



Accreditation Body Evaluation Procedure

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Part 1 Introduction

0. Purpose

The purpose of this document is to establish the procedure used by NACLA to evaluate Accreditation Bodies (ABs). This procedure is based on an evaluation to ISO/IEC 17011 with some additional NACLA Requirements. This procedure creates a mechanism for establishing the equivalence of the operation of calibration and testing laboratory accreditation programs, with the effect that laboratories accredited by such bodies will be considered to have met the same technical requirements for competence.

This procedure will provide for necessary confidence building opportunities through active participation of regulatory agencies, industry, and others that have the need to build confidence in ABs.

1. Scope

1.1. These procedures will be used by NACLA for the evaluation, and re-evaluation of laboratory ABs, the operation of their recognized accreditation schemes, and acceptance of data from their accredited laboratories.

1.2. When an AB submits an application to NACLA, it agrees to abide by the procedures published by NACLA and promote the NACLA mission and vision.

2. References

NACLA Timeline

NACLA Guidelines

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17011:2004, *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*

PART 2 REQUIREMENTS

3. Criteria

3.1. This document refers to ISO/IEC 17011 as minimum requirements with the applicable Sector Specific Technical Requirement(s). It is understood that some ABs may need to operate in accordance with other additional requirements or specifications (e.g., specific industry requirements, requirements mandated by law or contract).

3.2. Supplementary Requirements

3.2.1. Additionally, applicants (initial and renewal) shall:

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

3.2.1.2. Neither offer nor provide, directly, any conformity assessment service covered by any ILAC or IAF arrangements. This does not exclude related bodies from providing conformity assessment services subject to the conditions of 3.2.1.3.

Note 1: The word “directly” is inserted to make clear that, under the direction of the accreditation body management; no conformity assessment activity should be undertaken;

Note 2: ISO/IEC 17011:2004 defines a conformity assessment body (CAB) as “a body that performs conformity assessment services and that can be the object of accreditation.”

- 3.2.1.3. Ensure that activities of related bodies do not affect the confidentiality, objectivity or impartiality of its accreditation operations
- 3.2.1.4. Ensure that the accreditation body and any related body are effectively separate with respect to management and decision-making, and shall not have the same name or logo mark. The accreditation body shall ensure that there is adequate market place distinction between the accreditation program being evaluated by NACLA and other accreditation activities. These distinctions shall include the following:
 - 3.2.1.4.1. Separate accreditation body names;
 - 3.2.1.4.2. Separate symbols issued to the CAB;
 - 3.2.1.4.3. Separate guidance on the use of the symbols;
 - 3.2.1.4.4. Separate lists of CAB's; and
 - 3.2.1.4.5. Separate certificates of accreditation

4. Costs

- 4.1. ABs will pay expenses for pre-evaluations, evaluations, follow up evaluations, surveillances, and re-evaluations, and travel associated with observations of on-site assessments of the entity by the AB. The AB being evaluated shall pay the expenses for each member of the evaluation team engaged in travel related to the evaluation, including lodging, all transportation, and per diem or meals and expenses. Transportation expenses include airfare, taxis, privately owned vehicles, train fare, or other means of conveyance.
- 4.2. Applicants will pay NACLA a fee for the services of the Evaluation Team (time to be billed includes preparatory and follow-up work as well as pre-evaluation and evaluation visits, see NACLA Fee Schedule).
- 4.3. Expenses must be agreed upon in advance by the AB and the individual evaluators.
- 4.4. Observers, including those who are accompanying the evaluation team, must pay all of their own expenses.

Part 3 Evaluation Process

5. Basic Steps

5.1. The evaluation process involves a number of basic steps. The relevant steps for each type of applicant (initial and renewal) are indicated in the following table.

Steps in the process for type of evaluation

Step	Applicant Type		Applicable Section(s)
	Initial	Renewal	
Application	X	X	6
Decision to start the evaluation process	X	X	6.6/6.7
Appointing team leader	X	X	8
Documentation Review	X	X	9
Pre-evaluation visit: (optional) with decision to Continue	X		10
Composition of the team	X	X	11
Evaluation visit	X	X	13
Evaluation Report	X	X	14

More detailed steps in the evaluation process, including time allowed for each step, are available on the NACLA web site. (See also NACLA Timeline).

5.2. Wherever appropriate NACLA cooperates with other recognizing organizations when requested, in the conduct of joint evaluations of accreditation bodies. When requested, NACLA will follow the procedures in the appropriate NACLA Guideline for the particular organization.

6. Application

6.1. An application shall be made to the NACLA Evaluation Coordinator. All documents shall be submitted in duplicate (hard copy or electronic) in English and all communications must take place in English. An interpreter shall be provided, if necessary. Along with the completed application form, the applicant shall include payment of the application fee. (See [Appendix D](#) for Documentation Requirements, and the NACLA Fee Schedule for applicable fees.)

6.2. The application shall indicate that the AB is familiar with and agrees to the requirements and procedures in this document, and the provisions of recognition.

6.3. Applications shall be accompanied by all information required by the NACLA Application form, as well as the documentation listed in [Appendix D](#) of this document. The following documents are critical parts of that documentation:

6.3.1.A copy of the NACLA Indemnification and Hold Harmless Agreement, also signed by a member of top management of the company;

6.3.2.Proposed Scope of Recognition (See Section 8).

- 6.4. The AB shall appoint a person whom NACLA can contact for arrangements for the evaluation and for further information as required. Contact information shall be included on the application.
- 6.5. The NACLA Evaluation Coordinator shall confirm, in writing or electronically, the receipt of the application and shall review the submitted documentation to determine whether all required documents are included. If any documents are missing, the Evaluation Coordinator will request these from the applicant.
- 6.6. Applications shall be acknowledged and handled in an expeditious, non-discriminatory manner.
- 6.7. Before any evaluation takes place, the Evaluation Coordinator shall ensure that the AB understands and accepts that the evaluation will be conducted as described in this procedure.

7. Evaluation Scope

- 7.1. The range of accreditation activities covered by NACLA evaluation is described in an Evaluation Scope. The intent of the Scope is to provide laboratories, Specifiers, users of accredited laboratories, and accreditation bodies a transparent list. The AB may be evaluated against the criteria for testing, calibration and/or other technical requirements that an industry or government agency may require.

8. Appointment of Team Leader

- 8.1. The Evaluation Coordinator in coordination with the chair of the Recognition Committee appoints the team leader for each evaluation or re-evaluation. The team leader is selected from the list of team leaders compiled by the Training Committee and approved by the Recognition Committee. The list of team leaders is maintained by the Evaluation Coordinator. Team leaders shall be experienced senior staff members of ABs, industry representatives, or government agencies, and meet the requirements outlined in [Appendix C](#). The name of the team leader shall be communicated by the Evaluation Coordinator to the AB. The AB has the right to refuse the team leader (or any team member) for good reason (e.g., unacceptable conflict of interest).
- 8.2. In appointing team leaders for a specific evaluation, NACLA shall, if evaluator resources permit:
 - 8.2.1. avoid the appointment of team leaders that may give rise to their mutual evaluation of their respective ABs in a relatively short period; and
 - 8.2.2. not appoint the same team leader for more than two successive full evaluations of the same AB

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

9. Documentation

- 9.1. The complete list of documentation to be submitted in duplicate to the Evaluation Coordinator by the applicant AB is in [Appendix D](#).
- 9.2. When the team leader has been agreed upon, the Evaluation Coordinator will send a complete set of documentation to the team leader.
- 9.3. Document Review Process ¹
 - 9.3.1. The team leader shall confirm that all necessary documents have been provided by examination of the matrix references and the list of all documents. The team leader shall request any additional documents considered necessary for the document review, and request copies of applicable documents also be sent to other team members.
 - 9.3.2. The document review shall be conducted by the team leader, liaising as appropriate with the team members. The purpose of the document review is to determine whether the AB's documentation meets the requirements of ISO/IEC 17011 and the NACLA Accreditation Body

¹ The document review process should follow the NACLA timeline.

Evaluation Procedure, and that the documentation indicates that the AB accredits against all the requirements of applicable standards.

- 9.3.3. The outcome of the document review shall be recorded in a report. That report shall indicate compliance or non-compliance with the requirements and identify any gaps in the documentation of the system. For non-compliant areas the reason for the deficiency shall be indicated.
- 9.3.4. The team leader shall submit the document review report to the AB and the Evaluation Coordinator, with a request for a response on clarifications, corrective actions and an estimate of the time-scale to submit revised documents, if required.
- 9.3.5. The AB shall provide all amended or additional documents to the team leader for a further review. The team leader (and team members as appropriate) shall review the documents, and if necessary seek further clarification.
- 9.3.6. When the document review is complete and satisfactory the team leader shall issue a final document review report confirming the documents are acceptable and that the evaluation (or pre-evaluation) of the accreditation body can commence.

10. Pre-evaluation²

- 10.1. Before a full evaluation of a new applicant takes place, the team leader may recommend a pre-evaluation to assess whether the applicant is ready for evaluation. The applicant may also request a pre-evaluation.
- 10.2. The timing of the pre-evaluation is determined by the team leader and the AB in consultation with the Evaluation Coordinator. The pre-evaluation shall not take place until the initial document review has been completed in accordance with 9.3.1 through 9.3.4 above. However, it may be helpful to complete the pre-evaluation visit before the AB has finalized all document changes per 9.3.5 and 9.3.6 above.
- 10.3. Pre-evaluation Visit
 - 10.3.1. The pre-evaluation visit shall be conducted by the team leader, and at least one other team member chosen by the team leader from the list of team members maintained by the Evaluation Coordinator.
 - 10.3.2. The team leader shall advise the AB of his or her intended agenda for the pre-evaluation visit, asking for assurance that key personnel will be available during the visit.
 - 10.3.3. The team leader and the team member chosen by the team leader shall visit the AB. During the visit they shall review the quality system, quality documentation, traceability issues, and implementation of the AB's accreditation program(s).
 - 10.3.4. During the pre-evaluation visit, the team may also witness one or two assessments to gain an initial impression of the operation of the accreditation process, of the technical competence of the assessors and of the competence of the CAB. The CAB(s) that are proposed to be part of this evaluation shall be notified by the ABs prior to the visit.
 - 10.3.5. A pre-evaluation visit normally takes two to three days.
- 10.4. Pre-evaluation results
 - 10.4.1. At the end of the pre-evaluation visit (prior to departing the AB offices) the team leader shall submit a written draft summary report to the AB. The report shall as a minimum contain the following information:

² The pre-evaluation process should follow the NACLA timeline.

- 10.4.1.1. Indicate whether or not the AB is in compliance with the evaluation requirements (ISO/IEC 17011:2004) and applicable Sector Specific Technical Requirement(s);
- 10.4.1.2. If assessments are witnessed, the outcome of those witness visits, including whether the AB's accreditation process ensures compliance with applicable standards and the competence of the CAB and assessors;
- 10.4.1.3. Main non-compliances found (required to be submitted and acknowledged by the AB prior to leaving the closing meeting);
- 10.4.1.4. A recommendation whether to continue, suspend or terminate the evaluation process;
- 10.4.1.5. A recommendation on the type and number of team members necessary and the estimated duration of any subsequent evaluation visit;
- 10.4.1.6. The conditions to be fulfilled before the full evaluation visit are conducted.
- 10.4.2. The AB shall be given the opportunity to comment, in writing, on any factual errors in the report. This can normally be accomplished during the closing meeting.
- 10.4.3. The report shall be issued to the AB, with a copy to the Evaluation Coordinator, for guidance on the steps to be taken before the full evaluation. It may not be used to claim that the AB has been fully evaluated or recognized by NACLA.
- 10.4.4. On the basis of the report the AB shall outline the corrective actions to be taken, and the estimated dates for completion of the corrective actions.
- 10.4.5. The Evaluation Coordinator in consultation with the Chair of the Recognition Committee and the Team Leader shall decide whether or not to continue with the evaluation. The AB's contact person shall be informed of the decision by the Evaluation Coordinator, in writing or electronically and orally.
 - 10.4.5.1. The Evaluation Coordinator may refer the decision to the body that will be making the recognition decision.
 - 10.4.5.2. In the event that the decision is to not proceed to full evaluation, the AB can appeal that decision in accordance with the procedure described in Section 21.

11. Composition of the Evaluation Team

- 11.1. The evaluation process is based on peer review, with involvement by organizations that have a critical need to rely upon the competence of the AB and have chosen to participate in NACLA.
- 11.2. For a full evaluation, the team leader, in coordination with the Evaluation Coordinator, shall choose the members of the team as needed to cover the technical fields, size, and complexity of the accreditation system.
 - 11.2.1. Team members shall be chosen from a list of team members prepared and kept up-to-date by the Evaluation Coordinator.
 - 11.2.2. The minimum qualifications of team members are described in [Appendix C](#).
 - 11.2.3. Additional technical experts from other sources may be invited for a specific evaluation or re-evaluation.
 - 11.2.4. Observers may be added to the team, e.g., from regulatory agencies or industries that may need greater confidence in the AB being assessed, with due regard to the need to manage the size of the groups involved in the evaluation process.
 - 11.2.5. If resources permit, there should not be more than one team member from the same organization.

11.2.6. If a pre-evaluation was performed, it is preferable that pre-evaluation team members be included in the full evaluation team if possible and appropriate.

11.3. Size of Team

11.3.1. The size of a full evaluation team shall take into account the activities of the Accreditation Body. The team leader shall decide the composition and size of the evaluation team. The team leader may consult with the Evaluation Coordinator for help in identifying resources. Several team members and observers from other NACLA member bodies or non-members may attend the evaluation if a request is received and approved by the AB.

11.3.2. The AB shall be informed of the names of the team members and observers nominated to carry out the evaluation with sufficient time that the AB is given the opportunity to appeal the appointment of any particular team member or observer. Appeals shall be filed in writing with the team leader within 15 days of such notice and shall include the basis for the appeal. Such appeal is normally on the grounds of conflict of interest or prior contractual arrangement between the body and the team members.

11.3.3. The team leader and team members, including technical experts shall meet the requirements for conflict of interest as defined in [Section 17](#), signs the Confidentiality and Impartiality Form provided in [Appendix F](#), and provide a copy to the applicant. The original shall become part of the final report.

12. Evaluation Preparation and Scheduling

12.1. The full evaluation visit shall not be scheduled before the team leader is confident that the AB is prepared.

12.1.1. In all cases, the document review process must be completed per Section 10, and the documentation and objective evidence supplied by the AB appear to meet the criteria.

12.1.2. If a pre-evaluation was conducted, the AB shall have completed all the actions agreed to at the pre-evaluation visit.

12.2. The team leader shall organize the full evaluation. The evaluation team shall conduct a full evaluation of the operational practices and procedures of the AB at its offices, and in the CAB undergoing assessment, surveillance, or re-assessment by the AB.

12.3. The AB shall supply all members of the team with copies of the documentation held by the team leader at least one month in advance of the evaluation visit, if possible.

12.3.1. In addition, the following information regarding assessments to be witnessed shall also be provided to the team at least one month in advance of those assessments, if possible:

12.3.1.1. Proposed scope of accreditation;

12.3.1.2. For reassessments or surveillance assessments, the currently accredited scope;

12.3.1.3. Composition of assessment team (e.g. number of assessors, background);

12.3.1.4. For visits to CAB's, a list of reference standards and main equipment used in the laboratories to realize the best measurement capability, including details of the traceability of reference standards; for equipment, the calibration intervals, etc. shall also be supplied.

12.3.2. If the documentation is supplied too late, the team leader may arrange to postpone the visit.

12.4. The team leader, in consultation with the team members and the AB shall decide upon the duration of the evaluation visit. The program of work to be undertaken, and the time needed to conduct an effective examination shall be taken into account and shall be documented in a detailed agenda of the main activities to be examined during the visit to the AB, including the CAB(s) to be visited.

- 12.4.1. The team shall allow itself sufficient time to discuss its findings in private at the end of each day or session. Closing meetings shall be held at the end of each day between the evaluation team and the AB to discuss any questions and/ concerns that may have come up during that day. The purpose of these daily closing meetings is to avoid misunderstandings that may arise and for the AB and the evaluation team to answer any questions.
- 12.4.2. The team should leave time at the end of the visit to follow up on outstanding queries arising from the assessment activities. Appendix A includes an example timeline for evaluations.
- 12.5. The team leader (in consultation with the team members, when necessary) and the applicant body together 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.
 - 12.5.1. The team leader shall then prepare, in consultation with the applicant body, a detailed agenda of the main activities to be examined during the visit to the applicant accreditation body, including the accredited or applicant organizations to be visited. An example of a typical timetable for an evaluation is given in [Appendix A](#) below. The evaluation shall include an initial assessment if possible and a mix of re-assessment and/or surveillance visits.
- 12.6. It may not always be possible to schedule the witnessed assessments during the same week as the evaluation at the AB headquarters. If this is the case, the preferred approach is to witness the assessments in advance of the headquarters visit.
 - 12.6.1. When assessments are witnessed prior to headquarters visit, the team leader shall ensure that the AB sends the following information (in addition to information in 12.3.1) to the team member witnessing the assessment:
 - 12.6.1.1. CAB application forms;
 - 12.6.1.2. For surveillance or renewal assessments, report of previous assessment visit and documentation of closure of any findings (if applicable).
 - 12.6.2. In the event that the witnessed assessment(s) can only be conducted after the headquarters visit, the schedule for those activities shall be finalized prior to completion of the headquarters visit.
- 12.7. The team leader shall also obtain confirmation that:
 - 12.7.1. The key personnel of the AB and the CAB(s) to be visited will be available during the visit;
 - 12.7.2. Visits have been arranged to the CAB as requested and that the team will be able to observe the AB's assessors carrying out surveillance or assessment/re-assessment visits;
 - 12.7.3. Extra technical visits, where applicable, have been arranged;
 - 12.7.4. When requested and if available, the evaluation team is provided with the opportunity to attend a meeting of the AB's committee concerned with decisions on accreditation if such a committee exists and is due to meet during the visit;
 - 12.7.5. Provisions for the evaluation team are made, such as deliberation rooms, computers, facilities for copying, etc;
 - 12.7.6. When requested, language interpretation arrangements have been made.

13. Conducting the Evaluation³

- 13.1. Introduction: Adherence of the AB to all of the applicable requirements of ISO/IEC 17011 and the NACLA Accreditation Body Evaluation Procedure and of their CAB shall be evaluated. Other key tasks of the evaluation team are to evaluate the effectiveness of the AB's assessment team by observing:
 - 13.1.1. whether the AB's requirements are implemented;
 - 13.1.2. whether the AB's procedures for assessment are implemented;

³ The evaluation process should follow the NACLA timeline

- 13.1.3. whether the requirements of the appropriate standard(s) are implemented satisfactorily by accredited CAB.
- 13.1.4. verify whether the competence of the CAB is appropriate to the accredited scope and
- 13.1.5. verify the competence of the assessor/technical experts to conduct assessments for the specified scope of accreditation.
- 13.2. Opening Meeting: An opening meeting shall be held with the senior management of the AB being evaluated to confirm the objectives of the visit, the criteria being used, the visit program, and the arrangements for reporting the observations and outcome of the on-site visit.
- 13.3. After this meeting, the team shall split up so that each member proceeds to that part of the evaluation assigned.
- 13.4. Administration of the AB's System:
 - 13.4.1. Part of the evaluation visit shall be devoted to establishing confidence in the AB's permanent secretariat and the administrative and organizational arrangements for overall operation of the system.
 - 13.4.2. The evaluation team shall set aside sufficient time for this part of the evaluation. ([Appendix A](#) indicates the amount of time typically needed.) During this time the team shall hold discussions with a cross-section of the staff operating at all levels in the organization, discuss the documentation used by the AB (i.e., quality manual, criteria, specific procedures, etc.), and make an appraisal of the effectiveness of the implementation of the documented policies and procedures of the AB as set out in its quality manual and associated documents.
 - 13.4.3. The files, records and archives of the AB shall be checked. The team shall also appraise the relationship with technical and other organizations and the existence and content of any Arrangements with other ABs.
 - 13.4.4. Due attention shall be given to the requirements of the ISO/IEC 17011 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 applicable standard(s) and supplementary requirements. A record shall be made of any requirements not covered and of any alternative or additional requirements used.
 - 13.4.5. After examination of the quality system documentation (or at the same time), the team shall check the extent to which the AB's criteria for laboratory assessments comply with the requirements of the applicable standard(s). Where the AB has adopted mandatory documents covering application of the applicable standard(s) in specific fields of testing or calibration, the evaluation team shall also establish that these or equivalent national documents have been complied with. A record shall be made of any requirements not covered and of any alternative or additional requirements used.
 - 13.4.6. The team shall verify that the AB complies with the additional requirements specified in Section 3.2 of this document.
 - 13.4.7. The team shall examine the guidance documents (or however appropriately titled) provided to the staff of the AB and to external assessors, detailing the use and implementation of the accreditation criteria, and any rules or regulations issued by the AB.
 - 13.4.8. The team shall evaluate how traceability and uncertainty of measurement is established.
 - 13.4.9. The team shall check the AB's procedures for issuing accreditation documents, defining the scope for which accreditation has been granted, identifying approved signatories or calibrations and maintaining such information up-to-date. Part of the evaluation visit shall be devoted to establishing confidence in the AB's permanent secretariat and the administrative and organizational arrangements for overall operation of the system.

13.5. Assessors:

- 13.5.1. The AB's policies and procedures for selecting, training, contracting, and appointing internal and external assessors shall be examined. Checks shall 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 shall ensure that each assessment conducted by the AB is conducted by personnel familiar with the quality system and technical requirements of the accreditation system and trained in the techniques of assessment.
- 13.5.2. Where the AB uses a staff member as leader or part of the team the same requirements apply.
- 13.5.3. Witnessing of assessments conducted by the AB provide the most effective means of evaluating assessor competence. The task of the evaluation team during witnessed assessments is to evaluate the effectiveness of the AB's assessment team by observing:
 - 13.5.3.1. The implementation of the AB's requirements and procedures for assessment;
 - 13.5.3.2. That applicable standard requirements are completely satisfied;
 - 13.5.3.3. That verification of the technical competence of the CAB is appropriate for the scope of accreditation.
 - 13.5.3.3.1. The evaluation team shall pay particular attention to the procedures used by the AB's assessment team and note deviations from the specified requirements by the AB's assessment team when they are observed.
 - 13.5.3.3.2. The evaluation team members shall maintain the role of observer at all times during the assessment, re-assessment and surveillance visits to avoid influencing the performance or procedures of the AB assessors and the responses by CAB staff. Any observations made by the evaluation team regarding the CAB being assessed, the assessors, the AB's staff, or the AB's procedures shall be provided to the AB only, after the assessment.
- 13.5.4. The evaluation team shall examine the AB's procedure for reporting the findings of assessment teams. In particular, the team shall check that any actions required of the CAB are carried out within the agreed time frame. 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 shall be examined. The evaluation team shall review the AB's records of the accreditation process to ensure they are sufficient to justify the decision to accredit.
- 13.5.5. Where the AB uses committees to assess the reports of assessments, to assist in the decision-making process, or to provide technical advice on criteria, assessors, etc., their terms of reference and the procedures for appointment of committee members shall be examined in accordance with the provisions of ISO/IEC 17011.

14. Evaluation Report

- 14.1. Before leaving the AB headquarters, the evaluation team shall make provision in the visit program for time to prepare and present a draft of the final report to the AB in a formal closing session. This draft shall be based on observations made and agreed to by the team during the evaluation and on other factual information.
 - 14.1.1. The identified nonconformities, concerns, and comments are included as an Annex in the report to be presented to the AB before leaving.

Note: Non-conformity is defined by ISO 9000:2000 as a non-fulfillment of a requirement. For evaluations, requirements are from ISO/IEC standards and guides, other normative references, supplementary requirements and application documents from specifiers, an AB's own rules, policies and procedures, and evaluator judgments of competence. Non-conformity is supported by objective evidence identified by the evaluation team. The AB would be expected to provide evidence of successful implementation of corrective action to resolve nonconformities before a

positive recommendation can be made. A *concern* is a statement questioning the practice or competence of the AB, but not supported by enough objective evidence to justify non-conformity. Concerns are often the type of findings an evaluation team has not been able to verify, given the limited time and samples involved in an evaluation. The AB must respond to concerns before a recommendation can be made. A *comment* is any of a number of less negative or more neutral findings such as non-prescriptive personal opinion, suggestions for improvement, recommendations regarding the practice of an AB. The AB would not be expected to respond to comments.

- 14.1.2. The information in the report and particularly that relating to non-compliances shall be accompanied by reference to the relevant clauses of ISO/IEC 17011, applicable standards or NACLA requirements, or other relevant sector-specific requirements.
- 14.2. The team shall also prepare a short summary (typically two pages) of the report identifying strengths, weaknesses and conclusions. This shall be signed by all team members and presented to the AB at the final meeting.
- 14.3. In addition, the team leader shall present a more detailed oral summary of the content of the draft final report to the AB at the final meeting of the visit. A final meeting takes place after the witnessed assessments are completed and reported, even if they occur after the week of the headquarters visit. Teleconferencing is acceptable. In the case where witnessed assessments are not completed, an exit meeting will be held at the end of the headquarters visit. At this meeting, the team leader shall give the AB an opportunity to discuss the team's findings and recommendations and to clear up any misunderstandings. The AB is then asked to sign the report to illustrate an understanding of the conclusions of the evaluation team.
- 14.4. The team shall also determine the method of follow-up of all nonconformities and concerns identified, including any follow-up visit, if applicable, with agreement of the AB.
- 14.5. After the on-site assessment the team leader shall complete the report and, subject to the approval of the final draft by the team members, submit it to the AB within one month. The report shall be of the format described in [Appendix B](#). It shall clearly highlight the elements of non-compliance with the requirements of ISO/IEC 17011, and when relevant, the NACLA application publications and the AB's own requirements.
- 14.6. The AB shall be given the opportunity to propose corrections, in writing, to any misunderstandings or errors appearing in the report. After taking into consideration the AB's corrections, the team leader shall submit to the AB and the NACLA Evaluation Coordinator a final draft summary report to the AB within 30 days from the date of the evaluation visit.

15. Corrective Action and Decision

- 15.1. The AB shall provide a written report on any corrective actions taken in response to the evaluation report, including a time schedule for completion of the corrective actions, to the team leader. (In the case of re-evaluations, the corrective-actions report shall be provided within one month of the receipt of the evaluation report.)
- 15.2. With the assistance of the evaluation team, the team leader shall evaluate the corrective actions taken by the AB and report to the Evaluation Coordinator, within one month of receipt of AB's response, whether or not, the team considers the corrective action(s) to be acceptable.
- 15.3. If the evaluation team finds the corrective action inadequate, it shall submit a written description of these inadequacies to the AB. The AB shall respond within one month of receipt of the report.
- 15.4. If the evaluation team finds the corrective action adequate, the team leader shall, after consultation with other members of the evaluation team, provide a written recommendation on whether the AB fulfils the NACLA requirements together with the evaluation report and the response(s) from the AB to the AB and the Evaluation Coordinator within one month of receipt of the AB's response. This recommendation might include a follow-up visit to verify corrective actions.

16. Confidentiality

- 16.1. All information relating to evaluations and re-evaluations, both in written and oral form shall be treated confidentially by all parties concerned. This includes information relating to both the AB evaluated and the CAB visited. The AB under evaluation shall advise the team members on the final disposition of any documents it has provided. For example, the AB may require the team members to return all documents to the AB; or simply to destroy the documentation.
- 16.2. All members of the evaluation team, the Evaluation Coordinator and the Recognition Committee Chair are expected to treat all information gained during the course of an evaluation as confidential. They are expected to refrain from public or private comment about the capabilities of the AB and its accredited CAB except as part of the process.
- 16.3. Where the law requires information to be disclosed to a party, the AB shall be notified of such disclosure and the information provided.

17. Conflict of Interest

- 17.1. Each member of the evaluation team shall be free from any interest that might cause team members to act in other than an impartial and non-discriminatory manner, for example:
- 17.1.1. During the last five years, evaluation team members or their organization shall not have been employed by or in any paid consultancy relationship with the AB under evaluation, so as to compromise the evaluation process and recommendation.
- 17.2. Evaluation team members shall inform NACLA, prior to the evaluation, about any existing, former or envisioned link between themselves or their organizations and the AB to be evaluated.
- 17.3. Members of the evaluation team shall not advise or serve as a consultant to an AB prior to, as part of, or following an evaluation.

18. Decision Making Regarding Evaluations

- 18.1. The decision process will be described in the NACLA Guidelines for those decision bodies.

19. Complaints

- 19.1. This procedure covers the handling of formal complaints against team members, the Evaluation Coordinator, NACLA members and/or the NACLA officials.

20. Responsibility

- 20.1. The NACLA Secretariat is responsible for recording and acknowledging receipt of all complaints, and for referring the complaints to the NACLA Executive Committee.
- 20.2. The NACLA Executive Committee is responsible for classifying complaints as either:
- 20.2.1. complaints against NACLA or,
- 20.2.2. complaints between NACLA members

21. Recording Complaints

- 21.1. Complaints must be submitted in writing to the NACLA Secretariat. If the complaint is against the NACLA Secretariat, the complaint shall be sent to the Board of Directors. Any complaints, whether originating within NACLA or externally, shall be recorded by the Secretariat. The Secretariat shall then send the complaint to the NACLA Executive Committee to discuss the merits of the complaint, classify it in accordance with Section 21.2 above and assign responsibility for its resolution. The Secretariat shall acknowledge receipt of the complaint and advise the complainant as to whom the complaint has been referred within 30 days.⁴
- 21.2. The NACLA BOD members will also be informed of receipt of the complaint and the intended action to resolve it.

⁴ If the complaint is by an CAB against its accreditation body, they shall be asked if it has been through the accreditation body's complaints/appeals procedure. If not, the complainant shall be advised to pursue that course of action.

21.3. Complainants will be advised of the approximate time it will take to resolve the issue within 30 days from receipt of the complaint and will be given status reports throughout the process.

22. Conflicts between NACLA Members

22.1. In dealing with conflicts between NACLA members, the NACLA Executive Committee shall invite the parties involved to settle the conflict between themselves.

22.2. If the parties fail to come to an agreement or if confirmation is needed whether the agreement is in line with NACLA policies and rules, the issue shall be referred to the NACLA Board of Directors.

22.3. If resolution of the complaint leads to a change in policy or a clarification of a policy, the final decision on the new or revised policy shall be concluded in accordance with the NACLA by-laws, Memorandum of Understanding, Quality manual and/or the NACLA Accreditation Body Evaluation Procedure.

Part 4 Maintenance NACLA Recognition

23. Notification of Change

23.1. ABs shall notify NACLA in writing within 30 days of any significant changes that might affect the NACLA evaluation or re-evaluation.

23.2. The following information on changes shall be transmitted as soon as possible:

23.2.1. Details of any change in the name, legal or corporate status of the AB;

23.2.2. Details of new agreements negotiated with other ABs or other parties and of the revision, suspension or termination of any existing agreements;

23.2.3. Details of any significant changes in the key senior staff and organizational structure of the AB;

23.2.4. Significant changes in the mode of operation of the system and in particular in the mechanisms used to assess Organization and / or enterprise that manage M&TE;

23.2.5. Changes to the scope of accreditations granted by the AB;

23.2.6. Any new programs conducted for regulatory agencies.

23.3. Other documentation, such as short directories, full directories, quality manuals and any updates shall be available upon request.

24. Contact Person

24.1. The AB shall identify a contact person for transfer of information to, or receipt of information from NACLA to ensure a consistent channel of communication.

24.2. To minimize confusion, all technical and administrative questions shall be handled by the appropriate contact person at the AB and the NACLA Evaluation Coordinator. Where individual members of the staff of the AB and NACLA formally correspond with one another, the contact person shall be notified.

25. Formal Monitoring and Re-evaluation

25.1. Periodic monitoring and re-evaluation of NACLA-evaluated ABs is necessary.

25.2. All elements of ISO/IEC 17011 shall be evaluated at least every four years as part of a re-evaluation.

25.3. Other monitoring may take place at an earlier date should there be due cause such as notification of significant changes in administration, finances, operational practices or a reduction/extension in the scope of accreditation available to the CAB. The Decision Making Body may also require additional monitoring or surveillance visits as a condition for initial or renewal recognition.

26. Modifications

26.1. This document may be modified by NACLA in accordance with established procedures.

26.2. New requirements added to later versions of this document will become mandatory two years after final publication by NACLA, or as specified upon release of the requirement.

APPENDIX A SAMPLE TIMETABLE FOR AN INITIAL EVALUATION VISIT

Before visit

Team Members examine documentation and prepare questions.

Sunday

Arrival at hotel - planning meeting between team members.

Monday

At offices of the applicant AB:

- Presentation by team leader outlining aims objectives and evaluation criteria.

AB presentation:

- Discussions with staff of AB on quality system and its implementation; and
- Demonstration by the staff of the AB of its administrative procedures.
- Onsite evaluation of additional documentation.

Tuesday

Attendance as observers at CAB assessment or surveillance visit or a visit specially arranged for the NACLA team (four to six visits).

Wednesday

Same as Tuesday

Thursday

Conclude CAB visits, verify CAB information in the AB's record, conclude evaluation of the system to ISO/IEC 17011, discuss observations, and/or draft the report.

Friday

- Completion of summary of report;
- Completion of an outline of the final report; and
- Presentation and discussion of findings to AB at its offices.

For small ABs and re-evaluations it may be appropriate to leave out one day of CAB visits.

APPENDIX B CONTENTS OF EVALUATION REPORTS

Cover page

The cover page states the type of evaluation, the name of the accreditation body that has been evaluated, the date of evaluation, the names of the team leader, team members, and observers, specifying the organization they belong to, and a clear indication that the report is confidential.

Contents

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

Summary page

About two pages, prepared and signed by team members and handed over to the Accreditation Body at the conclusion of the evaluation. This must identify strengths, weaknesses and conclusions.

Introduction

Reason for evaluation, participants, a summary of the content of the evaluation, criteria against which evaluation is performed, activities undertaken during evaluation, and follow up on previous evaluation findings. Provision of documentation, translations (if necessary) and CAB and institutions visited.

History of AB under evaluation

Including relationship to government, responsibilities, management, current scope of accreditation activities, number of accreditations, staffing levels, other general provisions (financing and liability provisions) and agreements with other bodies.

Administration of the system

The narrative may be based on a self-assessment conducted by the AB, modified by the evaluation team to include evidence observed and any issues identified.

Assessment of technical criteria

Details of examination of AB's technical criteria and guidance documents.

Evaluation of performance of assessors used by the system

Observations made at visits as compared with ISO/IEC 17011 and NACLA recognition requirements. Implementation of the AB's requirements, assessment techniques, depth, the competence of the assessors in obtaining the right information, selection of items to be assessed, uncertainty aspects, etc. Include organization of visits, compliance by the CAB, traceability, site testing, reporting of non-compliances and assessments reports, etc.

Annex

- Annex I Nonconformities, Concerns and Comments
- Annex II List of documents supplied before the evaluation
- Annex III Evaluation Program and Agenda for the visit
- Annex IV Organization Chart(s)
- Annex V Summary description of accreditation scope of organizations visited
- Annex VI Reports on witnessed assessments
- Annex VII Miscellaneous e.g. summary of participation in NACLA and other regional proficiency testing programs
- Annex VIII Follow up on previous evaluation findings
- Annex IX Declaration of confidentiality and impartiality from the evaluation team and observers
- Annex X AB corrective action and response report and evaluation team reply

APPENDIX C QUALIFICATIONS OF NACLA EVALUATORS

1. Selection of NACLA Evaluators

1.1. The NACLA Recognition Committee 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.

1.2. CAB accreditation bodies and Specifiers 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 NACLA Evaluation Coordinator.

Note: A Specifier is an organizational member of NACLA (but not a CAB itself) which requires or uses the CAB for its regulatory or contractual purposes.

2. NACLA Team Leaders

2.1. A NACLA team leader shall be able:

2.1.1. to lead the assessment in an efficient and effective way, including the distribution of the tasks among the team members;

2.1.2. to evaluate whether the AB complies with the requirements of the ISO/IEC 17011 and their accredited CAB;

2.1.3. to organize an evaluation team with an appropriate composition (maximum coverage of scope of the CAB and minimum number of members);

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

2.1.5. to report clearly and succinctly the findings of all team members, in compliance with NACLA Evaluation Procedures;

2.1.6. to evaluate whether the corrective actions, decided by the accreditation body are likely to be effective and to evaluate the corrective actions carried out;

2.1.7. to determine the criticality of the findings;

2.1.8. to adapt quickly and easily to different accreditation cultures.

2.2. In order to meet these criteria, a NACLA team leader shall:

2.2.1. be an experienced (at least five years) person within an accreditation body or organization which has relevant working experience (at least five years) with accreditation and have the appropriate technical background and experience (at least five years) of assessment;

2.2.2. have participated in at least two NACLA (or equivalent) evaluations of accreditation bodies as a team member;

2.2.3. have sound knowledge of the application of ISO/IEC 17011 and applicable standards, and relevant NACLA mandatory and guidance documents;

2.2.4. be able to communicate, both orally and in writing, with the Decision Making Body;

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

2.2.6. have good interpersonal skills.

2.3. The NACLA Recognition Committee shall appoint team leaders for a three-year term.

2.4. The NACLA Training Committee shall arrange periodic meetings for team leaders in order to improve and maintain the harmonization of the evaluations.

3. NACLA Team Members

3.1. A NACLA team member shall be able:

- 3.1.1. to evaluate whether an accreditation body complies with the requirements of the ISO/IEC 17011 and their accredited CAB's comply with the requirements of the applicable standards and other additional requirements or specifications (e.g., mandated by law or contract);
- 3.1.2. to report clearly and concisely the findings;
- 3.1.3. to determine the criticality of the findings.

3.2. A NACLA team member shall:

- 3.2.1. be an experienced person within his/her accreditation body or an experienced assessor used by an accreditation body under the NACLA Agreement;
- 3.2.2. successfully completed a relevant training course(s);
- 3.2.3. have sound knowledge of the application of ISO/IEC 17011 and the applicable standards, and relevant NACLA mandatory and guidance documents as appropriate.

3.3. Technical Expert

- 3.3.1. NACLA Technical Expert(s) are chosen for their expertise in an assigned field. They are responsible for performing their assigned duties, in their area(s) of expertise, effectively and efficiently, commensurate with the provisions of the NACLA evaluation process. They are responsible for evaluating the competence of the CAB, within their field(s) of expertise. A NACLA Technical Expert may be experienced personnel of a Specifier knowledgeable in his/her assigned area(s) of the evaluation.

4. Evaluator Attributes

4.1. Evaluators should:

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

4.2. Evaluators should be able to apply the attributes of 4.1 in order to:

- 4.2.1. obtain and assess objective evidence fairly;
- 4.2.2. remain true to the purpose of the evaluation without fear or favor;
- 4.2.3. evaluate constantly the effects of evaluation observations and personal interactions during an evaluation;
- 4.2.4. treat concerned personnel in a way that will best achieve the evaluation objective;
- 4.2.5. react with sensitivity to the local conventions of the area in which the evaluation is performed;
- 4.2.6. perform the evaluation process without deviating due to distractions;
- 4.2.7. commit full attention and support to the evaluation process;
- 4.2.8. react effectively in stressful situations;
- 4.2.9. arrive at generally acceptable conclusions based on evaluation observations; remain true to a conclusion despite pressure to change that is not based on evidence.

APPENDIX D DOCUMENTS TO BE SUBMITTED TO NACLA EVALUATION COORDINATOR BY APPLICANTS FOR NACLA EVALUATION

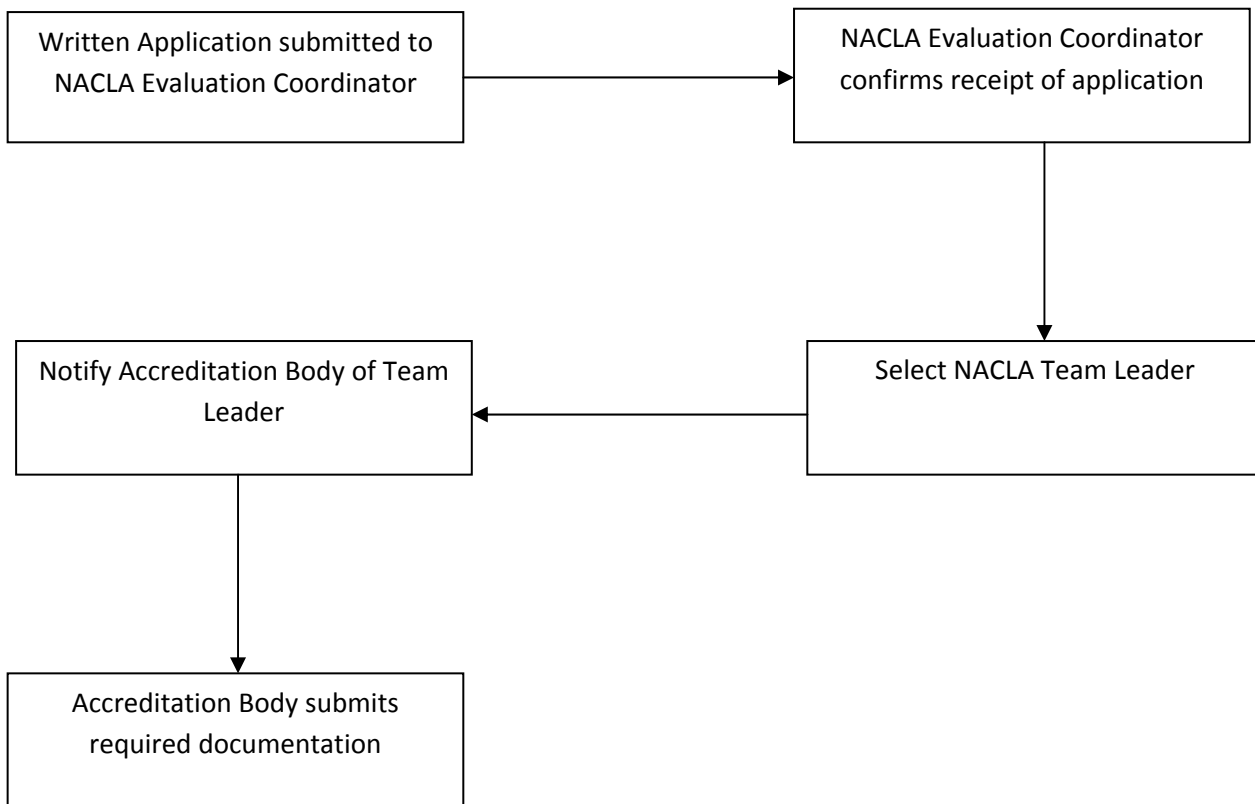
(NOTE: Each applicant shall submit two sets of these materials (either hard copy or electronic) , along with its application fee.)

1. Completed Application Form, and applicable fee.
2. The Accrediting Body's (AB) Quality Manual, in which the policies and procedures of the AB and the responsibility for implementation of the quality system are clearly designated (see also ISO/IEC 17011).
3. Full details of the staffing of the AB, including their backgrounds and length of experience in CAB's, if not given in the quality manual.
4. All accreditation criteria and associated technical criteria required by the AB for the evaluation of CAB.
5. All criteria published, including formal rules or regulations affecting the AB's operation and the responsibilities and obligations of its accredited CAB.
6. A document giving a clause-by-clause cross-referencing of the AB's compliance with each section of the requirements of ISO/IEC 17011, their CAB requirements and document with applicable standards.
7. The AB's policy for the applicable requirements that they are assessing the CAB's, see the appropriate Annexes for the applicable policies and procedures.
8. Guidance documents available to the organization and/ or enterprise published by the AB.
9. The policy on the surveillance and re-assessment of the accredited or applicant CAB.
10. Any other documentation that describes the mechanics of operation of the accreditation system, including annual reports, questionnaires, newsletters, etc.
11. A copy of the AB's Directory or other listings providing the name and scope of accreditation of each CAB accredited by the AB.
12. Detailed scopes of accreditation and draft scopes of accreditation of all CAB's to be visited during the pre-evaluation or evaluation visits.
13. Organizational charts describing the accreditation body and its relationships with any other related organizations.
14. Descriptions of any separate functions or affiliations of the AB for activities other than accreditation (such as product certification, standards writing, and management system registration).
15. Details of any formal agreement or recognition to which the accreditation body is party either nationally or internationally, including government authorities, private sector organizations, other accreditation systems, and any programs operated for other private or government agencies.
16. Reports on any relevant recent evaluations carried out by other 2nd and 3rd party organizations.

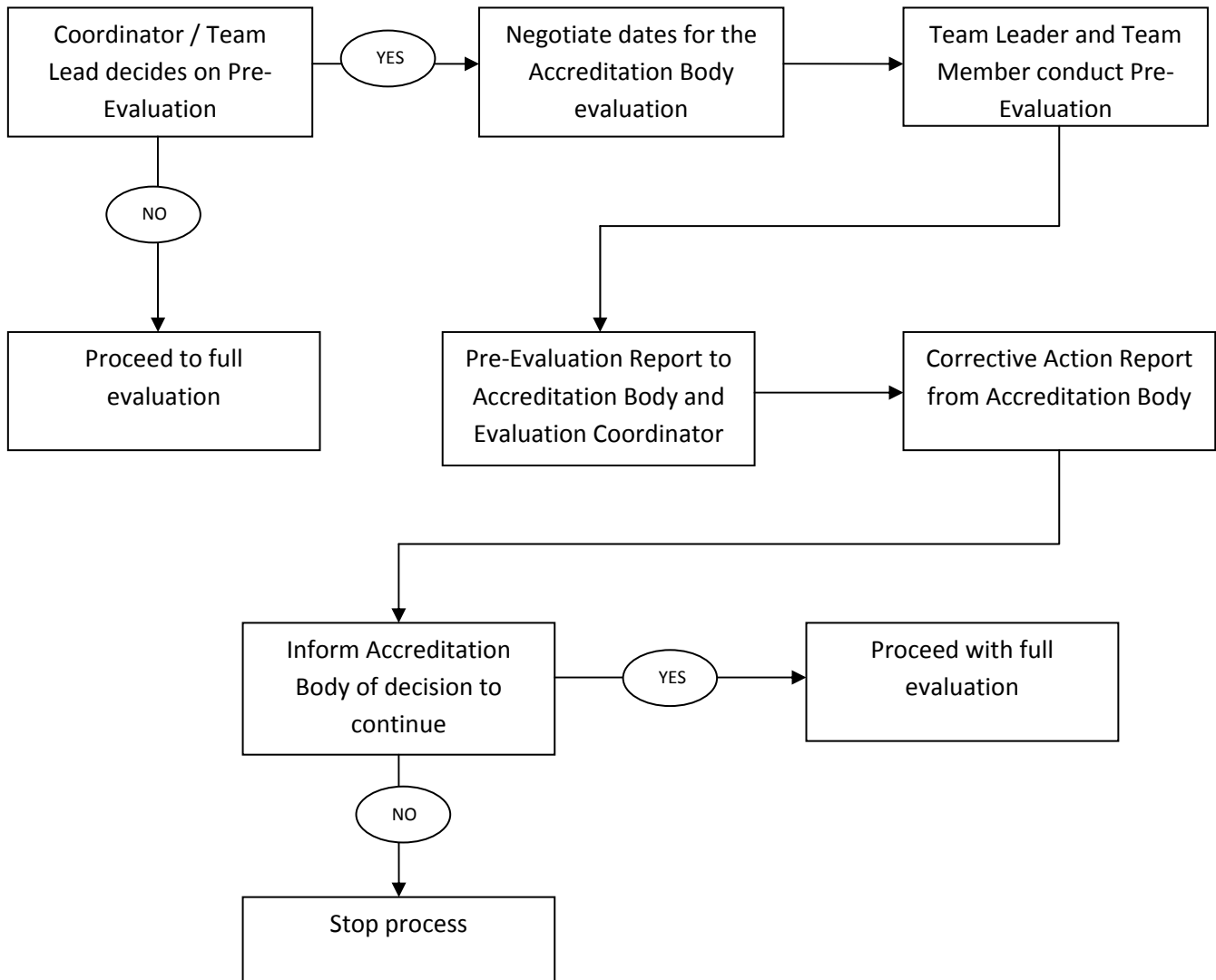
APPENDIX E FLOWCHARTS FOR THE NACLA EVALUATION PROCEDURE

Flow charts of the Application, Pre-evaluation, Evaluation and Corrective Action Processes are found on the following pages.

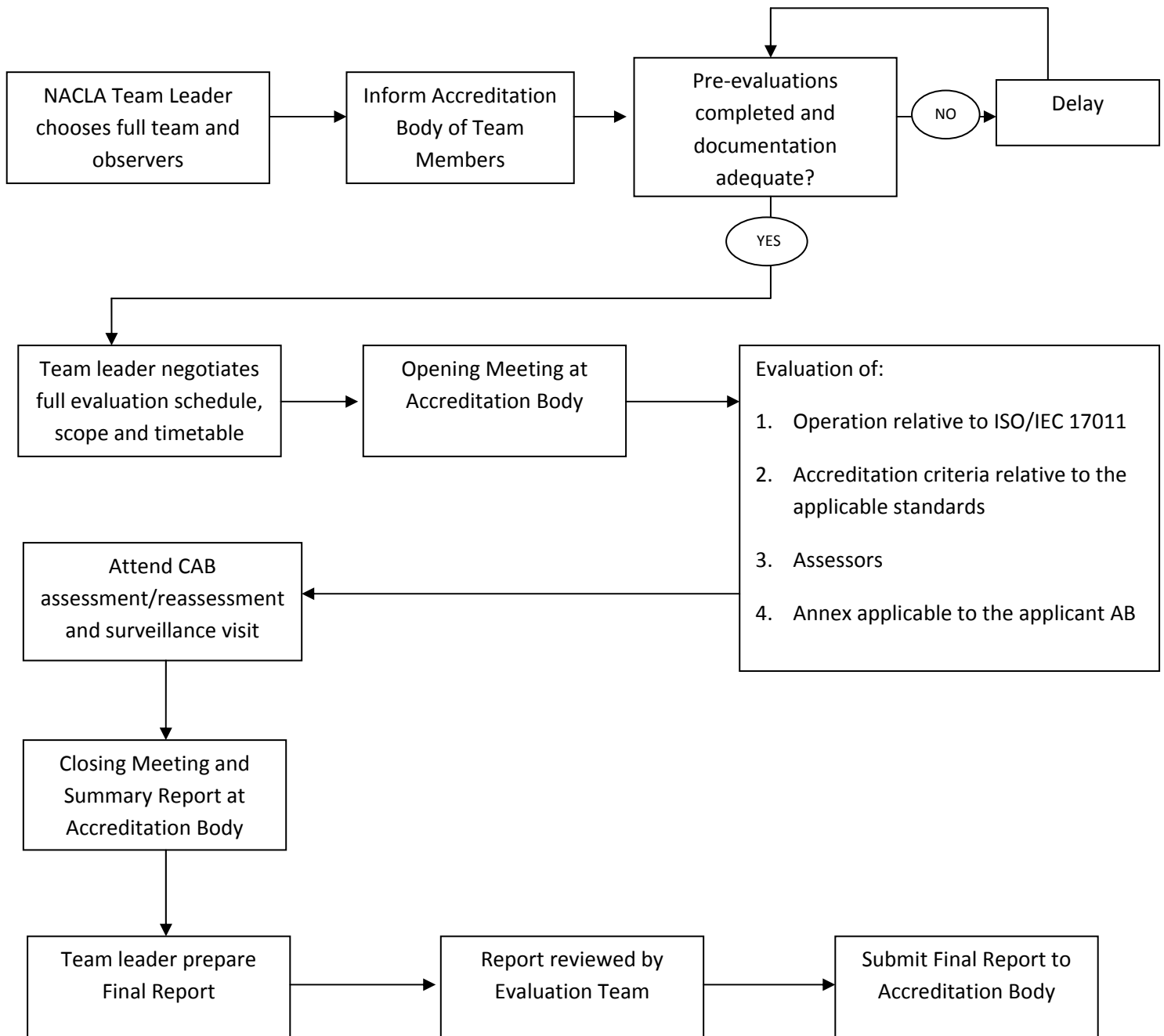
Application Process



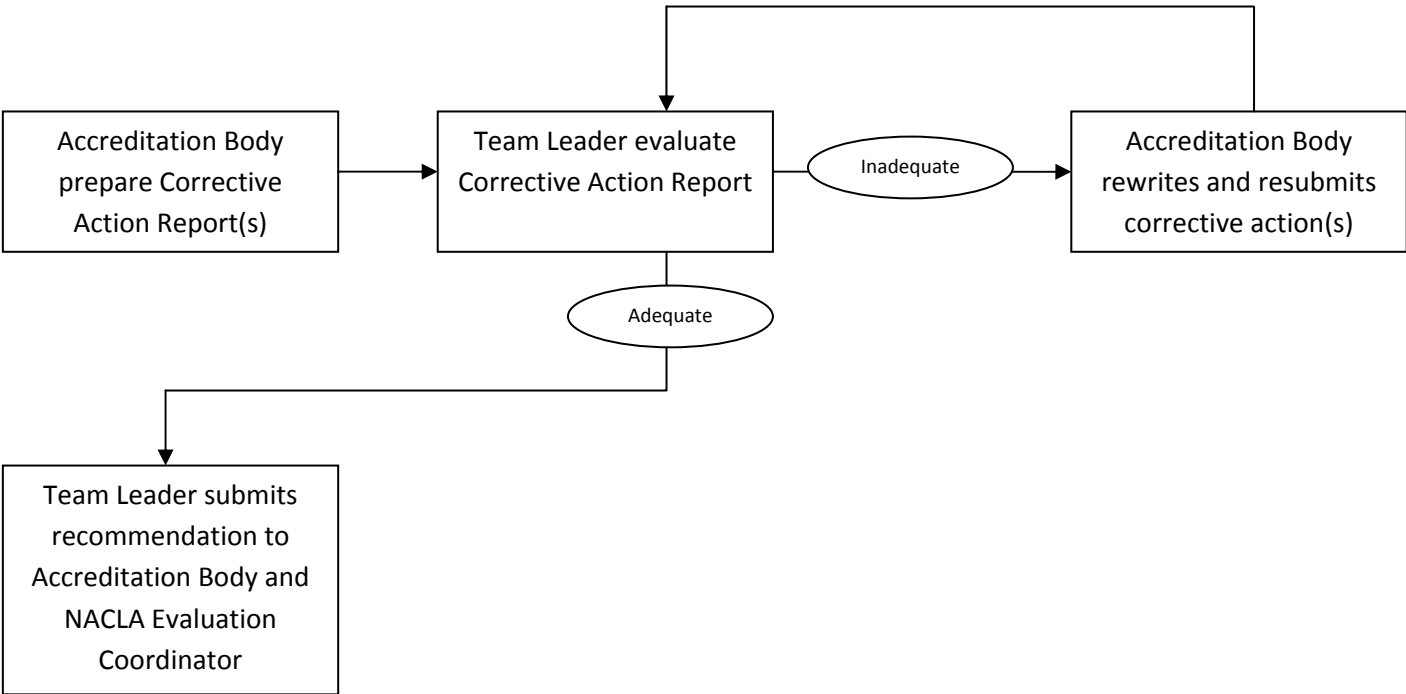
Pre-Evaluation Process



Evaluation Process



Corrective Action Process



APPENDIX F NACLA CONFIDENTIALITY AGREEMENT FORM

This is to acknowledge that I understand my responsibilities as a member of an Evaluation Team or a Decision Making Body used by the National Cooperation for Laboratory Accreditation.

I hereby commit myself to the following:

- I agree to comply with the policies, procedures and rules established by NACLA and the NACLA Recognition Committee while serving on a NACLA Evaluation Team or a Decision Making Body used by NACLA.
- I will maintain confidentiality of all information relating to applicants, evaluations, and recognitions of accrediting bodies and the CAB's they accredit. I will hold in strict confidence all information, proprietary or otherwise, obtained in the course of my service on an Evaluation Team or the Decision Making Body.
- I understand that I may reveal information about individual accreditors and organization and / or enterprise that manage M&TE only to NACLA, the accreditor or CAB itself, and members of a NACLA Evaluation Team or Decision Making Body.
- I will not offer consultancies or services to accrediting bodies or organization and / or enterprise that manage M&TE that might compromise my impartiality during any phase of the evaluation or decision-making process.
- For each accrediting body that I evaluate or that I make an acceptance decision about, I will be free of any commercial, financial or other pressures or conflicts of interest that might cause me to act in other than an impartial and nondiscriminatory manner.
- For each accrediting body that I evaluation or pass judgment on, I will keep NACLA informed, in a timely manner, of any activities, affiliations or relationships that might compromise my adherence to commitments made in this document. This includes informing NACLA of any prior association with any accrediting body to be evaluated or to be reviewed by the Decision Making Body used by NACLA.

Please send to NACLA, with this signed form, a listing of any possible conflict-of-interest affiliations and the nature of each.

Signature:

Printed Name:

Date:

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