



**IAF/ILAC Multi-Lateral
Mutual Recognition Arrangements
(Arrangements):
Requirements for Evaluation
of a Regional Group**

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PREAMBLE

The international community of accreditation Regional Groups, recognized Accreditation Bodies, and their stakeholders cooperate through the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum, Inc. (IAF). A principal objective of ILAC and IAF is to put in place world-wide, multi-lateral Mutual Recognition Arrangements (Arrangements). Both ILAC and IAF aim to demonstrate the equivalence of the operation of their Member Accreditation Bodies through these Arrangements. As a consequence, the equivalent competence of conformity assessment bodies accredited by these accreditation bodies is demonstrated. The market can then be more confident in accepting certificates and reports issued by the accredited conformity assessment bodies.

ILAC and IAF are linking the existing multi-lateral, mutual recognition Arrangements of the regional accreditation cooperations (Regional Groups) and are encouraging the development of new Regional Groups to complete world-wide coverage. For the purposes of their Arrangements, both ILAC and IAF delegate authority to their “recognized” Regional Group Members for the evaluation, surveillance and re-evaluation of full Member Accreditation Bodies within their defined territory and associated decision making relating to the membership of the ILAC and IAF Arrangements in that territory. Formal “Recognition” of a Regional Group with respect to the ILAC and IAF Arrangements is based on an external Evaluation of the Regional Group’s competence in mutual recognition Arrangement management, practice and procedures by a team composed of evaluators from other ILAC and IAF Member Regional Groups and Accreditation Bodies.

Evaluation relating to the development and maintenance of the ILAC and IAF Arrangements operate at two levels:

- the Evaluation of the competence of single Accreditation Bodies to accredit (see IAF/ILAC A2);
- the Evaluation of a Regional Group’s competence in managing the operations of regional mutual recognition Arrangements.

The requirements to be used by ILAC and IAF when evaluating the competence of a Regional Group in managing, maintaining, and extending a regional mutual recognition Arrangement for the purposes of ILAC and IAF “Recognition” are set out in the following chapters of this document.

PURPOSE

To provide the ILAC and IAF with requirements or criteria for evaluating Regional Groups for the purpose of recognition.

AUTHORSHIP

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

This latest revision was endorsed by letter ballot in ILAC and IAF in 2007.

SECTION 1: Introduction

1.1 Scope

This document identifies requirements for evaluation of Regional Groups of Accreditation Bodies operating a multi-lateral mutual recognition Arrangement. It includes requirements for the organization, management system and procedures for evaluating individual Accreditation Bodies for the Regional Group's multi-lateral, mutual recognition Arrangement(s). Section 3 is a framework for use by ILAC and IAF in order to provide (joint) evaluations with harmonized procedures. There are ten Annexes to describe in more detail the major steps of the process.

The fundamental requirements for an AB are set out in ISO/IEC 17011 and are therefore not repeated in this document.

1.2 Definitions

- 1.2.1 Accreditation Body (AB):** an organization that operates an accreditation system for one or more types of conformity assessment bodies.
- 1.2.2 Arrangement:** The ILAC Mutual Recognition Arrangement (Arrangement) or IAF Multi-Lateral Arrangement (MLA). The term can also refer to the Arrangements (MRAs or MLAs) of "recognized" Regional Groups which pre-date the establishment of the ILAC and IAF Arrangements and which, as a consequence of the "recognition" process, will be accepted as a subset of the ILAC or IAF Arrangements.
- 1.2.3 Regional Group:** A regional cooperation body member of ILAC or IAF. This term can also refer to a group of Accreditation Bodies (possibly involving other stakeholders) whose purpose is to develop and maintain a multi-lateral, mutual recognition Arrangement and is a group of different Accreditation Bodies representing different economies.
- 1.2.4 ISO/IEC Standard:** An ISO/IEC standard, guide or technical report related to accreditation and conformity assessment.
- 1.2.5 Peer Evaluation:** A structured process of assessment of a Regional Group or Accreditation Body.
- NOTE: In ISO/IEC 17040 is peer evaluation defined: evaluation of a body, against specified requirements, by representatives of other bodies in, or candidates for, an agreement group.*
- 1.2.6 Signatory:** A Member of ILAC and/or IAF who has signed one or more of the multi-lateral, mutual recognition Arrangements of a Regional Group or has signed the ILAC and/or IAF Arrangement.
- 1.2.7 Arrangement Group:** All signatories to an Arrangement (in IAF: MLA Group; in ILAC, Arrangement Signatories).

- 1.2.8 Management Committee (MC):** A small group responsible for the everyday management of the Arrangement process (In IAF: IAF MLA MC; In ILAC: ILAC Arrangement Management Committee).
- 1.2.9 MC Secretariat:** Secretariat for the Management Committee (In IAF: IAF MLA MC Secretariat; in ILAC: ILAC Secretariat).
- 1.2.10 Regional Arrangement Group:** All signatories of an Arrangement of a Regional Group.
- 1.2.11 Decision-making Group:** A body that decides on the status of membership of an Arrangement (may include more than just signatory representatives).
- 1.2.12 Evaluation Team Leader (TL):** A person responsible for leading an Arrangement peer evaluation team.
- 1.2.13 Evaluation Team Member (TM):** A person serving on an Arrangement peer evaluation team.
- 1.2.14 Regional Evaluation Team Leader (TL-R):** A person responsible for leading a team in the evaluation of regional body; sometimes called the evaluation manager
- 1.2.15 Regional Evaluation Team Member (TM-R):** A person serving on a team to evaluate a regional body
- 1.2.16 Accreditation program/scheme:** accreditation of bodies belong to a conformity assessment program/scheme

SECTION 2: Requirements for Regional Group**2.1 Regional Group – General**

- 2.1.1** The Regional Group shall make its services concerning its Arrangement(s) accessible to all accreditation bodies whose activities fall within its declared field of operation and geographic area.
- 2.1.2** The Regional Group shall confine its requirements, evaluations and decisions on accreditation bodies wishing to join its Arrangement to those outlined in the ISO/IEC 17011, other normative documents relevant to the function performed, and where appropriate supplementary requirements and guidance of the Regional Group harmonized with those of ILAC and IAF.
- 2.1.3** The Regional Group shall:
- 2.1.3.1** identify the management which will have overall responsibility for all of the following:
 - a) performance of Peer Evaluation of accreditation bodies as defined in this document,
 - b) formulation of policy matters relating to the operation of the Regional Group,
 - c) decisions on Signatories to the Arrangement, and
 - d) oversight of the implementation of its policies.
 - 2.1.3.2** ensure that each decision on the acceptability of an applicant to sign the Arrangement is taken by persons representing all Arrangement Signatories; these persons shall be different from those who carried out the Peer Evaluation;
 - 2.1.3.3** have policies and procedures for the resolution of complaints and appeals received from accreditation bodies or other parties about the handling of Peer Evaluations and Arrangement Signatory status or any related matters.

2.2 Management System

- 2.2.1** The Regional Group shall establish and maintain a management system to operate an Arrangement in accordance with the relevant elements of this document and appropriate to the type, range and volume of work performed. The Regional Group shall ensure effective implementation of the documented management system procedures and instructions. The Regional Group shall periodically audit and review the management system as a basis for improvement of the system.
- 2.2.2** The following elements of the management system shall be documented:
- 2.2.2.1** mission, policies, and objectives;
 - 2.2.2.2** organization chart and description of the organization,

- 2.2.2.3 procedures for peer evaluation
- 2.2.2.4 conduct of internal audits and management reviews;
- 2.2.2.5 control of documents;
- 2.2.2.6 selection, training, qualification and monitoring of Peer Evaluators;
- 2.2.2.7 records related to Peer Evaluation;
- 2.2.2.8 arrangements for ensuring confidentiality of Peer Evaluation information; and
- 2.2.2.9 arrangements for handling appeals and complaints.

2.3 Documentation

- 2.3.1** The Regional Group shall document, update at regular intervals, and make available (through publications, electronic media or other means) on request,
 - 2.3.1.1** information about the Peer Evaluation and recognition process;
 - 2.3.1.2** requirements, restrictions or limitations on ways of referring to its recognition and Signatory status;
 - 2.3.1.3** information for lodging complaints and appeals;
 - 2.3.1.4** information on Arrangement Signatories describing the scope of recognition of each.
- 2.3.2** The Regional Group shall control all documents and records that relate to its Peer Evaluation functions. These documents shall be reviewed and approved for adequacy by appropriately authorized and competent personnel prior to the issuing of any documents following initial development or any subsequent amendment or change being made. A listing of all appropriate documents with the respective issue and/or amendment status identified shall be maintained. The distribution of all such documents shall be controlled to ensure that the appropriate documentation is made available to Arrangement Signatories and personnel of the Regional Group, or Arrangement applicants, when required to perform any function relating to the activities of Arrangement applicants and Arrangement Signatories.

2.4 Confidentiality

- 2.4.1** All oral and written information received relating to evaluations, re-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 Arrangement Group. All members and observers of the evaluation teams; all members, observers and secretariat personnel of the MC and the Appeals Panel, other persons having access to confidential information and all applicants and members of the Arrangement Group which request access to any report on pre-evaluation, 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 Evaluations, re-evaluations and interim 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 Cooperation under Evaluation shall advise the team members how to treat the documents it has provided. This advice may require the team members to:
- ♦ return all documents to the Cooperation; or
 - ♦ destroy the documentation, when it is determined there is no further need to maintain the documents.

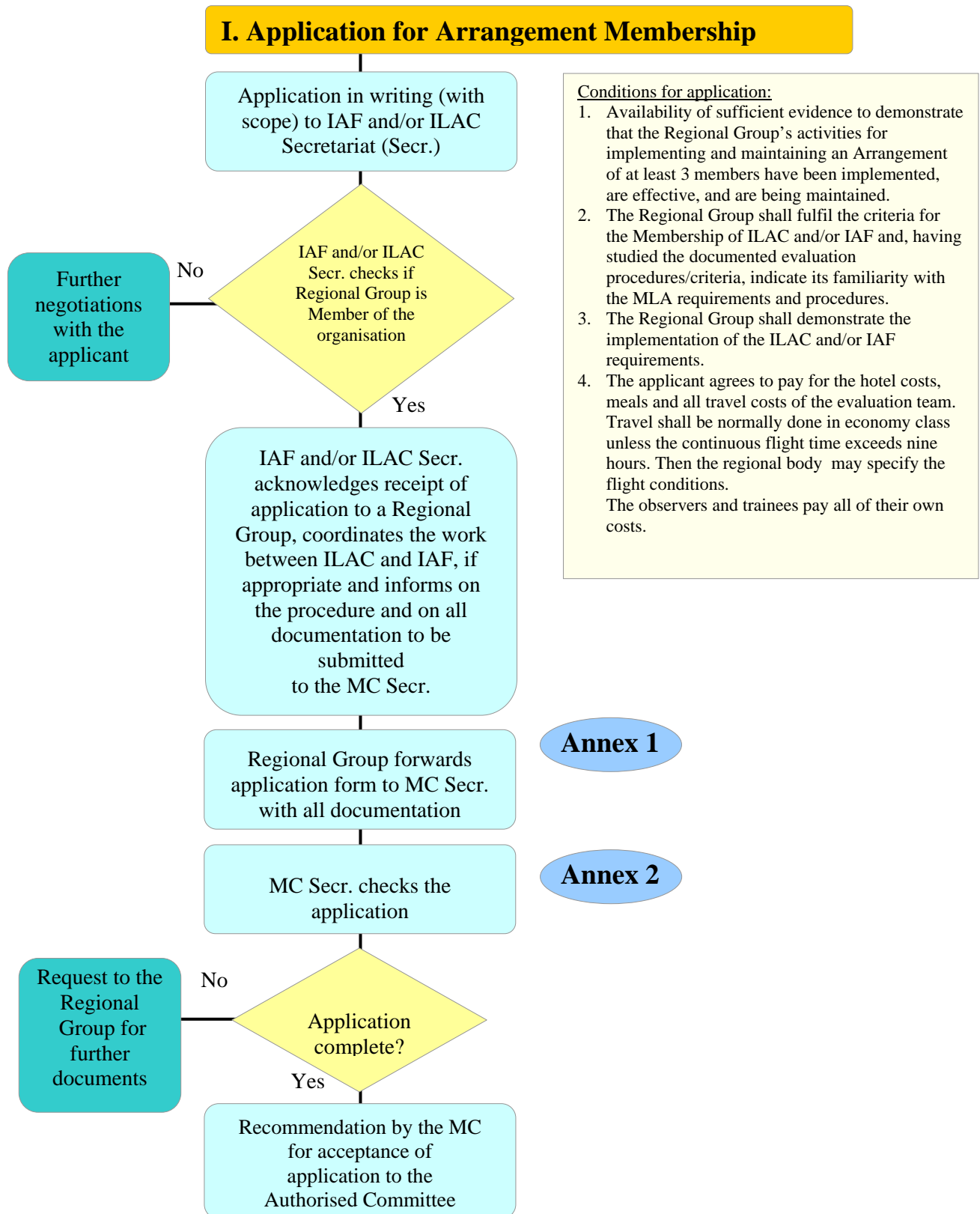
2.5 Regional Group Personnel

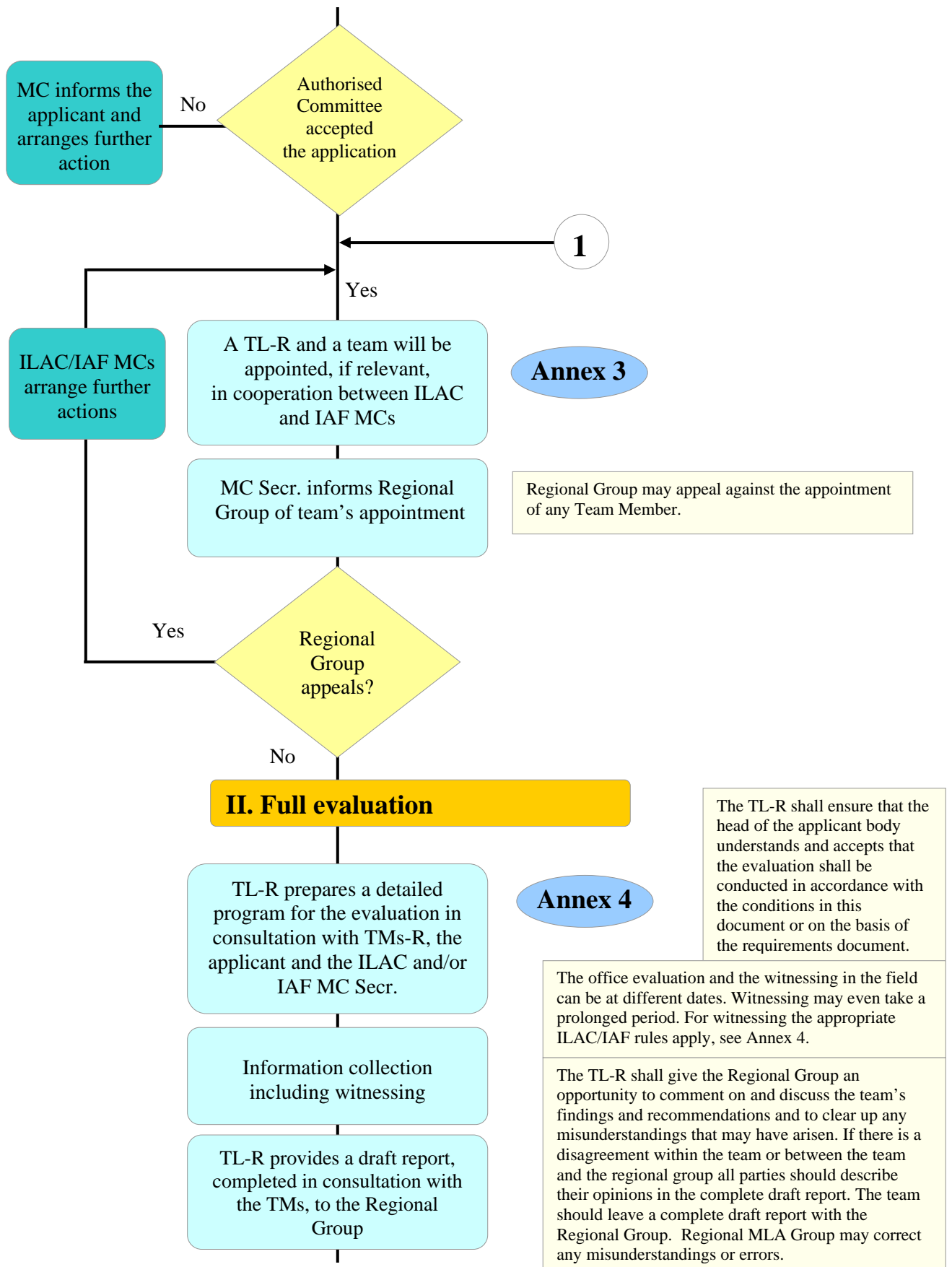
- 2.5.1** The personnel of the Regional Group involved in Arrangement applications, Peer Evaluation and recognition shall be competent for the functions they perform.
- 2.5.2** In order to ensure that the Peer Evaluations are carried out effectively and uniformly, the minimum relevant criteria for competence of peer evaluators, including trainees if necessary, shall be defined by the Regional Group.
- 2.5.3** Peer evaluators shall meet the requirements as presented in Annex 3.

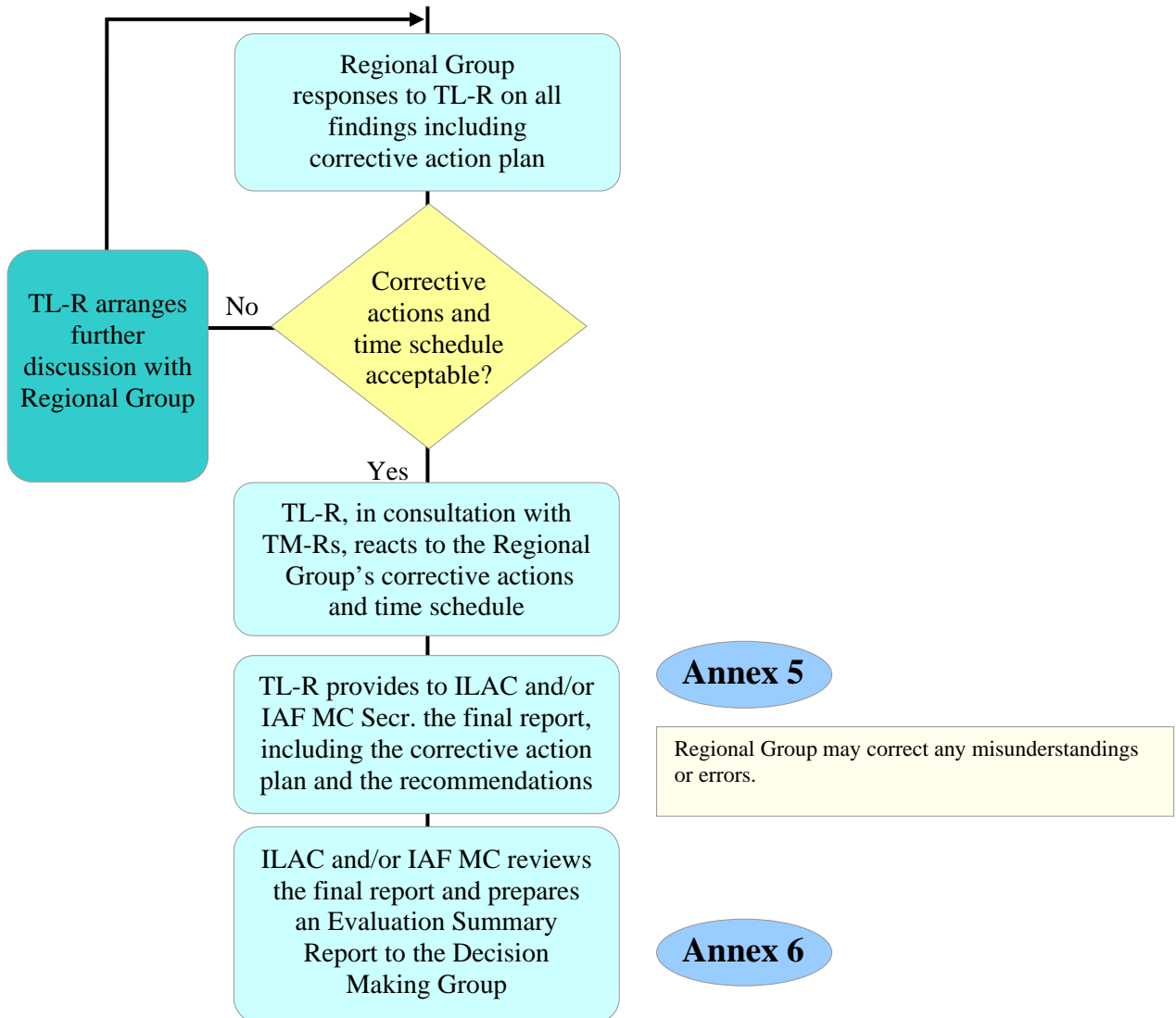
2.6 Other Obligations

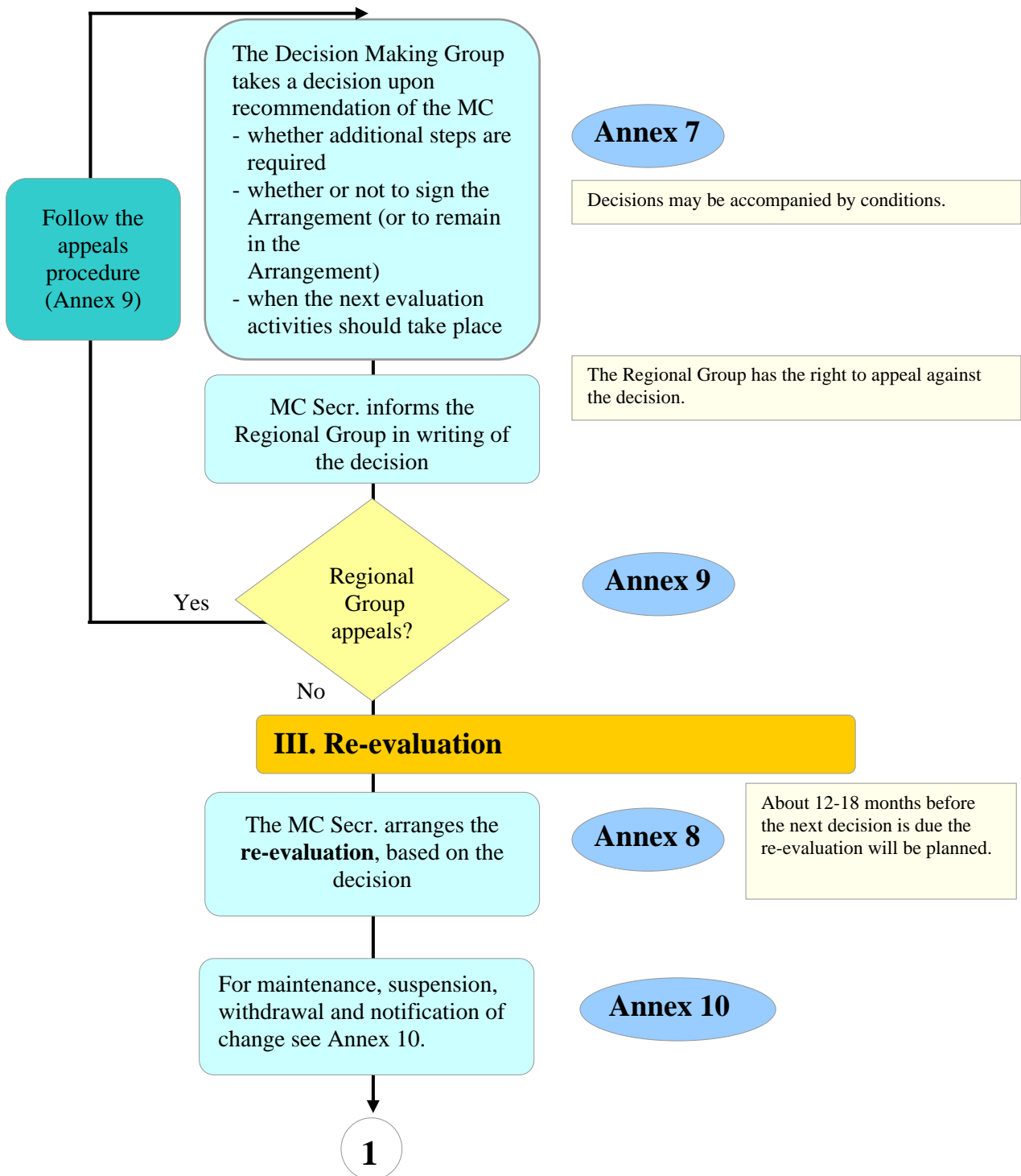
- 2.6.1** The Regional Group shall effectively implement tasks assigned to it by ILAC and/or IAF.
- 2.6.2** The Regional Group shall have a programme to promote the Arrangement with major stakeholders
- 2.6.3** The Regional Group shall provide appropriate technical support and enhance harmonization and education within the region through activities such as workshops, conferences, task groups, etc.
- 2.6.4** The Regional Group shall provide peer evaluator training and/or workshops as necessary, taking into account any changes carried out in the peer evaluation criteria and the availability of peer evaluators.
- 2.6.5** The Regional Group shall contribute its fair share of personnel resources for carrying out peer evaluations at the global level.
- 2.6.6** The Regional Group shall assure that all signatories of the Arrangement shall continuously fulfil the obligations in A2.
- 2.6.7** The Regional Group shall periodically indicate technical activities to support continuing demonstration of equivalence within the regional cooperation and between regional cooperations, such as proficiency testing or interlaboratory comparisons

SECTION 3: Flowchart for Peer Evaluation Procedures of a Regional Group









ANNEX 1: Application, from a Regional Group, to Join the Arrangement**1. Please tick the Accreditation Arrangement program being applied for:**

- Accreditation of calibration laboratories (Cal)
- Accreditation of testing laboratories (Test)
- Accreditation of inspection bodies (Insp)
- Accreditation of QMS Certification Bodies (QMS)
- Accreditation of EMS Certification Bodies (EMS)
- Accreditation of Product Certification Bodies (Product)
- Accreditation of Persons Certification Bodies (Persons)

2. Name of Regional Group (Applicant):

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

4. Region:**5. Economies covered:****6. Name of Applicant contact person:****7. Position of contact person:****8. Telephone (including international access):****9. Facsimile (including international access):****10. E-mail address:****11. Statement on the legal status of Applicant:**

12. History of the Applicant (Founding date, operational period, pertinent historical background).

13. Applicant's interactions with Regional/Economical Political Entities, if any.

Please answer the following questions for each area in which the applicant is seeking signatory status to the respective Arrangement.

	Cal	Test	Insp	QMS	EMS	Product	Persons
14. Operational period of the Applicant in the area of the Arrangement applied for.							
15. Accreditation criteria							
16. Number of Staff including management staff and evaluation personnel.							
17. Number of Arrangement Group members (attach a list of the names of the Arrangement Group members in each field or a link to the database on the internet, if any)							
18. Preferred month and year, if any, for peer evaluation.							

19. Please list all other Operational field(s) of the Arrangement.

20. Please attach a separate sheet, listing Name and Fields of Accreditation for each of the Applicant's Members.

21. Please include one (1) copy via electronic means of each of the following documents written in English

- the Regional Group constitutional documents;
- a statement indicating the legal status of the Regional Group to which the applicant belongs, if any;
- requirements for membership in the Regional Group and in the Arrangement;
- identification of any differences in the procedures documents of the Regional Group from those of IAF and/or ILAC;
- text of the Arrangement and the list of members of the Arrangement Group;
- procedures for granting, maintaining and suspending membership of the Arrangement Group;
- documented procedures for the management of the Arrangement;
- composition and Terms of Reference of the Regional MC and Decision Making group and Minutes of the last three meetings of the MC or Decision Making Group;

-
-
- list of documents to be implemented by signatories or recommended for use to the relevant Arrangement;
 - procedures for the selection, training and monitoring of evaluation team leaders and members;
 - cross-reference table between the requirements of the ILAC/IAF and the requirements of the Regional Group
 - list of team leaders and team members;
 - a schedule indicating the status of peer evaluations.
- 22. Other information related to the integrity of Arrangement activity (e.g. other activities of the applicant, mutual recognition agreements, relationships with other bodies, subcontracting).**
- 23. Please complete the Declaration on the following page.**

Please send your completed, signed and dated application, along with all requested documents to
for IAF MLA:

BOTH

IAF Secretariat

The IAF Secretariat
 53 Manuka Circle
 Cherrybrook NSW 2126
 Australia

Fax: +61 2 9481 7343
 Email: secretary@iaf.nu

AND

IAF MLA Secretariat

DAR Secretariat,
 c/o Bundesanstalt für Materialforschung und -prüfung,
 Unter den Eichen 87,
 DE-12205 Berlin
 Germany

Ph: +49 (30) 8104 1942
 Fax: +49 (30) 8104 1947
 Email: monika.wloka@deutscher-akkreditierungsrat.org

for ILAC Arrangement:

ILAC Secretariat

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 PO Box 7507
 Silverwater NSW 2128
 Australia

7 Leeds Street
 Rhodes NSW 2138
 Australia

Ph: +61 2 9736 8374
 Fax: +61 9736 8373
 Email: ilac@nata.asn.au

Declaration

As a Regional Group applying for recognition by IAF and/or ILAC, the Applicant, duly represented by the undersigned:

- ◆ Accepts the current joint ILAC/IAF procedures for evaluation for Regional Groups;
- ◆ Accepts the requirements and agrees with the terms of the Arrangement;
- ◆ Confirms that the operations of the Applicant comply with IAF and/or ILAC endorsed standards and guidance;
- ◆ Submits the completed Application;
- ◆ Applies to join the Arrangement Group.

Contact Person's Name

Date

Signature

ANNEX 2: Check-report on application**1. Name of the Regional Group applicant:****2. Date of Application:****3. Date of this report:****4. Name of person preparing this report:****5. General observations:**

The completeness of content filled in the application cover sheet and survey outline: Yes / No

Have all the following documents in English been supplied:

- The Regional Group constitution: Yes / No
- Statement on its legal status Yes / No
- Requirements for Arrangement Membership: Yes / No
- Identification of Differences in Regional Requirements from IAF and/or ILAC Requirements: Yes / No
- Text of the Arrangement and List of Arrangement Members: Yes / No
- Procedures for Granting , Maintaining and Suspending: Yes / No
- Arrangement Management Procedures: Yes / No
- composition and Terms of Reference of the regional MC: Yes / No
- Minutes of Last Three Meetings of the MC: Yes / No
- List of Documents used by the Arrangement: Yes / No
- Procedures for the Selection, Training and Monitoring of Evaluation Team Members: Yes / No
- Cross-reference table between appropriate ILAC/IAF requirements and the Regional Body's quality system documentation Yes / No
- List of Team Leaders and Team Member Evaluators: Yes / No
- Schedule Indicating Status of Peer Evaluation Visits: Yes / No

6. Others, if any:**Recommendation:**

- Does the Applicant Comply with all Application Criteria as specified in Annex 1: Yes / No
- Acceptance of application: Yes / No
- If "No", the reason for rejecting the application:

Signature

ANNEX 3: Appointment, composition and requirements of the qualifications and personal attributes of peer evaluation team leaders and members**1. Appointment and Duties of Team Leader**

- 1.1** In appointing team leaders for a specific evaluation, the IAF/ILAC Arrangement MCs should not appoint the same team leader for two successive evaluations of the same Applicant.

NOTE It is normal practice that evaluators from as many members as possible are used.

- 1.2** Team leaders shall be chosen from a list of team leaders prepared and kept up-to-date by the MC on the basis of the team leaders lists from the regions. These lists should record the scope of experience of team leaders. Team leaders shall comply with the minimum qualifications for evaluators as given in Clause 3.2
- 1.3** The team leader shall have ultimate responsibilities for all phases of evaluation and is delegated authority by the Arrangement MC to make final decisions regarding the conduct of evaluation.
- 1.4** The team leader shall normally, in addition to the responsibility for managing the evaluation and preparing the evaluation report, mentor any "trainee peer evaluator" assigned to the team. Mentoring trainees includes allocating tasks as each is capable of performing, supervising the work and providing a report to the Arrangement MC about the performance of each trainee.

2. Composition of Evaluation Team

- 2.1** For the full evaluation visit, members of the team shall be chosen as needed to cover the types of accreditation, the technical fields, size and complexity of the accreditation system under evaluation.
- 2.2** Team members shall be chosen from a list of team members prepared and kept up-to-date by IAF/ILAC MC on the basis of the team members lists from the regions. These lists should record the scope of experience of team members. At least one member of the team shall have sound experience with Regional Group evaluations. For laboratory accreditation, one member of the team should be familiar with proficiency testing. The minimum qualifications of team members shall be as described in Clause 3.
- 2.3** The team chosen shall consist of representatives from a cross-section of Regional Group and/or unaffiliated bodies of IAF/ILAC. The team shall be chosen to provide a balanced set of skills so as to be able to conduct an effective evaluation of the key components of the system under examination.

NOTE 1 There should only be one team member from each accreditation member body taking part.

NOTE 2 The team members should have working knowledge of the English language. Knowledge of the local language should be taken into account.

NOTE 3 Some of the evaluation team members may have as their only task to perform witnessing at different geographical places or at different times than the rest of the team.

3. Requirements for Qualifications of Peer Evaluators

3.1 Selection of Evaluators

3.1.1 IAF/ILAC authorised committees shall approve and oversee their performance in accordance with the criteria in the following sections.

3.1.2 IAF/ILAC Members may nominate evaluators (i.e., team leaders and team members) in writing, including a description of the experience and the scope of each proposed evaluator to IAF/ILAC MC.

3.2 Team Leader

3.2.1 A team leader shall be able:

3.2.1.1 to lead the Peer Evaluation team in an efficient and effective way, including the distribution of the tasks among the team members;

3.2.1.2 to evaluate whether an applicant complies with the requirements of this document (ILAC-IAF A1 Requirements for evaluation of regional groups) and comply with the requirements of the appropriate ISO/IEC Standard(s);

3.2.1.3 to decide from the submitted documentation any features requiring special study during the evaluation;

3.2.1.4 to report clearly and succinctly the findings of all team members, in conformity with the Arrangement requirements;

3.2.1.5 to evaluate whether the corrective actions decided by the applicant are likely to be effective and to evaluate the corrective actions carried out;

3.2.1.6 to determine the criticality of the findings;

3.2.1.7 to understand quickly and easily cultural differences, as far as essential for the evaluation process

3.2.2 In order to meet these criteria, a team leader shall:

3.2.2.1 be an experienced (at least three years) person within an Accreditation Body or organization which has relevant working experience (at least three years) with accreditation or be an experienced team leader in its Regional Group and have the appropriate technical background and experience of assessment;

- 3.2.2.2** have participated in at least two peer evaluations of Accreditation Bodies as a team member;
 - 3.2.2.3** have verifiable knowledge of the application of ILAC and IAF requirements, the appropriate ISO/IEC Standards and relevant Arrangement requirements;
 - 3.2.2.4** be able to understand and to express him/herself clearly, in speaking and writing in English;
 - 3.2.2.5** have experience in chairing meetings and in reaching consensus on delicate points;
 - 3.2.2.6** have good interpersonal skills.
- 3.2.3** IAF/ILAC authorised committees shall approve team leaders for a three-year term.
- 3.2.4** IAF/ILAC authorised committees shall arrange periodic training for team leaders in order to improve and maintain the harmonization of the evaluations.

3.3 Team Member

- 3.3.1** A team member shall be able:
- 3.3.1.1** to evaluate whether an applicant complies with the requirements of this document (ILAC-IAF A1 Requirements for Evaluation of a Regional Group) and comply with the requirements of the appropriate ISO/IEC Standard(s);
 - 3.3.1.2** to report clearly and succinctly the findings;
 - 3.3.1.3** to determine the criticality of the findings.
- 3.3.2** A team member shall:
- 3.3.2.1** be an experienced person or assessor within his/her Accreditation Body or organization which has relevant working experience with accreditation or an experienced team member in its Regional Group and have the appropriate technical background in the assigned areas of the evaluation (at least three years)
 - 3.3.2.2** successfully completed a relevant training course(s) and, as a trainee, have experience as a trainee in Peer Evaluation of Accreditation Bodies;

- 3.3.2.3 have sound knowledge of the application of ILAC and IAF requirements, the appropriate ISO/IEC Standard(s) and relevant Arrangement requirements;
- 3.3.2.4 have good interpersonal skills; and
- 3.3.2.5 be able to understand and to express him/herself clearly, in speaking and in writing in English.
- 3.3.2.6 follow the instructions given by the team leader.

3.4 Evaluator Attributes

3.4.1 Evaluators should:

- 3.4.1.1 be open minded and mature;
- 3.4.1.2 possess sound judgment, analytical skills, and tenacity; and
- 3.4.1.3 have the ability to perceive situations in a realistic way, to understand complex operations from a broad perspective, and to understand the role of individual units within an organization.

3.4.2 Evaluators should be able to apply the attributes of 3.4.1 in order to:

- 3.4.2.1 obtain and assess objective evidence fairly;
- 3.4.2.2 remain true to the purpose of the evaluation without fear or favor;
- 3.4.2.3 evaluate constantly the effects of evaluation observations and personal interactions during an evaluation;
- 3.4.2.4 treat concerned personnel in a way that will best achieve the evaluation objective;
- 3.4.2.5 react with sensitivity to the local conventions of the area in which the evaluation is performed;
- 3.4.2.6 perform the evaluation process without deviating due to distractions;
- 3.4.2.7 commit full attention and support to the evaluation process;
- 3.4.2.8 react effectively in stressful situations;
- 3.4.2.9 arrive at generally acceptable conclusions based on evaluation observations; and
- 3.4.2.10 remain true to a conclusion despite pressure to change that is not based on evidence.

ANNEX 4: Typical evaluation program of a Regional Group

1 Terminology

To avoid confusion the team leader used in the evaluation of a Regional Group is abbreviated as TL-R (sometimes the TL-R is also called evaluation manager). Team-members for evaluating a Regional Group are abbreviated as TM-R.

2 Considerations

It is the task of the TL-R to create a timetable for an evaluation of the Regional Group that allows for sufficient time to collect such information that confidence can be obtained in the evaluation process of all ABs that are signatory to a regional Arrangement to the extent that all signatories to the ILAC/IAF Arrangements can promote acceptance of results from CABs accredited by the signatory ABs of the evaluated region.

Evaluating a Regional Group on a fixed schedule and limited time frame is not sufficient to provide ongoing confidence in a required evaluation scheme. It is therefore necessary to introduce a two-step level of evaluation and witnessing/observing.

The evaluation process of a Regional Group consists of two separate tasks:

Task 1 involves the evaluation of the operations of the Regional Group secretariat and decision-making process.

Task 2 involves the ongoing collection and analysing of information gained from active participation in regional evaluations of ABs.

2.1 Task 1

For the evaluation of the secretariat, a team consisting of a TL-R and 1 to 2 TM-Rs (depending of the number of Arrangements handled by the secretariat) for 3 days should be sufficient. In addition, the TL-R or a designate should participate in at least one meeting of the Decision Making Group and/or Arrangement Management Committee (MC). The planning of such meetings and their frequency will determine the total duration of task 1.

2.2 Task 2 Ongoing monitoring

In consultation with the regional Arrangement secretariat the TL-R will select at least 2 evaluations, which collectively cover all MLA scopes of the regional group (preferably a mix of initial evaluations and re-evaluations) in which a TM-R as assigned by the TL-R or by the ILAC/IAF Arrangement MC could participate. Since the practise in a Regional Group may be to plan evaluations well ahead, the consultation should start early.

Effectively once a Regional Group is evaluated, the process of assigning TM-Rs is ongoing.

The task of the TM-R that is assigned to participate in the evaluation of the AB in the Regional Group under evaluation is a mixed one. On the one hand the TM-R is acting as a normal TM under the leadership of a TL of the Regional Group. The

amount of time involved is for this part the same as that described in annex 4 for the evaluation of single ABs. On the other hand the TM-R has to be observant during team discussions to gain insight in the team operations in the Regional Group. The TM-R has to write a brief report on these aspects. Such a task requires special skills from TM-Rs. It is recommended to use for this task only those persons who are qualified to act as TL in their own region.

2.3 Special aspects for new Region Groups

In addition to task 2, ongoing monitoring (item 2.2) for an initial evaluation of a Regional Group, the ILAC/IAF Arrangement MC may decide that witnessing by a Team Member may be necessary, in addition to the active participation by a Team Member in the Regional Group's evaluations.

2.4 Other factors

Factors that may influence the duration include:

- ♦ Need for interpreters and their effect on slowing down the evaluation
- ♦ Cultural differences in a region

3 Managing the evaluation

3.1 Preparation and planning

The time for the evaluators to spend on preparation largely depends on the quality of the documents that the Regional Group is forwarding. The documents that are required are specified in Annex 1. Accurate translation into English of the documents is essential. A complete document review is performed by the Team resulting in a report on conformity to the requirements. The Regional Group should be provided an opportunity to respond to the report before proceeding with the on-site evaluation.

3.2 On-site evaluation

An on-site visit typically consists of:

- ♦ Opening meeting, presentation by team leader outlining aims, objectives and procedure to be used by evaluation team
- ♦ Evaluation of the Regional Group secretariat and management system, including review of files and records
- ♦ Closing meeting to discuss the findings in the secretariat and discuss, if possible, the findings from participating in meetings of decision-making groups as well as to discuss the findings of the TM-Rs who participated in the evaluations
- ♦ Witness Assignments when performed before the on-site visit should be discussed at this occasion; otherwise they need to be incorporated into the final report.

Day/hours	Actions	Evaluators
4 hours	Preparation with the team	TL-R + 1/2 TM-R
8 -10 hours	Office, opening meeting + studying records (split team)	TL-R + 1/2 TM-R
8 -10 hours	Studying records (split team) + preparing evaluation report (office part) + closing meeting	TL-R + 1/2 TM-R

3.3 Activities separate from the on-site office evaluation

- ◆ Participation of TM-Rs in evaluations and reporting of those findings
- ◆ Participation of the TL-R or a designated person to attend the committee meetings, preferentially those where the decision will be taken on one or more of the evaluations in which a TM-R participated.
- ◆ Collecting corrective actions proposed by the regional secretariat and commenting on the proposals
- ◆ Preparing the final full evaluation report with opportunity for the Regional Group to comment.
- ◆ Amending the report and writing the recommendation to the ILAC/IAF Management Committee(s).

ANNEX 5: Evaluation Reporting on a Regional Group**A) Steps in Evaluation Reporting on a Regional Group**

- 1 Preparation of the Regional Group Headquarters Report** (including any nonconformities, concerns and comments presented in table format, and perhaps a completed checklist). This is completed and is preferably to be confirmed by the applicant at the end of the on-site visit to the regional body's headquarters or shortly thereafter.
- 2 Preparation of Reports on Witness Assignments by TM-R Participants in Regional Group Evaluations of Single Accreditation Bodies** (including any nonconformities, concerns and comments presented in table format, and perhaps a completed checklist). These reports are submitted to the Team Leader for compilation with a copy to the Regional Group Secretariat(s).
- 3 Compilation of the Secretariat and Witness Assignment Reports into an Intermediate Report** (compiling the intermediate report on the Regional Group, including nonconformities, concerns and comments presented in table format)
- 4 Response by the Regional Group to intermediate reports**
Ideally, the Regional Group's response can simply be inserted text under each finding presented in table format with attachments of supporting evidence of corrective action as appropriate. (see what is expected as to Regional Group's response and corrective actions described in c))
- 5 Preparation of Complete Report** (compiling the intermediate report including responses from the Regional Group and the team' counter-responses)
- 6 Formal Response of the Regional Group to the Findings**
- 7 Formal Reaction of the Team to this Response.** It is handed over by the team to the Regional Group for consideration.
- 8 Steps 5 and 6 may be repeated.**
- 9 Preparation of a Final Report to the ILAC and/or IAF MC(s).** This report consists of the items identified under steps 3, 4 and 5 (i.e, full report on the Regional Group, formal response of the Regional Group and formal team reaction). In addition, the final recommendation of the team is stated as the leading page of the team's final report. Items 4 and 5 should be combined into one table stating the nonconformities/concerns, the formal response of the Regional Group including corrective actions, and team's reaction. This will ease the review process of the MC(s) and the Decision-making Group(s).

B) Typical Structure and Content of a Full Evaluation Report on a Regional Group**0 Cover page**

The cover page states the type of evaluation, the name of the Regional Group that has been evaluated, time span of the evaluation, the name of the team leader, other team members and observers, specifying the organisation to which they belong, and a clear indication that the report is confidential.

1 Contents

For a full evaluation, a page giving the contents of the report including appendices.

2 Summary

For a full evaluation, the summary should include the name and type of Regional Group evaluated, the next steps in the process, proposed recommendations, and reference to the nonconformities, concerns and comments, see appendix below.

3 Introduction

The introduction should give the scope, content and reason for the evaluation, the participants, the criteria against which the evaluation was performed, activities undertaken during the evaluation including evaluations observed or participated in with dates and places identified.

4 Background on the Regional Group

This section should state the history and background of the Regional Group, including fields of accreditation covered, types of Arrangements, legal status, information on number of members, number of Arrangement signatories, number of peer evaluators, etc.).

5 Management of the Regional Group

This section should describe the management of the Regional Group and its compliance with section 2 of ILAC/IAF A1.

6 Consolidated Findings on Individual Evaluations Observed or on Active Participation in Regional Evaluation

(including report on the performance of peer evaluators of the Regional Group)

7 Reporting on Regional Group Decision-Making Process**8 Obligations of the Regional Group for Recognition by ILAC and/or IAF**

For re-evaluations, the steps taken by the Regional Group to implement the obligations of recognition by ILAC and/or IAF.

9 Appendices

9.1 Nonconformities, Concerns and Comments.

9.2 List of documents supplied before evaluation.

9.3 Evaluation programme (includes visit(s) to Regional Group headquarters, observation/participation in evaluations of single accreditation bodies and meeting(s) of the Regional Group Decision-making Group.

9.4 Organisation chart of Regional Group.

9.5 Declaration of confidentiality statement signed by all team members and observers.

Note: If reference is made to appendices in the narrative of the full report a clear indication to the specific appendix number that is referenced shall be included.

C) Guidance on Classification of Findings

Finding: To be used as a general term

Nonconformity: Finding where the Regional Group does not meet a requirement of any applicable standard(s), its own management system and the Regional Group requirements (ILAC-IAF A1) in a way that discredits its competence or jeopardizes the quality of its work.

The evaluated Regional Group is expected to respond to each nonconformity by taking appropriate corrective action and providing the team with evidence of implementation.

Concern: Finding where the Regional Group's practice may develop into a non-conformity or the team is not fully satisfied.

The evaluated Regional Group is expected to respond to a concern by providing the team with an appropriate action plan and time schedule or a clarification.

Comment: Finding about documents or Regional Group's practices with a potential of improvement; but still fulfilling the requirements. The evaluated Regional Group is not expected to respond to comments but may do so if it wishes.

ANNEX 6: Evaluation Summary Report for a Regional Group

Applicant:

Evaluation team:

Identification of the Full Report:

Evaluation sites and dates:

Applicant's secretariat:

AB evaluations involved:

Applicant's Decision-making Group meeting(s):

Scope of evaluation:

Applicant organisation

Areas of Arrangement(s):

Number of Arrangement signatories:

Number of members:

Organisational structure:

Decision making process:

Findings of the evaluation team (nonconformities and concerns and comments):

Conclusions:

Statements of closeout of nonconformities and concerns:

Unresolved issues:

Conclusion and recommendation:

ANNEX 7: Decision Making Regarding Evaluations of Regional Groups

1. Decision Making Regarding Evaluations

- 1.1** The evaluation report, the corrective actions and the recommendations of the team leader shall be submitted as the final report to the ILAC Arrangement Management Committee and/or IAF MLA Management Committee.
- 1.2** The ILAC Arrangement Management Committee and/or IAF MLA Management Committee develop a summary report for the respective Decision-making Groups of ILAC and IAF.
- 1.3** The appropriate Decision-making Group(s) shall decide:

in the case of an initial evaluation, whether or not the Regional Group be recognized;

in the case of a re-evaluation, whether or not the Regional Group will remain recognised under the appropriate Arrangement(s). Positive decisions can be accompanied by conditions (see 2.0 Hierarchy of Decisions).

NOTE 1 The Decision- making Group may decide to carry out a re-evaluation, partly or totally prior to the normal 4-year period. Normally this would be the case after initial evaluations or fundamental re-organisations.

NOTE 2 For voting rules see the By laws of ILAC and IAF.

2. Hierarchy of Decisions

- 2.1** Decisions made as a result of peer evaluations of Regional Groups can take many forms. Implicit in these decisions is the possibility of a variety of "sanctions". This guidance outlines a hierarchy of the major types of decisions from the most positive decision to the least positive decision (i.e., conditions or sanctions of increasing severity are imposed).
- 2.2** Decisions on new Regional Groups applicants are made by either or both of the decision-making bodies of ILAC and IAF. Decisions on the on-going re-evaluations of recognised Regional Groups also reside with the respective Decision-making Group(s). This becomes a prerequisite for signatories to the Arrangement of recognised Regional Groups to attain and maintain status as signatories to the respective ILAC and/or IAF Arrangements.¹
- 2.3** The ILAC Arrangement Council and IAF MLA Group make all decisions on Arrangement(s) of a Regional Group. There are primarily two situations to address: *New Applicant Regional Groups* and *Recognized Regional Groups*. A third situation that is not addressed below is the possibility of adverse decisions or sanctions imposed on a recognized Regional Group which fails to abide by its obligations for recognition.

¹ Provided that ILAC/IAF dues are paid and other obligations are fulfilled

2.4 Decisions on New Applicant Regional Groups:**2.4.1** Approval without conditions (re-evaluation to occur 4 years hence)**2.4.2** Approval with conditions (e.g., shortened interval for re-evaluation)**2.4.3** Defer approval pending submittal of required evidence of corrective actions and/or re-visit by one or more members of the evaluation team to confirm implementation of corrective actions**2.4.4** Disapproval with a new evaluation required²**2.5** Decisions on Recognized Regional Groups:**2.5.1** Approval without conditions (re-evaluation to occur 4 years hence)**2.5.2** Approval with conditions (e.g., shortened interval for re-evaluation)**2.5.3** Defer re-approval pending submittal of required evidence of corrective actions and/or re-visit by one or more members of the evaluation team**2.5.4** Reduction of recognition for one or more types of Arrangements**2.5.5** Withdrawal of Regional Group recognition (subject to Appeals Process)(a new application and evaluation of the Regional Group would be required to reinstate recognition)(Re-evaluation of signatories of the formerly recognised Regional Group would become the responsibility of ILAC and/ IAF).

² Disapproval for New Applicant Regional Groups should rarely happen since an evaluation report is only submitted for a decision once a consensus of the Evaluation Team and the ILAC Arrangement Management Committee or IAF MLA Group has concluded that all requirements have been met.

ANNEX 8: Monitoring and Re-Evaluation of a Regional Group

1. Periodic monitoring and re-evaluation of the Regional Group is necessary (see also Annex 4).
2. All recognised Regional Groups shall be formally re-evaluated at maximum intervals of four years. The re-evaluation will normally start three years after the initial or continuing decision of recognition is taken.
3. The Regional Group under re-evaluation shall provide the evaluation team with all the documents which are required for an initial evaluation (see Annex 1, Chapter 21). In addition, the evaluation team shall get the full evaluation report from the last evaluation (re-evaluation) or any special evaluation.
4. Partial to total re-evaluation may be conducted at an earlier date as directed by ILAC/IAF decision-making bodies, should there be due cause such as notification of significant changes in administration, finances, operational practices or an extension in the scope of recognition available.
5. Monitoring of changes notified by a recognised Regional Group shall be appropriately examined.
6. Re-evaluation visits should be led by a team leader other than the one who led the previous evaluation.
7. On going joint evaluations to maintain confidence in the regional evaluations are conducted and reported on as agreed to by the Decision-making Group

ANNEX 9: Appeals**1 Scope**

This Annex describes the procedures for appeals, to ensure that matters related to the MLA are settled objectively and impartially.

2 Handling of appeals

- 2.1** When an applicant Regional Arrangement Group or Signatory to the Arrangement Group does not agree with the decision it may appeal in writing to the ILAC and/or IAF Secretariat.
- 2.2** After authentication of the appeal, the ILAC and/or /IAF Secretariat shall inform the ILAC/IAF Chairmen, who will, in conjunction with the Chairman of the MC, appoint an Appeals Panel comprising two impartial full members of ILAC/IAF and one ILAC/IAF evaluator from outside the applicant Regional Arrangement Group to investigate the appeal.
- 2.3** No member of the Appeals Panel shall have been involved in the peer evaluation team that evaluated the appellant, or have a direct interest in the subject of the appeal, in any form. The ILAC/IAF Chairmen shall ensure that the composition of the Appeals Panel satisfies the requirements of objectivity and impartiality and no conflict of interests exists.
- 2.4** The appellant has the right to object to the appointment of any member of the Appeals Panel for valid reason(s). The Chairmen, in conjunction with the MC, shall make a decision on any objection by the appellant to an appointment. That decision shall be final.

3 Recommendation and decision

- 3.1** The Appeals Panel shall decide its recommendation on the appeal and inform the Chairmen, the Management Committees and the appellant, in writing, of the recommendation not later than five (5) business days after the date of decision.
- 3.2** The Management Committees shall forward the recommendation to the Arrangement Group for a decision.
- 3.3** That decision shall be final.

ANNEX 10: Maintenance, suspending and withdrawal of Regional Groups**1 Notification of change**

1.1 Each regional Arrangement Group member shall report any significant changes in its status and/or its operating practices (e.g. as listed below) without delay to all Arrangement Group members through the Management Committee.

- ◆ Legal status;
- ◆ Management personnel;
- ◆ Contact person or liaison officer for the Arrangement;
- ◆ Operational Arrangement program;
- ◆ Criteria and procedures, related to the Arrangement;
- ◆ Office address (and postal address, if different), including head office and any offices;
- ◆ Other changes that significantly affect the competence or credibility of the regional group.

1.2 The Regional Arrangement shall notify the ILAC and/or IAF Secretariats without delay of any significant changes that have occurred or will occur in its status. The Regional Arrangement shall report to the Secretariats on new members and/or withdrawal of existing members of its Regional Arrangement and provide information on new members as required by the Secretariat. The Regional Arrangement shall inform the Management Committees about the results of evaluations and re-evaluations including providing access to the evaluation reports on request, as well as the plan for future evaluations within this Regional Arrangement.

1.3 The regional Arrangement shall give an annual update to the Management Committees for consideration of the changes and, if necessary, for recommendation to the Arrangement Group. The Arrangement Group shall be informed about the annual updates of the regional Arrangement.

2. Maintenance, suspension and withdrawal

- 2.1** It may be that the Management Committee cannot accept the significant changes notified by a Regional Group or the corrective action taken by a regional Arrangement Group or major nonconformities which have been found or substantiated complaints from interested parties. The Management Committee shall report the situation to the Arrangement Group with a recommendation and ask the MLA Group to take appropriate action. This action can be suspension for a maximum period of 6 months or withdrawal from the Arrangement Group.
- 2.2** Maintenance, suspension or withdrawal of a recognised Regional Arrangement Group shall be decided by the ILAC and/or IAF Arrangement Group after receipt of the recommendation by the Management Committee in accordance with the same procedures used for acceptance of a Regional Arrangement Group. Any suspension or withdrawal decided by ILAC and/or IAF Arrangement Group shall be accompanied by an appropriate explanation stating the reason for suspension or withdrawal to the regional group.
- 2.3** The suspended or withdrawn regional group may appeal the decision in accordance with Annex 9.
- 2.4** If the regional group is suspended the regional group must inform its recognized signatories and applicants that their signatory status will remain unchanged during the suspension period. Any new signatory and applicant to regional Arrangement during the suspension period are not covered by the Arrangement and not recognized by ILAC/IAF.
- 2.5** If the recognition of the regional group is withdrawn the regional group has to inform all applicant and members of the regional MLA that the regional group and its members are no longer accepted under the ILAC/IAF Arrangement and shall no longer make reference to the ILAC/IAF Arrangement.
- 2.6** When a withdrawn regional group applies to become a recognized cooperation again, the procedure for new applicants must be followed.