



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

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PREAMBLE

The international accreditation community comprising Regional Groups, recognized accreditation bodies, and their stakeholders cooperate through the International Accreditation Forum, Inc. (IAF) and the International Laboratory Accreditation Cooperation (ILAC). A principal objective of IAF and ILAC is to put in place world-wide, multi-lateral Mutual Recognition Arrangements (Arrangements). Both IAF and ILAC aim to demonstrate the equivalence of the operation of the recognized Regional Groups and 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.

IAF and ILAC are linking the existing Arrangements of the Regional Groups (also called regional accreditation cooperations or regional cooperations) and are encouraging the development of new Regional Groups to complete world-wide coverage. For the purposes of their Arrangements, both IAF and ILAC 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 IAF and ILAC Arrangements in that territory. Formal “Recognition” of a Regional Group with respect to the IAF and ILAC Arrangements is based on an external evaluation of the Regional Group’s competence in mutual recognition Arrangement management, practice and procedures by an evaluation team composed of regional evaluators from other IAF and ILAC Member Regional Groups and accreditation bodies.

Evaluation relating to the development and maintenance of the IAF and ILAC 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 IAF and ILAC when evaluating the competence of a Regional Group in managing, maintaining, and extending a regional mutual recognition Arrangement for the purposes of IAF and ILAC Recognition are set out in the following chapters of this document.

PURPOSE

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

AUTHORSHIP

This publication was prepared by a joint IAF/ILAC working group on Harmonization of Peer Evaluation Processes and endorsed for publication by the respective General Assemblies of IAF and ILAC in 2004 and reviewed by a joint IAF/ILAC working group on maintenance of A-series documents first in 2006 and next time in 2009.

This latest revision was endorsed by letter ballot in IAF and ILAC in 2010.

SECTION 1: Introduction**1.1 Scope**

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

1.2 Definitions

For the purpose of this document the following definitions apply:

- 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 *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.
- 1.2.3 *Arrangement*: The IAF Multilateral Recognition Arrangement (MLA) or ILAC Mutual Recognition Arrangement (MRA). The term can also refer to the Arrangements of recognized Regional Groups which pre-date the establishment of the IAF and ILAC Arrangements and which, as a consequence of the recognition process, will be accepted as a subset of the IAF and ILAC Arrangements.
- 1.2.4 *Arrangement Group*: All signatories to an Arrangement (In IAF: MLA Group; In ILAC: Arrangement Signatories).
- 1.2.5 *Decision Making Group*: A body that decides on the status of membership of an Arrangement. (In IAF: MLA Group; In ILAC: Arrangement Council).
- 1.2.6 *Evaluation Team Leader (TL)*: A person responsible for leading an Arrangement peer evaluation team in the evaluation of an accreditation body.
- 1.2.7 *Evaluation Team Member (TM)*: A person serving on an Arrangement peer evaluation team in the evaluation of an accreditation body.
- 1.2.8 *ISO/IEC Standard*: An ISO/IEC standard, guide or technical report related to accreditation and conformity assessment.
- 1.2.9 *Management Committee (MC)*: A small member group responsible for the everyday management of the Arrangement process (In IAF: IAF MLA MC; In ILAC: ILAC AMC.)

- 1.2.10 *MC Secretariat*: Secretariat for the Management Committee (In IAF: IAF MLA MC Secretariat; In ILAC: ILAC Secretariat).
- 1.2.11 *Peer Evaluation*: A structured process of evaluation of a Regional Group or accreditation body by representatives of accreditation bodies.
- NOTE: In ISO/IEC 17040, instead of peer evaluation, the term peer assessment is used and is defined slightly differently.*
- 1.2.12 *Regional Arrangement Group*: All signatories to an Arrangement of a Regional Group.
- 1.2.13 *Regional Evaluation Team Leader (TL-R)*: A person responsible for leading a team in the evaluation of Regional Group.
- 1.2.14 *Regional Evaluation Team Member (TM-R)*: A person serving on a team to evaluate a Regional Group.
- 1.2.15 *Regional Group*: A regional cooperation body member of IAF and/or ILAC. This term can also refer to a group of accreditation bodies (possibly involving other stakeholders) whose purpose is to develop and maintain an Arrangement and are a group of different accreditation bodies representing different economies.
- 1.2.16 *Signatory*: A Member of IAF and/or ILAC who has signed one or more of the Arrangements of a Regional Group or has signed the IAF and/or ILAC Arrangement.

SECTION 2: Requirements for Regional Groups**2.1 Regional Group - General**

- 2.1.1 The Regional Group shall define the scopes of its Arrangement.
- 2.1.2 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.
- 2.1.3 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 IAF and ILAC.
- 2.1.4 The Regional Group shall:
- 2.1.4.1 identify the management which will have overall responsibility for each 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.
- 2.1.4.2 ensure that each decision on the acceptability of an applicant to sign the Arrangement is taken by persons representing all Arrangement Signatories.

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 parts 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 work 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:
- Mission, policies, and objectives;
 - Organization chart and description of the organization;
 - Procedures for peer evaluation of a single accreditation body that are consistent with those specified in IAF/ILAC A2 and its relevant annexes;
 - Conduct of internal audits and management reviews;

- Control of documents;
- Selection, training, qualification and monitoring of Peer Evaluators;
- Records related to Peer Evaluation;
- Arrangements for ensuring confidentiality of Peer Evaluation information;
- 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; and
- Policy and procedure for suspension, including the subsequent actions by the Regional Group and the consequences of suspension.

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) upon request;
- 2.3.1.1 information about the Peer Evaluation and MRA/MLA recognition process;
 - 2.3.1.2 requirements, restrictions or limitations on ways the signatories of the Regional Group's Arrangements(s) can refer to that recognition and to the accreditation body's signatory status;
 - 2.3.1.3 information on how to submit complaints and appeals;
 - 2.3.1.4 information on Arrangement Signatories describing the scope of recognition of each signatory.
- 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. For all documents describing the performance of any function related to the activities of Arrangement applicants and Arrangement signatories, the distribution shall be controlled to ensure that the appropriate issue is made available to Arrangement applicant and signatories and to personnel of the Regional Group.

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 signatories of the Arrangement Group. Declarations of confidentiality shall be signed by all persons before being given access to confidential information, including:
- all members and observers of the regional evaluation teams;
 - all members, observers and secretariat personnel of the MC and (where relevant) the Appeals Panels;

- 2.4.2 All applicants and signatories of the Arrangement Group who request or are given access to any report on pre-evaluation, evaluation and re-evaluation of other applicants and members; other persons having access to confidential information.
- 2.4.3 The Regional Group under evaluation shall advise the regional team members how to treat the documents it has provided. This advice may require the regional team members to:
- return all documents to the Regional Group; 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 evaluations 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, clauses 3.2 – 3.4 in IAF/ILAC A2.

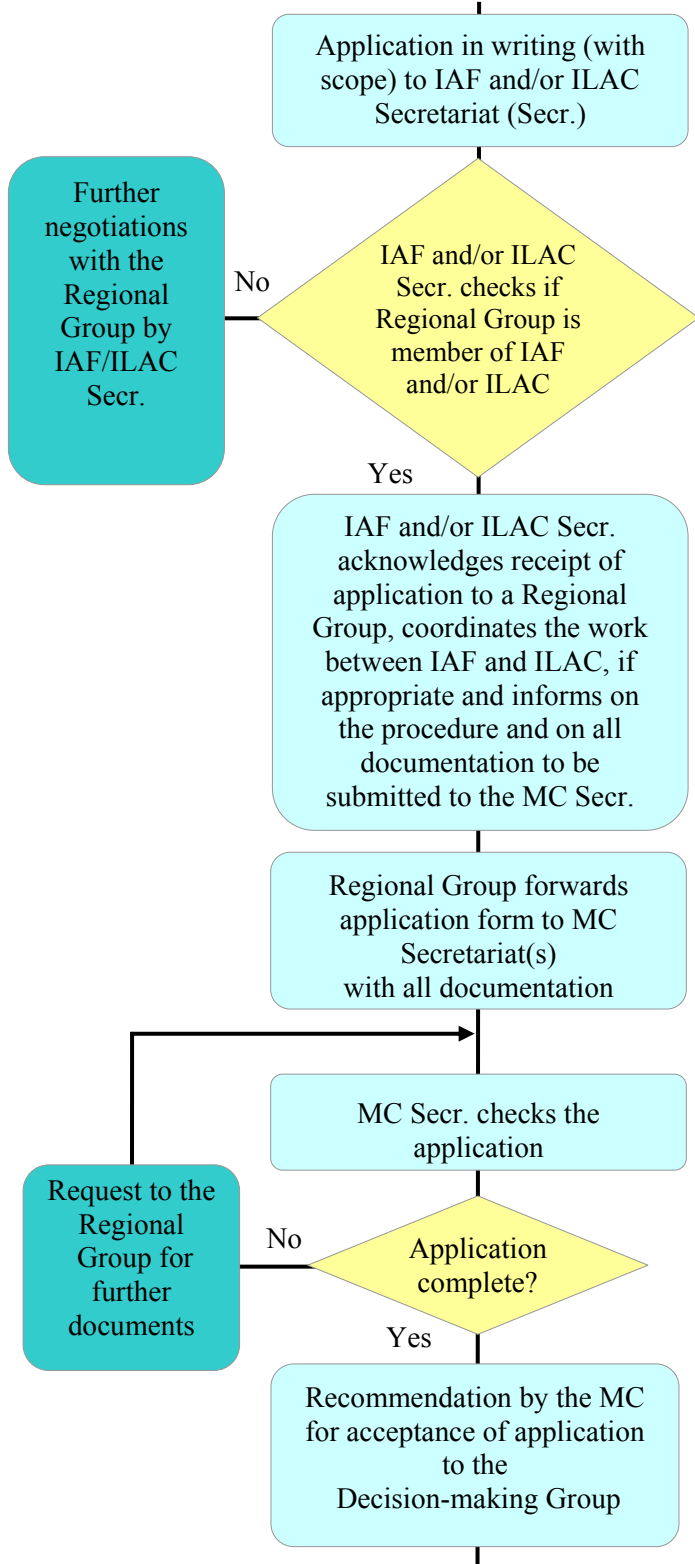
2.6 Other obligations

- 2.6.1 The Regional Group shall effectively implement tasks assigned to it by IAF and/or ILAC.
- 2.6.2 The Regional Group shall have a program 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 made to the peer evaluation criteria and to 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 continually fulfil the obligations in IAF/ILAC A2.

- 2.6.7 The Regional Group shall periodically report technical activities to support continuing demonstration of equivalence within the Regional Group and between Regional Groups, such as proficiency testing or interlaboratory comparisons (see Annex 9).
- 2.6.8 See obligations in Annex 10.

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

I. Application for Arrangement Membership

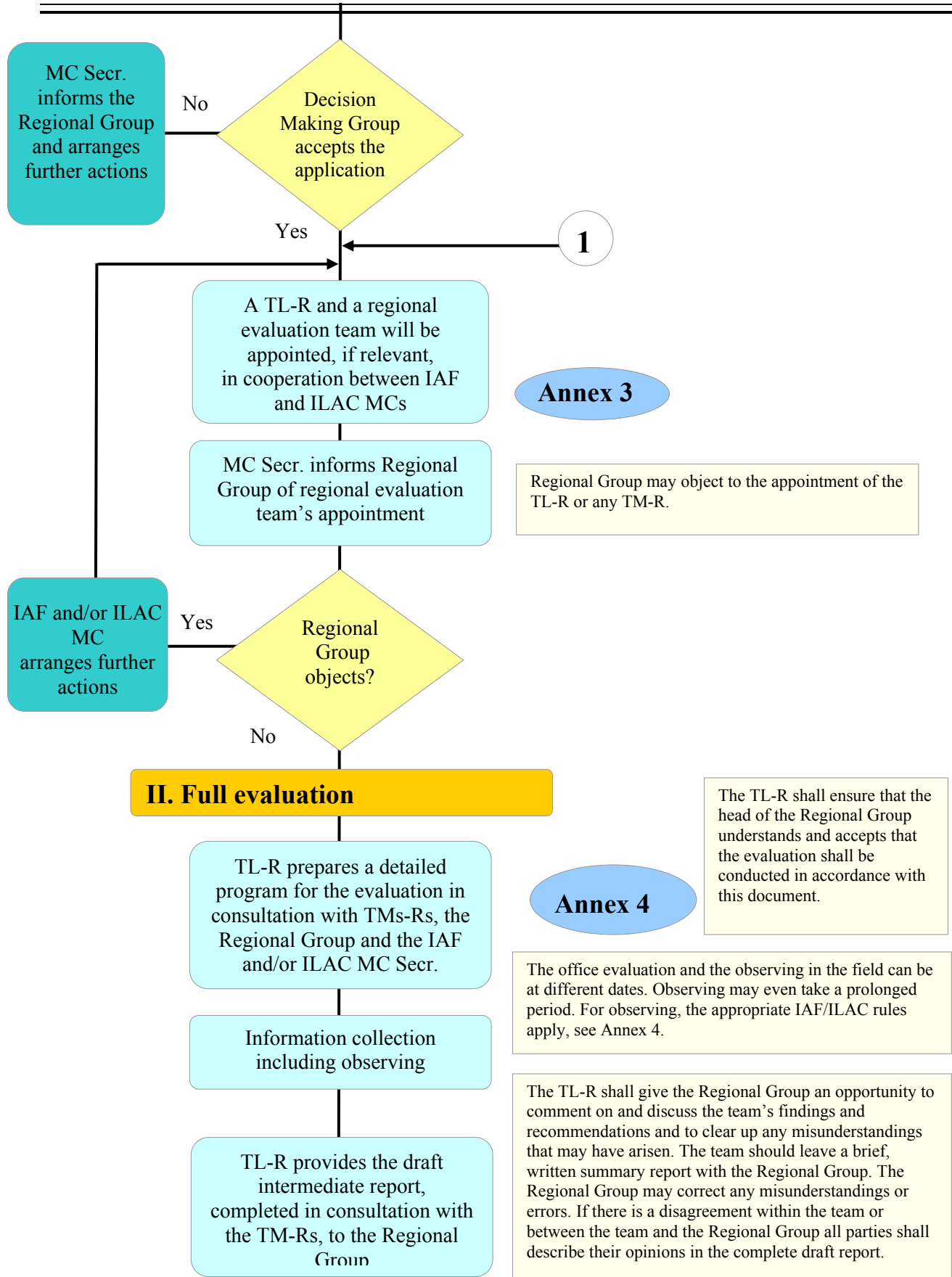


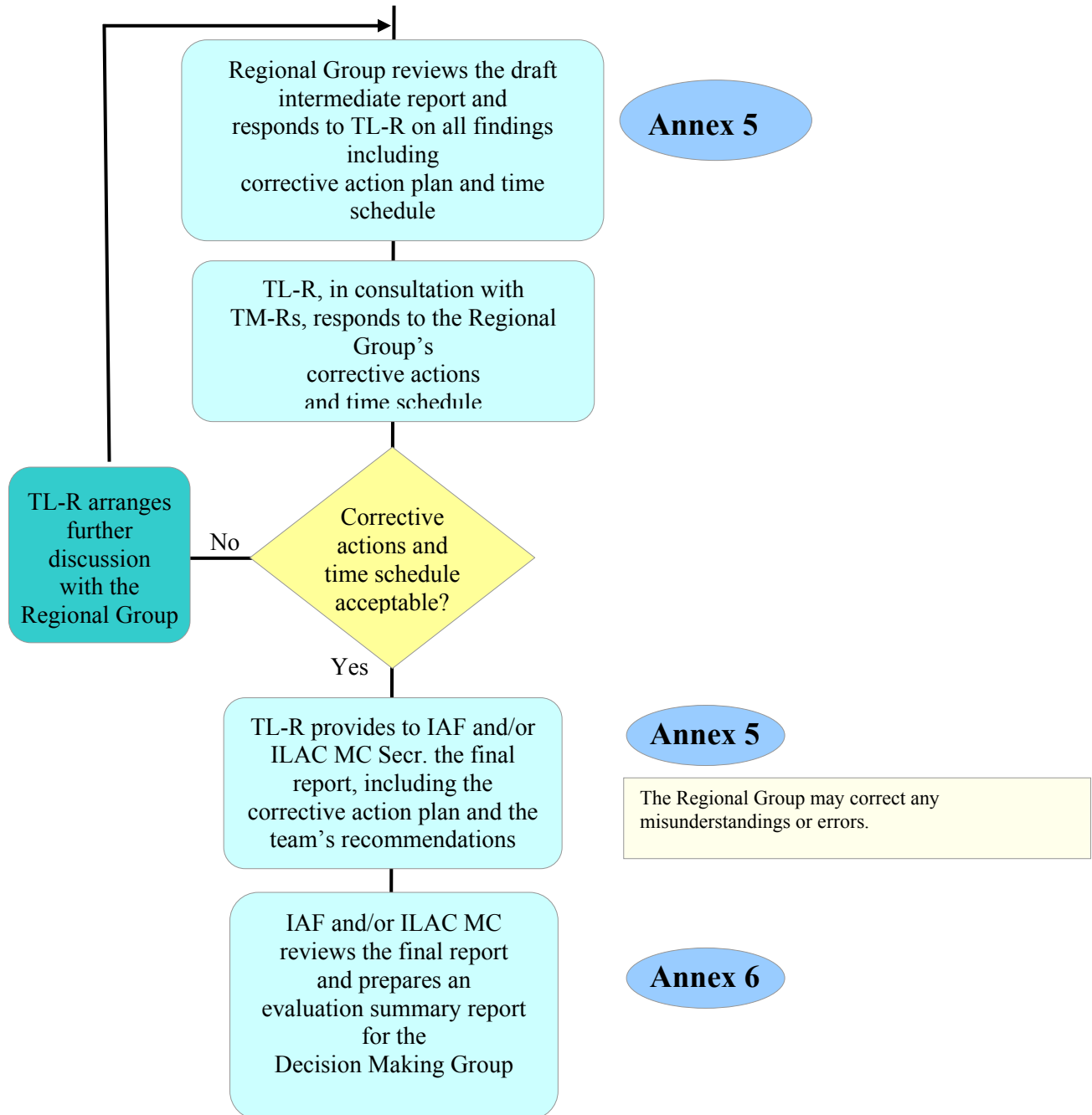
Conditions for application:

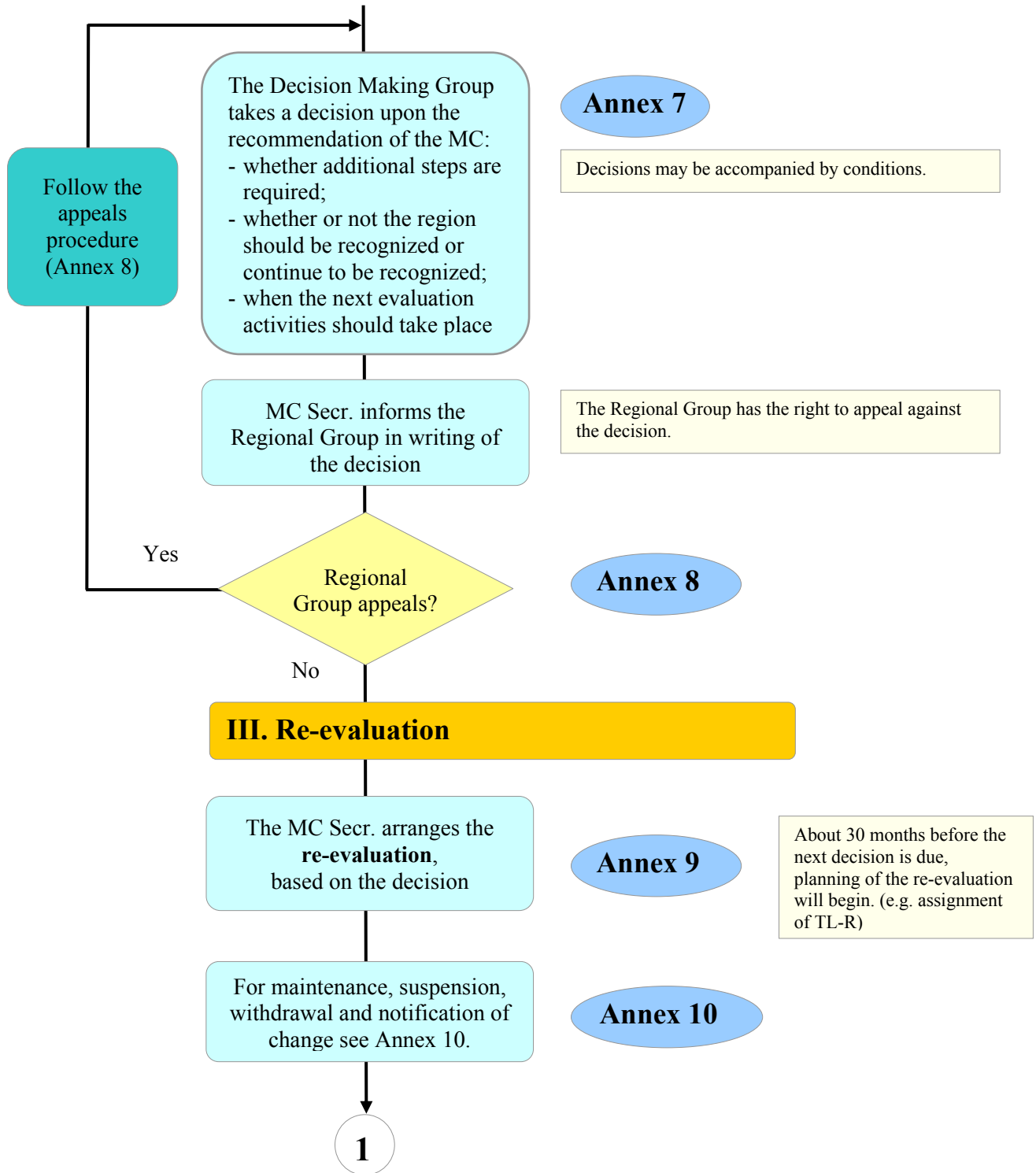
1. Availability of sufficient evidence to demonstrate that the Regional Group’s activities for implementing and maintaining an Arrangement of at least 3 members have been implemented, are effective, and are being maintained.
Note: For extensions to the scope of recognition, each application will be treated on a case by case basis.
2. The Regional Group shall fulfil the criteria for the Membership of IAF and/or ILAC and, having studied the documented evaluation procedures/criteria, indicate its familiarity with the Arrangement requirements and procedures.
3. The Regional Group shall demonstrate the implementation of the IAF and/or ILAC requirements.
4. The Regional Group agrees to pay for the hotel costs, meals and all travel costs of the regional evaluation team.
Travel shall be normally done in economy class unless the continuous flight time exceeds nine hours. Then the Regional Group may specify the flight conditions.
The observers and trainees pay all of their own costs.

Annex 1

Annex 2







ANNEX 1: Application of a Regional Group to join the Arrangement**1. Please select the Arrangement scope(s) being applied for:**

- Accreditation of Testing Laboratories (Test)(ISO/IEC 17025; ISO 15189)
- Accreditation of Calibration Laboratories (Cal) (ISO/IEC 17025)
- Accreditation of Inspection Bodies (Insp.) (ISO/IEC 17020)
- Accreditation Management Systems (ISO/IEC 17021)
- QMS
- EMS
- ISMS
- FSMS
- Accreditation of Product Certification Bodies (Product) (ISO/IEC Guide 65)
- Accreditation of Person Certification Bodies (Persons) (ISO/IEC 17024)

2. Name of Regional Group (applicant):**3. Address**

3a Regional Group Secretariat Office Street Address: Postal Address (if different):	3b. Arrangement Secretariat Office Address (if different from Regional Group Secretariat Office) Postal Address (if different)
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4. Name of region:**5. List of economies covered:****6. Name of applicant contact person:****7. Position of contact person:****8. Telephone no. (including country code):****9. Facsimile no. (including country code):****10. E-mail address:****11. Legal status of applicant:**

12. History of the applicant (date of establishment; relevant background):

13. Applicant's relationship with its regional economic and/or political entities, if any:

Please answer the following questions for the scope in which the applicant is seeking recognition under the respective Arrangement.

	Test 17025/15189	Cal	Insp.	Management systems QMS/EMS/ISMS/FSMS				Product	Persons
14. Date of initial signing of the applicant's Arrangement for the scope(s) for which recognition as a Regional Group is sought									
15. Number of Arrangement signatories for each of the applicable scope(s) (attach a list of the names of the Arrangement signatories in each scope or a link to the database on the internet, if any)									
16. Preferred month and year, for initial evaluation									

17. Please list all other operational scope(s) of the Regional Group's Arrangement.

18. Please send electronically one (1) copy of each of the following documents (in English translation if not written originally in English)

- 1 a table that cross-references the Regional Group's management system documentation to the requirements of IAF and/or ILAC (as set out in this document);
- 2 the Regional Group's constitution (by whatever name);
- 3 a statement of the legal status of the Regional Group;

- 4 requirements for membership of the Regional Group and of its Arrangement;
 - 5 text of the Regional Group's Arrangement and the list of signatories to the Arrangement and their scope(s) of recognition;
 - 6 procedures for granting, maintaining and suspending membership of the Regional Group's Arrangement;
 - 7 procedures for the management of the Regional Group's Arrangement;
 - 8 terms of reference of the Regional Group's Arrangement Management Committee (by whatever name); minutes of the last three meetings of that Committee;
 - 9 list of mandatory documents to be implemented by applicants to the Regional Group's Arrangement and a list of documents recommended for use;
 - 10 procedures for the selection, training and monitoring of evaluators (lead evaluators, evaluators, etc);
 - 11 current list of all evaluators;
 - 12 current evaluation schedule.
- 19. Other information related to the Regional Group's Arrangement (e.g. other activities of the applicant, Arrangements, relationships with other bodies).**
- 20. Please complete the Declaration on the following page and proceed with item 21.**

Declaration

As a Regional Group applying for recognition by IAF and/or ILAC, the applicant,

_____, duly represented by the undersigned:
Name of applicant

- ◆ Accepts the current joint IAF/ILAC procedures for evaluation for Regional Groups;
- ◆ Accepts the respective requirements and agrees with the terms of the Arrangement(s);
- ◆ Confirms that the operations of the applicant comply with IAF and/or ILAC requirements;
- ◆ Submits the completed application; and
- ◆ Applies to become a Recognized Regional Group.

Contact person's name and contact details

Contact person's position

Date

Signature

21. Please send your completed application (items 1 to 17 and 19), along with all requested documents (item 18), and the signed and dated Declaration (item 20):

for IAF Arrangement:

BOTH TO

IAF Secretariat

P.O. Box 819
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Email: ilac@nata.com.au

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:**

Has the Regional Group provided all information required in the application form (Annex 1): Yes / No

Have all the following documents in English been supplied:

- | | |
|---|----------|
| - Regional Group constitution: | Yes / No |
| - Statement on its legal status: | Yes / No |
| - Requirements for Arrangement Membership: | Yes / No |
| - Text of the regional Arrangement, list of regional Arrangement signatories and their scopes of recognition: | 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 TMs: | Yes / No |
| - Cross-reference table between appropriate IAF and/or ILAC requirements and the Regional Body's management system documentation: | Yes / No |
| - List of TLs and TMs: | Yes / No |
| - Schedule indicating status of peer evaluation visits: | Yes / No |

6. Other observation 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

Date

Name and position

ANNEX 3: Requirements for the qualifications and personal attributes of regional evaluation team leaders and members, and appointment and composition of regional evaluation teams**1. Appointment and duties of the regional evaluation team leader**

- 1.1** In appointing a regional evaluation team leader (TL-R) for a specific evaluation, the IAF and/or ILAC MCs should not appoint the same TL-R for two successive evaluations of the same applicant.

NOTE: It is normal practice that regional evaluators are appointed from as many IAF and/or ILAC members as possible.

- 1.2** TL-R shall be approved and chosen from a list of TLs prepared and kept up-to-date by the MC on the basis of the TL names and their qualifications provided by the Regional Groups or unaffiliated IAF/ILAC members. This list should record the scope of experience of the TLs. The minimum qualifications of TL-R shall be as described in clause 3.2.
- 1.3** The TL-R shall have ultimate responsibilities for all phases of the evaluation and is delegated authority by the IAF and/or ILAC MC to make final decisions regarding the conduct of the evaluation.
- 1.4** The IAF and/or ILAC MCs shall arrange periodic training for TL-Rs in order to improve and maintain the harmonization of the regional evaluations.

2. Composition of the regional evaluation team

- 2.1** For the full regional evaluation visit, members of the regional evaluation team shall be chosen as needed to cover the types of accreditation, and size and complexity of the Regional Group under evaluation.
- 2.2** Regional evaluation team members (TM-Rs) shall be approved and chosen from a list of TM-Rs prepared and kept up-to-date by the MC on the basis of the TL and/or TM names and their qualifications provided by the regions or unaffiliated bodies. This list should record the scope of experience for the TM-R. The minimum qualifications of TM-Rs shall be as described in clause 3.3.
- 2.3** The regional evaluation team (including the TL-R) chosen shall consist of representatives from a cross-section of Regional Groups and/or unaffiliated IAF and/or ILAC members. The regional evaluation team shall be chosen to provide a balanced set of skills so as to be able to conduct an effective evaluation of the key components of the system under examination.
- 2.4** No team member shall have provided consultancy to the Regional Group under evaluation within three years prior to the evaluation.

NOTE 1 There should be no more than one member from each accreditation member body represented in the regional evaluation team.

NOTE 2 The TM-Rs should have working knowledge of the English language. Knowledge of the local language should be taken into account.

NOTE 3 Some of the TM-Rs may have as their only task the observing of peer evaluations at different geographical places or at different times than the rest of the team. In the case of observing joint peer-evaluations, a TM-R should not observe a person from the same region.

3. Requirements for Qualifications of Regional Peer Evaluators

3.1 Selection of Regional Evaluators

- 3.1.1 The IAF and/or ILAC MC shall approve and oversee the performance of regional evaluators in accordance with the criteria in the following sections.
- 3.1.2 The Regional Groups and unaffiliated IAF and/or ILAC members may nominate regional evaluators (i.e., TL-R and TM-R) in writing, including a description of their experience and the scope covered by each proposed regional evaluator to the IAF and/or ILAC MC.

3.2 Regional evaluation team leaders

- 3.2.1 A TL-R shall meet the requirements of ILAC/IAF A2, Annex 3, clauses 3.2 and 3.4 and:
 - 3.2.1.1 have successfully participated in at least three peer evaluations of accreditation bodies as a TL and have attended at least two decision making meetings at the regional/international level;
 - 3.2.1.2 have knowledge of the application of IAF and/or ILAC requirements that apply to Regional Groups; and
 - 3.2.1.3 be able to understand and to express himself/herself clearly, in spoken and written English.

3.3 Regional evaluation team members

- 3.3.1 A TM-R shall meet the requirements of IAF/ILAC A2, Annex 3, clauses 3.3 and 3.4, and be able to evaluate whether a Regional Group complies with the requirements of this document (IAF/ILAC A1).
- 3.3.2 A TM-R shall be an experienced person within an accreditation body who has relevant working experience with accreditation and shall be a TL or have been a TM in two accreditation body peer evaluations. In case the TM-R is tasked with observing a meeting of the Decision Making Group, the TM-R shall have attended at least one decision making group at the regional/international level.

3.4 Regional evaluator attributes

- 3.4.1 Regional Evaluators shall meet the requirements of IAF/ILAC A2, Annex 3, clause 3.4.

ANNEX 4: Typical evaluation program of a Regional Group

1. Introduction

The task of an evaluation of a Regional Group is to collect sufficient information about the evaluation and decision-making processes of the Regional Group to have confidence in the results from conformity assessment bodies (CABs) accredited by signatory accreditation bodies of the Regional Group.

It is the task of the TL-R to create a timetable (in a timely manner) prior to the evaluation of the Regional Group that allows sufficient time to collect information for obtaining such confidence.

The evaluation process of a Regional Group involves the evaluation of the operations of the Regional Group Secretariat and decision-making process, and the collection and analysis of information gained from observing evaluations of accreditation bodies done by the Regional Group.

2. Evaluation program

2.1 The process for the initial evaluation of a Regional Group

A regional evaluation team of at least two persons, depending on the number of scopes of Arrangements handled by the Regional Group Secretariat (one of whom shall be the TL-R) shall be appointed by the relevant MC. This regional evaluation team shall evaluate the region to ensure it complies with the requirements of IAF/ILAC A1. The regional evaluation team will also ensure the region follows the requirements of IAF/ILAC A2 in undertaking evaluations of accreditation bodies.

For the evaluation of the Regional Group Secretariat three days should be sufficient. The regional evaluation team shall also observe at least three evaluations done by the region. These shall be evaluations that collectively encompass the scopes of the Arrangement applied for by the region.

In addition, the TL-R or a designate shall observe at least one meeting of the Decision Making Group, preferably involving the decision making for an observed evaluation. The planning of such meetings and their frequency will determine the total duration of the evaluation.

2.2 The process for the re-evaluation of a recognized Regional Group

A regional evaluation team of at least two persons, depending on the number of scopes of Arrangements handled by the Regional Group Secretariat (one of whom shall be the TL-R) shall be appointed by the relevant MC. This regional evaluation team shall re-evaluate the region to ensure it continues to comply with the requirements of IAF/ILAC A1. The regional evaluation team will also ensure the region follows the requirements of IAF/ILAC A2 in undertaking evaluations of accreditation bodies.

For the evaluation of the Regional Group Secretariat two days should be sufficient.

The regional evaluation team shall, in consultation with the region being evaluated, select at least two evaluations to observe. As far as practicable, these should be evaluations of full scope accreditation bodies. Such observations should occur as closely in time as possible (preferably less than six months apart).

During this process the regional evaluation team shall also evaluate a meeting of the Decision Making Group preferably involving the decision making for an observed evaluation.

2.3 Other factors

Factors that may influence the duration of the evaluation of the region include:

- Need for translators;
- Extensive travel and travel circumstances; and
- Cultural differences in a region.

3. Managing the regional evaluation

3.1 Preparation and planning

The time for the regional evaluators to spend on preparation largely depends on the quality of the documents that the Regional Group provides. The documents that are required are specified in Annex 1. Accurate translation of the documents into English is essential. A complete document review is performed by the regional evaluation 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 evaluation of the Regional Group Secretariat.

The TL-R shall provide a copy of the proposed timetable for the evaluation of the Regional Group Secretariat in a timely manner prior to the visit.

NOTE: It is preferable to perform the evaluation of the Regional Group Secretariat before any observing.

3.2 Evaluation of the Regional Group Secretariat

The visit to the Regional Group Secretariat typically consists of:

- Opening meeting, presentation by TL-R outlining aims, objectives and procedure to be used by the regional evaluation team;
- Evaluation of the Regional Group's management system and administration of the Arrangement, including review of files and records;
- Closing meeting to present a brief written summary report, and discuss findings (both confirmed and provisional) with the Regional Group Secretariat; and
- Observation of Decision Making Groups. When performed before the Regional Group Secretariat visit, the observations should be discussed at this occasion; they need to be incorporated into the final report, as well.

Hours Scheduled	Actions	Evaluators
4 hours	Preparation with the regional evaluation team	TL-R + 1 TM-R
8 -10 hours	Office, opening meeting + studying records (split regional evaluation team)	TL-R + 1 TM-R
8 -10 hours	Studying records (split regional evaluation team) + preparing brief summary report and the list of findings (office part) + closing meeting	TL-R + 1 TM-R

3.3 Additional activities

In addition, the following activities shall be accomplished by the TM-Rs or TL-R:

- Observing by TM-R of evaluations by the region and reporting the observations and any findings to the rest of the regional evaluation team as soon as possible;
- Observing by the TL-R or TM-R of Decision Making Group meetings, preferably those where the decision will be taken on one or more of the evaluations observed by a TM-R;
- Reviewing corrective actions proposed by the Regional Group and commenting on the proposals;
- Preparing the final full evaluation report with opportunity for the Regional Group to comment; and
- Amending the report and writing the recommendation to the IAF and/or ILAC Management Committee(s).

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

- 1 Preparation of a brief written summary report**, including as an appendix, the non-conformities, concerns and comments presented, preferably in a table format, on the evaluation of the Regional Group Secretariat provided to the Regional Group being evaluated at the closing meeting.
- 2 Preparation of the Regional Group Secretariat visit report** (with the nonconformities, concerns and comments) within 2 months after closing the Regional Group Secretariat visit.
- 3 Preparation of reports on observation assignments with findings (confirmed and provisional)**

The reports on the observed evaluations shall include:

- (1) oral report to the TL-R at the end of the evaluation, if possible;
 - (2) written report of the findings, to the TL-R and the Regional Group Secretariat within two weeks of the evaluation for review by the region, followed by a written report of the observation within 2 months. These reports are submitted to the TL-R for compilation and forwarding to the Regional Group Secretariat(s).
- 4 Preparation of reports on observation of decision-making:**
 - Oral reports on the general observations shall be provided to the Chair of the Decision Making Group at the close of the decision making meeting.
 - Written report of the findings, to the TL-R and the Regional Group Secretariat within two weeks of the close of the decision making meeting for review by the region, followed by a written report of the decision making meeting within 2 months. These reports are submitted to the TL-R for compilation and forwarding to the Regional Group Secretariat(s).
 - 5 Compilation by the TL-R of the Regional Group Secretariat, Decision Making and Observation Assignment reports into a draft intermediate report** (including an overall summary, and classification of findings into non-conformities, concerns and comments) that is sent to the TM-Rs for their comments. The TL-R considers these comments and then sends the revised draft intermediate report to the Region for their comments. The comments are considered and a revised intermediate report is sent to the Region and the regional evaluation team.
 - 6 Formal response of the Regional Group to the findings** for recognized regions within three months, new regions are free to respond when completed.
 - 7 Formal reply of the regional evaluation team to this response.** This is provided by the regional evaluation team to the Regional Group for consideration, within one month of the Regional Group's formal response.

8 Steps 6 and 7 may be repeated.

9 Preparation of a final report to the IAF and/or ILAC MC(s). This report consists of the items identified under steps 5, 6, and 7 (i.e., full report on the Regional Group, formal response of the Regional Group and formal regional evaluation team reaction). In addition, the final recommendation of the regional evaluation team is stated in the Summary Section (see clause B 3 of this annex) of the regional evaluation team's final report. The final report shall be provided no later than 3 months after completion of steps 6 and 7.

B. Typical Structure and Content of a Final Evaluation Report on a Regional Group (see Annex 11)

1 Cover page

The cover page states the type of evaluation, the name of the Regional Group that has been evaluated, dates of the evaluation, the name of the TL-R, other regional TM-Rs and observers, specifying the organization to which they belong, and a clear indication that the report is confidential.

2 Contents

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

3 Summary

For a full evaluation, the summary should include the name of Regional Group evaluated, the scopes of the Regional Group's Arrangement, the next steps in the process, proposed recommendations, and reference to the non-conformities, concerns and comments.

4 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.

5 Background on the Regional Group

This section should state the history and background of the Regional Group, including accreditation programs covered, scopes of the Regional Group's Arrangement, legal status, information on number of members, number of Arrangement signatories, number of peer evaluators, etc.

6 Management of the Regional Group

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

7 Consolidated findings on individual AB evaluations observed

This section should describe the performance of peer evaluators of the Regional Group.

8 Reporting on Regional Group decision-making process

9 Obligations of the Regional Group for Recognition by IAF and/or ILAC

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

10 Appendices

- 10.1 Non-conformities, Concerns and Comments
- 10.2 List of documents supplied before evaluation
- 10.3 Evaluation program (includes visit(s) to Regional Group Secretariat, observation of evaluations of single ABs and observations of meeting(s) of the Regional Group Decision Making Group)
- 10.4 Organization chart of Regional Group
- 10.5 Declaration of confidentiality statement signed by all TM-Rs and observers

NOTE: If reference is made to appendices of the final 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

Non-conformity: Finding where the Regional Group does not meet a requirement of any applicable standard(s), its own management system or the Regional Group requirements (IAF/ILAC A1).

The evaluated Regional Group is expected to respond to each non-conformity by taking appropriate corrective action and providing the regional evaluation team with evidence of effective implementation.

Concern: Finding where the Regional Group's practice may develop into a non-conformity. The evaluated Regional Group is expected to respond to concerns by providing the regional evaluation team with an appropriate action plan and time schedule for implementation.

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

ANNEX 6: Evaluation Summary Report for Decision-making Purpose

(This report is prepared by the IAF and/or ILAC MC for presentation to the Decision Making Groups)

Regional Group:

Regional evaluation team:

Identification of the full report:

Evaluation sites and dates:

Regional Group's secretariat:

AB evaluations observed:

Regional Group's Decision Making Group meeting(s):

Scope of evaluation:

General Information regarding the Regional Group:

Number of Arrangement signatories:

Scopes of the Arrangement:

Number of members:

Organizational structure:

Decision making process:

Findings of the regional evaluation team (non-conformities, concerns, and comments):

Conclusions:

Statements of closeout of non-conformities 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 regional evaluation team shall be submitted as the final report to the IAF and/or ILAC MC.
- 1.2** The IAF and/or ILAC MC may prepare a summary report for the respective Decision Making Groups of IAF and/or ILAC which shall decide:
- in the case of an initial evaluation, whether or not the Regional Group will be recognized under the appropriate scopes of the Arrangement;
 - in the case of a re-evaluation, whether or not the Regional Group will remain recognized under the appropriate scopes of the Arrangement. Positive decisions can be accompanied by conditions (see clause 2 of this annex).

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-organizations.

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

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 "conditions". This guidance outlines a hierarchy of the major types of decisions from the most positive decision to the least positive decision (i.e., conditions of increasing severity are imposed).
- 2.2** Decisions on applicant Regional Groups are made by either or both of the decision-making bodies of IAF and/or ILAC. Decisions on the on-going re-evaluations of recognized Regional Groups also reside with the respective Decision Making Groups. Recognition of a Regional Group is a prerequisite for signatories of its Arrangement to attain and maintain signatory status with the respective IAF and/or ILAC Arrangements.
- 2.3** The IAF MLA Group and/or ILAC Arrangement Council make all decisions on recognition 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 conditions imposed on a recognized Regional Group which fails to abide by its obligations for recognition.
- 2.4** Decisions on New Applicant Regional Groups:
- ◆ Approval without conditions (re-evaluation to occur 4 years hence);
 - ◆ Approval with conditions (e.g., shortened interval for re-evaluation);

- ◆ Defer recognition pending submittal of required evidence of corrective actions and/or re-visit by one or more members of the regional evaluation team to confirm implementation of corrective actions; or
- ◆ Delay the decision on recognition pending a new evaluation;
- ◆ Disapproval for New Applicant Regional Groups should rarely happen since an evaluation report is only submitted for a decision once a consensus of the regional evaluation team and the IAF and/or ILAC MC has concluded that all requirements have been met.

2.5 Decisions on recognised Regional Groups:

- ◆ Approval without conditions (re-evaluation to occur 4 years hence);
- ◆ Approval with conditions (e.g., shortened interval for re-evaluation);
- ◆ Defer re-approval pending submittal of required evidence of corrective actions and/or re-visit by one or more members of the regional evaluation team;
- ◆ Reduction of recognition for one or more types of Arrangements; or
- ◆ 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 recognized Regional Group would become the responsibility of IAF and/or ILAC.)

ANNEX 8: Appeals**1. Scope**

This annex describes the procedures for appeals, to ensure that matters related to the MRA and/or MLA are settled objectively and impartially.

2. Handling of appeals

2.1 When an applicant Regional Group or recognized Regional Group does not agree with the decision it may appeal in writing to the IAF and/or ILAC Secretariat.

2.2 After authentication of the appeal, the IAF and/or ILAC Secretariat shall inform the IAF and/or ILAC Chairmen, who will, in conjunction with the Chairmen of the Management Committee (MC), appoint an Appeals Panel comprising two impartial representatives of full members of IAF and/or ILAC and one IAF and/or ILAC evaluator from outside the appellants Regional Group to investigate the appeal.

2.3 No member of the Appeals Panel shall have been involved in the regional evaluation team that evaluated the appellant, or have a direct interest in the subject of the appeal, in any form. The IAF and/or ILAC Chairmen shall ensure that the composition of the Appeals Panel satisfies the requirements of objectivity and impartiality and no conflict of interests exists. The Appeals Panel should normally be set up within 30 days after its authentication.

2.4 The appellant has the right to object to the appointment of any member of the Appeals Panel for valid reason(s). The IAF and/or ILAC Chairmen, in conjunction with the Chairmen of the MC, shall make a decision on any objection by the appellant to an appointment. That decision shall be final.

2.5 During the course of the Regional Group's appeal against suspension or withdrawal of its recognition, the recognition shall remain in effect.

3. Recommendation and decision

3.1 The Appeals Panel shall decide its recommendation on the appeal within six months after setting up the panel and inform the IAF and/or ILAC Chairmen, the Management Committee and the appellant, in writing, of the recommendation not later than five (5) business days after the date of decision.

3.2 The Management Committee shall forward the recommendation to the IAF and/or ILAC Arrangement Groups for a decision.

3.3 That decision shall be final.

ANNEX 9: Re-evaluation of Regional Groups and On-going Confidence Building Activities

1. Periodic monitoring and re-evaluation of the Regional Group is necessary (see also Annex 4).
2. All recognized Regional Groups shall be formally re-evaluated at maximum intervals of four years from the last day of the previous evaluation of the Secretariat.
3. The Regional Group under re-evaluation shall provide the regional evaluation team with all the documents which are required for an initial evaluation (see Annex 1, item 18). In addition, the regional 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 IAF and/or ILAC Decision Making Groups, should there be due cause such as notification of significant changes in administration, finances, operational practices or an extension of the scope(s) of Arrangement.
5. The impact of changes notified by a recognized Regional Group shall be evaluated (see Annex 10, clause 1).
6. Re-evaluation visits should be led by a TL-R other than the one who led the previous evaluation.
7. On-going joint evaluations (evaluations of accreditation bodies by more than one Regional Group) to maintain confidence in the regional evaluations are conducted and reported on as agreed by the IAF/ILAC Decision Making Group.
8. In addition to attending IAF and/or ILAC General Assembly and Committee Meetings, Regional Groups are encouraged to take part in a number of joint activities.

Examples of such activity include:

- ◆ Joint signatory membership of Regional Groups (e.g., some signatories to the APLAC MRA are also signatories to the IAAC MLA). This includes joint participation in evaluations.
- ◆ Attendance (by invitation as an observer) at other Regional Group MRA Council meetings/Regional Decision Making Group meetings (especially by members/Chairs of such Committees/Councils).
- ◆ Participation in other Regional Group' peer evaluator training courses.

All Regional Groups also provide a report each year to the respective IAF MLA Management Committee (MC) and/or ILAC Arrangement Management Committee (AMC) on their MLA and/or MRA activities. Such reports should include any joint activities, as outlined above and be provided to the next TL-R who will evaluate the Regional Group.

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

1.1 Each recognized Regional Group shall report any significant changes in its status and/or its operating practices (e.g. as listed below) without delay to all IAF and/or ILAC signatories through the Management Committee(s).

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

1.3 The Regional Group shall give an annual update to the IAF and/or ILAC MC for consideration of the changes and, if necessary, for recommendation to the IAF and/or ILAC Arrangement Group. The IAF and/or ILAC Arrangement Group shall be informed about the annual updates of the Regional Group (see Annex 9, clause 8).

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 Group or major non-conformities 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 Arrangement 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 recognized Regional Group shall be decided by the IAF and/or ILAC Arrangement Group after receipt of the recommendation by the Management Committee in accordance with the same procedures used for acceptance of a Regional Group. Any suspension or withdrawal decided by the IAF and/or ILAC Arrangement Group shall be accompanied by an appropriate explanation stating the reason for suspension or withdrawal to the Regional Group.
- 2.3** In the case of suspension or withdrawal, the Regional Group may appeal against the decision in accordance with Annex 8.
- 2.4** If the recognition of the Regional Group is suspended the Regional Group shall inform its recognized signatories and applicants that their signatory status will remain unchanged during the suspension period. Any new signatory and applicant to the regional Arrangement during the suspension period are not covered by the Arrangement and not recognized by IAF and/or ILAC.
- 2.5** If the recognition of the Regional Group is withdrawn the Regional Group shall inform all applicant and signatories of the regional Arrangement that the Regional Group and its signatories are no longer accepted under the IAF and/or ILAC Arrangement and shall no longer make reference to the IAF and/or ILAC Arrangement.
- 2.6** When a withdrawn Regional Group applies to become a recognized Regional Group again, the procedure for new applicants shall be followed.

ANNEX 11: Typical template for a full evaluation report for an initial evaluation of a Regional Group

FULL REPORT OF

**THE INITIAL EVALUATION OF THE XYZ REGION
FOR MEMBERSHIP AS A REGIONAL COOPERATION
OF THE IAF MULTILATERAL RECOGNITION ARRANGEMENT (MLA)
AND THE ILAC MUTUTAL RECOGNITION ARRANGEMENT (MRA)**

- Phase 1 i) Evaluation of XYZ MRA Secretariat
 ii) Follow up visit to Secretariat (if necessary – changes etc.)
- Phase 2 i) Observation of XYZ evaluation of ABC
 ii) Observation of XYZ evaluation of DEF
 iii) Observation of XYZ evaluation of GHI
- Phase 3 Observation of Decision making of XYZ MRA Council Meeting

Regional evaluation team:

**A Boss
A N Other
A N Other**

This report is CONFIDENTIAL and is prepared on behalf of the IAF and ILAC MLA Management Committees

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- 6. Report on the Regional Group Decision-making Processes**
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- 8. Appendices**
 - 8.1 Consolidated list of Non-conformities, Concerns and Comments for all interventions.
 - 8.2 List of documents supplied before the evaluation
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 - 8.4 Organizational chart of the Regional Group
 - 8.5 Reports
 - 8.5.1 Initial evaluation or re-evaluation of XYZ Secretariat
 - 8.5.2 Observation report of AB 1
 - 8.5.3 Observation report of AB 2
 - 8.5.4 Observation report of AB 3
 - 8.5.5 Follow-up visit to XYZ Secretariat (following change)
 - 8.5.6 Report on Decision making process of XYZ
 - 8.6 Declaration of confidentiality statement signed by all the TM-Rs and observers.

1. Executive Summary

This report is on the initial (re-) evaluation of the XYZ Cooperation (XYZ) to join or maintain the IAF and ILAC Multilateral Recognition Arrangements (MLAs) as a Regional Arrangement. As this was a joint IAF and ILAC evaluation, only one report will be completed, and the report will comply with the requirements of the IAF and ILAC A1 document.

Background covering region and the scope of activities covered in the evaluation:

The evaluation consisted of 3 phases:

- 1) Evaluation of the Secretariat in as far as they are responsible for much of the administration and management of the MLA and the MLA committee. (This process involved a follow up visit to the Secretariat to close out findings from the initial visit.)
- 2) Witnessing of XYZ perform 3 evaluations in total. This included (number) observations for IAF specifically and (number) observations for ILAC. [(number) of the observing activities allowed the regional evaluation team to observe both laboratories and certification.] All observing activities were initial applications for membership to the XYZ MLA.
- 3) Observation of the decision making process of XYZ with regard to the MLA. This was the final activity to be completed. This allowed the regional evaluation team to witness XYZ take decisions on x Reports involving y Accreditation Bodies (ABs).

The regional evaluation team noted the following strengths of the XYZ Regional Arrangement:

Comments on strengths and commitment:

A total of x Non-conformities, y Concerns and z Comments were raised by the regional evaluation team over all observations in the evaluation process.

All non-conformances and concerns have been addressed adequately by XYZ to the satisfaction of the regional evaluation team. The evaluation team appreciated the regional body's response to the comments as well.

The regional evaluation team recommends that XYZ be a recognized IAF or ILAC region or continue to be recognized as an IAF or ILAC region:

- 1) The IAF MLA as a Regional Body for Recognition of accredited certification bodies for [scope] and;
- 2) The ILAC MLA as a Regional Body for Recognition of accredited calibration laboratories/testing laboratories.
- 3) The ILAC/IAF MLMRA as a Regional Body for Recognition of accredited inspection bodies.

The regional evaluation team further recommends that the next evaluation of XYZ should be in approximately x years.

Comment on documentation and criteria used (both ILAC/IAF and the regional group):

The next step in this process is in accordance with the current (or previous) version of IAF/ILAC A1, the regional evaluation team provides this report to the IAF and ILAC Secretariats who then prepare a summary report in accordance with Annex 6 of A1:200X. This report is sent to the decision making bodies of IAF and ILAC.

2. Introduction

2.1 General

This peer evaluation of XYZ was undertaken in order to determine if the XYZ Arrangement complies with its own Policies and Procedures as well as those of IAF and ILAC for recognition of their Multilateral Arrangement by IAF and ILAC as a Regional Group. It was also to determine if the Policies and Procedures of XYZ were equivalent and resulted in equivalent outcomes to those of IAF and ILAC (i.e. competent laboratories and certification bodies). The criteria used for the evaluation were:

IAF/ILAC A1: 200x IAF/ILAC Multi-Lateral Mutual Recognition Arrangements: Requirements for Evaluation of a Regional Accreditation Group (Regional Group).

IAF/ILAC A2: 200x IAF/ILAC Multi-Lateral Mutual Recognition Arrangements: Requirements for Evaluation of a Single Accreditation Body.

IAF ML4: 2005 IAF Policies and Procedures for a Multilateral Recognition Arrangement on the Level of ABs and on the Level of Regional Groups (Issue 4, Issued on 15 December 2005).

NOTE (if relevant): Previous versions of these documents were also used at the initial stages of the evaluation.

The list of XYZ Co-operation documents supplied and used by the regional evaluation team are given in appendix 8.2.

2.2 Scope of Evaluation

The scope of the XYZ evaluation included the following:

Details of laboratory scopes (testing, calibration, etc.); certification body scopes (Management systems, Products, Persons, Sector specific etc.), and inspection body.

2.3 Steps in the Evaluation

In order to evaluate if XYZ meet all the requirements, the following activities took place:

- i) Documentation review and report completed. Document Report sent to XYZ prior to the on-site visit to Secretariat.

- ii) On site evaluation of the offices of the Secretariat of the XYZ MLA Committee. (Refer to appendix 8.5.1 for the Summary Report).
- iii) Observation of XYZ performing evaluations of various ABs for laboratory and certification. (X findings were raised as a result of these activities). (Refer to appendix 8.5.2/3/4/5 for the Summary Report).
- iv) Follow-up visit to clear the findings raised at the Secretariat during the initial evaluation. (Refer to appendix 8.5.5 for a list of the clearance of findings).
- v) Observation of XYZ decision making process. (Refer to appendix 8.5.6 for the Summary Report).
- vi) Completion of the final report.

In addition to the above the regional evaluation team provided to the IAF and ILAC MLA joint committee meetings summary reports of the progress made at each stage. These reports form part of the IAF/ILAC Joint MLA Committee records. (Copies are attached to this report. Refer to appendix 8.5.7)

2.4 Regional Evaluation Team Composition

The regional evaluation team was composed of:

- A Boss (Polar Accreditation)
- A N Other 1 (Paradise Accreditation)
- A N Other 2 (Better Accreditation)

The participants from the XYZ as well as being indicated in the individual reports for the specific areas were as follows [Regional Accreditation Evaluation team (RAW)]:

<i>Secretariat</i>	<i>Observed AB 1</i>	<i>Observed AB 2</i>	<i>Observed AB 3</i>
A person	RAW team 1	RAW team 2	RAW team 3

It is important to note that other XYZ staff were encountered in the process but did not form part of the official evaluation process.

3. Background on the Regional Group

3.1 General

The XYZ Cooperation has an Arrangement among member ABs that conduct and administer accreditation systems of certification bodies, inspection bodies, testing and calibration laboratories whose objective is to facilitate trade and commercial exchange amongst its members or other economies in the Geographical Region.

Background

History

Relationships with other Regional Cooperations/Arrangements

3.2 Legal Status

3.3 Structure of XYZ

3.4 Membership

There are X categories of membership in XYZ:

- 1) **Full members**
- 2) **Associate members** are:
 - i) All those ABs in the region that do not as yet operate in accordance with the relevant ISO/IEC guides and standards and other international documents.
 - ii) Countries or blocks of countries in the region that do not have an established AB.
 - iii) Other organizations with an interest in conformity assessment and do not fit into the definition given in 3) below.
- 3) **Stakeholder members.** [If any]

Details of membership requirements, categories etc.

3.5 XYZ MLA

The XYZ Region has established a Mutual Recognition Arrangement/Multilateral Arrangement for:

Details of coverage of scope of MRA/MLA, including the Regional Group's specific procedures and policies, comment on the effectiveness of these in giving assurance of competence of accredited laboratories and certification bodies.

The XYZ Region Group has the following signatories:

Country	Accreditation body	IAF Scope	ILAC Scope
Economy 1	AB1	QMS and EMS	Testing and Calibration
Economy 2	AB2	N/A	Testing only
Economy 3	AB3	QMS, EMS and Product	Testing and Calibration

Economy 4	AB4	N/A	Testing only
Economy 5	AB5	N/A	Testing and Calibration
Economy 6	AB6	QMS and Product	Testing and Calibration
Economy 7	AB7	QMS	N/A
Economy 8	AB8	N/A	Testing and Calibration
Economy etc.	AB etc.	Etc.	Etc.

N/A = Not Applicable

The XYZ conditions for joining the XYZ MLA are as follows:

- 1) Full XYZ membership and agreement to abide by the terms and conditions of the XYZ MLA.
- 2) Demonstration through evaluations and witnessing that an AB and its accredited facilities comply with all relevant requirements (IAF, ILAC and XYZ).
- 3) Completion of at least one accreditation for each accreditation program for which it applies, as well as having implemented effective management review and internal audit processes.

3.6 Regional Body Evaluators

How many?

Where from?

Knowledge of up-to date criteria

Comments on their effectiveness, knowledge, and appropriate outcomes

Communications (within evaluation teams, and with ABs)

Process for monitoring performance of evaluators

4. Management of the Regional Group

4.1 General

Structure of regional MRA Council/Executive

Voting

Requirements on signatories

- 4.2 Executive [Board] Committee**
- 4.3 MLA Management Committee [if existing]**
- 4.4 Management Committee [if existing]**
- 4.5 Technical Committee [if existing]**
- 4.6 Other committees (please describe)**
- 4.7 Management System**

Discussion of management system for regional MRA activities, include:
 Policies and procedures;
 The control of documents;
 The selection, training, qualification and monitoring of Peer evaluators;
 Records related to peer evaluation;
 Arrangements for ensuring confidentiality of Peer evaluation information;
 Handling of appeals and complaints; and
 Review of Documents
 The web site contains all the necessary information on the MLA, including the signatories. The web site is maintained by the XYZ Secretariat.

- 4.8 Regional Group Personnel**
- 4.9 Other Obligations**

5. Consolidated findings on individual evaluations observed

The table below details the breakdown of the findings for the full evaluation. It also details the regional evaluation team members involved in that specific evaluation.

Findings	Secretariat	AB1	AB2	AB3	MLA Committee
IAF/ILAC Evaluators in attendance as observers	A Boss A N Other1	AB & AO1	AB & AO2	AB & AO3	AO1
Non-conformances	x	X1	X2	X3	X4
Concerns	y	Y1	Y2	Y3	Y4
Comments	z	27	38	14	7

The findings for all the above observed evaluations have been consolidated in appendix 8.1. This table also includes the responses from XYZ and the regional evaluation team response. The findings have all been closed.

5.1 Secretariat (refer to appendices 8.5.1 and 8.5.5 for full reports)

Describe evaluation of secretariat

List any findings, gaps in documentation etc.

Comments on secretariat

Addressing of any findings

5.2 Witness of AB1, Economy 1 (refer to Appendix 8.5.2 for the full report)

Comments on the evaluation

Conclusion:

The XYZ evaluation team reached a valid recommendation.

The XYZ invited AB1 to join the MLA/MRA for QMS, EMS, Calibration, and Testing.

5.3 Witness of AB2, Economy 2 (refer to Appendix 8.5.3 for the full report)

Comments, including (for example): The technical concepts of laboratories with regard to PT, UoM and Traceability were generally evaluated appropriately and valid conclusions were reached.

The XYZ evaluation team reached a valid recommendation.

On the basis of the recommendation of the initial evaluation of AB2, a follow-up visit was completed in 20xx, and a recommendation for AB2 to join the MLA for testing was made.

The XYZ region invited AB2 to join the MLA for Testing.

5.4 Witness of AB3, Economy 3 (refer to Appendix 8.5.4 for the full report)

Example only:

This evaluation was witnessed by two TM-Rs as the scope was for the full scope applied for by AB3 (Testing, Calibration and QMS, EMS and Product). There were issues regarding the readiness of the AB to be evaluated that the team discussed prior to the on-site visit. These issues have been addressed by XYZ in their response to the regional evaluation team findings. The team worked very well and effectively. The team leader managed the process well and was in full control at all times. The team members were

very knowledgeable in their fields and also in the general requirements. It was evident that all team members had prepared well for the evaluation. The team recommended a follow-up visit to AB3 in order to check the implementation of the corrective actions. This follow-up visit has not taken place at the time of writing this report. The technical concepts of laboratories with regards to PT, UoM and Traceability were evaluated appropriately, and valid conclusions were reached.

The team reached a valid recommendation.

The XYZ region has not taken any decisions on AB3.

6. Report on Decision making process of XYZ (refer to Appendix 8.5.6 for the full report)

6.1 General

6.2 Reports from Evaluations

6.3 Observations

6.4 Conclusion

7. Obligations of the Regional group for recognition by IAF and/or ILAC

This section is not applicable as this was an initial evaluation of the regional group. However, it is the opinion of the regional evaluation team that the XYZ region is in a position to meet all obligations of both IAF and ILAC as a Regional Group.

APPENDIX 8.1
FINDINGS
**TABLE OF NON-CONFORMITIES CONCERNS AND COMMENTS
ON THE XYZ SECRETARIAT EVALUATION**

NO.	FINDING (First Visit to XYZ Secretariat)	TYPE OF FINDING (NC, CONCERN, COMMENT)	XYZ RESPONSE	IAF/ILAC RESPONSE TO CORRECTIVE ACTIONS (Follow up visit January 200x)
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For Each AB observed:
**TABLE OF FINDINGS ON THE XYZ EVALUATION OF ECONOMY 1-AB1
3 to 4 February 2018**

NO.	FINDING	TYPE OF FINDING (NC, CONCERN, COMMENT)	XYZ RESPONSE	IAF/ILAC RESPONSE TO CORRECTIVE ACTIONS
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**TABLE OF FINDINGS
ON THE REGIONAL GROUP EVALUATION OF ECONOMY 3 – AB2
3 to 4 JANUARY 2019**

NO.	FINDING	TYPE OF FINDING (NC, CONCERN, COMMENT)	XYZ RESPONSE	IAF/ILAC RESPONSE TO CORRECTIVE ACTIONS
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**TABLE OF FINDINGS
ON EVALUATION OF DECISION MAKING**

NO.	FINDING	TYPE OF FINDING (NC, CONCERN, COMMENT)	XYZ RESPONSE	IAF/ILAC RESPONSE TO CORRECTIVE ACTIONS
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APPENDIX 8.2

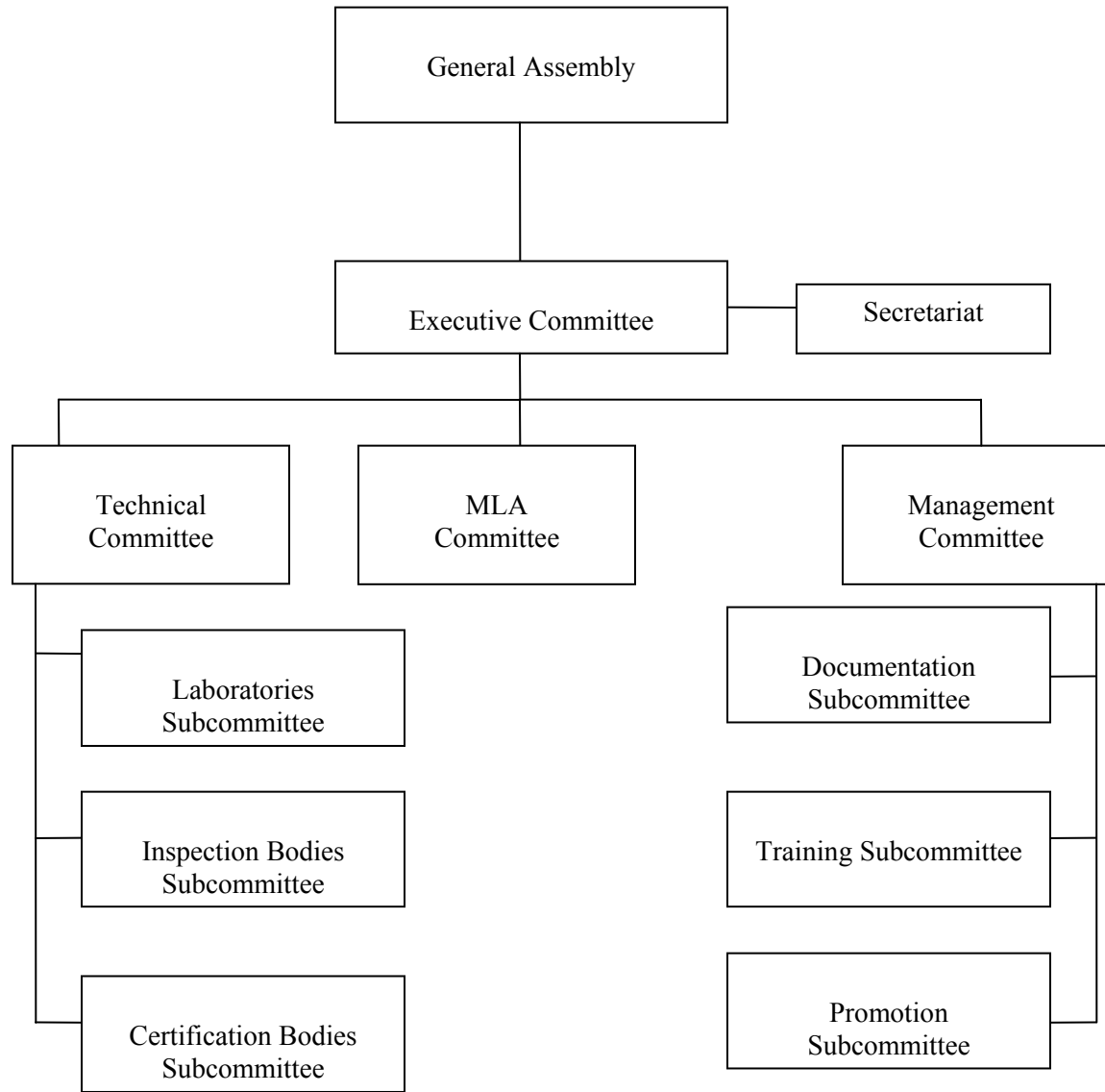
LIST OF XYZ DOCUMENTS SUPPLIED

APPENDIX 8.3

LIST OF EVALUATION PROGRAM

APPENDIX 8.4

XYZ STRUCTURE (example)



Appendix 8.5.1
Report on the Secretariat

Appendix 8.5.2
Report on Observations of XYZ Evaluation of AB1; AB2; AB3

APPENDIX 8.5.3
Report on XYZ MLA/MRA Committee Meeting Decision Making

XYZ MLA/MRA meeting
Somewhere in the region
6 to 7 August 2019

- 1. Background**
- 2. MLA/MRA Meeting**

Participants and Chair

The MLA/MRA Committees discuss the evaluation reports and decide on signatory status. The GA shall ratify this decision [if this is a requirement of the region].

Following issues were on the agenda:

- ◆ Reports from evaluations, initial and re-evaluation (continuation of signatory status)
- ◆ Self declaration according to ISO/IEC 17011
- ◆ Plans for future evaluations
- ◆ Follow up of XYZ evaluation by IAF and ILAC
- ◆ Changes and adoption of documents
- ◆ Future work
- ◆ Evaluators

Reports
Summary of reports

The team leader or a team member when relevant introduced the reports and the MLA/MRA committee had the opportunity to clarify possible questions with the team leader. The representative from the AB under evaluation left the room during the decision-making.

Appeals against decisions

Evaluations scheduled for 2027-2028

The MLA/MRA committee was informed about the evaluations scheduled for the next year.

- ◆ Initial Evaluation of ...
- ◆ Follow up of Testing and Calibration for:...
- ◆ Surveillance evaluation of Testing and Calibration of ...
- ◆ Pre-evaluation of ...
- ◆ Follow up evaluation of QMS for ...
- ◆ Follow up of the initial evaluation of ...

Follow-up of XYZ Evaluation by IAF and ILAC and corrective actions as a result of internal audit

The chair informed about the corrective action plan and the corrective actions taken.

Changes and adoption of documents

Future work

Peer evaluators

3. Observations

4. Conclusion

Date

Signed: A N Other

APPENDIX 8.6

Declaration of Confidentiality