Present version of the EA-2/02 is an update of the November 2008 version. Changes were necessary to bring the EA-2/02 further in line with the ISO/IEC 17011, the IAF/ILAC-A2 document, the appropriate requirements of Regulation (EC) No 765/2008 and day-to-day practice.

Note: The annexes may be revised independent of the core document. The valid version is the version available on the Internet. Forms are also available as word-file.
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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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Category: Peer Evaluation Process documents

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1 INTRODUCTION

1.1 Scope
This document describes the procedures that EA has adopted for the evaluation and re-evaluation of National Accreditation Bodies (NABs), the operation and effectiveness of their accreditation systems when these NABs are or wish to be signatories to EA Multilateral Agreement (EA MLA).
This procedure is fully based on the common IAF/ILAC document for the evaluation of single ABs (IAF/ILAC A1:2010). The document is to be used by (potential) signatories, by evaluators, by Task Force Group (TFG) members and MAC members.
The relevant documents and forms for evaluation are available at a special folder on the EA Intranet.

1.2 Definitions
The following definitions are applicable only for this document.

- Accreditation program: set of criteria specified in a standard or normative document included in IAF and/or ILAC Arrangements used for the accreditation of conformity assessment bodies.
- 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.
- Observing: activity where an evaluation team is watching the Accreditation Body (AB) witnessing the conformity assessment body (CAB) performing its conformity assessments (for example performing a test or inspection or auditing a management system).
- Scope: Accreditation Activity, evaluated through the peer-evaluation process in which the AB has demonstrated competence to perform accreditation
- Signatory: An AB 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: activity where an evaluation team is watching the AB’s staff preparing for an assessment, watching of the AB assessing the CABs premises, management system and records and dealing with assessment reports. Note: Witnessing is an essential part of the evaluation and observing may be an integral part of the witnessing.

1.3 References
ISO/IEC 17011 ‘Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies’;
Regulation (EC) No 765/2008 ‘setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing’;
Regulation (EEC) No 339/93’;
EA-2/11 ‘EA Policy for Conformity Assessment Schemes’;
EA-MAC/01-S12 ‘Questionnaire ABs evaluation of the team performance’;
EA-MAC/01-S15 (Part I and Part II), ‘Review of Performance’ of Team Leader and Team Members.
2. **EA MLA**

There are five levels of mutual recognition in the EA MLA structure. Two of which (levels two and three) are used to define the scope of the MLA:

- The second level is the conformity assessment activity (e.g. inspection and testing).
- The third level is the conformity assessment standard (e.g. ISO/IEC 17020 and ISO/IEC 17025).
- The fourth level is the sector specific standards and schemes (like ISO/TS 22003 and ISO/IEC 27006, respectively WADA and BRC) and normative documents based on European directives or regulations in combination with one of the harmonised standards in level 3. National accreditation schemes are also part of level 4.
- The fifth level is standards or normative documents used by the accredited CAB to deliver an accredited conformity assessment, like standards or other documents defining test methods at the laboratories or management systems standards (ISO 9001 or ISO 14001).

3. **OBJECTIVES**

The objectives of an evaluation shall be to establish confidence that the AB conducts its assessments and accreditations in accordance with and meet all the requirements of the criteria of ISO/IEC 17011 and the appropriate requirements of Regulation (EC) No 765/2008.

4. **CRITERIA**

4.1 **Standards**

This document refers to the ISO/IEC 17011, the appropriate requirements of the Regulation (EC) No 765/2008 and the standards used by the NAB to assess the CAB’s technical competence.

EA/ILAC/IAF have developed guidance on a number of clauses from these standards and published this guidance in application documents. EA categorises these documents to make clear which of them are mandatory for the EA MLA. Applicant ABs and signatories shall bring these guidance documents to the attention of the accredited organisations for their use as accreditation criteria supporting the requirements in the accreditation standards.

4.2 **Supplementary requirements for requesting/maintaining signatory status**

The ABs shall fulfil the following supplementary requirements:

- shall be fully operational;
- shall have demonstrated experience in the assessment of its accredited CABs and have carried out and granted at least one accreditation in each of the scopes of the Arrangement for which it applies;
NOTE: This experience may be obtained by having accredited more than one CAB in a particular accreditation program and/or having accredited one CAB in a particular accreditation program and having carried out on site surveillance and reassessment of the CAB.

- Have demonstrated experience in operating an Accreditation Body, and have access to technical expertise in all aspects of its accreditation activities. Where the number of accredited testing or calibration laboratories 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 EA-MAC.

- shall implement or fulfil other requirements of EA as described in the documents listed in EA-1/01 in accordance with the document categories described in EA-1/14.

4.3 Proficiency Testing and other Laboratory Comparisons

Proficiency Testing (PTs) and other Laboratory Comparisons are important for accredited laboratories to demonstrate their competence. ABs shall have an overview of the performance of their accredited bodies in PTs and other Laboratory Comparisons.

An Accreditation Body shall demonstrate that it has an effective policy in place in accordance with ISO/IEC 17011 and ILAC/EA mandatory documents to ensure appropriate participation by its accredited bodies in PT and other Laboratory Comparison activities. The AB shall ensure that accredited bodies implement appropriate corrective action where necessary.

Every applicant Accreditation Body or Signatory to the MLA in the fields of calibration and testing shall ensure its laboratories participate in regional or national PTs and other Laboratory Comparisons where available and appropriate. ABs shall ensure that the results of the regional activities are reviewed and appropriate corrective action taken as necessary.

Note: The AB should also be aware of the cooperation of specific PT Providers with the EA which provide the opportunity to laboratories to participate in particular rounds of PT that are utilised by EA in order to monitor the effectiveness of the MLA.

4.4 Subcontracting

An AB can only subcontract assessment activities to ABs having signed the MLA/MRA/BLA for that particular activity (IAF/ILAC or an MLA/BLA from a recognised region).

5. 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.
Application to become Signatory to MLA or Bilateral Agreement

Application in writing (with required scope) to EA Secretariat (Secr) according to rules described in Annex 1

AB is informed with reasoning and steps to follow

EA Secr checks if AB is Full Member or Signatory to a Contract of Cooperation

Yes

EA Secr acknowledges receipt of application to AB and informs about the procedure and about all documentation to be submitted to the EA MAC Secr

EA Secr forwards application, including the documentation already received, to EA MAC Secr

EA MAC Secr checks the application and, if needed, further documents are requested

Application complete?

No

Yes

EA MAC Secr recommends the Management Group (MG) to accept the application

EA MAC Secr informs the AB and arranges further action

See Annex 1

See Annex 2

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Conditions:

1. Requests shall be acknowledged and handled in an expeditious, non-discriminating manner.

2. The AB (accepted as EA Full Member or as Signatory to a Contract of Cooperation) shall, having studied the documented evaluation procedures / criteria, indicate its familiarity with the MLA requirements and procedures.

3. The AB shall demonstrate the implementation of the EA requirements.

4. The AB agrees to pay for the hotel costs, meals and all travel costs of the evaluation team (within Europe through Economy Class, outside Europe through Business Class).

5. The AB or EA MAC shall provide sufficient translators to assist the team during the evaluation process.
Within 60 days of the application EA MAC MG assigns Team Leader

EA MAC Secr informs all parties involved *) about TL’s assignment

Yes

AB objects?

No

AB supplies doc.

Within 60 days of the application EA MAC MG assigns Team Leader

EA MAC Secr informs all parties involved *) about TL’s assignment

AB objects?

No

AB supplies doc.

Pre-evaluation

Based on a review of the documentation and possible evaluation reports from previous evaluations, the TL makes a proposal, within 90 days of receipt of all documents, to the EA MAC MG

AB is informed with reasoning

No

Continuation useful?

Yes

EA MAC MG confirms to continue *) with the pre-evaluation

Yes

Pre-evaluation

EA MAC MG assigns in agreement with TL one Team Member

EA MAC Secr informs all parties involved *) about Team’s assignment

AB objects?

No

AB supplies doc.

TL requests the AB to supply additional up to date documentation to the Team

AB may object to the assignment of the TL.

*) the AB under evaluation
+ the TL and his employer
+ EA MAC Members

AB may object to the assignment of the TL.

*) the AB under evaluation
+ the TL and his employer
+ EA MAC Members

Only after any identified NC(s) during the document review is/are corrected

AB objects?

Yes

No

AB supplies doc.

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In consultation with the TM and the Applicant, the TL decides on preferable period for the pre-evaluation.

Team performs the **on-site pre-evaluation visit** and draft list of findings.

After the pre-evaluation visit, the TL submits, in consultation with the TM, a short written report.

The TL submits recommendation to the EA MAC MG.

The EA MAC MG decides whether a "full" evaluation can take place.

**Full evaluation**

EA MAC MG assigns, in consultation with TL, entire Team for the evaluation.

EA MAC Secr informs all parties involved *) about evaluation and Team's assignment.

**AB objects?**

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

In EA evaluations a Deputy TL will be assigned.

In ILAC/IAF evaluations an EA Deputy TL can be assigned to ensure appropriate reporting according to EA rules.

AB may object to the assignment of any member of the team.

*) the AB under evaluation
+ the TL/TMs and their employers
+ EA MAC members

Reserving dates for the evaluation should be agreed between the team and the AB preferentially at least 6 months in advance.

AB supplies documentation as in Annex 1.

TL requests the AB to supply the required documentation to the Team, at least 3 months in advance of the visit, or as agreed with the TL.

TL + TM(s) decide whether documents allow for an appropriate preparation.

AB is informed with reasoning and steps to follow.

The AB responds to report and takes corrective actions.

AB is informed with reasoning and steps to follow.

The AB will respond to the findings and is given the opportunity to comment on any factual errors in the report.

If a pre-evaluation has taken place, the full evaluation visit will not be carried out before the AB has taken all the actions agreed at the pre-evaluation visit.

The EA MAC MG may consult other EA MAC members to review the report.

A provisional date for the pre-evaluation will be agreed at least one month in advance of the visit.
Documents satisfying?

Yes

TL prepares a detailed program for the visit in consultation with TMs and the AB

Team performs the on-site evaluation visit

Team presents during the final meeting at least a signed list of findings

TL provides the draft report, completed in consultation with the TMs, to the AB within the shortest possible time

AB corrects any misunderstandings or errors and elaborates the corrective actions

AB reports to TL

The TL shall give the AB an opportunity to comment on and discuss the team’s findings and to clear up any misunderstandings that may have arisen. No recommendation needs to be given at this time.

TL provides to EA MAC Secr the final report, the corrective actions followed by the Team’s comments and the motivated recommendation

MAC Chair assigns TFG and informs AB, team and MAC members

TL arranges further discussion with AB *)

Proposed corrective actions and time schedule acceptable?

Yes

No

Contact MAC MG for further steps

See Annex 5

See Annex 6

Timing for reporting and corrective actions:

One month between draft report and corrective actions proposed. One month for team to react. One month for finalising report and recommendation

In case of controversial issues, both the AB and the team may already at this stage consult other experienced evaluators and/or the appropriate technical committee in EA.

*) The possibility to correct NCs and Concerns can only take place twice in order to ensure that the evaluation does not continue too long.

**) Did the team receive and verify documentation on the actual implementation?

The final report must contain a justification for the recommendation. The recommendation might include an extra visit to verify corrective actions.

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Follow procedure ‘EA MAC TFG for studying evaluation reports’

See Annex 7

The EA MAC takes a decision upon recommendation of the EA MAC TFG (as assigned by the EA MAC MG)
- whether additional steps are required
- whether or not to sign the MLA or to maintain the MLA
- whether or not to sign the Bilateral or to maintain the Bilateral
- when the next evaluation activities should take place

See Annex 8

Decisions may be accompanied by conditions.

EA MAC Secr informs AB about the decision and the timeframe of the next visit and requests the AB to complete the Questionnaire on their performance

See EA-MAC/01-S12

About 12-18 months before the next decision is due, the re-evaluation will be planned.

EA MAC Secr informs EA GA in writing about the decision

EA MAC Secr takes care of implementation of MAC decisions and arranges further steps

See Annex 9

The EA MAC Secr arranges the re-evaluation, based on the last decision

Re-evaluation

Full evaluation
ANNEX 1 Application form
(for Full Members of EA to sign the MLA or for associate Members to sign the Bilateral Agreement)

1. Please tick the scopes for which signatory status is being applied:
   - Accreditation of calibration laboratories (Cal)
   - Accreditation of testing laboratories (Test)
   - Accreditation of Product Certification (Prod)
   - Accreditation of Management Systems Certification (MS)
   - Accreditation of Persons Certification (Pers)
   - Accreditation of inspection bodies (Insp)

2. Name of AB (Applicant):

3. Addresses

   3a. Head Office street address:  
   3b. Head Office postal address:

   3c. Website address (if any):

4. Do you have offices other than Head Office? (if yes attach a list with details)

5. If the applicant conducts accreditation in more than one country, provide a list of activities and countries.

6. Name of Applicant contact person:

7. Position of contact person:

8. Telephone and facsimile (including international access):

9. Email address:

10. Statement on the legal status of Applicant:

11. History of the Applicant (Foundation date, operational period, pertinent historical background).

12. Applicant’s relationship to government (including involvement in the mandatory sector):

13. For associate Members: indicate signatory status to other regional MLAs:
14. Please provide for each scope you apply for, the period of experience in accreditation and number of accreditations granted.

15. Please list any other operational field(s) of accreditation.

16. Please include three hard copies (or provide electronic copy) of each of the following documents in the English language:
   - the applicant's management system documentation stating the policies and procedures as well as the responsibility and authority for implementation/maintenance of the management system. Main procedures supporting the quality manual should also be included in order to allow the evaluation team to perform a proper document review and to prepare for the on-site visit;
   - all accreditation criteria and associated generally applicable criteria that the applicant publishes, including the AB’s cross frontier accreditation policy;
   - all other published criteria, including formal rules or regulations that apply to the applicant's operation and the responsibilities and obligations of its accredited bodies;
   - the completed checklist against the ISO criteria (see EA-MAC/01-S17);
   - statistical information (EA-MAC/01-S16);
   - report of the self-evaluation according to the requirements of the ISO/IEC 17011 and the other requirements of the EA/IAF/ILAC-MLA as applicable (IAF/ILAC A3);
   - results of recent management review (including references to the applicable ISO/IEC and EA/ILAC/IAF documents);
   - report on the use of accreditation for the purpose of notification, identifying the arrangements (legal, contractual or informal) in place with the relevant National Authorities;
   - (for cal and test) a report on participation of accredited laboratories in internationally organised proficiency testing activities including an overview of the performance level;
   - details of implementation of EA Cross Frontier Policy, identifying all accreditations granted to foreign CABs and to local CABs with key activities in foreign countries, with the applicable arrangements with the foreign national accreditation bodies;
   - participation in EA (ILAC/IAF) committees/working groups/task forces;
   - policy for implementation of the ILAC/IAF MRA/MLA mark;
   - policy for implementation of the EA-2/11.

17. Other information related to the integrity of accreditation activity (e.g. other activities of the applicant, mutual recognition agreements, relationships with other bodies, subcontracting).

18. Information about technical assistance programmes (international or by individual countries) through which support in setting up the Accreditation Body was received including the names of the ABs providing the actual support.

Please complete the Declaration on the following page and send your completed, signed and dated, application along with all requested documents to the EA Secretariat.
Note 1: EA MAC confirms the need for significant documents to be provided for the evaluation and their delivery in time. If the team is not satisfied with the contents of the documents or the reaction of the AB, a concern is raised. If the AB’s attitude is not improved at the next evaluation, a Non-conformity (NC) will be raised.

Note 2: Electronic versions of all documents are available from the EA website: http://www.european-accreditation.org

The relevant documents and forms for evaluation are available from a special folder on the EA Intranet: http://www.european-accreditation.org/members/intradoc.mpi?dirid=151

Declaration

As an AB which is Full Member or associated Member of EA or as an AB holding a Contract of Cooperation with EA, the Applicant, duly represented by the undersigned:

- Accepts the procedures defined or referred to in EA-2/02;
- Accepts the requirements and agrees with the terms of the MLA
- Confirms that the operations of the Applicant comply with the relevant documents as mentioned in Chapter 4 ‘Criteria’ of this document;
- Submits the completed Application;
- Applies to attend the EA MLA Council meetings (EA MAC) (for EA Full Members only). An AB holding a Contract of Cooperation and/or a Bilateral Agreement is allowed to attend the meetings as observer only.

Contact Persons Name

Date Signature
ANNEX 2 Administrative check of the application to join the MLA

1. Name of the AB applicant:

2. Date of application:

3. Date of this report:

4. Name of person preparing this report:

5. General observations:
   - The completeness of information provided on the application form:

6. Have the following documents in English been supplied:
   - Quality Manual
   - List of documents supporting the Quality Manual
   - Statement on the regional group to which the applicant belongs, if any
   - Full details of the staffing
   - Specified criteria, which includes formal rules or regulations that apply to the applicant's operation and the responsibilities and obligations of its accredited bodies
   - Checklist (EA-MAC/01-S17)
   - Statistical information (EA-MAC/01-S16)
   - Results of the self-assessment on the basis of the requirements of the ISO/IEC 17011 and the other requirements of the EA/IAF/ILAC-MLA (IAF/ILAC A3) and management review
   - Report on the use of accreditation for the purpose of notification
   - (for cal and test) report on PTs including an overview of the performance level
   - Implementation of EA Cross Frontier Policy
   - Participation in EA committees etc.
   - Policy for implementation of IAF/ILAC Arrangement mark
   - Policy for implementation of the EA 2/11
   - Has the declaration been duly signed?

7. Others, if any:

Recommendation (to be filled out by the EA-MAC Secretariat):

- Does the applicant comply with all application criteria: Yes / No
- Acceptance of application: Yes / No
- If "No", the reason for rejecting the application.

Signature:
ANNEX 3 EA Evaluators  
Appointment, composition and qualification requirements

1. Nomination of evaluators and evaluation of their performance

EA MAC members must nominate evaluators in writing, including a description of the experience and competence to EA MAC Secretariat. A standard CV form must be used for this purpose and has to be signed by the Head of the AB assuring the correctness of the data and suitability of the candidate.

Based on the approval of the CV, the EA MAC MG invites the applicant to take part in a training for ‘newcomers’. During the training the applicant’s performance is evaluated by the trainers based on the level of participation in group work and discussions, the ability to speak English, the demonstrated understanding of the evaluation criteria and procedures and the work in teams.

The applicant and the applicant’s AB are informed about the outcome of the evaluation which may be:

- the trainers consider the applicant to be ready to participate in evaluations and recommend to invite the applicant to act as a Trainee in an evaluation, or
- the trainers are not convinced that the applicant is ready and recommend that the applicant first takes part as an Observer in an evaluation, or
- the trainers do not consider the applicant to be ready to participate in evaluations. They mention the reason(s) why the applicant has not yet been accepted and what he/she should improve to get a positive recommendation.

The performance of TLs and TMs is evaluated once a year by the EA MAC MG, based on feedback provided by the AB under evaluation (Questionnaire EA-MAC/01-S12) and on the mutual “Review of Performance” of TL and TM (EA-MAC/01-S15 Part I and Part II). If necessary, corrective actions are taken. The EA MAC MG reports annually to EA MAC on general conclusions.

Whenever necessary, evaluators shall be requested to update their CVs. This might occur in particular relating to specific fields, with respect to a general improvement of the evaluation process and/or possible implementation of new standards and sector specific schemes.

2. Appointing an evaluation team

2.1 For an effective evaluation visit, evaluators will be chosen to provide a balanced set of skills covering the full scope of evaluation. Each evaluation team shall have a team member with the competence necessary to evaluate the general requirements coming from EC Directives and sector schemes, where applicable.

2.2 A TL shall normally be accompanied by at least one other TM for a pre-evaluation and evaluation visits to ensure “the four eyes principle” for each evaluation.

2.3 The team chosen shall consist of representatives from a cross-section of members of EA and/or of other regions if relevant. The team shall preferably include one Trainee or Observer as accepted by the EA-MAC-MG.
NOTE 1 Only one evaluator per Accreditation Body should take part in a team.

NOTE 2 Evaluators should, in addition to working knowledge of the English language, preferably have knowledge of the local language of the country where the evaluation takes place. If considered useful by the EA MAC Secretariat an independent translator will be added to the team.

2.4 Evaluators are chosen from formal lists of evaluators (TL list and TM list) prepared and kept up-to-date by the EA-MAC Secretariat. These lists record their competence and experience. At least 50% of the TMs in an evaluation team shall have participated already in an evaluation with positive feedback. For laboratory accreditation, one member of the team should be familiar with proficiency testing.

2.5 No member of the team should be associated with any AB that has provided consultancy service to the Accreditation Body being evaluated for at least 5 years preceding the evaluation.

NOTE 3 A Declaration ‘Conflict of Interest’ (EA-MAC/01-S14) must be signed by each member of the team prior to the evaluation visit.

2.6 In appointing TLs and TMs for a specific evaluation, the EA-MAC Management Group should:
- avoid the appointment of TLs and TMs that may give rise to mutual evaluation of their parent organizations in a three years time; and
- not appoint the same TL for two successive full evaluations of the same AB.

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 MAC Secretariat.

3 Requirements and expectations about the evaluation team

General attributes

Evaluators should:
- be open minded and mature,
- possess sound judgement, analytical skills and tenacity,
- have the ability to perceive situations in a realistic way to understand complex operations from a broad perspective,
- have good interpersonal skills
- be able to communicate clearly in English

These attributes are indispensable to:
- obtain and assess objective evidence fairly,
- remain true to the purpose of the evaluation without fear or favour,
- treat concerned personnel in a way that will best achieve the evaluation objective,
- react with sensitivity to the local conventions of the area
- commit full attention and support to the evaluation process,
- perform the evaluation without deviating due to distractions,
- come to generally acceptable conclusions based on evaluation observations.
3.1 TL

3.1.1 Duties

a. has ultimate responsibilities for all phases of evaluation and is delegated authority by EA MAC to make final decisions regarding the conduct of evaluation,
b. prepares and manages the evaluation and takes responsibility for the evaluation report,
c. leads evaluation team efficiently and effectively, including the distribution of tasks among Deputy TL and TMs,
d. mentors the trainee assigned to the team, allocating him/her such tasks as he/she is able to perform and supervises its work,
e. decides from the submitted documentation any features requiring special study during the evaluation,
f. reports clearly and succinctly the findings of all TMs and reaches consensus on the grading,
g. evaluates whether corrective actions decided by the AB are likely to be effective and evaluates the corrective actions carried out,
h. evaluates whether the CABs comply with the requirements of the relevant standard(s) and other requirements if possible by time.

3.1.2 Preconditions

a. has at least 3 years experience in the operation of an AB and has appropriate technical background and experience in assessment,
b. has participated successfully in at least two evaluations of ABs as a TM and as a deputy TL in at least one evaluation,
c. has sound knowledge of the application of the appropriate EN/ISO/IEC standard for ABs and relevant MLA requirements,
d. has enough working experience in an AB to be able to understand requirements of any of the relevant standards that are applicable to the accreditation of CABs,
e. is a permanent staff member of an AB,
f. has the experience in chairing meetings and in reaching consensus on delicate points.
3.2 Deputy TL

3.2.1 Duties

a. takes over tasks assigned by the TL in preparation and managing the evaluation,
b. replaces TL when TL is not available (e.g. in case of illness or other circumstances preventing the TL to do his duty).

3.2.2 Preconditions

c. is a Team Leader or is an experienced Team Member capable to act as a Team Leader
d. is a permanent staff member of an AB
e. the role of Deputy TL may be used as a training for future Team Leader
f. the Deputy TL shall have different competences than the TL to cover as much as possible of the accreditation activities of the AB under evaluation

See further preconditions under 3.3.2.

3.3 TM

3.3.1 Duties

a. evaluates whether AB complies with the requirements of the appropriate EN/ISO/IEC standard and its CABs comply with the requirements of the appropriate standard(s) and other requirements,
b. reports clearly and succinctly the findings,
c. determines appropriately the grading of findings.

3.3.2 Preconditions

d. has at least 3 year experience in the operation of an AB and has appropriate technical background and experience in assessment,
e. has successfully completed relevant training course(s) and should have experience as trainee in peer evaluation of ABs,
f. has experience in at least one standard that is applicable to the accreditation of a CAB,
g. has experience in at least one technical field in which a CAB operates,
h. has preferably participated in an EA/ILAC/IAF working group/committee,
i. is preferably a staff member of an AB.

3.4 Trainee

3.4.1 Duties

A Trainee Team Member acts as a Team Member in his/her field of expertise (see 3.3.1). However, during the first activity, a person in the team, with competence in the same field (Team Leader, Deputy Team Leader or experienced Team Member) is assigned to mentor the Trainee and assist where needed.

3.4.2 Preconditions

- after having participated in a training for 'newcomers' be recommended as a Trainee,
- the Trainee’s AB pays all expenses (travel + accommodation), including for witnessing purposes,
3.5 Observer

3.5.1 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. The Team Leader is informed in advance of the reason(s) why the Observer has not yet been accepted as a Trainee, if this is applicable. The Team Leader can assign specific tasks to the Observer to be able to reflect, together with the Team Member ‘linked’ to the Observer, on possible constraints. A positive report, to the MAC Secretariat, from the Team Leader on the Observer’s performance is required to promote him/her to the Trainee level.

3.5.2 Preconditions

- after having participated in a training for ‘newcomers’ be recommended as an Observer,
- the Observer’s AB pays all expenses (travel + accommodation), including for witnessing purposes.

4 Training

4.1 The AB nominating an evaluator is responsible for ensuring that the nominee is qualified.

4.2 EA will provide trainings covering the following topics:
- harmonisation of interpretation of requirements applicable to ABs,
- evaluation procedures (EA 2/02),
- EA evaluation documents (checklists, self assessment tools),
- harmonisation in the evaluation of critical findings,
- evaluating ABs competences with regard to EC directives and the appropriate requirements of EC Regulation 765/2008.

4.3 The EA MAC shall organise periodic training courses for TLs and TMs in order to improve and harmonise the outcome of evaluations.

4.4 The EA MAC shall approve TLs and TMs for a three-year term.
ANNEX 4 Document Review and Pre-evaluation

1. Document review
The TL will normally conduct the document review (the TL can delegate some of the review to TM(s)) before each evaluation visit. There is no prescribed format for the document review. Under normal circumstances the document review is for use by the team and the AB. Only 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.

2. Preparation and planning of the pre-evaluation
The TM has studied the documents and the documents review report of the Team Leader before the pre-evaluation takes place.

<table>
<thead>
<tr>
<th>Days</th>
<th>Actions</th>
<th>Evaluators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1 and 2</td>
<td>team preparation</td>
<td>TL + 1 TM</td>
</tr>
<tr>
<td></td>
<td>opening meeting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>discuss presented documents and review the</td>
<td></td>
</tr>
<tr>
<td></td>
<td>corrective actions from former evaluations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>getting impressing by selection of records</td>
<td></td>
</tr>
<tr>
<td></td>
<td>witnessing one assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(entirely or partly)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>closing meeting /</td>
<td></td>
</tr>
<tr>
<td></td>
<td>preparing list of findings</td>
<td></td>
</tr>
</tbody>
</table>

It is sufficient if the report provides a brief overview of the AB’s legal status and impartiality, the scope and accreditation activity of the AB and other general information including cross frontier accreditation activity. In addition all NCs, concerns and comments should be documented in a list of findings. The AB will give its response to these findings.

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).

NOTE: The report shall be drafted following the reporting template for evaluation reports. The purpose of a pre-evaluation is to determine whether the AB is ready for the initial evaluation.
ANNEX 5 Timetable for an evaluation

1. Principles of performance of an AB

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 AB to such an extent that the signatories to the MLA can promote acceptance of results from the CABs accredited by the AB. The TL has to undertake all actions to achieve this aim. The TL might adapt the guidance in this annex in agreement with the AB or possibly the MAC MG if 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 AB 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 visits must be performed in connection with the evaluation of the management system, the procedures and the filing.

Appropriate measures to collect information are:
- careful study of the documents passed by the AB in advance including information on accreditation scope, accreditation activities and cross frontier accreditation activities of the AB
- interviews with the ABs management, staff, experts, assessors, clients or authorities
- vertical audits of files
- analysis of minutes from AB’s committees, SOPs, accreditation procedures etc.
- witnessing and observation

To achieve the aim of the evaluation the TLs and the TMs have to act as given in the team’s assignment and according to the requirements stated above.

Especially they have to
- develop a timetable
- be highly interactive with the AB and among themselves
- communicate with the MAC chair if deviations seem necessary
- set out requirements in order to fulfil their duties as early as possible.

2. Types of evaluation

- Pre-evaluation
- Full evaluation
  The course of events for a full evaluation is given in the tables below.
- Extraordinary evaluations
  The duration and the tasks of the extraordinary evaluations are basically determined by the MAC requirements.
- Re-evaluation
  Given the long interval (approximately 4 years) between evaluations, the duration of a re-evaluation is comparable to that of an initial evaluation.

3. Preparation of the visit

An evaluation visit needs good and advanced planning, so that efficient use of resources is implemented – for this, the following time table is recommended to be followed whenever possible.
Note: Enabling the MAC Secretariat to assign an evaluation team in line with the AB's accreditation activities and with the appropriate requirements of the Regulation (EC) No 765/2008 the AB 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 AB. The TL has the lead and the obligation to ensure that all necessary documents are provided to him and/or 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 by this way the time at site can be used for the verification and witnessing. In case the extent or the content of the documents are not enough, further documents have to be demanded by interaction with the AB. The evaluation visit will be postponed if the documents are not satisfying.

The AB must send all necessary documents (as referred to in Annex 1 clause 16) 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 AB the final agenda of the evaluation at least 1 month prior to the evaluation.

The MAC Secretariat will inform the TL about the AB’s ability to carry out its duties in relation to the MLA. It includes whether the AB is supporting the MLA system with sufficient number of suited evaluators and the AB’s ability and willingness to take on the tasks given by MAC MG for evaluation of other signatories.
**Witnessing and observing**

Normally there shall be one witness of an initial accreditation or re-accreditation of a CAB for every scope, or two surveillances. The Team Leader makes a selection of them. 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 AB).

The form of the witness report 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 AB’s office.

Note: Discussions are still continuing about the value of observing especially in the field of management certification when the evaluator has to observe the AB’s assessors witnessing the CAB auditors at their client. Until the discussion is finalised, it is left to the evaluation team to judge the value of observing in a particular evaluation. If the expectation is that the time invested in observing will provide little added value, the team may consider performing an additional witness of the AB’s assessment at the CAB premises.

**4. Duration of evaluation**

Typical examples for the duration of an evaluation of a full scope AB are given in Table 1.

<table>
<thead>
<tr>
<th>Day</th>
<th>Action</th>
<th>Number of evaluators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sunday</td>
<td>Preparation: key issues and evaluation plan</td>
<td>TL and 4 TM</td>
</tr>
<tr>
<td>Monday</td>
<td>office (the whole team) and preparation of the witnessing and observing</td>
<td>TL and 4 TM</td>
</tr>
<tr>
<td>Tuesday (full day of witnessing)</td>
<td>Office and witnessing/observing preferable vertical audits together with the AB staff and technical experts, flexible split between TL and TM</td>
<td>TL and 4 TM</td>
</tr>
<tr>
<td>Wednesday (full day of witnessing)</td>
<td>Office and witnessing/observing preferable vertical audits together with the AB staff and technical experts, flexible split between TL and TM</td>
<td>TL and 4 TM</td>
</tr>
<tr>
<td>Thursday</td>
<td>Office and witnessing/observing preferable vertical audits together with the AB staff and technical experts, flexible split between TL and TM and preparation of the final evaluation report.</td>
<td>TL and 4 TM</td>
</tr>
<tr>
<td>Friday</td>
<td>office for finalising the list of findings and presentation to the AB</td>
<td>TL and 4 TM</td>
</tr>
</tbody>
</table>

Note 1: On agreement with the AB, the team might spend a full supplementary day without interactions with the AB in order to get the report ready, agreed by the whole team for presentation at the closing meeting.
Note 2: A continuous interaction with the management of the AB 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. The departure must be on Saturday.

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

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

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

<table>
<thead>
<tr>
<th>Number of scopes</th>
<th>Initial evaluation</th>
<th>Later extension of scope after initial evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Minimum of man-days on site</td>
<td>8</td>
<td>10-12</td>
</tr>
<tr>
<td>1 TL, 1 TM 4 days</td>
<td>1 TL, 1 TM 5 days (preferred option) or 1 TL, 2 TM 4 days</td>
<td>1 TL, 1 TM 3 days</td>
</tr>
</tbody>
</table>
5. **Elements extending the duration of evaluation**
   - Extensive travel and travel circumstances
   - Need of translation
   - multi-site AB-offices
   - possibilities for witnessing/observing
   - 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.

**Remarks:**
- The team should be prepared to make long working days (12-14 hours).
- The size of the AB (not the scope) should be of no influence to the duration.
- The economical power of the country should not influence the duration but considering witnessing/observing of special arrangement might be necessary.

6. **Reporting**
   The report should follow the form as given in the Annex 6.

   Note: General aspects of the report have to be prepared largely by the AB before the visit. This preparation allows the team to finish the evaluation report on site.
ANNEX 6 Evaluation Reporting

1. Descriptions

1.1 The evaluation report
The evaluation report consists of the following elements:

1. General information
   0. Executive summary
   1.1. Evaluation details (s requested by….for…)
   1.2. EA team (names and organisations of team members and team leader, signatures and the fields they are assigned to cover)
   1.3. Time-schedule, place and scope for the evaluation
   1.4. Name and contact details for AB
   1.5. Legal status and description of structure
   1.6. Fields of activity
   1.7. Short history
   1.8. Additional information if necessary (for example Cross Frontier activity)
   1.9. Actions for findings from previous evaluation (specify for each NC and Concern whether the corrective actions give sufficient output and are effective for sustainable closing)

2. Compliance with requirements of ISO/IEC 17011 and the MLA requirements based on a self-evaluation carried out by the AB (IAF/ILAC A3)

3. Witnessing (list of witnesses/observations with individual summary reports (type of CAB, scope in general terms, type of assessment)) (format available)

4. List of findings (complete list of elaborated findings including the report about the way the findings have been closed and recommendation of the evaluation team)

5. Appendix
   5.1. Organisation chart with key personnel
   5.2. Report on participation in international PTs/ILCs including an overview of the performance level
   5.3. Statistical Information (format available, EA-MAC/01-S16)
   5.4. Confidentiality Declaration, signed by individual team members (format available, EA-MAC/01-S5)
   5.5. Evaluation plan
   5.6. Original of signed list with findings

NOTE: The statement of compliance to the relevant EN/ISO/IEC standards and MLA obligations (the checklist) is not part anymore of the report but the TL will send it, after the evaluation visit, to the EA MAC Secretariat for verification and preparing the next evaluation visit.
1.2 The final evaluation report

The final evaluation report is identical with the evaluation report (see 1.1) but the list of findings (element 5 of the evaluation report) now contains the proposed corrective actions including the time table as agreed between the team and the AB 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 list will end with a recommendation of the team to the MAC.

1.3 Classification of findings

<table>
<thead>
<tr>
<th>Finding</th>
<th>To be used as a general term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-conformity (NC):</td>
<td>Finding where the AB does not meet a requirement of the applicable standard (ISO/IEC 17011), its own management system and the EA-MLA requirements. The evaluated AB is expected to respond to a NC by taking immediate corrective action and providing the team with evidence of implementation.</td>
</tr>
<tr>
<td>Concern (CN):</td>
<td>Finding where the AB’s practice may develop into a NC. The evaluated AB is expected to respond to a CN by providing the team with an appropriate action plan and time schedule for implementation.</td>
</tr>
<tr>
<td>Comment (Cm):</td>
<td>Finding about documents or AB’s practices with a potential of improvement; but still fulfilling the requirements. The evaluated AB is encouraged to respond to comments.</td>
</tr>
</tbody>
</table>

2. Steps in evaluation reporting on an AB

2.1 Presentation of the evaluation report to the AB

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

The AB may correct any misunderstandings and must provide corrective actions, supporting evidence and time schedule within one month 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.

2.2 Response of the AB to the findings

Ideally, the AB’s response can simply be inserted into the text under each finding according to the form, with attachments of supporting evidence of corrective actions as appropriate. The team’s reaction to each response is submitted to the AB for consideration. If the AB does not agree with the team’s reaction, the TL and the AB can try to achieve consensus possibly with involvement of the TFG. 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 MAC secretariat within two months after the AB has submitted their first set of corrective actions.
2.3 Studying of the final report
The final report will be studied according to Annex 7.

2.4 Confidentiality
2.4.1 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 Task Force, 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.

2.4.2 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.

2.4.3 The AB under evaluation shall advise the team members how to treat the documents it has provided. This advice may require the team members to
  o return all documents to the AB after use
  o destroy the documentation, when it is determined there is no further need to maintain the documents.
ANNEX 7 EA-MAC TFG
Task Force Group for Studying Evaluation Reports

A Task Force Group (TFG), composed of four members, is assigned to study the evaluation report.
Criteria to be a TFG member:
- represent a signatory
- three (out of four members) have at least one year experience in the EA-MAC

One of the members is also a member of the MAC Management Group (MAC-MG). The MG member must ensure that sufficient discussions, when relevant, have taken place between the AB, the EA evaluation team and the TFG. He/she does not, actively, take part in the TFG recommendation.
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 EA-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. The TFG is expected to communicate with the evaluation team and, in exceptional cases, with the AB under evaluation when there are open, missing or unclear issues in the report in order to solve or clarify the situation. 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 AB.

Details on the process of the studying of evaluation reports by a Task Force Group (TFG) are provided in the flowchart of this annex.
Below is a layout for the review report. Under each heading (bold typeface) is a brief explanation given between brackets. The review report has to be provided to the EA-MAC Secretariat within 3 weeks after receiving the evaluation report.

1. **AB evaluated:**
   (Name of the AB and location)

2. **Scope of evaluation:**
   (type of evaluation and fields of accreditation (testing, product certification, EMS etcetera) being evaluated)

3. **Evaluation team:**
   (repeat the names of the team and the respective fields to evaluate)

4. **TFG composition:**
   (members of the TFG reviewing the report, name of member who prepared the review report, reporter)

5. **Identification of the reviewed report and documents:**
   (including documents with comments from the AB, if any)

6. **TFG conclusions:**
   **Short summary:**
   (give a short summary of the evaluation process and the evaluation report)
Statements on findings observed by the evaluation team:
(It is especially important to clearly identify the findings, which TFG, AB and
team do not agree upon. It is beneficial if a table is provided with the following
column headings: finding, team’s view, AB’s view and TFG’s view)

Interaction by TFG with the team and, in exceptional cases, with the AB:
(summarize the reasons for interaction (additional information, questions, etc)
with the team and/or AB and the results of these interactions)

7. Recommendation with justification:
Recommendation of EA evaluation team:
(summarize the EA evaluation team’s recommendation)

Recommendation and justification of TFG:
- The TFG can recommend in line with the evaluation team, in such case
  no further justification is required.
- The TFG can, in addition to the evaluation team’s recommendation,
  propose, well justified, that the AB has to deal with certain issues first and
  provide for instance proof in writing or through an additional visit etcetera
  (conditions).
- The TFG can disagree with the evaluation team’s recommendation. This
  should obviously be reflected in the above-mentioned statements and
  well justified, If necessary use an appendix to explain details.

The TFG recommends:

AB remains a signatory in the field(s) of ....
AB becomes a signatory in the field(s) of ...
AB remains a signatory in the field(s) of ..... pending (specific conditions)
AB becomes a signatory in the field(s) of ..... pending (specific conditions)
Postpone decision due to insufficient information
AB is suspended as a signatory in the field(s) of ...... for a period of six
months, or more, due to the following motivations (describe the reasons and
the conditions to withdraw/review the decision).
EA MAC Secr receives from the TL the **final** report, including the corrective actions and the recommendation.

EA MAC Secr forwards the final report to the TFG *)

TFG studies report

Report ok?

Yes

TFG agrees with Team’s recommendation?

Yes

One member of the TFG, not being the EA MAC MG member, makes a report.

No

Team/AB is contacted for further information

TFG, Team, AB persist in different views?

Yes

A

No

EA MAC is informed with reasoning

EA MAC MG will contact TL and AB to discuss the problems and ask for amended report

TFG agrees with Team’s recommendation?

No

B

*) The AB, the evaluation team and MAC members are also informed on the TFG’s composition.

Does the report provide the information according to requirements and is the quality sufficient? The entire TFG must agree that the report is (in)sufficient.

The lay-out of the review report is described in Annex 7.

*The MG member must ensure that sufficient discussion has taken place between AB, EA team and TFG. He/she does not actively participate in the TFG’s recommendation.*

*‘Final evaluation docs’ consist of the final report TL and the TFG recommendation.*
Presence of the AB and TL/TM (depending on the issue of disagreement) in EA MAC meeting is required and decision must be made in an EA MAC meeting.

EA MAC meeting within three months?

Yes

No

EA MAC Secr forwards final evaluation docs to the EA MAC members, requesting individual decision by electronic voting to be returned to EA MAC Secr. **)

The final docs will be included in the agenda papers for discussion in next EA MAC meeting.

EA MAC members take a decision **) during their meeting on final evaluation docs.

Approval? ***)

Yes

Decision taken and the AB informed.

No

EA MAC Secr forwards final evaluation docs to the EA MAC members, requesting individual decision by electronic voting to be returned to EA MAC Secr. *

*) This decision is only possible for new evaluations or extensions and should only be taken if the expected outcome of the voting is positive for the AB.

**) During the decision-taking, the EA MAC Secr must ensure that EA MAC members who participated in the evaluation as TL/TM are excluded from the decision-taking step. Also excluded are members of those ABs recently having provided assistance in setting up the AB.

***) A majority of two thirds of the votes with at least three quarters of the members voting.
ANNEX 8 Decision making

The MAC is responsible for the decision-taking regarding peer evaluations. Every Full EA Member is entitled to nominate a representative to participate 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 Full 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 (e.g. part of the peer evaluation team or having provided assistance to the evaluated body in the last four years).

A Full 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 Chair may invite other observers as appropriate.

1. Decision Making Regarding Evaluations
   1.1. The evaluation report, the corrective actions and the recommendations of the Team Leader and the EA-MAC Task Force Group (TFG) (see Annex 7) shall be submitted as the final report to the listed members of the EA-MAC.

   1.2. The EA-MAC shall decide:
       - in the case of an initial evaluation, whether or not the Applicant Body may enter the Agreement;
       - in the case of a re-evaluation, whether or not the Applicant Body will remain, with or without conditions, a Signatory to the Agreement, whether or not sanctions need to be applied.

2. Decisions for applicants
   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 for NCs and concerns and/or an additional visit by one or more members of the team.
   - Disapproval with a new evaluation being required.

3. Decisions for signatories
   For signatories the following decisions can be made:
   - Continuation without condition (re-evaluation in 4 years)
   - Continuation with conditions (e.g. extraordinary evaluations, shortened re-evaluation interval, additional information or follow-up reports) (Note 1).
   - Suspending the AB.
Accreditations granted during the suspension period are not covered by the MLA and are not internationally recognised. Therefore the AB has to inform (with a copy to the MAC) all CABs requesting accreditation that their reports/certificates will not be accepted under the MLA and shall not make reference to the MLA. There is no consequence for the CABs accredited before the suspension (Note 2). 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 and when relevant an extraordinary visit can be conducted (Note 3).

- Lift the suspension and reinstate the signatory status (in this case if required the MAC can decide to ask for supplementary information on open issues).
- **Immediate withdrawal** of signatory status to the MLA or particular field within the MLA (Note 4).
  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.

**Note 1:** The MAC must decide on:
- the applicable action to confirm implementation of corrective actions (see paragraph 4).
- the maximum time span for the subsequent decision by the MAC.

**Note 2:** The EA-MAC will inform the AB’s Board 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. In case of suspension a note will be published on the EA website and ILAC and IAF MRA/MLA committees will be informed.

**Note 3:** Based on the result of the extraordinary evaluation*) the MAC will decide as follows:
- to lift the suspension and reinstate the signatory status
- 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.

**Note 4:** 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.

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

4. Reasons to perform extraordinary evaluations
In the past years experience has shown that additional evaluation visits are sometimes necessary. A decision to conduct such extraordinary evaluations will be based among others on the following criteria:

- The AB does not offer the evaluation team an acceptable choice in witnessing activities or does not provide all needed documentation preventing the evaluation team to prepare correctly in the required timeframe.
- An AB 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 visit shows lack of implementation of the corrective actions.
- There are major changes in the structure or processes of the AB, which could affect issues such as competence, impartiality and operational ability.
- Complaints to EA made by CABs, ABs, regulators or other concerned parties.

The MAC-MG must in addition decide whoever has to pay the costs for the extraordinary visit and what should be included in those costs.

5. Practice in case of serious lack of confidence during evaluations
When an evaluation team detects a situation at an AB that results in a total lack of confidence in the AB’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 the report of the evaluation without awaiting the corrective actions of the AB.
During the evaluation the AB’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 of the MAC is required.

6. Feedback to evaluators and WG ‘MLA-Training and Procedures’
Feedback is given to the evaluators and, where relevant, to the Chair of the WG ‘Training’ about relevant issues that are identified during the Task Force Group’s reviews of the peer evaluation reports, the ABs evaluation of the teams performance (questionnaire EA-MAC/01-S12), the mutual ‘Review of Performance’ of Team Leader and Team Members (EA-MAC/01-S15 Part I and Part II) and/or those items identified by the EA MAC (-MG) meetings.
ANNEX 9 Monitoring and re-evaluation

Periodic monitoring and re-evaluation of the signatories to the MLA(s) is necessary.

1. All signatories shall be formally re-evaluated at maximum intervals of four years (–3 to +6 months).

2. Either partial or total re-evaluation may be conducted at an earlier date as directed by the EA-MAC Management Group, should there be due cause such as notification of significant changes in administration, finances, operational practices or an extension in the scope of accreditation.

3. Monitoring of changes notified by a signatory shall be appropriately examined.

Note: see also Annex 8 paragraph 4.