



Accreditation Body Evaluation Procedure for ISO/IEC 17020

Rev A Date

Table of Contents

Section Number	Title of Section
<u>0</u>	<u>Purpose</u>
<u>1</u>	<u>Scope</u>
<u>2</u>	<u>References</u>
<u>3</u>	<u>Objectives</u>
<u>4</u>	<u>Criteria</u>
<u>4.3.3</u>	<u>Measurement Traceability Requirements</u>
<u>4.3.4</u>	<u>Uncertainty of Measurement Requirements</u>
<u>Appendix A</u>	<u>Appendix A Documents to be submitted to NACLA Evaluation Coordinator by Applicants for NACLA Evaluation</u>
<u>Appendix B</u>	<u>Appendix B Flowcharts for the NACLA Evaluation Procedure</u>

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 inspection bodies for ISO/IEC 17020. This procedure creates a mechanism for establishing the equivalence of the operation of inspection body accreditation programs, with the effect that inspection bodies 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 inspection body AB's, the operation of their recognized accreditation schemes, and acceptance of data from their accredited inspection bodies.
- 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.
- 1.3 Testing performed by an inspection body may fall into one of two categories namely functional and analytical. Functional testing, for example load testing of a crane, forms a normal part of the activities of an inspection body and is therefore within the scope of ISO/IEC 17020. Analytical testing, (which must be performed inside a laboratory under well-controlled environmental conditions and using more sophisticated equipment or testing procedures) is a laboratory activity and therefore does not come within the scope of ISO/IEC 17020. Inspection bodies wishing to undertake such laboratory type analytical testing as part of an inspection will need to do so in accordance with the relevant requirements in ISO/IEC 17025.

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*
ISO/IEC 17020:2012, *General criteria for the operation of various types of bodies performing inspection*
ISO/IEC 17043:2010, *Conformity Assessment – General requirements for proficiency testing*
IAF/ILAC-A4:2004, *Guidance on the Application of ISO/IEC 17020*
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 inspection bodies 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 4).
 - 3.1.2 That the inspection bodies accredited by the AB fully meet the requirements for accreditation as stated in ISO/IEC 17020, and as specified by the AB;
 - 3.1.3 That an inspection body 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 inspection bodies.

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
- 3.2.3 An appraisal of Proficiency Testing Activity, where relevant and applicable;
- 3.2.4 An evaluation, on-site, of the implementation of these policies and procedures; and
- 3.2.5 An evaluation of the AB's ability to accredit inspection bodies, including an appraisal of whether the AB obtains sufficient evidence that their inspection bodies are technically competent to perform the work for which they have been accredited.

4 Criteria

4.1 This document refers to ISO/IEC 17020 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).

4.2 Supplementary requirements:

- 4.2.1 Additionally, applicants (initial and renewal) shall:
- 4.2.2 Be fully operational (i.e., having carried out surveillance and reassessment);
- 4.2.3 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 4.3.1.1.

Note 1: The word "directly" is inserted to make clear that, under the direction of the accreditation body management; no conformity assessment activity, other than accreditation, 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.

4.3 Independence, Impartiality and Integrity

4.3.1 The categorization of inspection bodies as Type A, B or C is essentially a measure of their independence from the activities of the design, production, and delivery of the objects of inspection for which they are providing inspection services. Demonstrable independence of an inspection body strengthens the confidence of the inspection body's customers in the body's ability to carry out inspection work with impartiality and objectivity. The terms *first party* and *second party*, as defined in ISO/IEC 17000, are not used in ISO/IEC 17020, because application of them would not be helpful. However, since conventional thinking has been in terms of first, second or third parties for many years, it is necessary to offer some explanation on the relationship between the two sets of categories, as included below.

- 4.3.1.1 A Type A Inspection Body, to claim to be independent of the parties involved, shall demonstrate that it is not linked to a party directly involved in design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected or similar competitive items by:
 - a) common ownership (except where the owners have no ability to influence the outcome of an inspection),
 - b) common ownership appointees on the boards (or equivalent) of the organizations (except where these have functions that have no influence on the outcome of an inspection)
 - c) directly reporting to the same higher level of management

- d) contractual arrangements, informal understandings or other means that may have an ability to influence the outcome of an inspection
- 4.3.1.2 In addition to the above, an Inspection Body shall not be accredited as a Type A Inspection Body if another part of the same organization is directly involved in design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected or similar competitive items, when such other parts of the organization do not have a separate legal identity.
- 4.3.1.3 The Chief Executive of the legal entity of which the Inspection Body is a part shall define and document its policy for maintaining the Type A status of the Inspection Body. The Accreditation Body shall examine the evidence of implementation of this policy in respect of ownership interests, constitution of board of directors, means of financing, decision making methods and other such factors that may have an influence on the impartiality, independence and integrity of a Type A Inspection Body.
- 4.3.2 Ensure that activities of related bodies do not affect the confidentiality, objectivity or impartiality of its accreditation operations.
- 4.3.2.1 A Policy or procedures shall be documented to assure inspection body staff is free from commercial, financial or other pressures which might affect their judgment.
- a) The categorization of inspection bodies as Type A, B or C is essentially a measure of their independence. Demonstrable independence of an inspection body may strengthen the confidence of the inspection body's customers in the body's ability to carry out inspection work with impartiality and objectivity. The terms *first party* and *second party*, as defined in ISO/IEC 17000, are not used in ISO/IEC 17020, because application of them would not be helpful. However, since conventional thinking has been in terms of first, second or third parties for many years, it is necessary to offer some explanation on the relationship between the two sets of categories, as included below.
 - b) A Type A Inspection Body, to claim to be independent of the parties involved, shall demonstrate that it is not linked to a party directly involved in design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected or similar competitive items by common ownership (except where the owners have no ability to influence the outcome of an inspection).
- 4.3.2.2 Accreditation bodies present the scope of accreditation for which accreditation of inspection bodies is granted in a formal statement that accompanies the Certificate of Accreditation. The Scope of Accreditation and Certificate of Accreditation shall indicate what type of inspection body has been accredited.
- a) Type A Inspection Body – The inspection body providing “third party” services shall meet the criteria of annex A of ISO/IEC 17020.
 - b) Type B Inspection Body – The inspection body which forms a separate and identifiable part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects and has been established to supply inspection services to its parent organization shall meet the criteria of annex B of ISO/IEC 17020.
 - c) Type C Inspection Body – The inspection body which is involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects or of similar competitive items and may supply inspection services to other parties not being its parent organization shall meet the criteria of annex C of ISO/IEC 17020.
- 4.3.3 Measurement Traceability Requirements
- 4.3.3.1 The AB shall have a policy or procedure for the requirements of measurement traceability.

4.3.3.2 Inspection body Accreditation Bodies. It is a fundamental requirement of ISO/IEC 17020 that all measurements made in an inspection body be traceable to national or international standards of measurement wherever this is appropriate for the science involved in the inspection activities.

- a) 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*.
- b) Where any calibrations to support traceability of measurement are performed in-house within the inspection body or any of its subcontracted testing facilities, metrological traceability to the SI through a national metrology institute or national standard should be assured by using reference standards of measurement for which the inspection body holds a current calibration certificate or equivalent from a competent body. The certificate or equivalent should detail an uncertainty of measurement that is appropriate for the equipment that is to be calibrated from the reference standard.
- c) If any calibration laboratories providing measurement traceability to the inspection body or its subcontracted testing laboratories or their 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.
- d) When no such calibration laboratories exist, the arrangements used by the inspection body and its subcontracted testing laboratories 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 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.).
- e) This requirement should, wherever possible, be satisfied by the use of either:
 - I. a calibration laboratory accredited by an accreditation body recognized by NACLA, or
 - II. a calibration laboratory accredited by an accreditation body recognized by ILAC or an ILAC-recognized region; or
 - III. a National Metrology Institute

4.3.4 Uncertainty of Measurement Requirements

4.3.4.1 The AB shall have a policy or procedure for the requirements for the uncertainty of measurement, when appropriate.

4.3.4.2 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 for those calibration laboratories providing metrological traceability of measurement to inspection bodies accredited by the accreditation body.

4.3.4.3 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 JCGM 100: *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

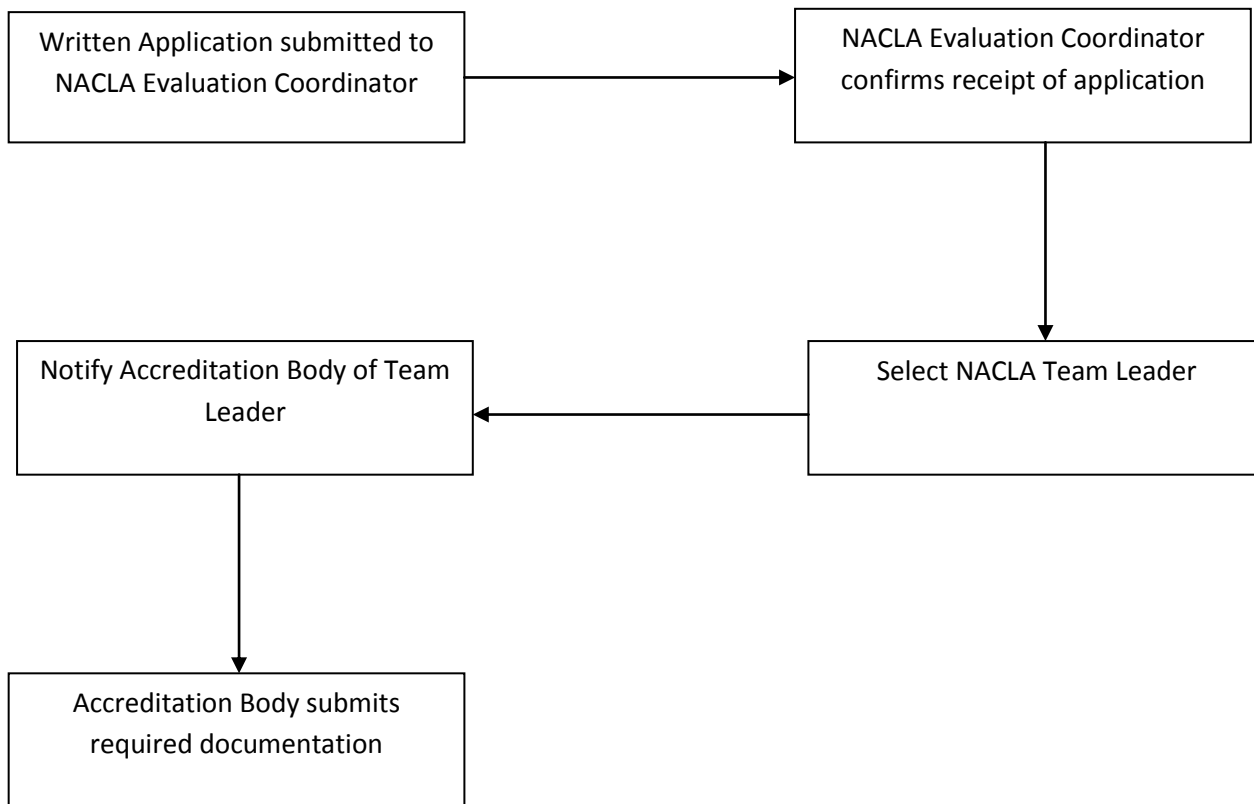
(NOTE: Each applicant shall submit two sets of these materials (either hard copy or electronic) , along with its application fee.)

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.

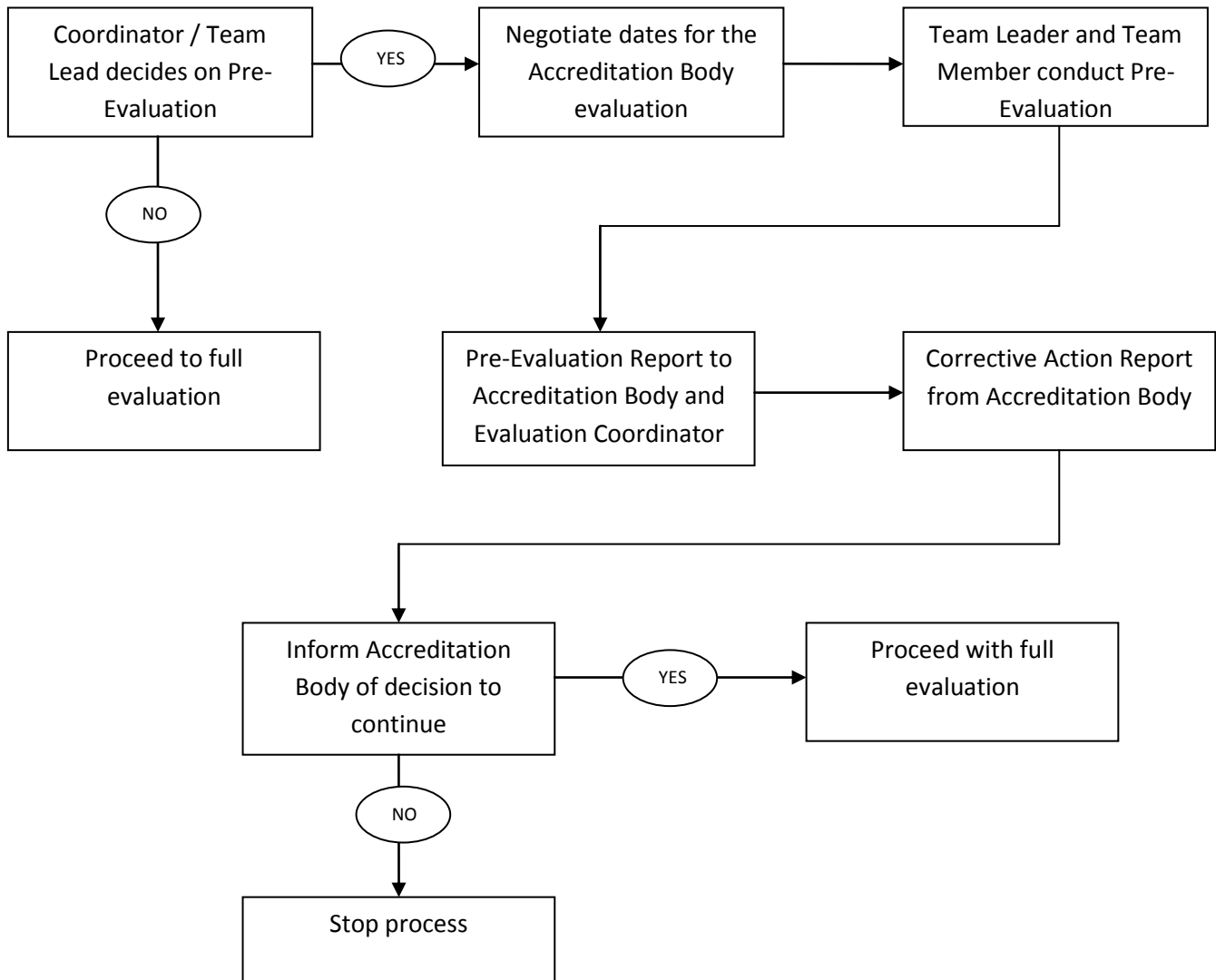
APPENDIX B FLOWCHARTS FOR THE NACLA EVALUATION PROCEDURE

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

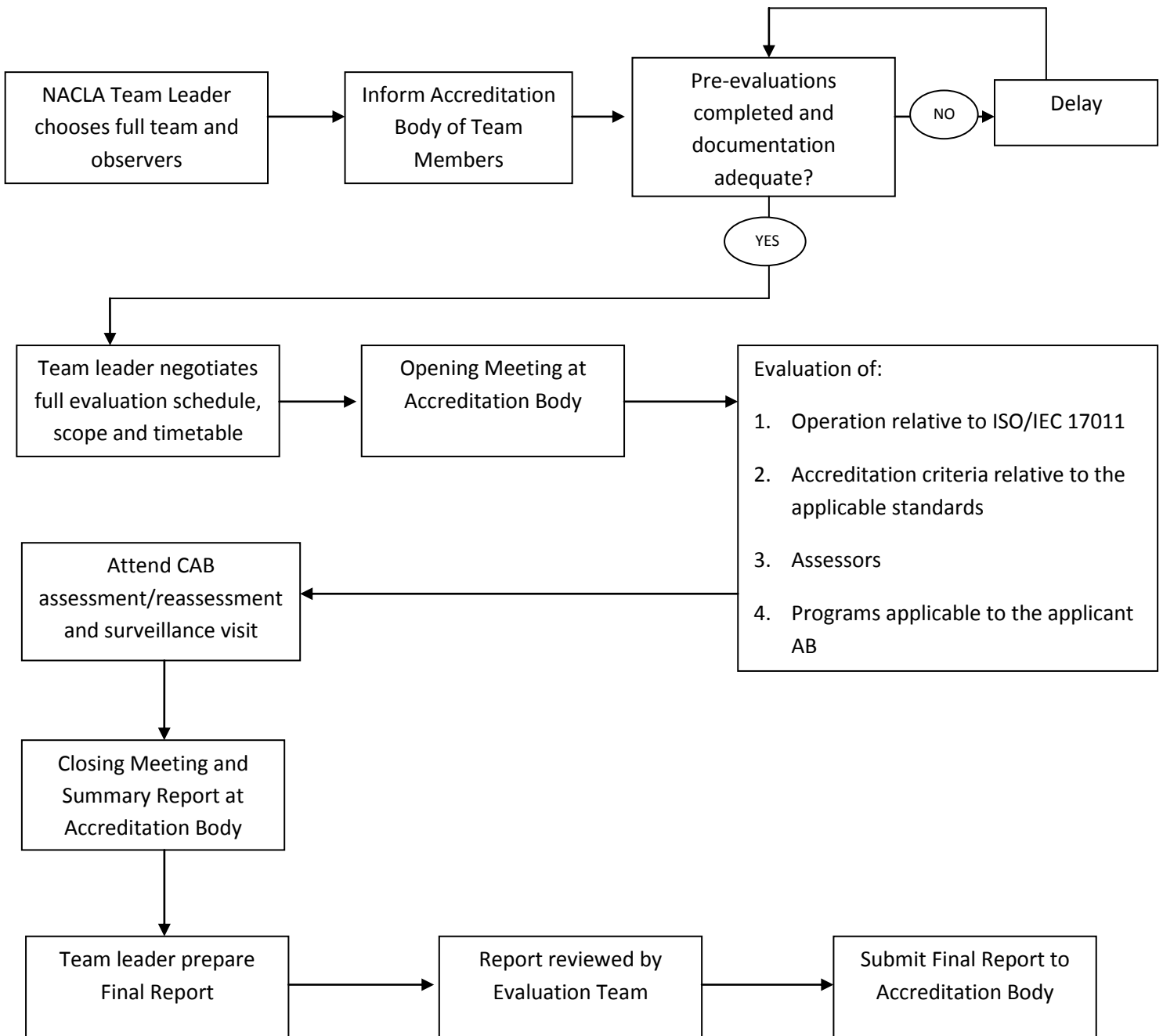
Application Process



Pre-Evaluation Process



Evaluation Process



Corrective Action Process

