

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

### IEC SCHEME FOR CERTIFICATION TO STANDARDS FOR SAFETY OF ELECTRICAL EQUIPMENT FOR EXPLOSIVE ATMOSPHERES (IECEX SCHEME)

#### Ex Management Committee, ExMC

#### ILAC Operational Document

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#### Introduction

This ILAC Operational Document is submitted to the ExMC for information purposes for discussion under agenda item 9 of the 2000 ExMC Meeting to be held in Braunschweig. Refer ExMC/56/DA, Draft Agenda.

**COVER**

**ILAC-P2:2000**

**ILAC Mutual Recognition  
Arrangement  
(Arrangement):  
Procedures for the  
Evaluation of  
Regional Cooperation  
Bodies for the Purpose  
of Recognition**

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**ILAC Mutual Recognition  
Arrangement (Arrangement):  
Procedures for the Evaluation of  
Regional Cooperation Bodies  
for the Purpose of Recognition**

**PREAMBLE**

The international community of accreditation Cooperations, recognised laboratory Accreditation Bodies and their stakeholders cooperate through the International Laboratory Accreditation Cooperation (ILAC). A principle objective of ILAC is to put in place a world-wide Mutual Recognition Arrangement (Arrangement). ILAC aims to demonstrate the equivalence of the operation of its Member Accreditation Bodies through this Arrangement. As a consequence, the equivalent competence of laboratories accredited by these bodies is demonstrated. The market can then be more confident in accepting certificates and reports issued by the accredited laboratories.

At present, this Arrangement covers only the accreditation of testing and calibration laboratories. In due course, it is envisaged that a mutual recognition Arrangement will evolve to cover the accreditation of inspection bodies. ILAC expects to cooperate with IAF (International Accreditation Forum), the inspection industry and its stakeholders in the development of such an Arrangement and its associated procedures.

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

Evaluation relating to the development and maintenance of the ILAC Arrangement operates at two levels:

- ♦ the Evaluation of the competence of individual ILAC Member Accreditation Bodies to accredit;
- ♦ the Evaluation of a Cooperation’s competence in managing the operations of regional mutual recognition Arrangements.

The essential requirements to be used for the first of these are set out in document ILAC-P1.

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

**PURPOSE**

To provide the ILAC Arrangement Council with a procedure for evaluating Cooperations for the purpose of Recognition.

**AUTHORSHIP**

This publication was prepared by the ILAC Accreditation Policy Committee and endorsed for publication by the ILAC General Assembly in 2000.



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**PART A: INTRODUCTION****1 SCOPE**

This document sets out the procedures to be used by ILAC in the Evaluation of a regional accreditation Cooperation for the purpose of the formal Recognition of the Cooperation's competence in managing a mutual recognition arrangement (Arrangement).

Criteria and procedures specified below are applicable for the initial Evaluation of a regional Cooperation and for subsequent re-evaluations.

**2 DEFINITIONS**

**2.1 Accreditation Body:** an organisation that operates an accreditation system for calibration laboratories and/or testing laboratories.

**2.2 Arrangement: the ILAC Mutual Recognition Arrangement:** This term, also can refer to the Arrangements (MRAs or MLAs) of "recognised" Cooperations which pre-date the establishment of the ILAC Arrangement and which, as a consequence of the "Recognition" process, will be accepted as a subset of the ILAC Arrangement.

**2.3 Member:** a Full Member Accreditation Body of ILAC.

**2.4 Cooperation: a Regional Cooperation Body Member of ILAC:** This term can also refer to a group of Accreditation Bodies (possibly involving other stakeholders) whose purpose is to develop and maintain a mutual recognition Arrangement (Arrangement).

**2.5 Signatory:** A Member who has signed the mutual recognition Arrangement of a Cooperation.

**2.6 Accredited Laboratory:** a calibration laboratory or testing laboratory accredited by an Accreditation Body.

**2.7 Evaluation:** the structured process of assessment of a Cooperation or Accreditation Body.

**2.8 Evaluation Manager:** the lead evaluator appointed by the ILAC Arrangement Management Committee to evaluate an Applicant Cooperation.

**2.9 Recognition:** the action taken by ILAC, following an evaluation conducted according to the procedures set out in this document, whereby ILAC acknowledges a Cooperation's competence to manage a regional mutual recognition Arrangement which can then be integrated into the ILAC Arrangement.

**2.10 Applicant Cooperation:** a Regional Cooperation Body Member of ILAC which has applied for Recognition.

**2.11 Constitutional Documents:** the set of formal documents which define the constitution and operation of a Cooperation, e.g. memoranda of understanding, statutes, bylaws, etc.

**2.12 Proficiency Testing Activity:** for the purpose of this document, all activity used by Accreditation Bodies to assess performance including proficiency tests (refer to ISO/IEC Guide 43, "Proficiency testing by means of interlaboratory comparisons") and measurement audits conducted by Cooperations, Accreditation Bodies, commercial organisations, or other providers

**3 OBJECTIVE**

**3.1** The objective of the ILAC Arrangement is to establish cross-border stakeholder confidence in the competence of Accredited Laboratories and the technical equivalence of reports and certificates issued by these laboratories. In this context, the objective of the Evaluation of a Cooperation is to establish that a Cooperation conducts its Evaluations as defined in ILAC-P1 for the purposes of managing and maintaining its mutual recognition Arrangement, and takes decisions relating to membership of its Arrangement, in a manner consistent with documented ILAC practice.



**3.2** In order to achieve this objective, the Evaluation team shall carry out the following:

- (i) an initial appraisal of the Cooperation's constitutional documents, and its other documented policies and procedures in particular those relating to the management and operation of its Arrangement;
- (ii) an Evaluation, at the premises of the secretariat of the Arrangement, of the implementation of these policies and procedures;
- (iii) an Evaluation of the Cooperation's ability to evaluate Accreditation Bodies; this Evaluation shall include an appraisal of the accreditation work of these Accreditation Bodies.

Evaluations are conducted according to the procedures in Part 3 against the criteria stated in Clause 4 of Part 1.

**3.3** The Evaluation process will require the exercise of some judgement and perhaps interpretation as it is possible that some requirements or activities may not be addressed in exactly the same way in all Cooperations. The Evaluation team must therefore collect sufficient information on each topic to enable it to appraise the suitability of the practices used by the Applicant. Any significant difference in approach must be highlighted, since it must be made known to all Signatories to the Arrangement.

## **4 CRITERIA**

### **4.1 Evaluation Criteria**

Although no formal standards or guides cover the operation of Cooperations as they do for the operation of Accreditation Bodies and of laboratories, the ILAC-P1 sets out the requirements for procedures to be employed by a Cooperation when evaluating an Accreditation Body and in managing a regional Arrangement. Applicant Cooperations shall demonstrate that they operate their Arrangement in line with these.

### **4.2 Additional Requirements**

In addition, the Applicant Cooperations shall fulfil the following requirements:

- (i) the Cooperation shall be a formally constituted group of Accreditation Bodies which fulfil the criteria for ILAC membership;
- (ii) the Cooperation shall be a Regional Cooperation Body Member of ILAC;
- (iii) the Cooperation shall have experience in the Evaluation of Accreditation Bodies, having evaluated at least three, and shall have carried out enough surveillance and/or re-evaluation to demonstrate to an ILAC evaluator, competence in correcting Accreditation Body inadequacy;
- (iv) the Cooperation shall have a formally constituted committee to manage a regional Arrangement in line with agreed international practice;
- (v) the Cooperation shall have documented procedures covering all aspects of the operation and management of its Arrangement;
- (vi) the Cooperation shall have a demonstrable regional policy of ensuring that its member bodies operate their accreditation systems in an environment of accessibility to traceability to SI or other internationally agreed reference standards, and which is obtained through national metrology institutes recognised under the BIPM (Bureau des Poids et Mesures) Mutual Recognition Arrangement of the Metre Convention;
- (vii) all member bodies of the Cooperation which have signed the Cooperation's Arrangement shall conform to the requirements set out in ILAC-P1, Section 5.2.1 and 5.3; and
- (viii) the Cooperation shall have a demonstrable regional policy of improving and harmonising technical competence (e.g., Lead evaluators, from time to time, should participate in the Evaluation and re-evaluation of the Accreditation Bodies of other Cooperations. As this experience is



gained over time, such extra-regional experience should become a selection criterion for ILAC evaluators.)

### 4.3 Proficiency Testing Activity

An Applicant Cooperation shall:

- ♦ have in place means whereby its member bodies can involve their applicant and accredited laboratories in participating in regional and international Proficiency Testing Activity;
- ♦ have, and demonstrate, a policy requirement that the performance in such tests by laboratories accredited by its member bodies is taken into account in accreditation decisions;
- ♦ demonstrate that performance in Proficiency Testing Activity is assessed by the Cooperation during Evaluation of Accreditation Bodies in its region for the purposes of joining an Arrangement and thereafter, during subsequent re-evaluations for the purpose of maintaining Signatory status of an Arrangement.

## 5 COSTS

The travel and subsistence costs of Evaluation of a Cooperation and of an unaffiliated body are met by the evaluated Cooperation or unaffiliated body.

## 6 CONFIDENTIALITY

- 6.1** All information received, both in writing and orally relating to Evaluations, re-evaluations and interim visits, other than that which is already publicly accessible, shall be treated confidentially by all parties and persons concerned. This relates to information relating to both the Cooperation under Evaluation and any Signatories of its Arrangement visited. All members of the team shall sign a declaration of confidentiality and impartiality. Reports on Evaluations, re-evaluations and interim visits may only be copied on a “need to know” basis to the representatives of members who have a role to play in decision making.

- 6.2** 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.

## 7. BASIC STEPS IN ESTABLISHING RECOGNITION

The process of initial Evaluation of a Cooperation for the purpose of Recognition by ILAC and the subsequent, on-going process of monitoring and periodic re-evaluation involves a number of basic steps. These are:

For initial Evaluation:

- ♦ Application (see section 8)
- ♦ appointment of Evaluation Manager (see section 9)
- ♦ document review (see section 10)
- ♦ selection of team (see section 12)
- ♦ agreement of the evaluation agenda (see section 13.1)
- ♦ evaluation of the Cooperation secretariat (see section 13.2.2)
- ♦ participation in Accreditation Body Evaluations (see section 13.2.3)
- ♦ the technical aspects (see section 13.3)
- ♦ reporting (see section 13.4)
- ♦ corrective actions and decisions (see section 14)

For re-evaluation, the application stage and much of the document review and Evaluation of the secretariat for the Cooperation's mutual recognition Arrangement will be unnecessary if these have remained unchanged since the last Evaluation.



**PART B: APPLICATION AND TEAM  
SELECTION**

**8 APPLICATION**

- 8.1** Application by a Cooperation for ILAC Recognition shall be made in writing in English to the ILAC Secretariat. The Secretary shall copy the application to all Members of the Arrangement Management Committee and shall confirm the receipt of the application.
- 8.2** The application shall indicate that the Cooperation is familiar with the requirements and procedures in this document and the provisions of the ILAC Arrangement.
- 8.3** Applications shall be accompanied by a statement indicating the Cooperation's legal status, if any, a copy of its constitutional documents, a copy of the text of its Arrangement and a summary of its membership and of the Signatories to its mutual recognition Arrangement. The application should also include copies of the Cooperation's documented procedures relating to the operation of its Arrangement.
- 8.4** Applications from Cooperations shall be considered by the ILAC Arrangement Council at its next meeting, or in writing if the next Arrangement Council meeting is more than 3 months ahead. The Applicant Cooperation will be informed in writing on the steps to be followed. Any reason for not continuing with the application, stemming from this consideration by the Arrangement Council, shall be communicated to the Applicant by the Secretariat.
- 8.5** Following the Arrangement Council's decision to proceed with the application, the Arrangement Council will invite the Arrangement Management Committee to initiate and manage the Evaluation process.

**9 APPOINTMENT OF EVALUATION  
MANAGER**

- 9.1** ILAC evaluators shall be drawn from the set of experienced Evaluation team leaders of ILAC Member Cooperations

and Accreditation Bodies which are already Signatories to the ILAC Arrangement and their names included on a list of ILAC evaluators. This list and the records of their experience shall be maintained by the Arrangement Management Committee. Before a new name is put on this list, the Chairman of the Arrangement Management Committee shall consult with those who have had Evaluation team experience of the candidate.

- 9.2** The Arrangement Management Committee shall appoint an Evaluation Manager from its approved list of selected and trained lead evaluators for an Evaluation or re-evaluation. The Evaluation Manager shall be a senior lead evaluator from an ILAC-recognised Cooperation. The task of the Evaluation Manager shall be:

- (a) to prepare a plan for the entire Evaluation in discussion with the Applicant Cooperation for approval by the Arrangement Management Committee before the Evaluation team is selected;
- (b) to direct the entire Evaluation process on behalf of the Arrangement Management Committee;
- (c) to undertake the Evaluation of the Cooperation's Arrangement management procedures;
- (d) to compile and present the Evaluation report on the Applicant Cooperation to the Arrangement Management Committee and to the ILAC Arrangement Council.

- 9.3** The Applicant Cooperation shall be informed of the name of the Evaluation Manager nominated to manage the Evaluation who will then plan with the Applicant Cooperation the scope of the Evaluation.

**10 DOCUMENTATION TO BE  
SUPPLIED BY THE APPLICANT  
COOPERATION**

- 10.1** The following documents relating to the operation of the Cooperation, translated

into English as appropriate, shall be supplied to the Evaluation Manager:

- ♦ constitutional documents of the Cooperation;
- ♦ copy of the most recent annual report describing the work carried out by the Cooperation and its working groups;
- ♦ organisation structure and brief description of members of its board of management and other key officers;
- ♦ text of the Cooperation's mutual recognition Arrangement;
- ♦ documented regional procedures for the management of its Arrangement together with those for the Evaluation and re-evaluation of member bodies of its Arrangement;
- ♦ composition and terms of reference of the Cooperation's committee for the management of its Arrangement and copies of the minutes of its last three meetings;
- ♦ composition and terms of reference of its council for decision making relating to its Arrangement (if different from the management committee mentioned above) and copies of the minutes of the last three meetings. (If the Cooperation's general assembly acts as its Arrangement council, only extracts of the general assembly minutes relating to the decision making and operation of the Arrangement need be supplied.);
- ♦ procedures for the selection, training and monitoring of Evaluation team leaders and members;
- ♦ list of lead evaluators and evaluators used;
- ♦ summary status report on the Cooperation's Arrangement including the current membership, its historical record of Evaluation and re-evaluation dates and its proposed programme of Evaluation and re-evaluation for the forthcoming 12 months;

- ♦ copies of statements of Cooperation policy relating to Proficiency Testing Activity, traceability and uncertainty of measurement;
- ♦ compilation of Proficiency Testing Activity used by the cooperation;
- ♦ evidence that the Cooperation monitors the activities of the Signatories to its Arrangement with respect to the implementation and use of Proficiency Testing Activity, including evidence that appropriate corrective action is undertaken where necessary
- ♦ evidence that cross-border equivalence within the Cooperation in the outcome of Proficiency Testing Activity is being realised;
- ♦ list of mandatory documents to be implemented by Signatories to the relevant Arrangement;
- ♦ list of guidance documents recommended for use and the Cooperation's statement of their status for use in relation to the operation of the Arrangement.

**10.2** In addition to these documents, and after the set of Evaluations and re-evaluations of Accreditation Bodies to be visited has been selected, copies in English of the documents listed under the first seven bullet points of Section 10 of the ILAC-P1 document, for each Accreditation Body to be visited, should be submitted.

## **11 PRE-EVALUATION**

It is unlikely that there should be any need for pre-evaluation in the context of the ILAC Evaluation of Cooperations

## **12 SELECTION OF EVALUATION TEAM**

Although the initial Evaluation of a Cooperation will be a relatively rare occurrence, in that no more than 6 or 7 Cooperations are likely to seek ILAC Recognition in the foreseeable future, each Evaluation, by its nature, will be more extended in time than the Evalua-



- tion of an Accreditation Body. Apart from a study of documentation, each Evaluation shall typically consist of a visit to the secretariat of the Cooperation's Arrangement by the Evaluation Manager and one other evaluator and the participation of an ILAC evaluator in at least three Evaluations and/or re-evaluations of Accreditation Bodies by the Applicant Cooperation to determine whether its Evaluation procedures comply with ILAC-P1.
- 12.1** The Evaluation team shall be appointed by the Arrangement Management Committee in consultation with the Evaluation Manager and shall consist of the Evaluation Manager plus at least two but no more than three ILAC evaluators one of whom shall undertake the Evaluation of the secretariat of the Arrangement with the Evaluation Manager. An ILAC evaluator shall participate as a team member in each of the selected Evaluations and re-evaluations of the selected Accreditation Bodies.
- 12.2** The set of ILAC evaluators selected for a given Evaluation shall, between them, provide a balanced set of the skills needed and, while technical speciality is of less importance than Evaluation experience, the team shall include the capability to assess critically the Cooperation's approach to, and use of, Proficiency Testing Activity. Attention shall be paid to the predominant spoken language of the Cooperation and to the languages used in the Accreditation Bodies to be visited. If possible, at least one member of the Evaluation team should be capable of understanding the local language.
- 12.3** In appointing team members for a specific Evaluation the Arrangement Management Committee shall:
- 12.3.1** Prevent the appointment of team members that would result in the mutual Evaluation of each other's Accreditation Bodies;
- 12.3.2** Avoid appointing the same team member for two successive Evaluations of the same Cooperations; and
- 12.3.3** Ensure that evaluators from as wide a range of Members as possible are used.
- 12.4** The Applicant Cooperation should be informed of the names of the team members and observers nominated to carry out the Evaluation, with sufficient notice so that either the Cooperation itself, or any of the Accreditation Bodies to be visited, has the opportunity to appeal against the appointment of any particular team member.
- 12.5** Neither the Evaluation Manager nor any team member should be associated with any Accreditation Body that have been engaged in any consultancy activity relating to the Cooperation under Evaluation, or to the selected Accreditation Bodies, in the four years preceding the Evaluation.

**PART C: THE EVALUATION PROCESS****13 EVALUATION****13.1 Preparation**

13.1.1 The principle elements of an initial Evaluation, following study of the documents listed in Section 10 by the Evaluation Manager shall be an Evaluation visit to the Secretariat of the Cooperation's Arrangement by the Evaluation Manager and one other team member and participation by an ILAC team member in three Evaluations and/or re-evaluations of Accreditation Bodies by the Applicant Cooperation. At least one of these should, where possible, be an initial Evaluation and the set of Evaluations of Accreditation Bodies to be attended shall cover more recent additions to the Cooperation's Arrangement as well as its more mature members.

13.1.2 The selection of the Accreditation Body Evaluations to be attended shall be made by the Evaluation Manager in discussion with the Applicant Cooperation and approved by the Chairman of the Arrangement Management Committee. Wherever possible, Evaluations should not be undertaken purely for the purposes of ILAC participation. They should be part of the Cooperation's on-going programme so that the Cooperation's performance of their Evaluation can be evaluated. During these Evaluations, the ILAC team member's participation shall be managed by the Cooperation's team leader.

13.1.3 Since on-site Evaluation of a Cooperation will consist of several visits separated in time and involving different people a single opening briefing meeting may well be impractical. The Evaluation Manager shall provide written guidance, including the Evaluation agenda and documentation supplied by the Cooperation, to ensure team members are fully aware of their function. It is also important that, before commencement, the Applicant Cooperation fully understands what to expect from the Evaluation.

**13.2 Conduct of the Evaluation Visits****13.2.1 Introduction**

The "on-site" element of the Evaluation shall consist of four elements:

a) appraisal of the effectiveness of the secretariat of the Cooperation's Arrangement to observe:

- ♦ whether the Cooperation's documented requirements are implemented;
- ♦ whether the Cooperation's procedures for Evaluation are implemented;
- ♦ whether decision making regarding Signatory status of the Arrangement is consistent with that of the other ILAC-recognised Cooperations.

b) participation in at least three of the Cooperation's Evaluations or re-evaluations of Accreditation Bodies to:

- ♦ observe the Cooperation's evaluators in action;
- ♦ gain a first hand impression of the operation of bodies which are Signatories to the Arrangement in the region;
- ♦ appraise the consistency with world standards of the technical competence of the practices and assessments of the selected Accreditation Bodies.

c) appraisal of the technical aspects of the Cooperation's Arrangement practice; and

d) appraisal of all confidence building activities which have been undertaken regarding the Cooperation prior to its application.



### 13.2.2 Evaluation of the secretariat of the Cooperation's Arrangement

After having studied all of the documentation listed at Section 10 above, the Evaluation Manager and one other member of the Evaluation team shall undertake a visit to the secretariat of the Cooperation's Arrangement. During this visit this team shall :

- ♦ review the re-evaluation programme and re-evaluation records for the past 3 years or since inception of the Arrangement (whichever is shorter);
- ♦ review membership of the Committee responsible for the management of the Arrangement and (optional) interview some members and
- ♦ observe a meeting of this Committee;
- ♦ select at random and appraise several Evaluation reports on Accreditation Bodies and check out follow-up actions recommended; and
- ♦ study past minutes of the Committee responsible for decision making relating to the Arrangement, in particular to evaluate decision making relating to Arrangement membership;
- ♦ review procedures and practice for the selection, training and monitoring of the evaluators used by the Cooperation in the Evaluation of Accreditation Bodies;
- ♦ review procedure for maintenance of records, archives and the procedures for handling changes of Chair and Secretariat of the Arrangement committees
- ♦ review reports of any internal audits and reviews;
- ♦ appraise regional policy for surveillance and re-evaluation;
- ♦ appraise regional policy for achieving

regional consistency of non-conformities and subsequent decision making regarding accreditation;

- ♦ appraise regional policy regarding their Evaluation of an Accreditation Body's ability to extend its operation into new fields (which would be included in the scope of the ILAC Arrangement);

### 13.2.3 Observation of evaluations of the selected accreditation bodies

As proposed in Section 13.1.2, the Evaluation or re-evaluation of at least three Accreditation Bodies should be observed.

In addition to acting as a full member of the Cooperation's Evaluation team, the ILAC team member has an additional and independent role:

- ♦ to observe the Evaluation and to assess its compatibility with the ILAC and the Cooperation's published Evaluation criteria;
- ♦ to assess the Cooperation's Evaluation team in action;
- ♦ to consider the current scope ( e.g. fields of testing) of the Accreditation Body under Evaluation and to check out the procedures for extending its activity into new fields;
- ♦ on completion of the Evaluation, to evaluate the Cooperation's report of the Evaluation;
- ♦ to prepare a report on the Evaluation for the ILAC Evaluation Manager.

This report shall clearly state the role played by the ILAC team member in the Cooperation's Evaluation team.

## 13.3 Technical Aspects

### 13.3.1 Proficiency testing activity

Cooperations shall make use of Proficiency Testing Activity to demonstrate

satisfactory performance of the calibration and testing laboratories accredited by their Signatories. Requirements and guidance for Proficiency Testing Activity are set out in section 5.3 of ILAC P1. The Evaluation of the secretariat of the Cooperation's Arrangement by the ILAC Evaluation team shall include an appraisal of this function. This appraisal shall include an assessment of the Cooperation's capability to harmonise technical accreditation issues, within and between Cooperations, including the use of practical surveillance activities (e.g. measurement audits) which are considered essential for an equivalent accreditation process. The Cooperation shall have the means to organise, monitor and review of results of Proficiency Testing Activity within their Cooperation and shall have access to technical expertise where needed. It shall also take note of the outcome of participation in international and inter-Cooperation Proficiency Testing Activity including those conducted by BIPM, regional metrological organisations and the Cooperations themselves.

#### 13.3.2 **Traceability and measurement uncertainty**

During Evaluation, the Cooperation shall demonstrate to the ILAC Evaluation team that its policies regarding traceability and measurement uncertainty, and the fulfilment of these policies by its member bodies and their Accredited Laboratories are fully compliant with the requirements of ISO/IEC 17025:1999 (and future versions thereof), ISO/IEC Guide 58 (and future versions thereof) and other relevant documents (e.g., ILAC G2 on Traceability of Measurements and ISO Guide for the Expression of Uncertainty in Measurement or equivalent).

#### 13.3.3 **Harmonisation of technical issues**

The Cooperation shall have the means to harmonise technical accreditation issues, particularly if they are deemed essential for an equivalent accreditation process within the Cooperation.

### 13.4 **Evaluation Reports**

A report on the entire Evaluation shall be prepared by the Evaluation Manager from his own report on the Cooperation's secretariat function and the separate ILAC team member reports on the observed Evaluations. This report, should be checked by the other team members and then disclosed to the Cooperation for correction of misunderstanding, errors of fact and preliminary comment.

### 14. **CORRECTIVE ACTION AND DECISION**

The Applicant shall be invited to address any observed deficiencies that would prejudice "Recognition" and to offer evidence of corrective action.

Corrective actions taken by the Applicant shall be discussed by the Evaluation team (if necessary by correspondence) and a collective view formed on acceptability. This, together with the original Evaluation report and the Applicant Cooperation's response (with corrective action set out where appropriate), shall form the dossier for consideration by the Arrangement Management Committee. The Committee shall then draft a summary report, recommending "Recognition", continuation of "Recognition" or otherwise, for the ILAC Arrangement Council. This summary report shall be passed to the Evaluation Manager for his endorsement. The Evaluation Manager is entitled to have his opinion recorded if, for any reason, he or she is unable to endorse it.

The ILAC Arrangement Council shall make the decision on the Recognition status and inform the Applicant Cooperation in writing.

### 15. **APPEALS**

Appeals shall be made to the Chair of ILAC who shall appoint an independent chairperson to preside over an Appeals Panel of two impartial full members of ILAC and two ILAC evaluators from outside the applicant Cooperation and who had not been involved in the Evaluation.



## **PART D: MAINTENANCE OF “RECOGNITION” STATUS**

### **16 NOTIFICATION OF CHANGE**

- 16.1** In order to maintain the value and meaning of the “Recognition” it is essential that all parties concerned notify the others as soon as possible of any significant changes that occur.
- 16.2** Each “Recognised” Cooperation should ensure that all other Signatories of the ILAC Arrangement are informed, in writing, of any significant changes in status and/or operating practices that are to occur in the region. The following information shall be transmitted as soon as possible to the Arrangement Management Committee:
- (i) details of any change in the name, legal or corporate status of the Cooperation;
  - (ii) details of accessions of Member Accreditation Bodies to the Cooperation’s Arrangement and of the suspension or termination of any existing membership of Accreditation Bodies;
  - (iii) details of any significant changes in the key senior staff and organisational structure of the Cooperation;
  - (iv) significant changes in the mode of operation of the system and in particular in the mechanisms used to evaluate Accreditation Bodies.

### **17 ANNUAL REPORT**

“Recognised” Cooperations shall supply to the Arrangement Management Committee an annual report listing the membership of its Arrangement highlighting any additions to membership that had occurred during the year. The report shall also summarise the outcome of the previous year’s Evaluations, surveillance and re-evaluations and set out the Cooperation’s Evaluation and re-evaluation programme for the forthcoming year.

The report shall summarise Proficiency Testing Activity of the Cooperation and include reference to any inter-regional proficiency testing participation that has occurred. Other documentation should be available on request.

### **18 RE-EVALUATION**

- 18.1** Achievement of world-wide equivalence in the practice of laboratory accreditation and of accredited testing and calibration laboratory competence will be assisted by an on-going programme of inter-Cooperation membership of the Evaluation teams used by a Cooperation to evaluate its Accreditation Bodies.
- 18.2** In addition to full participation in the Evaluation team, such “external” evaluators should make an independent report on the participation, in line with the requirements of Section 13.2.3 of this document, for submission to their parent Cooperation, the host Cooperation and the Arrangement Management Committee.
- 18.3** Formal re-evaluation of a Cooperation shall be undertaken at least every four years. The Arrangement Management Committee shall appoint an Evaluation Manager to plan the re-evaluation. The principle of re-evaluation is to determine whether the recognised Cooperation continues to comply with this document (and its future versions) in order to decide whether ILAC Recognition should be renewed. Depending on the nature of on-going confidence building measures like those mentioned in paragraph 13.2.1 and described in paragraphs 18.1 and 18.2 above, this will not necessarily require the re-implementation of the entire procedure.
- 18.4** The Evaluation Manager shall seek a declaration from the Cooperation under re-evaluation of which documents and procedures listed at paragraph 10 above remain unchanged and which have been revised since the previous Evaluation. The Cooperation shall submit those that have been revised for appraisal by the Evaluation Manager.



- 18.5 The Evaluation Manager shall review the Cooperation's annual reports to the ILAC Arrangement Council and reports of extra-regional evaluators that have participated in the Cooperation under re-evaluation during the previous four years. From this review, the Cooperation's declaration and the appraisal of revised documents, the Evaluation Manager shall prepare a report for the Arrangement Management Committee recommending the balance of re-evaluation action that remains to be undertaken to fulfil the requirements of this document and to ensure confidence in the on-going Recognition of the Cooperation.
- 18.6 The Arrangement Management Committee shall put in hand, under the management of the Evaluation Manager, whatever re-evaluation programme is required.
- 18.7 On completion of the work, a report on the re-evaluation shall be submitted by the Arrangement Management Committee to the ILAC Arrangement Council.