



Accreditation Body Evaluation Procedure for ANSI / NCSL Z540.3-2006 subclause 5.3

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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 to ISO/IEC 17011:2004 with additional Sector Specific Technical Requirements. This procedure creates a mechanism for establishing the equivalence of the operation of organization(s) and / or enterprise(s) that manage measuring and test equipment (M&TE) in accordance with the requirements of ANSI/NCSL Z540.3-2006 assessment and accreditation programs. The effect will be such that organization(s) and / or enterprise(s) that manage M&TE 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 and organizations and / or enterprises that manage M&TE to the requirements of ANSI/NCSL Z540.3-2006.

*The word “accredited” as used herein is meant to include acceptance through an approved formal assessment process.

1. Scope

1.1 This annex will be used by NACLA for the evaluation, and re-evaluation of organization(s) and / or enterprise(s) that manage M&TE AB's, the operation of their recognized accreditation schemes, and acceptance of their products and services from their accredited organization(s) and / or enterprise(s) that manage M&TE.

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

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

ANSI/NCSL Z540-2-1997 (R2002) *For guidance on the expression of measurement uncertainty*

ANSI/NCSL Z540.3-2006 *Requirements for the Calibration of Measuring and Test Equipment*

Handbook for the Application of ANSI/NCSL Z540.3-2006 Requirements for the Calibration of Measuring and Test Equipment

JCGM 200:2008 *International vocabulary of metrology – Basic and general concepts and associated terms (VIM)*

3. Definitions

3.1 The definitions in the documents referenced in Clause 2 apply for the purposes of NACLA evaluation. In addition, the following definitions apply:

- 3.1.1 **Calibration system, calibration program** - The set of interrelated or interacting elements necessary to maintain the measurement performance of measuring and test equipment to defined requirements.
- 3.1.2 **Measurement decision risk** - The probability that an incorrect decision will result from a measurement.
- 3.1.3 **Measurement assurance** - The result of a process to provide adequate confidence that a measurement will satisfy stated requirements.
- 3.1.4 **Measurement uncertainty** - Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.
- 3.1.5 **Measurement traceability** - Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

4. Objectives

4.1 The stated objective of NACLA's evaluation procedure is to establish stakeholder confidence in the reports and certificates issued by organization(s) and / or enterprise(s) that manage M&TE accredited by NACLA recognized accreditation bodies. The objectives of an evaluation shall be to establish confidence:

- 4.1.1 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).
- 4.1.2 That the organization and / or enterprise that manage M&TE accredited by the AB fully meet the requirements for accreditation as stated in ANSI/NCSL Z540.3-2006, and as specified by the AB.
- 4.1.3 That an organization and / or enterprise that manage M&TE accredited by the AB follows all elements of the required standards relevant regulatory requirements and/or contract requirements needed to obtain accredited status.
- 4.1.4 That the AB ensures the competence of accredited organization and / or enterprise that manage M&TE.

4.2 The evaluation shall include the following:

- 4.2.1 An appraisal of the documented policies and procedures of the AB as set out in its quality manual and associated documentation.
- 4.2.2 An appraisal of the documented policies and procedures on inclusion of M&TE into the calibration system; establishment of measurement reliability requirement; monitoring of measurement reliability and adjustment of related calibration intervals; measurement traceability establishment including measurement uncertainty validation; as well as implementation of Measurement Assurance processes;
- 4.2.3 An evaluation, on-site, of the implementation of these policies and procedures; and
- 4.2.4 An evaluation of the AB's ability to accredit organization and / or enterprise that manage M&TE, including an appraisal of whether the AB obtains sufficient evidence that their organization and / or enterprise that manage M&TE are technically competent to perform the work for which they have been accredited.

5. Criteria:

- 5.1 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.
- 5.2 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.
- 5.3 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.
- 5.4 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 ANSI/NCSL Z540.3-2006 and supplementary requirements. A record shall be made of any requirements not covered and of any alternative or additional requirements used.
- 5.5 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 organization and / or enterprise that manage M&TE assessments comply with the requirements of ANSI/NCSL Z540.3-2006. Where the AB has adopted mandatory documents covering application of ANSI/NCSL Z540.3-2006, 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.
- 5.6 The team shall verify that the AB complies with the additional requirements specified in Section 5.2 of this document.
- 5.7 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.
- 5.8 The team shall evaluate the criteria and process used to include M&TE into the organization's calibration system, including criteria for determining that M&TE do not require periodic calibration.
- 5.9 The team shall evaluate the criteria and process used to determine performance quality of measuring and test equipment used in the calibration system.
- 5.10 The team shall evaluate the criteria and process used to establish measurement reliability requirements for M&TE, including their use in M&TE performance and calibration intervals.
- 5.11 The team shall evaluate the process of monitoring the M&TE measurement reliability and the adjustment of calibration intervals to maintain the reliability.
- 5.12 The team shall evaluate the process of documenting and assuring that measurement traceability requirements are established and maintained.
- 5.13 The team shall evaluate the process for establishment of measurement uncertainty requirements, their uniform determination, and their application in calibration processes.
- 5.14 The team shall evaluate the process for establishment of measurement decision risk requirements, including "false accept risk" and "false reject risk", their determination, and their application in the calibration process.
- 5.15 The team shall evaluate the process for using and managing the results of measurement assurance methodology.
- 5.16 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.

6. The following areas have specific requirements in relation to the calibration servicing component, whether internal or external to the organization and / or enterprise that manage M&TE that will need to be reviewed during the evaluation of an AB.

6.1 Calibration system, calibration program

6.1.1 The organization shall establish, document, operate, and improve a system to manage the calibration of measuring and test equipment. The organization shall identify and include measuring and test equipment in the calibration system having an influence on the quality of the organization's product and its conformity to determined requirements. Requirements for the product include

- 6.1.1.1 requirements specified by the customer, including the requirements for delivery and post delivery activities;
- 6.1.1.2 requirements not stated by the customer but necessary for specified or intended use, where known;
- 6.1.1.3 statutory and regulatory requirements related to the product; and
- 6.1.1.4 any additional requirements determined by the organization

6.2 Measurement decision risk

6.2.1 The scope of the calibration capability shall be consistent with the calibration requirements and provide levels of measurement decision risk acceptable to both the customer and supplier.

- 6.2.1.1 Where calibrations provide for reporting measured values, the measurement uncertainty shall be acceptable to the customer and shall be documented.
- 6.2.1.2 Where calibrations provide for verification that measurement quantities are within specified tolerances, the probability that incorrect acceptance decisions (false accept) will result from calibration tests shall not exceed 2% and shall be documented. Where it is not practicable to estimate this probability, the test uncertainty ratio shall be equal to or greater than 4:1.

Note 1: Achieving these requirements may involve adjustment and management of calibration system parameters such as: measurement reliability, calibration intervals, measurement uncertainty, calibration tolerances, and/or guard bands.

Note 2: See the Handbook for the Application of ANSI/NCSL Z540.3-2006 Requirements for the Calibration of Measuring and Test Equipment

6.3 Measurement Assurance process

6.3.1 Measurement assurance procedures are employed to monitor the validity of tests and calibrations. Data resulting from applying the procedures provide a means to identify offsets, trends, and process instabilities on a near "real time" basis. Check standards, control charts, statistical techniques, statistical process control, etc., are tools that are typically described in measurement assurance procedures.

- 6.3.1.1 identification of areas where Measurement Assurance processes are required;
- 6.3.1.2 criteria for the selection of Measurement Assurance process;
- 6.3.1.3 criteria for accepting Measurement Assurance process provided by external bodies;
- 6.3.1.4 policies and procedures, for implementing corrective action for unsatisfactory results of the Measurement Assurance process.

Note: Calibration servicing components are encouraged to participate in carefully designed and documented measurement assurance programs (MAPs), round robins, proficiency tests, or other types of intercomparison programs between organizations that provide increased confidence in processes and procedures. The appropriateness of such programs may be determined by the calibration servicing component and/or customer needs.

6.4 Measurement uncertainty

6.4.1 A documented procedure shall be used to estimate and express the uncertainty of measurement for all calibrations. As a minimum, the procedure shall address:

- 6.4.1.1 sources of measurement uncertainty;
- 6.4.1.2 estimation and combining of uncertainties;
- 6.4.1.3 conditions and assumptions;
- 6.4.1.4 documentation and reporting criteria; and
- 6.4.1.5 bibliography.

Note: For guidance on the expression of measurement uncertainty see ANSI/NCSL Z540-2-1997 (R2002)

6.5 Measurement Traceability

6.5.1 The results of a calibration or measurement shall be traceable through a controlled, unbroken chain of competent calibrations to and through the National Institute of Standards and Technology to the SI units of measurement.

6.5.2 This traceability to a national measurement institute other than the National Institute of Standards and Technology is acceptable when:

- 6.5.2.1 a mutual recognition agreement, such as the Comité International des Poids et Mesures (CIPM) Mutual Recognition Arrangement (MRA), is in effect with the National Institute of Standards and Technology and sufficient equivalence of applicable calibration services exists; or
- 6.5.2.2 when the calibration service of the National Institute of Standards and Technology is not available or does not meet the measurement performance requirements.

6.5.3 Where traceability to SI units through national metrology institutes is not available, or SI units are not established, a consensus standard including a reference standard and related calibration procedures, which are clearly specified and mutually agreed upon by all parties concerned, shall be applied.

Note: The elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals

6.5.4 If the calibration servicing component providing measurement support to the organization and / or enterprise that manage M&TE 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.

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

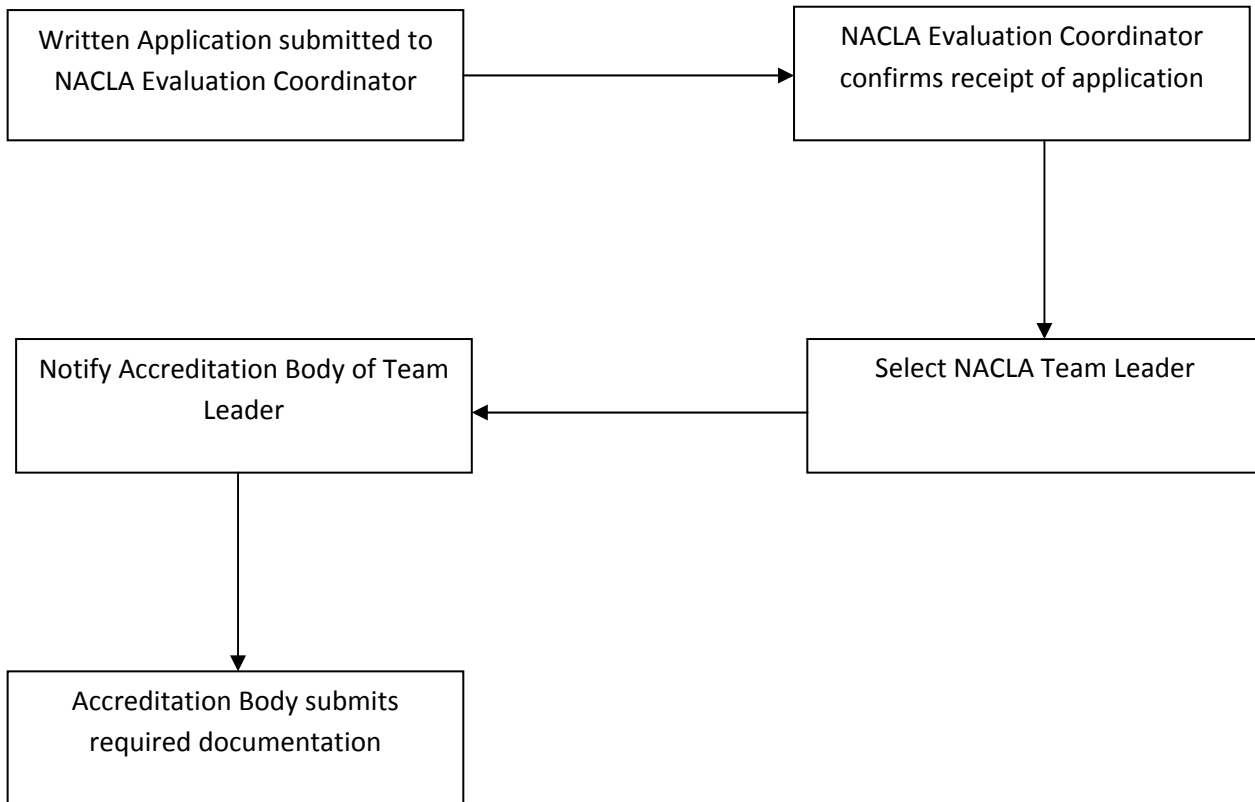
(NOTE: Each applicant shall submit two sets of these materials (either hard copy or electronic) , along with its application fee.)

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, 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.

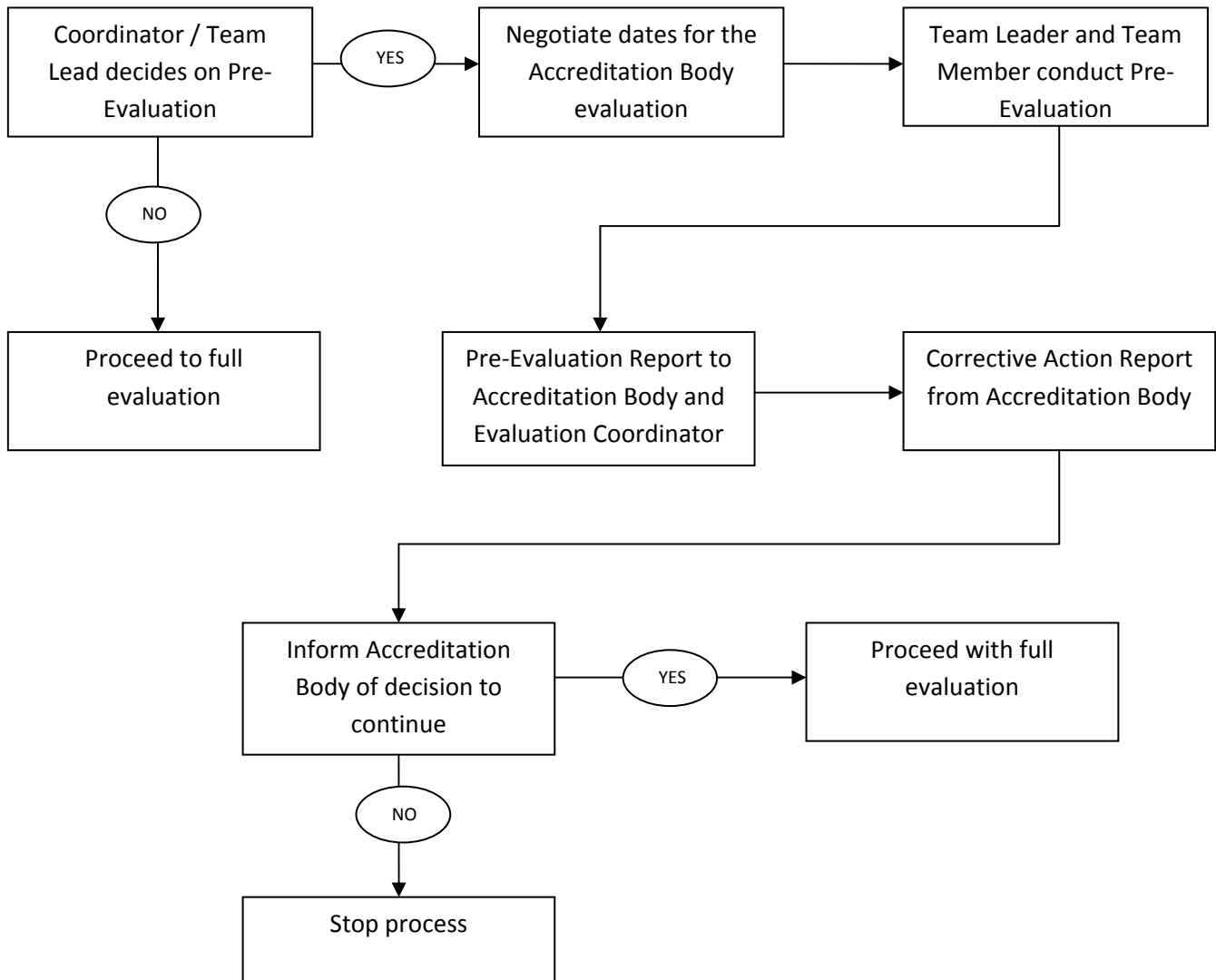
APPENDIX B FLOWCHARTS FOR THE NACLA EVALUATION PROCEDURE

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

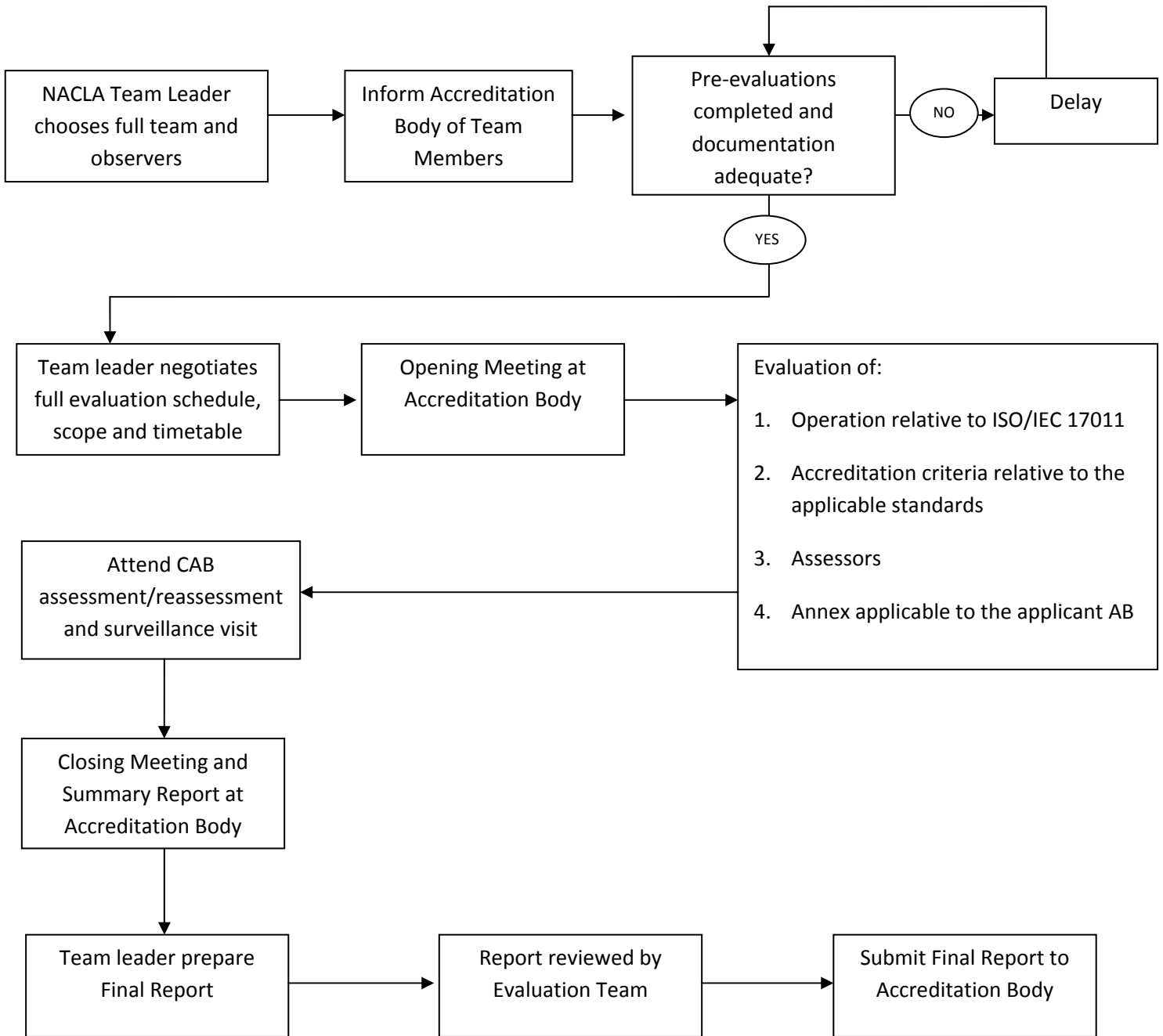
Application Process



Pre-Evaluation Process



Evaluation Process



Corrective Action Process

