC meetings and discussions, and the EA MAC Chair may invite other observers as appropriate.

### **1 DECISION MAKING REGARDING EVALUATIONS**

**1.1** The final evaluation report, and the EA-MAC Task Force Group (TFG) (see Annex 5) shall be submitted to the listed members of the EA-MAC.

**1.2** In the case of an initial evaluation, the EA MAC shall decide whether or not the Applicant NAB may enter the Agreement.

Basically three types of decisions to join an MLA exist:

- Approval with establishing of the period of the first re-evaluation. Normally a 2-year period is used for initial evaluations after entering into the MLA. This procedure does not apply to 'extension(s) of scope.
- Defer approval pending submittal of required evidence of corrective actions and/or progress reports for NCs and concerns and/or an additional visit by one or more members of the team.
- Disapproval with a new evaluation being required.

**1.3** In the case of a re-evaluation, the EA MAC shall decide whether the Applicant NAB will remain, with or without conditions, a Signatory to the Agreement, or whether sanctions need to be applied.

For signatories the following decisions can be made:

**1.3.1 Continuation without condition** (re-evaluation in 4 years after the originally planned date for the previous re-evaluation)

**1.3.2 Continuation with conditions** (e.g. extraordinary evaluations, shortened re-evaluation interval, additional information or progress reports)

The MAC must decide on:

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

**1.3.3 Suspension of signatory status to the MLA or particular field within the MLA**

Accreditations granted during the suspension period are not covered by the MLA and are not internationally recognised; all CABs requesting accreditation shall be informed accordingly by the NAB under suspension.

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



The EA-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 NCs and Concerns 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 EA MAC.

#### **1.3.4 Immediate withdrawal of signatory status to the MLA or particular field within the MLA.**

A withdrawn signatory has to inform (with a copy to the MAC) all applicant and accredited CABs that their reports/certificates are no longer accepted under the MLA and shall not make reference to the MLA.

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 on the Member State, has assigned the National Accreditation Body.

When withdrawn signatories apply to become signatory again, they will have to follow the procedure for new applicants.

## **2 REASONS TO PERFORM 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 be based among others on 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.
- An 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.

- Complaints have been made to EA made by CABs, NAs (National Authorities), regulators or other concerned parties. In this case and depending on the results of the examination of the complaint, EA Ex must in addition decide whoever has to pay the costs for the extraordinary visit and what should be included in those costs.

### **3 PRACTISE IN CASE OF SERIOUS ISSUES DURING EVALUATIONS**

When an evaluation team detects a situation at an 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 EA-MAC 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 must 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.

### **4 DELAY IN THE EVALUATION PROCESS**

#### **4.1 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 may, at any stage, inform EA Secretariat and propose to suspend the evaluation process.

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

#### **4.2 Caused by Adverse Travel Advisory**

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

EA 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, EA-MAC shall decide on a case-by-case basis, the impact on the maintenance of the MLA signatory status.

## **ANNEX 7 NOTIFICATION OF CHANGE, MONITORING AND RE-EVALUATION**

### **1. NOTIFICATION OF CHANGE**

As required in EA MLA (EA-1/06) each signatory shall report on any significant changes in its status and/or its operating practices.

Significant changes are those that could affect issues such as competence, impartiality and operational ability and include, but are not limited to, those related to legal status, relationship with government, key personnel, contact persons, accreditation criteria and procedures, and offices addresses.

A notification on the significant changes shall be sent by the NABs without delay to the EA Secretariat within maximum 1 month since the changes occur.

According to EA-1/06 clause 5 (l) the notification shall be accompanied by an impact analysis. If necessary, the Secretariat will request the impact analysis upon receipt of the notification of change.

The impact analysis prepared by the NAB shall be a self-evaluation report addressing the relevant clauses of ISO/IEC 17011 and the EU Regulation 765/2008.

In case of changes of persons in key management functions, NAB shall send to the EA Secretariat a brief CV accompanied by a justification for being the right candidate and his/her involvement in the daily practice 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 MG shall review the impact analyses provided by the NAB in order to judge whether compliance to the EU Regulation 765/2008 and the standard ISO/IEC 17011 is still met.

Depending on the changes and on the impact analysis provided by the NAB, EA MAC MG will decide whether further action is needed.

If an extraordinary evaluation should be carried out the final decision shall be made by the MAC.

The EA Secretariat shall:

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

In case no further action is needed, EA MAC Chair informs the MAC members on the decision by the MAC MG. This is normally done during a MAC meeting.

### **2. MONITORING AND RE-EVALUATION**

EA MAC is periodically monitoring and re-evaluating the signatories to the MLA(s).

The EA Secretariat arranges the re-evaluation of the NABs based on the decision taken by EA MAC.

- All signatories shall be formally re-evaluated at maximum intervals of four years since the day of the last re-evaluation visit (–3 to +6 months).
- Either partial or total re-evaluation may be conducted at an earlier date as directed by the EA-MAC Management Group and decided by EA MAC, should there be due cause such as notification of significant changes in NAB’s status, finances, operational practices or an extension in the scope of accreditation.
- Monitoring of changes notified by a signatory shall be appropriately examined.

Note: see also Annex 6 paragraph 2 on “Reasons to perform extraordinary evaluations”.