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Ex Management Committee, ExMC

ILAC Operational Document

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-P1:2000

ILAC Mutual Recognition Arrangement (Arrangement): Requirements for Evaluation of Accreditation Bodies

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ILAC-P1:2000

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 the accreditation of calibration and testing laboratories. 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) and the inspection industry and its stakeholders in the development of such an Arrangement and its associated procedures.

ILAC is linking the existing regional 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 for 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 competence of individual ILAC Member Accreditation Bodies to accredit; and
- the evaluation of a Cooperation's competence in managing the operations of regional mutual recognition Arrangements.

The procedures to be used by ILAC for the second of these are set out in document ILAC-P2.

The requirements for procedures to be used by ILAC "recognised" Cooperations when evaluating individual Accreditation Bodies for the purposes of the ILAC Arrangement are set out in this document.

PURPOSE

To provide the ILAC Arrangement Council with criteria for evaluating the procedures used by Cooperations in their mutual recognition Arrangement evaluation process.

AUTHORSHIP

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

1. SCOPE

This document identifies requirements for procedures used by ILAC-recognised Regional Cooperation Body Members (Cooperations) in evaluating individual Accreditation Bodies for its mutual recognition Arrangements.

The topics to be covered by evaluation procedures are listed in paragraph 3. Subsequent paragraphs 4-16 set out ILAC's minimum requirements for each of these topics. In many cases, these requirements are followed by *"NOTES"* (in italic script) which offer advice and guidance, based on evaluator experience to date. These notes may be used by Cooperations when drafting their evaluation procedures which, however, must at least include the minimum requirements.

Procedures and requirements specified below are equally applicable to initial evaluation of an Accreditation Body and to 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 **Applicant Body**: an Accreditation Body that applies to become a Signatory to the Arrangement of an ILAC Member Cooperation of Accreditation Bodies or ILAC.

2.3 **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).

2.4 **ISO/IEC standard**: An ISO/IEC standard, guide or technical report related to conformity assessment.

2.5 **Member**: A Full Member Accreditation Body of ILAC.

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

2.7 **Arrangement**: The ILAC Mutual Recognition Arrangement. The term can also 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.

2.8 **Arrangement Council**: The ILAC decision making body on recognition of Cooperations and on the Signatory status of individual Accreditation Bodies.

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

3. CONTENTS OF PROCEDURES

Evaluation procedures used by Cooperations shall address at least the following topics:

4. OBJECTIVE(S) OF EVALUATION

4.1 The stated objective(s) of a Cooperation's evaluation procedure shall be clearly stated to include the goal of establishing cross-border stakeholder confidence in the reports and certificates issued by accredited laboratories. The evaluation shall be focused on how the Applicant Body ensures the competence of accredited laboratories.

4.2 In order to achieve this objective for Applicant Bodies, the evaluation procedure shall include the following:

4.2.1 An initial appraisal of the documented policies and procedures of the Applicant Body as set out in its quality manual and associated documentation;

4.2.2 An initial appraisal of the documented policies and procedures on traceability routes and measurement uncertainty as well as participation in Proficiency Testing Activity;

4.2.3 An evaluation, on-site, of the implementation of these policies and procedures; and

4.2.4 An evaluation of an Applicant Body's ability to accredit laboratories, including an appraisal of whether the Applicant Body obtains sufficient evidence that laboratories are technically competent to perform the work for which they have been accredited.

5. CRITERIA FOR AN EVALUATION

5.1 Standards

5.1.1 The procedures shall require Applicant Bodies to comply with provisions of ISO/IEC Guide 58 (and future versions thereof) for calibration and testing laboratory accreditation.

5.1.2 The procedures shall also make reference to ILAC and other application documents as appropriate.

5.2 Supplementary Requirements

5.2.1 Additionally, the procedures shall require Applicant Bodies to:

5.2.1.1 Demonstrate the ability of accredited organisations to obtain valid results with reference to the appropriate ISO/IEC standards;

5.2.1.2 Have a permanent secretariat;

5.2.1.3 Employ a head of the Applicant Body, or senior support staff with sufficient experience in the operation of an accreditation system;

5.2.1.4 Be fully operational (i.e., having carried out surveillance and reassessment);

5.2.1.5 Be able to demonstrate that assessments and procedures are satisfactory (i.e., leading to accreditation of competent laboratories);

5.2.1.6 Have access to an appropriate measurement system that enables them to make measurements that are traceable to national or international standards of measurement;

5.2.1.7 Neither offer nor provide, directly, those services that it accredits other organisations to perform;

5.2.1.8 Ensure that activities of related bodies do not affect the confidentiality, objectivity or impartiality of its accreditation operations; and

5.2.1.9 Ensure that it meets the suitable requirements for Proficiency Testing Activity.

5.3 Proficiency Testing Activity

NOTE Proficiency testing is one of the important tools used by laboratories and Accreditation Bodies for monitoring test and calibration results and for verifying the effectiveness of the accreditation process. As such, it is an important element in establishing confidence in the competence of Signatories and their accredited laboratories covered by this Arrangement.

5.3.1 The procedures shall require an Applicant Body for calibration and/or for testing to demonstrate the technical competence of its accredited laboratories by their satisfactory participation in Proficiency Testing Activity. The minimum amount of appropriate proficiency testing required per laboratory shall be specified.

NOTE One activity prior to gaining accreditation and one activity relating to each major sub-area of major disciplines of a laboratory's scope of accreditation at least every four years is recommended. It is recognised that there are particular areas where proficiency testing is just not practical.

5.3.2 An Applicant Body shall demonstrate that the Proficiency Testing Activity that its accredited or applicant laboratories undertake is effective, linked to the assessment process and that appropriate corrective action is carried out when necessary.

5.3.3 Every applicant or Signatory to the Arrangement for calibration and testing shall participate in and use, as far as available and practicable, Proficiency Testing Activity offered by Cooperations, in order to verify the competence of its accredited laboratories and to demonstrate the Accreditation Body's ability to take appropriate actions if necessary.

6. COSTS

6.1 There shall be a documented policy on the costs associated with the evaluation process.

NOTE Travel and hotel costs of the evaluation team could be covered by the Applicant Body, either directly to the team members' organisations or indirectly through a fee charged by the Cooperation (e.g., as part of a contract of cooperation). It is normal practice for observers to cover their own costs.

7. CONFIDENTIALITY

7.1 All confidential information received, both in writing and by spoken word, during pre-evaluations, evaluations, re-evaluations and interim visits shall be treated as such by all parties and persons concerned. This includes information relating to both the Applicant Body and the organisations visited. Provision shall be made to ensure that all members of the team agree to or sign a declaration of confidentiality. Reports on pre-evaluations, evaluations, re-evaluations and interim visits shall only be copied on a "need to know" basis to the representatives of Cooperation members who have a role to play in decision making.

7.2 The Applicant Body and evaluation team shall agree on the storage and safe disposal of documents that have been provided as part of the evaluation process.

8. APPLICATION FOR EVALUATION

8.1 The procedures shall describe the application process.

8.2 The Applicant Body shall, having been supplied with documented evaluation procedures and criteria, indicate its familiarity with the Arrangement requirements and procedures.

8.3 The Applicant Body shall declare its operational status, the accreditation criteria it uses, its staffing, the fields of accreditation in which it operates, the number of accreditations granted and the number of assessment, surveillance/re-assessment visits already performed. The Applicant Body shall also indicate its relationship to government and its authority to operate. Its involvement in the mandatory sector should be made clear.

8.4 Applications shall be acknowledged and handled in an expeditious, non-discriminatory manner.

9. APPOINTMENT OF TEAM LEADER

9.1 In appointing team leaders for a specific evaluation, a Cooperation shall:

9.1.1 avoid the appointment of team leaders that may give rise to their mutual evaluation of their parent organisations in a relatively short period; and

9.1.2 not appoint the same team leader for two successive evaluations of the same Applicant Body.

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

9.2 Team leaders shall comply with the minimum qualifications of evaluation as given in Appendix A.

9.3 An Applicant Body shall be informed of the name of the team leader nominated to carry out the evaluation and the scope of the evaluation, with sufficient notice, so that the

Applicant Body is given the opportunity to appeal against the appointment of the team leader.

10. DOCUMENTATION TO BE SUPPLIED BY THE APPLICANT BODY

The documents to be supplied to the team leader shall be specified in the evaluation procedures so that a complete document review can be performed against the documentation requirements of the applicable ISO/IEC standard(s). These documents typically include:

- the Applicant Body's quality manual in which the policies and procedures of the Applicant Body and the responsibility for implementation of the quality system are clearly designated. Full details of the staffing of the Applicant Body including their backgrounds and length of experience in each type of accreditation shall also be provided if not given in the quality manual;
- accreditation criteria and associated generally applicable criteria that the Applicant Body publishes;
- all other general criteria published which include formal rules or regulations affecting the Applicant Body's operation and the responsibilities and obligations of its accredited laboratories;
- a record of the Applicant Body's compliance with the requirements of the appropriate ISO/IEC standard(s);
- the policy for traceability routes for calibration and testing;
- in the case of a calibration laboratory accreditation Applicant Body, the written guidance provided for the calculation of measurement uncertainty;
- the policy on the surveillance and reassessment of accredited laboratories;
- the policy on the implementation and use of Proficiency Testing Activity;
- summary listing of all Proficiency Testing Activity, including a list of applicant and accredited participants in regional or international Proficiency Testing Activity;
- operational procedures covering Proficiency Testing Activity including criteria for statistical evaluation and corrective action procedures;
- a list of international comparisons in which the economy's national metrology institute has been involved (e.g., BIPM or regional metrology Cooperation);
- any other documentation that describes the mechanics of operation of the accreditation system, including annual reports, questionnaires, newsletters, guidance documents, etc;
- a copy of the body's directory or other listings providing the name and scope of accreditation of each accredited laboratory;
- detailed scopes of accreditation and draft scopes of accreditation of all laboratories to be visited during the pre-evaluation or evaluation visits;
- descriptions of any separate functions or affiliations of the body to activities other than accreditation (such as standards writing, etc);
- details of any formal arrangement or recognition to which the body is party either nationally or internationally, including government authorities, private sector organisations, other accreditation systems, etc;
- reports on any recent evaluations carried out by other relevant organisations, if applicable.

11. PRE-EVALUATION

11.1 Provisions shall be made for a pre-evaluation if requested by the Applicant Body or deemed appropriate by the Cooperation before a full evaluation would take place. The purpose of a pre-evaluation is to determine whether the Applicant Body is ready for evaluation.

NOTE 1 Before any evaluation takes place, the team leader should ensure that the head of the Applicant Body understands and accepts that the evaluation will be conducted in accordance with the requirements and procedures set out in the Cooperation's documents.

NOTE 2 A minimum interval for supply of the required documentation in advance of the visit should be specified.

11.2 The team leader shall propose an agenda for the pre-evaluation visit and ask for assurance that key personnel be available during the visit.

NOTE 1 A team leader should normally be accompanied by at least one other team member for a pre-evaluation visit to ensure more than one person is involved in establishing an Applicant Body's readiness for a full evaluation visit. Evaluation of the documentation shall take place before the team visits the Applicant Body. During a pre-evaluation visit, the team shall discuss at least the quality system, quality documentation and its implementation and make recommendations, where necessary, on actions to be taken before the full evaluation. The team shall also indicate how many days the full evaluation will take.

NOTE 2 A part of the pre-evaluation shall be an assessment of the existence of laboratories providing traceability on the highest level in the economy or region. This is especially necessary where traceability is not clear and where participation in BIPM and related activities is not fully known. The participation in international Proficiency Testing Activity should also be covered.

NOTE 3 During the pre-evaluation visit, the team should be allowed to observe the Accreditation Body carrying out an assessment of one or two accredited laboratories, as appropriate, to gain an initial impression of the operation of the accreditation system and of the competence of its accredited laboratories.

A pre-evaluation visit should normally be from two to three days.

11.3 At the end of the pre-evaluation visit, the team leader shall submit a short written report to the Applicant Body. The report shall indicate the competence of the Applicant Body for preparing documentation and procedures that comply with the requirements of the appropriate ISO/IEC standard(s) and any relevant application documents. In particular, the report shall highlight any major non-conformities with the standards, what actions are needed, and any areas of concern or weakness.

NOTE The report should, as a minimum, contain the following information:

- *main non-conformities found;*
- *the degree to which the Applicant Body fulfils the criteria;*
- *a recommendation or decision whether to continue, suspend or terminate the evaluation process;*
- *a recommendation or decision on the type and number of team members necessary and the estimated duration of any proposed evaluation visits; and*
- *the conditions to be fulfilled before the full evaluation visit is conducted.*

11.4 The Applicant Body shall be given the opportunity to comment on any factual errors in the report. On the basis of the report, the Applicant Body shall be required to describe the corrective actions to be taken.

NOTE The report should normally be issued to the Applicant Body for guidance only on the steps to be taken before the full evaluation. The procedures should prohibit its use to claim that the Applicant Body has been evaluated by the Cooperation.

12. COMPOSITION OF EVALUATION TEAM

12.1 For the full evaluation visit, members of the team shall be chosen as needed to cover the types of accreditation, the technical fields, size and complexity of the accreditation system under evaluation.

Team members shall be chosen from a list of team members prepared and kept up-to-date by the Cooperation. This list should record the experience of team members. At least one member of the team shall have sound experience with these evaluations. One member of the team should be familiar with proficiency testing.

The minimum qualifications of team members shall be as described in **Appendix A.**

12.2 The team chosen shall consist of representatives from a cross-section of Accreditation Body members of the Cooperation. The team shall be chosen to provide a balanced set of skills so as to be able to conduct an effective evaluation of the key components of the system under examination.

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

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

12.3 The Applicant Body shall be informed of the names of the team members nominated to carry out the evaluation and any observers, with sufficient notice so that the Applicant Body is given the opportunity to appeal against the appointment of any particular team member or observer.

12.4 No team member should be associated with any Accreditation Body that has provided consultancy service to the body being evaluated for the last four years.

13 EVALUATION

13.1 Preparation

13.1.1 If a pre-evaluation has taken place, the full evaluation visit shall not be carried out before the Applicant Body has undertaken all the actions agreed at the pre-evaluation visit and before it appears from the documentation supplied by the Applicant Body to meet the criteria.

13.1.2 The team leader shall organise the full evaluation. The evaluation team shall conduct a full evaluation of the operational practices and procedures:
- of the Applicant Body at its offices; and
- in organisations undergoing assessment/ re-assessment and surveillance.

Identification of suitable assessments to witness during the evaluation visit shall be arranged before the visit to the office takes place.

NOTE It is acceptable that some of the evaluation team members may have as their only task to perform witnessing at different geographical places or at different times than the rest of the team. The possibility to exchange views among team members and to discuss observations of any of them during the evaluation period is, however, considered quite important and should be ensured wherever possible.

13.1.3 The team leader shall be responsible for the document review.

NOTE The team leader may delegate specific tasks associated with this review to the other team members.

13.1.4 All members of the team shall be supplied with copies of the necessary documentation at least one month in advance of the evaluation visit.

NOTE If the documentation is supplied too late, the team leader could arrange to postpone the visit

13.1.5 The team leader (when necessary in consultation with the team members) and the Applicant Body shall decide upon the agenda for the evaluation visit taking into account the scope of the accreditations offered and the time needed to conduct an effective evaluation. The agenda shall include the itinerary and assessment/re-assessment, surveillance visits. The agenda shall also include an examination of the Proficiency Testing Activity used by the Applicant Body and the participation of its accredited laboratories.

NOTE 1 It is important that a representative sample of the accreditation work under evaluation can be witnessed by the team.

NOTE 2 The team leader also obtain confirmation that:
(i) the key personnel of the Applicant Body will be available during the visit
(ii) visits have been arranged to organisations as requested and that the team will be able to observe the Applicant Body's assessors carrying out surveillance or assessment/reassessment visits;
(iii) that any extra technical visits, where applicable, have been arranged;
(iv) when requested, the team is provided with the opportunity of attending a meeting of the committee concerned with decisions on accreditation if such a committee exists and is due to meet during the visit;

(v) provisions for the evaluation team are made, such as rooms, personal computer, facilities for copying etc; and
(vi) where requested, arrangements have been made for translators.

13.2 Conduct of the Evaluation Visit

13.2.1 All of the requirements of the appropriate ISO/IEC standard(s) and Arrangement supplementary requirements require appraisal. Two other key tasks of an Arrangement evaluation team are to:

13.2.1.1 evaluate the effectiveness of the Applicant Body's assessment team by observing :

(a) whether the Applicant Body's requirements are implemented;

(b) whether the Applicant Body's procedures for assessment are implemented;

(c) whether the requirements of the appropriate ISO/IEC standard(s) are implemented satisfactorily by accredited laboratories; and

13.2.1.2 verify whether the competence of the laboratories is appropriate to the accredited scope.

NOTE The team members should be allocated specific tasks during the evaluation and that visits to organisations be made after preliminary discussions have been held with the Applicant Body and after any initial queries about the operational procedures and technical requirements of the body have been answered. The team should allow itself sufficient time to discuss its findings in private at the end of each day or session and should leave time at the end of the visit to follow up any outstanding queries arising from visits, etc, before presenting its findings to the Applicant Body.

13.2.2 **Opening meeting**

An initial meeting shall be held with the senior management of the Applicant Body.

NOTE Such meetings should address the objectives of the visit, the criteria to be used, the visit agenda, and the arrangements for reporting the observations and outcome of the on-site visit. After this meeting, the team should split up so that each member proceeds to that part of the evaluation assigned.

13.2.3 **Evaluation of the administration**

13.2.3.1 Part of the evaluation visit shall be devoted to establishing confidence in the Applicant Body's permanent secretariat and the administrative and organisational arrangements for overall operation of the system.

NOTE 1 The evaluation team should set aside sufficient time for this part of the evaluation. During this time they should hold discussions with a cross-section of the staff operating at all levels in the organisation and should discuss the documentation used by the Applicant Body, and should make an appraisal of the effectiveness of the implementation of the documented policies and procedures of the Applicant Body as set out in its quality manual and associated documents. Part of the evaluation should be to check files, records and archives of the Applicant Body. The team should also appraise The relationship with technical and other organisations in the economy and the existence and content of any Arrangements with other Accreditation Bodies.

13.2.3.2 Due attention shall be given to the requirements of the appropriate ISO/IEC standard(s) to check that all the necessary elements are in place and being implemented. After examination of the quality system documentation (or at the same time) the team shall check the extent to which the accreditation criteria for the system incorporate the requirements of the appropriate ISO/IEC standard(s) and Arrangement supplementary requirements. A record should be made of any requirements not covered and of any alternative or additional requirements used.

NOTE 1 The team should examine the guidance documents provided to the staff of the Applicant Body and to external assessors, detailing the use and implementation of the accreditation criteria, and any rules or regulations issued by the Applicant Body.

NOTE 2 The team should check the availability and content of any documents containing additional requirements or guidance to assessors and laboratories.

NOTE 3 The team should check the Applicant Body's procedures for issuing accreditation documents, defining the scope for which accreditation has been granted, identifying approved signatories or key personnel, as appropriate, and maintaining such information up-to-date.

13.2.4 **Assessors**

13.2.4.1 The body's policies and procedures for selecting, training, contracting, appointing and monitoring the performance of internal and external assessors shall be examined.

NOTE Checks should be made to ensure that up-to-date records detailing the qualifications, experience, expertise, training and performance monitoring of assessors are maintained. The evaluation team should ensure that each assessment is conducted by personnel familiar with the requirements of the accreditation system and trained in the techniques of assessment, and possess appropriate technical expertise for their assignment. The team should check that the team leader or a member of the assessment team has sufficient knowledge in the evaluation of quality systems appropriate for the accredited or applicant laboratories. Where applicant bodies use a staff member as leader or part of the team, the same requirements apply.

13.2.5 **Evaluation of performance of assessors and competence of laboratories**

13.2.5.1 The evaluation team shall attend an initial assessment and either re-assessments and/or, where possible, surveillance visits.

NOTE 1 The visits should involve a range of technical fields representative of the accreditations granted by the Applicant Body.

NOTE 2 The evaluation team should pay particular attention to the procedures adopted by the assessment team and note deviations from the specified requirements by the Applicant Body's assessment team when they are observed.

13.2.5.2 The evaluation team members shall maintain the role of observer at all times during the assessment, re-assessment and surveillance assessments to avoid influencing the performance or procedures of the assessors and the responses by staff of the laboratory under assessment. Any observations made by the evaluation team regarding the laboratories under assessment, the assessors, the Applicant Body's staff or the Applicant Body's procedures shall be provided to the Applicant Body after the assessment.

13.2.6 **Assessment reports**

The evaluation team shall examine the procedure for reporting the findings of assessment teams.

NOTE In particular, the team should check that any actions required of laboratories assessed are carried out within the required time scale. If the assessment findings are subject to endorsement by a committee before a decision on accreditation is made, records of the decisions of such committees should be examined. The evaluation team should review the Applicant Body's records of the accreditation process to ensure these are sufficient to justify the decision to accredit.

13.2.7 Committees

Where committees are used to assess the reports of assessments, to assist in the decision-making process or to provide technical advice on criteria, assessors, etc., then their terms of reference and the procedures for appointment of committee members shall be examined in accordance with the provisions of ISO/IEC Guide 58 (and future versions thereof).

13.2.8 **Proficiency testing activity**

13.2.8.1 The way in which the results of Proficiency Testing Activity are used by the Applicant Body shall be established.

NOTE The evaluation team should discuss with the relevant members of the Applicant Body's staff the following matters:

- *identification of areas where Proficiency Testing Activity is available or should be initiated;*
- *criteria for the selection, organisation and use of Proficiency Testing Activity*
- *criteria for accepting Proficiency Testing Activity provided by external bodies;*
- *policies and procedures, including corrective action, for implementing proficiency testing results in the assessment process; and*
- *criteria for the selection of laboratories when access to a particular Proficiency Testing Activity is limited.*

13.2.9 **Traceability and measurement uncertainty**

The team shall evaluate how traceability of measurement and associated estimates of measurement uncertainty are established wherever applicable in accordance with the provisions of ILAC G2:Traceability of Measurements and the ISO Guide for the Expression of Uncertainty in Measurement or equivalent.

NOTE: If the calibration laboratories providing measurement support to the testing laboratories are accredited by a separate Accreditation Body, it may be necessary to hold discussions with the secretariat of that body as part of the overall agenda for the evaluation, particularly if the Accreditation Body is not a Member of the Cooperation.

13.3 **Evaluation Report**

13.3.1 The evaluation team shall make provision in the visit agenda for time to prepare a draft of the final report, the major findings of which are included, to be presented to the Applicant Body before leaving. This draft should be based on observations made and agreed by the team during the evaluation and on other factual information.

NOTE The information in the report and particularly that relating to non-conformities should be accompanied by reference to the relevant clauses of the ISO/IEC standard(s) or mutual recognition Arrangement supplementary requirements.

13.3.2 The team shall prepare a short summary (typically two pages) of the report indicating the main findings and recommendations. This shall be signed by all team members and presented to the Applicant Body at the final meeting. The team leader shall give the Applicant Body an opportunity to comment on and discuss the team's findings and recommendations and to clear up any misunderstandings that may have arisen.

NOTE The team leader should also present a more detailed oral summary of the content of the draft final report to the Applicant Body at the final meeting at the end of the visit.

13.3.3 After the visit, the team leader shall complete the report and, subject to the approval of the final draft by the team members, provide it to the Applicant Body, within two months. The report should basically follow the format described in Appendix B.

NOTE It should clearly highlight the compliance with the requirements of the relevant ISO/IEC standard(s), when relevant the Arrangement supplementary requirements and the Applicant Body's own requirements.

13.3.4 The Applicant Body shall be given the opportunity to correct any misunderstandings or errors appearing in the report.

14. CORRECTIVE ACTION AND DECISION

14.1 Corrective Action

14.1.1 The Applicant Body shall report on any corrective actions, including a time schedule, to the team leader (in the case of re-evaluations within one month) of receiving the final report.

NOTE The team leader should state within one month of receiving the response of the Applicant Body whether the corrective actions are acceptable.

14.1.2 The team leader shall, after consultation with other members of the evaluation team, provide a written recommendation on whether the Applicant Body fulfils the requirements for Signatory status together with the corrected final report and the response(s) from the Applicant Body to the decision making body. This recommendation might include a follow-up visit to verify corrective actions.

NOTE This would normally occur within one month of receiving the response(s) from the

applicant. The recommendation should take into consideration the evaluation findings and the response from the applicant. The justification should also be stated.

14.2 Decision Making Regarding Evaluations

14.2.1 The evaluation report, the corrective actions and the recommendations of the team leader shall be submitted together as the final report to the listed members of the decision making body. For evaluations of unaffiliated Accreditation Bodies, the final report shall be submitted to the ILAC Arrangement Council through the ILAC Arrangement Management Committee.

14.2.2 The decision making body shall decide:
in the case of an initial evaluation,
- whether or not the Applicant Body may enter the Cooperation's Arrangement;

in the case of a re-evaluation,
- whether or not the Applicant Body will remain a Signatory to the Arrangement.
  Positive decisions can be accompanied by conditions.

NOTE 1 In the case of an existing Signatory, the decision making body may recommend, if major non-conformities have been found, to suspend the respective Signatory temporarily for a maximum period of 6 months, until the non-compliances have been discharged.

NOTE 2 The decision making body may decide to carry out a re-evaluation, partly or totally prior to the normal 4 year period. Normally this would be the case after initial evaluations or fundamental re-organisations.

15. APPEALS

15.1 The procedures shall provide for an appeals process by which an Applicant Body may appeal any adverse decision including pre-evaluation recommendations.

15.2 The appeals process shall be documented and provide for an objective statement of the facts of the initial decision and adequate due process.

16. FORMAL MONITORING AND RE-EVALUATION

16.1 Periodic monitoring and re-evaluation of the Arrangement is necessary.

16.2 All Arrangement Signatories shall be formally re-evaluated at maximum intervals of four years.

16.3 Formal re-evaluation shall take place at an earlier date should there be due cause such as notification of significant changes in administration, finances, operational practices or an extension in the scope of accreditation available.

16.4 Re-evaluation visits should be led by a team other than that which undertook the previous evaluation.

APPENDIX A

REQUIREMENTS FOR THE QUALIFICATIONS OF EVALUATORS

A1. Selection of Evaluators

A1.1 A regional Cooperation shall approve and appoint evaluators, maintain a list of the qualified evaluators, and oversee their performance in accordance with the criteria in the following sections.

A1.2 Members of the regional Cooperations may nominate evaluators (i.e., team leaders and team members) in writing, including a description of the experience and the scope of each proposed evaluator to the appropriate committee of the Cooperation.

A2. Team Leaders

A2.1 A team leader shall be able:

A2.1.1 to lead the evaluation in an efficient and effective way, including the distribution of the tasks among the team members;

A2.1.2 to evaluate whether an Accreditation Body complies with the requirements of the appropriate ISO/IEC standard(s) and its accredited laboratories comply with the requirements of the appropriate ISO/IEC standard(s);

A2.1.3 to organize an evaluation team with an appropriate composition (maximum coverage of scope of the Accreditation Body and minimum number of members);

A2.1.4 to decide from the submitted documentation any features requiring special study during the evaluation;

A2.1.5 to report clearly and succinctly the findings of all team members, in compliance with the Cooperation's procedures;

A2.1.6 to evaluate whether the corrective actions decided by the Accreditation Body are likely to be effective and to evaluate the corrective actions carried out;

A2.1.7 to determine the criticality of the findings;

A2.1.8 to adapt quickly and easily to different accreditation cultures.

A2.2 In order to meet these criteria, a team leader shall:

A2.2.1 be an experienced (at least three years) person within an Accreditation Body or organisation which has relevant working experience (at least three years) with accreditation and have the appropriate technical background and experience (at least three years) of assessment;

A2.2.2 have participated in at least two evaluations of Accreditation Bodies as a team member;

A2.2.3 have sound knowledge of the application of the appropriate ISO standards and relevant Arrangement supplementary requirements;

A2.2.4 be able to understand and to express him/herself clearly, in speaking and writing;

A2.2.5 have experience in chairing meetings and in reaching consensus on delicate points;

A2.2.6 have good interpersonal skills.

A2.3 The Cooperation shall appoint team leaders for a three-year term.

A2.4 The Cooperation shall arrange periodic meetings for team leaders in order to improve and maintain the harmonization of the evaluations.

A3. Team Members

A3.1 A team member shall be able:

A3.1.1 to evaluate whether an Accreditation Body complies with the requirements of the appropriate ISO/IEC standard(s) and its accredited laboratories comply with the requirements of the appropriate ISO/IEC standard(s) and other application documents;

A3.1.2 to report clearly and succinctly the findings;

A3.1.3 to determine the criticality of the findings.

A3.2 A team member shall:

A3.2.1 be an experienced person within his/her Accreditation Body or an experienced assessor used by an Accreditation Body, or an experienced person of another organisation knowledgeable in his/her assigned areas of the evaluation;

A3.2.2 successfully completed a relevant training course(s) or have experience in evaluating laboratory Accreditation Bodies;

A3.2.3 have sound knowledge of the application of appropriate ISO/IEC standard(s), and relevant Arrangement supplementary requirements;

A3.2.4 have good interpersonal skills; and

A3.2.5 be able to be understood and to express him/herself clearly.

A4. Evaluator Attributes (based on ISO 10011-2:1991)

A4.1 Evaluators should:

A4.1.1 be open minded and mature;

A4.1.2 possess sound judgement, analytical skills, and tenacity;

A4.1.3 have the ability to perceive situations in a realistic way, to understand complex operations from a broad perspective, and to understand the role of individual units within an organization.

A4.2 Evaluators should be able to apply the attributes of A4.1 in order to:

A4.2.1 obtain and assess objective evidence fairly;

A4.2.2 remain true to the purpose of the evaluation without fear or favour;

A4.2.3 evaluate constantly the effects of evaluation observations and personal interactions during an evaluation;

A4.2.4 treat concerned personnel in a way that will best achieve the evaluation objective;

A4.2.5 react with sensitivity to the local conventions of the area in which the evaluation is performed;

A4.2.6 perform the evaluation process without deviating due to distractions;

A4.2.7 commit full attention and support to the evaluation process;

A4.2.8 react effectively in stressful situations;

A4.2.9 arrive at generally acceptable conclusions based on evaluation observations;

A4.2.10 remain true to a conclusion despite pressure to change that is not based on evidence.

APPENDIX B

GUIDANCE ON THE STRUCTURE AND CONTENT OF AN EVALUATION REPORT

B1 Cover Page
The cover page states the type of evaluation, the name of the Accreditation Body that has been evaluated, the dates of evaluation, the names of the team leader, other team members and observers, specifying the body or organisation they belong to, and a clear indication that the report is confidential.

B2 Contents
For a full evaluation, a page giving the contents of the report, including the appendices.

B3 Summary Page
(about 2 pages), for a full evaluation, the name and type of applicant and the organisations involved in the evaluation. The summary must include the main conclusions with respect to section 5 of this document and be signed by the team members, indicating the organisations to which they belong. The summary report shall be handed over to the applicant on the last day of the evaluation visit.

B4 Introduction
The introduction should give the reason for the evaluation, the participants, a summary of the content of the evaluation, criteria against which the evaluation was performed, activities undertaken during the evaluation, provisions of documentation and translations, type of assessments observed and institutions visited.

B5 Background of the Applicant Body
This section shall give the history and background of the Applicant Body, including fields of accreditation, relationship to government, responsibilities, management, number of accreditations, staffing levels and arrangements with other bodies.

B6 Administration of the System

B6a **General provisions**
e.g., compliance with the appropriate ISO/IEC standard(s) and Arrangement supplementary requirements.

B6b **Organisation**
e.g., staff structure and responsibilities, access to expertise (experts and technical committees); ability to extend to different fields of testing and calibration; accreditation decision responsibilities

B6c **Quality system**
e.g., internal audits and management reviews, corrective action procedures, handling complaints and disputes, commitment to continuous improvement, procedural documentation and records

B6d **Application and assessment**
e.g., assessment and assessment reports

B6e **Surveillance and reassessment**
e.g., adequate mix of surveillance, reassessment and proficiency testing

B6f **Accreditation Decision Making**
e.g., granting, maintaining, extending, suspending and withdrawing; impartiality, technical consistency, objectivity, handling non-conformities, corrective actions, confidentiality, and appeals

B6g **Certificates and reports issued by accredited organisations**
e.g., control of logo use

B6h **Measurement traceability (as appropriate)**
e.g., role of national measurement institute, calibration scope, needs and services, access to national and international measurement standards

B6i **Proficiency testing activity**
(as appropriate)
e.g. , report from appropriate Cooperation committee, commitment, breadth and depth, how analysed, what follow-up corrective actions are taken for unacceptable results

B7 Evaluation of the technical criteria used by the applicant
e.g., against ISO/IEC 17025:1999

B8 Personnel and Assessors

B8a **Staff**
e.g, know how, training, commitment, technical qualifications, personal competence

B8b **Requirements for assessors including qualification criteria**

B8c **Selection, contracting, and performance monitoring of assessors**

B8d **Records of assessors and applicant personnel**
(e.g. training, experience and performance monitoring records)

B8e **Assessor support system**
(e.g. ensuring consistency)

B9 Evaluation of performance of assessors used by the applicant
(e.g. implementation of the requirements of the Accreditation Body, assessment techniques, depth, the competence of assessors in obtaining the right information, selection of items to be assessed, uncertainty aspects, etc. Observations made at visits as compared with the appropriate ISO/IEC standard(s) and Arrangement supplementary requirements. Include organisation of visits, compliance by organisations, traceability in laboratories, site testing, reporting of non-conformities and assessment reports.)

B10 Appendices
- List of documents supplied before evaluation
- Evaluation programme and agenda for visit
- Organisation chart of the Applicant Body
- Accreditation scopes of organisations visited
- Declaration of confidentiality statement signed by all team members and observers
- Miscellaneous