



Accreditation Body Evaluation Procedure for ISO/IEC 17025

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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 of ISO/IEC 17011 with additional Sector Specific Technical Requirements for AB's providing accreditation to laboratories for ISO/IEC 17025. 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 AB's.

1. Scope

1.1 This evaluation procedure will be used by NACLA for the evaluation, and re-evaluation of laboratory AB's, 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 Accreditation Body Evaluation Procedure

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

ISO/IEC 17025:2005, *General requirements for the competence of calibration and testing laboratories*

ISO/IEC 17043:2010, *Conformity Assessment – General requirements for proficiency testing*

ILAC P10, *ILAC Policy on Traceability of Measurement Results*

3. Objectives

3.1 The stated objective of NACLA's evaluation procedure is to establish stakeholder confidence in the reports and certificates issued by laboratories accredited by NACLA recognized accreditation bodies. The objectives of an evaluation shall be to establish confidence:

3.1.1 That the AB conducts its assessments and accreditations in accordance with the requirements given in ISO/IEC 17011 and other requirements established by NACLA (see section 5).

3.1.2 That the laboratories accredited by the AB fully meet the requirements for accreditation as stated in ISO/IEC 17025, and as specified by the AB;

3.1.3 That a laboratory accredited by the AB follows all elements of the required standards relevant regulatory requirements and/or contract requirements needed to obtain accredited status.

3.1.4 That the AB ensures the competence of accredited laboratories.

3.2 The evaluation shall include the following:

3.2.1 An appraisal of the documented policies and procedures of the AB as set out in its quality manual and associated documentation;

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

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

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

4 Criteria

- 4.1.1 This document refers to ISO/IEC 17025 and ISO/IEC 17011 as minimum requirements. 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).
- 4.1.2 Supplementary requirements:
- 4.1.2.1 Additionally, applicants (initial and renewal) shall:
- 4.1.2.2 Be fully operational (i.e., having carried out surveillance and reassessment);
- 4.1.2.3 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 4.1.2.4.
- 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 defines a conformity assessment body (CAB) as “a body that performs conformity assessment services and that can be the object of accreditation.” Possible examples of CABs are: laboratories, inspection bodies, QMS certification bodies, product certification bodies, EMS certification bodies, personnel certification bodies.
- 4.1.2.4 Ensure that activities of related bodies do not affect the confidentiality, objectivity or impartiality of its accreditation operations.
- 4.1.2.5 Ensure that the laboratory 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 laboratory accreditation body shall ensure that there is adequate market place distinction between the ISO/IEC 17025 accreditation program being evaluated by NACLA and other accreditation activities. These distinctions shall include the following:
- 4.1.2.5.1 Separate accreditation body names;
- 4.1.2.5.2 Separate symbols issued to laboratories;
- 4.1.2.5.3 Separate guidance on the use of the symbols;
- 4.1.2.5.4 Separate lists of accredited laboratories; and
- 4.1.2.5.5 Separate certificates of accreditation.
- 4.1.3 Proficiency Testing Requirements
- 4.1.3.1 The AB shall have a policy or procedure for the requirements of proficiency testing.
- 4.1.3.2 An AB being evaluated for calibration and/or for testing shall demonstrate the technical competence of its accredited laboratories by their satisfactory participation in proficiency testing activity where such activity is available. The minimum amount of appropriate proficiency testing required per laboratory is:
- 4.1.3.2.1 One activity prior to gaining accreditation;
- 4.1.3.2.2 One activity relating to each major sub-area of major disciplines of a laboratory’s scope of accreditation at least every four years.
- Note 1: Appropriate proficiency testing activity includes international or national inter-laboratory comparisons or measurement audits run or approved by the AB itself.

Note 2: Four years is the maximum interval. Accreditation bodies are encouraged to shorten that interval where there are significant changes to a laboratory's staff or scope of accreditation.

Note 3: An AB should use proficiency testing programs which comply with the operational procedures detailed in ISO/IEC 17043.

- 4.1.3.3 An AB shall fully document its policies and procedures in relation to the selection and use of proficiency testing programs (refer to ISO/IEC 17043, and the requirements of applicable ILAC documents).
 - 4.1.3.4 An AB shall demonstrate that the proficiency testing its accredited or applicant laboratories undertake is effective and linked to the assessment process and that appropriate corrective action is carried out when necessary.
 - 4.1.3.5 When NACLA runs proficiency testing programs or inter-laboratory comparisons (ILCs), every applicant AB whose evaluation scope includes the subject testing or calibration shall nominate laboratories to participate, as far as available and practicable.
 - 4.1.3.6 If the AB operates proficiency testing or inter-laboratory comparison programs in its own right, detailed discussions shall be held with the relevant members of the AB's staff to obtain details of the body's arrangements for design, implementation and analysis of proficiency testing or inter-laboratory comparison programs. The evaluation team shall discuss with the relevant members of the AB's staff the following matters:
 - 4.1.3.6.1 identification of areas where Proficiency Testing Activity is available or should be initiated;
 - 4.1.3.6.2 criteria for the selection, organization and use of Proficiency Testing Activity;
 - 4.1.3.6.3 criteria for accepting Proficiency Testing Activity provided by external bodies;
 - 4.1.3.6.4 policies and procedures, including corrective action, for implementing proficiency testing results in the assessment process; and
 - 4.1.3.6.5 criteria for the selection of laboratories when access to a particular Proficiency Testing Activity is limited.
 - 4.1.3.7 If other organizations operate mandatory proficiency testing or inter-laboratory comparisons for the AB, the evaluation team shall include discussions with such external organizations or examine the AB's procedures to determine whether they are consistent with the provisions of ISO/IEC 17043 and ILAC Guide G13. The evaluation team shall examine the way in which unsatisfactory results of proficiency testing or inter-laboratory comparisons, and corrective action are handled by the AB in the accreditation process.
- 4.1.4 Measurement Traceability Requirements
- 4.1.4.1 The AB shall have a policy or procedure for the requirements of measurement traceability.
 - 4.1.4.2 Calibration Laboratory Accreditation Bodies. It is a fundamental requirement of ISO/IEC 17025 that all measurements made in a calibration laboratory be traceable to national or international standards of measurement.
 - 4.1.4.2.1 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 P10, *ILAC Policy on Traceability of Measurement Results*.
 - 4.1.4.2.2 If the calibration laboratories providing measurement support to these calibration laboratories are accredited by a separate AB, it may be necessary

to hold discussions with the secretariat of that AB as part of the overall program for the evaluation, particularly if the AB is not recognized by NACLA. The purpose of the discussions is to determine the acceptability of the systems required to ensure the traceability of measurement.

- 4.1.4.3 Testing Laboratory Accreditation Bodies. It is a fundamental requirement of ISO/IEC 17025 that, wherever applicable, all measurements made in a testing laboratory shall be traceable to national or international standards of measurement where available. The evaluation team shall establish whether or not this requirement is being satisfied and that the measurements performed have an appropriate uncertainty. The team shall check whether full and proper use is being made of competent calibration laboratories by the testing laboratories being assessed.
 - 4.1.4.3.1 When no such calibration laboratories exist, the arrangements used by the laboratory must be examined in detail to ensure compliance with the requirements of ISO/IEC 17025. When traceability to national or international standards of measurement is not applicable, the evaluation team shall check that laboratories are required to provide satisfactory evidence of correlation or accuracy of test results (for example, by participation in a suitable program of inter-laboratory comparisons, original equipment manufacturers where accredited services are not available, by the use of reference materials that are traceable to national or international standard reference materials, etc.).
 - 4.1.4.3.2 This requirement should wherever possible, be satisfied by the use of either:
 - 4.1.4.3.2.1 a calibration laboratory accredited by an accreditation body recognized by NACLA ;
 - 4.1.4.3.2.2 a calibration laboratory accredited by an accreditation body recognized by ILAC or an ILAC-recognized region; or
 - 4.1.4.3.2.3 a National Metrology Institute.
- 4.1.4.4 Testing and Calibration Accreditation Bodies. If the AB under examination offers accreditation to calibration laboratories as well as testing laboratories, the evaluation team shall check the relationship between the accreditation system and the national or regional measurement system and the arrangements made to ensure traceability of measurement to appropriate primary standards of measurement.
- 4.1.5 Uncertainty of Measurement Requirements
 - 4.1.5.1 The AB shall have a policy or procedure for the requirements for the uncertainty of measurement.
 - 4.1.5.2 The evaluation team shall establish whether or not this requirement is being satisfied, that the measurements performed have an appropriate measurement uncertainty, and that appropriate calibration and measurement capabilities are assigned and published on scopes of accreditation.
 - 4.1.5.3 The team shall evaluate how traceability of measurement and associated estimates of measurement uncertainty are established wherever applicable in accordance with the provisions of the *ISO Guide for the Expression of Uncertainty in Measurement* or equivalent.

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

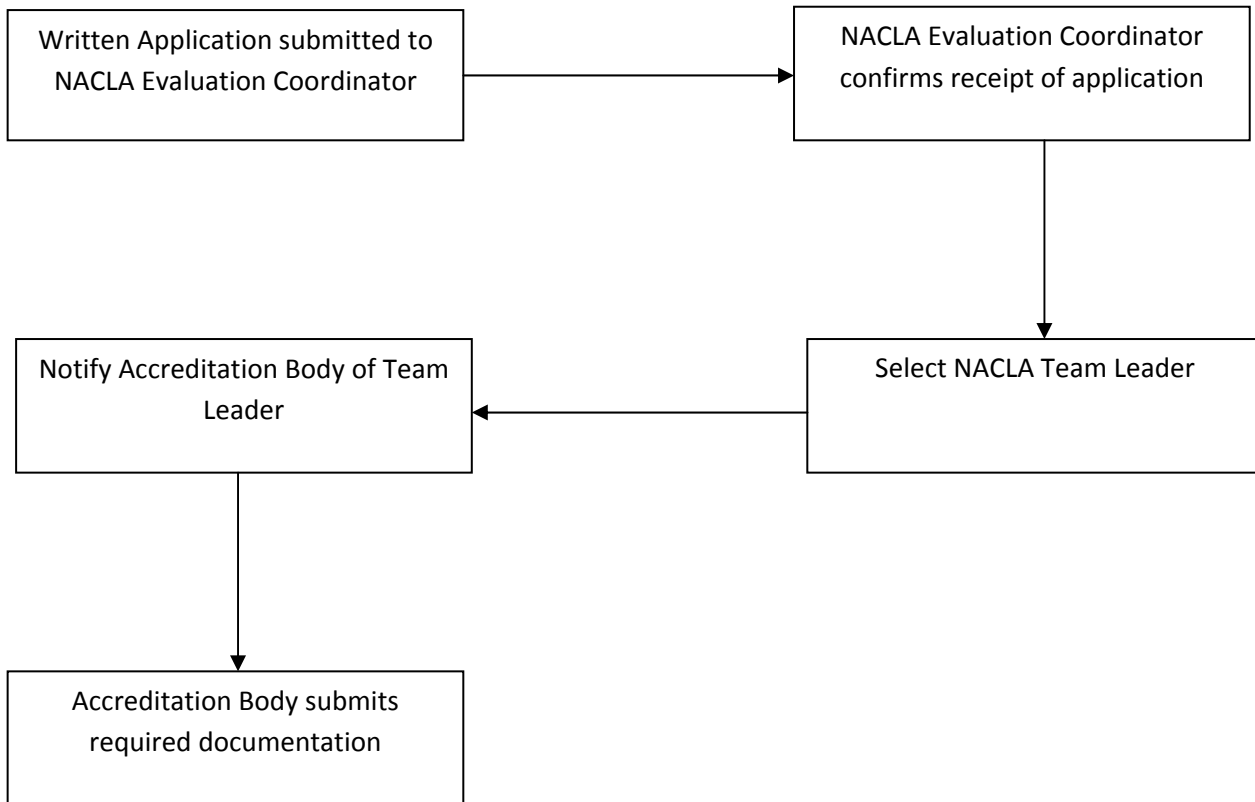
(NOTE: Each applicant shall submit two sets of these materials (either hard copy or electronic) , along with its application fee.)

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
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.

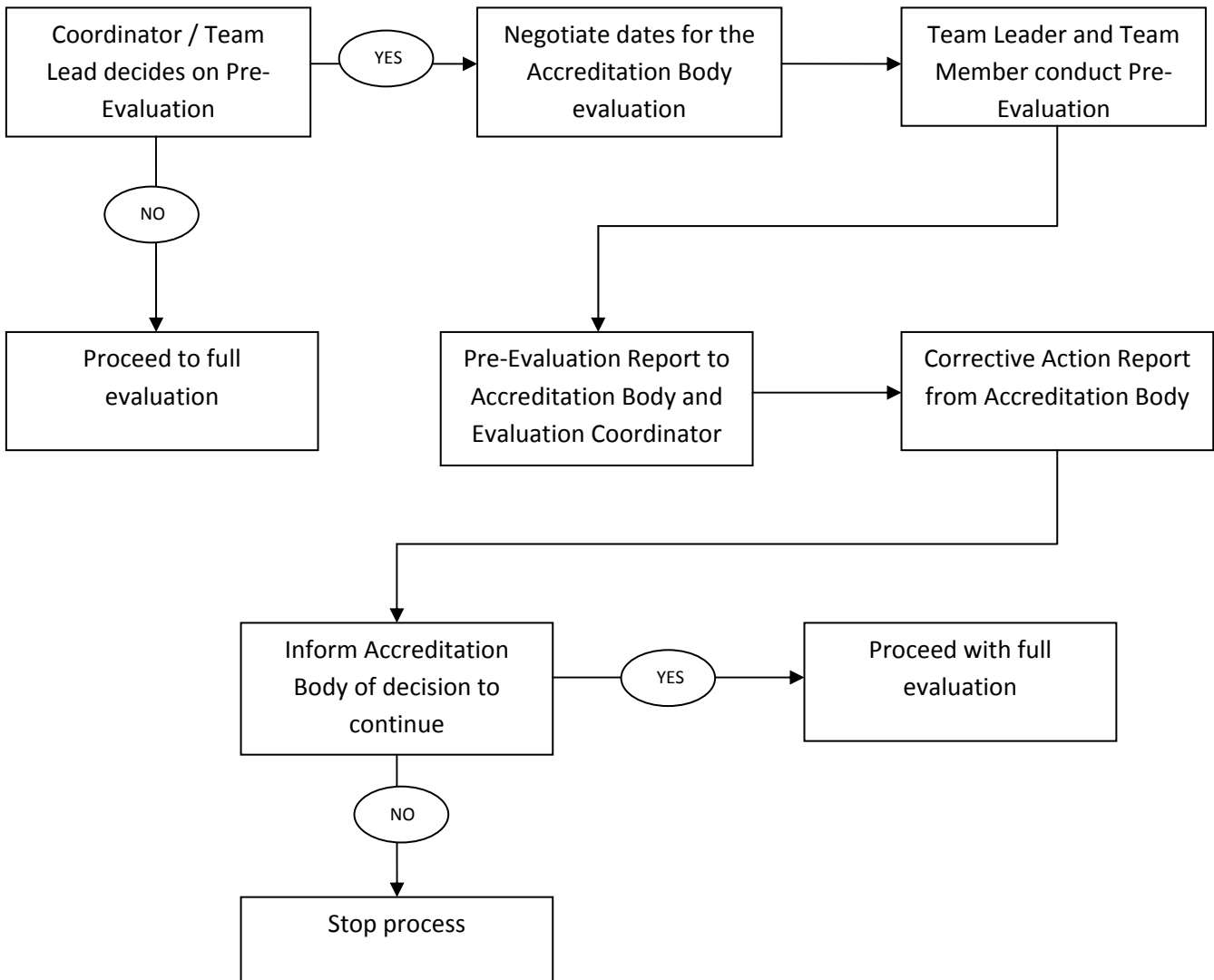
APPENDIX B FLOWCHARTS FOR THE NACLA EVALUATION PROCEDURE

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

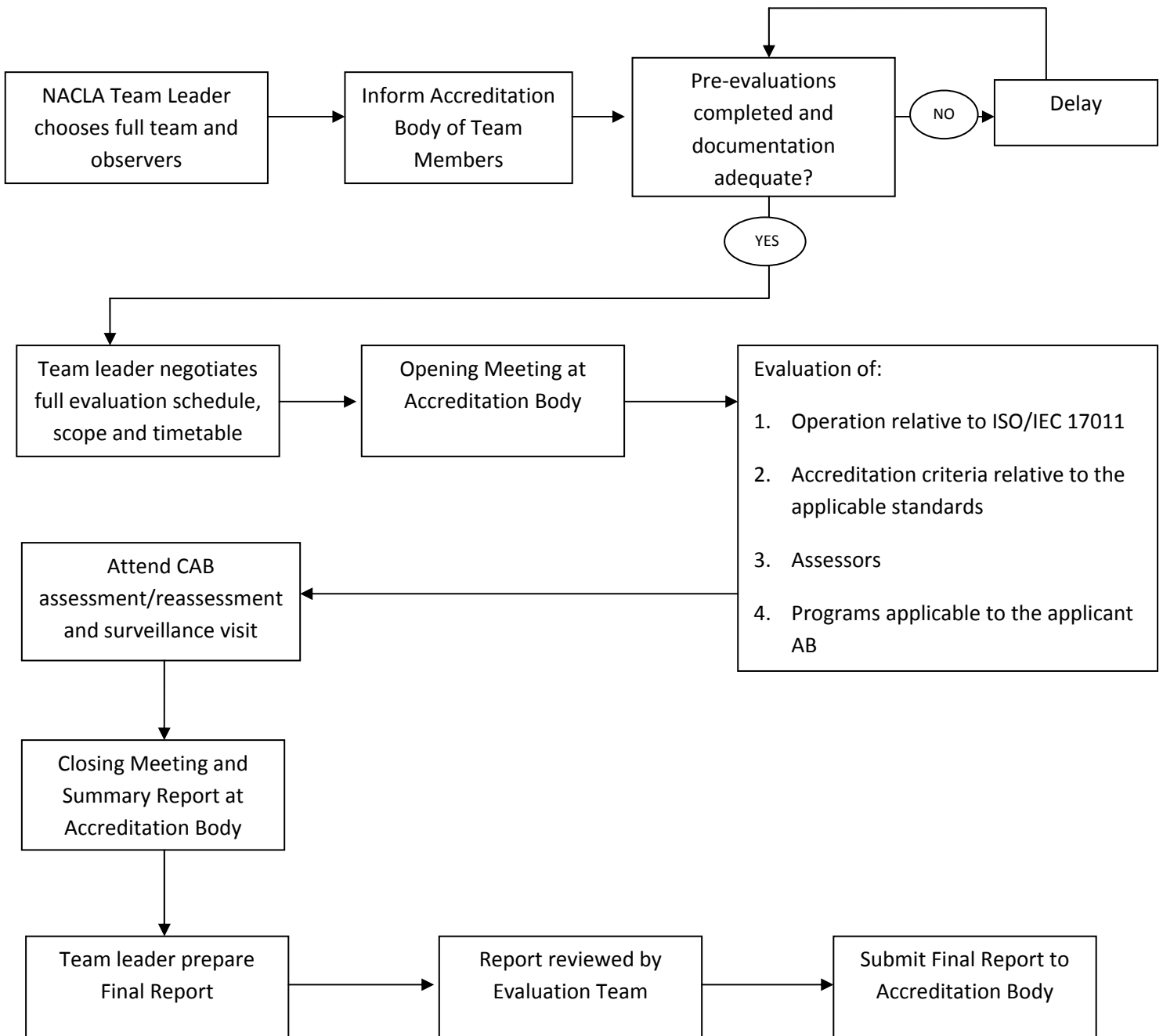
Application Process



Pre-Evaluation Process



Evaluation Process



Corrective Action Process

