



NACLA Quality Manual

AUTHORSHIP

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1.0 INTRODUCTION

The Quality Manual of the National Cooperation for Laboratory Accreditation (NACLA) identifies the operations and processes by which NACLA operates. It serves as the primary control document for the NACLA Bylaws, NACLA Accreditation Body (AB) Evaluation Procedure and all NACLA Procedures. The Quality Manual outlines the structure of NACLA, provides information on policies and procedures, provides an overview of the accreditation body recognition program and other NACLA activities.

2.0 FORWARD

2.1 PURPOSE OF NACLA:

To provide coordination and focus for laboratory accreditation in the United States of America by:

- Developing evaluation procedures and requirements that are in accordance with international standards and guidelines and that are accepted by all NACLA members and stakeholders.
- Administering NACLA evaluation procedures with impartiality and integrity.
- Recognizing accreditation bodies (ABs) for compliance with the NACLA requirements.
- Coordinating the development of sector specific technical requirements and associated programs that meet industry specifier or government/regulatory agency requirements for use by all accreditation bodies and testing or calibration laboratories.
- Reducing redundant AB evaluations through the acceptance of NACLA and/or International Laboratory Accreditation Cooperation (ILAC) recognition.
- Promoting the acceptance of NACLA and ILAC recognition.
- Working with industry specifiers and government/regulatory agencies in the United States to coordinate the development of sector specific technical requirements beyond those included in international guidelines used for AB recognition and laboratory accreditation.

2.2 VISION OF NACLA

The NACLA vision is to establish national and international stakeholder confidence in the competence of Accreditation Bodies (ABs) and their accredited laboratories (technical confidence in the results contained in reports and certificates issued by these laboratories).

This NACLA vision achieves the following:

- For NACLA recognized accreditation bodies, a NACLA scope of recognition to a common international model, and, where applicable,

with fields of recognition specific to sector specific technical programs that meet specifier and/or regulator requirements.

- For ILAC recognized accreditation bodies, a NACLA scope of recognition utilizing the ILAC recognition as the basis for meeting the international model, and, where applicable, with NACLA approval of each field of recognition to sector specific technical programs that meet specifier and/or regulator requirements.
- For testing and calibration laboratories, a single accreditation in a given field(s) of testing and/or calibration, based on International requirements for purposes of acceptance by specifiers and/or regulators (users of accreditation).
- For specifiers and regulators, confidence that an accredited test or calibration is performed by a competent laboratory that meets the specifiers' or regulators' requirements.

2.3 OBJECTIVES OF NACLA

- NACLA's first objective is to increase stakeholder (specifiers, regulators and laboratories) confidence in the laboratory accreditation system within the United States. Increased confidence by stakeholders will assure that comparable, safe and reliable data produced by accredited laboratories will reduce the cost to re-accredit, re-test and re-sample laboratories and the outcome of their work in the laboratory community.
- NACLA's second objective is to assure the National Institute of Standards and Technology (NIST), through its MoU, of its continued dedication to impartiality and integrity and the use of accepted international standards and sector specific technical requirements that meet relevant government and specifier requirements.
- NACLA's third objective is to coordinate the efforts of accreditation bodies, laboratories, specifiers, and regulators in the United States through the use of the international model of accreditation in order to develop programs that meet the needs of all stakeholders. Where the international model does not fully meet the needs of the stakeholders, to coordinate the development of sector specific technical requirements that meet all stakeholders needs.

2.4 QUALITY POLICY

2.4.1 It is the policy of NACLA to operate a comprehensive national accreditation body recognition system that meets the requirements of internationally accepted standards and practices and the sector specific requirements of US Specifiers and Regulators

NACLA strives to:

- Achieve customer satisfaction through meeting the needs of accreditation bodies, testing and calibration laboratories, government agencies, and industry specifiers.
- Reduce redundant accreditations within the United States.
- Establish national acceptance of NACLA recognized ABs and the test and calibration results produced by their accredited laboratories in order to facilitate trade.
- Respond to the needs of its member organizations and the needs of the international community including regulators and specifiers within the United States and abroad.

2.4.2 NACLA recognized accreditation bodies shall meet the requirements of the NACLA Accreditation Body Evaluation Procedure.

2.4.3 NACLA personnel shall work to continuously improve all aspects of its operations and internal procedures. NACLA has negotiated and will continue to negotiate arrangements with other similar national and international organizations.

2.4.4 NACLA shall establish and maintain prompt, open and effective communications with its customers; i.e. NACLA members; recognized ABs, applicant ABs, users of accredited laboratories, and government agencies and industry specifiers.

2.5 QUALITY SYSTEM STRUCTURE

2.5.1 NACLA maintains a documented quality system as a means to ensure conformance to national and internationally recognized standards. The quality system is comprised of the following documents:

- NACLA Quality Manual
- NACLA Evaluation Procedure(s)
- NACLA Sector Specific Technical Requirements
- NACLA General Procedures and associated records, forms and reports
- NACLA Committee Charters and associated records, forms and reports

2.5.2 The NACLA "Quality Manual" is maintained by the NACLA Operations Committee. The NACLA Board of Directors/Operations Council is responsible for approval of the NACLA Quality Manual and all revisions.

2.5.3 The NACLA Evaluation Procedure(s) is maintained by the NACLA Recognition Committee. The Board of Directors/Operations Council is responsible for approval of the procedure and all revisions.

2.5.4 The NACLA Technical Requirements of the Evaluation Procedure are maintained by the Technical Committee.

2.5.4 The General Procedures and associated records, forms and reports are maintained by the NACLA Operations Committee. The approval of all procedures and associated forms is the responsibility of the Executive Committee. The Executive Committee may decide to defer the approval to the Board of Directors/Operations Council as appropriate.

2.5.5 The NACLA Committee Charters and associated records, forms and reports are maintained by each Committee Chair. The approval of Committee Charters and associated forms is the responsibility of the Executive Committee. The Executive Committee may decide to defer the approval to the Board of Directors/Operations Council as appropriate.

3.0 GENERAL INFORMATION, POLICY, AND PROCEDURES

3.1 ORGANIZATION

3.1.1 The National Cooperation for Laboratory Accreditation (NACLA) was incorporated in 1998 to operate as an authority within the United States for the recognition of competent accreditation bodies. NACLA is a cooperation of public and private organizations including government agencies (federal, state, and local), industrial firms and associations, standards organizations, accreditors, testing laboratories, calibration laboratories and laboratory associations, and other interested parties.

3.1.2 NACLA has established Memorandums of Understanding (MoU's) with national and international organizations to further its purpose, mission and authority. The NACLA membership is the primary body of NACLA, and the Board of Directors/Operations Council and its Executive Committee are responsible to the membership for the effective pursuit of NACLA objectives. The Board of Directors/Operations Council also is responsible for the management of NACLA. The NACLA Secretariat supports the work of the Board of Directors/Operations Council and the NACLA membership.

3.2 MEMBERSHIP

3.2.1 NACLA is a membership organization that is run by volunteers representing its member organizations. The bulk of the member bodies are in four major stakeholder groups: industry, government, laboratories and

accreditation bodies. However, NACLA membership is open to any organization with an interest in laboratory accreditation, regardless of size. Membership dues are modest, and the amount of an organization's dues obligation is tailored to its annual income/budget.

3.2.2 Representatives of member bodies chair and serve on NACLA committees and elect its Board of Directors/Operations Council (which has balanced representation from the four major stakeholder groups). The contributions of its members provide the financial and human resources that are vital ingredients in NACLA's operations and essential elements to its success.

3.3 BOARD OF DIRECTORS/OPERATIONS COUNCIL

3.3.1 NACLA is governed by the Board of Directors/Operations Council as described in the NACLA Bylaws. The Board of Directors/Operations Council is the policy-making body of NACLA and membership represents a balanced representation of interests from laboratories, accreditors, users and government (those in government abide by federal and state requirements in their Board of Directors/Operations Council appointed duties). The Board of Directors/Operations Council oversees all NACLA standing and ad hoc committees and is responsible for the operational activities of NACLA along with oversight of the Secretariat.

3.3.2 The Board of Directors/Operations Council maintains liaison(s) with other national and international accreditation and recognition bodies.

3.3.3 Executive Committee: The Executive Committee consists of the President, Vice President, Immediate Member at Large, Treasurer, Secretary, Quality Manager, Technical Committee Chair, Recognition Committee Chair and Board appointed Liaisons.

3.3.4 Between meetings of the NACLA Board of Directors/Operations Council, the Executive Committee shall address any affairs of the organization requiring immediate formal action. The NACLA Board of Directors/Operations Council may appoint other members to the Executive Committee to maintain liaison activities as appropriate.

3.4 COMMITTEES

3.4.1 NACLA has developed four standing committees responsible for assisting the Board of Directors/Operations Council in the operations of NACLA. The standing committees are the: Operations Committee, Recognition Committee, Technical Committee and Recognition Council. Each Committee has a charter describing their roles and responsibilities in detail. A summary of each is as follows:

3.4.1.1 Operations Committee:

- The Operations Committee is responsible for assisting the NACLA Treasurer with the financial affairs of NACLA. Some of the Treasurer's responsibilities include submitting an annual budget to the Board of Directors/Operations Council, establishing fees, capital expenditure approval, and the investment of funds; preparing budgets and financial reports as required.
- The Operations Committee also assists the Quality Manager in implementing and maintaining the Quality System of NACLA. The committee assures the Quality Manager directs internal quality audits and reviews complaints to ensure that they are addressed in a timely manner. Additionally the committee assists the Quality Manager in maintaining and revising the Quality Manual, Procedures, Committee Charters, Job Descriptions and Forms as required. It recommends revisions and improvements in NACLA processes to reflect changes in the operation of the organization. The Quality Manager reports to the Board of Directors/Operations Council any Complaints, Non-compliances, Corrective Actions as well as Preventative Actions.
- The Operations Committee is responsible in assisting the Member at Large in his/her Nominating responsibilities to prepare and draft a slate of nominees for the election of the NACLA Board of Directors/Operations Council and Officers. The Member at Large will assure a proper docket is prepared and voted on at the appropriate intervals.
- The Operations Committee is responsible in assisting the Vice President with his/her External Affairs responsibilities which include business development, internet and website development, membership/outreach, awards, and international affairs. The committee will assist the Vice President in the operational responsibilities in relations to MoU development and administration. The Vice President will report on the progress and development in these areas to the Board of Directors/Operations Council.

3.4.1.2 Recognition Committee

- This committee defines and has oversight of the recognition process and is responsible for the Evaluation Procedure for NACLA. The Recognition Committee Chair is a member of the Board of Directors/Operations Council and reports changes and improvements made to the process and the Evaluation Procedure. The committee members periodically review and

update the Evaluation Procedure; examine documents, both national and international, related to evaluation procedures with a view to keeping the recognition process up-to-date; form teams to discuss and compare recognition arrangements with similar bodies.

- The Recognition Committee will cooperate with the Technical Committee to assure the best interests of all stakeholders are considered in the development of NACLA Recognition and sector specific technical requirements. The Recognition Committee is to assure NACLA's overall recognition process meets or exceeds the expectations of its stakeholders.

3.4.1.3 Technical Committee

- The Technical Committee identifies, facilitates and develops sector specific technical requirements for use in NACLA recognition programs. When applicable the committee works in conjunction with NACLA MoU partners to do the same. The Technical Committee Chair is a member of the Board of Directors/Operations Council and reports requirements in development and those maintained by NACLA. The committee members periodically review and update the sector specific Technical Requirements and hold meetings with specifiers and regulators to assure their requirements are met and expectations exceeded.
- The Technical Committee will cooperate with the Recognition Committee to assure the best interests of all stakeholders in the development of NACLA Recognition and sector specific technical requirements. When required the Committee is responsible for developing training programs for the technical requirements they develop. Additionally they may be required to develop proficiency testing programs in conjunction with NACLA stakeholders.

3.4.1.4 Recognition Council

- The Recognition Council reviews the recommendations and evaluation reports submitted by the NACLA Evaluation Teams and grants recognition to applicant ABs found to be in compliance with NACLA requirements. The Recognition Council is chaired by the NACLA Executive Director and is comprised of the Chair of the Technical Committee, the Chair of the Recognition Committee, the chair of the Operations Committee and the NIST representative who is monitoring the NIST/NACLA MoU, Additionally representatives of various specifier and laboratory organizations that have been appointed by the NACLA Board of Directors/Operations Council may participate.

A delegate alternate may represent each permanent member. Approved observers may also be present for a given meeting. Voting responsibilities are detailed in the NACLA Recognition Council Charter.

- The council reviews final evaluation reports, with corrective actions, submitted by the appointed NACLA Evaluation Teams when recommending applicants for initial or continuing recognition. Each member of the council shall review the evaluation documentation and submit all concerns to the Chair. The Chair of the council shall work with evaluation teams to resolve any outstanding issue(s). The Chair will also work closely with the Chair of the Technical Committee.

3.5 PERSONNEL

3.5.1 Board of Directors/Operations Council: The NACLA Board of Directors/Operations Council is elected by the NACLA membership and manages the organization.

3.5.2 Secretariat: The Secretariat is the administrative office of NACLA. It supports the Board of Directors/Operations Council and other units of the organization as required.

3.5.2.1 Executive Director: The Executive Director is appointed by the NACLA Board of Directors/Operations Council. The Executive Director administers and coordinates the activities of the NACLA Secretariat within the policies and objectives established by the Board of Directors/Operations Council; prepares proposed performance objectives for the Office for approval by the Board of Directors/Operations Council. They ensure sound services and working relationships with NACLA members and outside public and private bodies.

3.5.3 Liaisons: Liaisons represent the position of important national/government or organizations with whom NACLA interfaces. The voting members of the NACLA Board of Directors/Operations Council appoint liaisons.

3.5.4 Evaluators: Evaluators perform evaluations leading to NACLA recognition. All evaluators shall meet the training, qualification, and monitoring requirements as specified in NACLA procedures. A roster of approved evaluators is maintained by the Evaluation Coordinator.

4.0 OPERATIONAL POLICIES AND DECISION-MAKING PROCESSES

All personnel shall use and follow the NACLA Bylaws, policies, procedures, and other related quality documents.

4.1 OVERVIEW

NACLA's policy and decision-making processes are described in the NACLA Bylaws and by those policies and decisions adopted by the Board of Directors/Operations Council. The Board of Directors/Operations Council oversees the policies and procedures of NACLA. Minutes of all Board of Directors/Operations Council meetings are kept at the Secretariat. Federal members of the Board of Directors/Operations Council follow appropriate federal regulations with respect to NACLA activities. The Bylaws and related procedures provide policy and decision making processes for:

- Adjudication of all matters relating to NACLA's operations (Board of Directors/Operations Council);
- Review of implementation of policies (Board of Directors/Operations Council);
- Creation of committees (President and Board of Directors/Operations Council).
- Granting, extending, reducing, denying, suspending, and withdrawing recognition of an accrediting body (Recognition Council).
- Removal of a member of the Board of Directors/Operations Council (Board of Directors/Operations Council).

4.2 FUNDING

NACLA is funded by dues from members, donations, revenue from workshops, training courses, contracts, grants and recognition fees. Fee schedules are adopted and approved by the Board of Directors/Operations Council.

4.3 CONFLICT OF INTEREST, CONFIDENTIALITY and CODE OF ETHICS

4.3.1 NACLA holds statements of principles related to conflict of interest, confidentiality and code of ethics that apply to members, personnel, evaluators, committee members and the Board of Directors/Operations Council. All persons occupying positions must sign all statements as appropriate. All members must adhere to the code of ethics. Additionally the conflict of interest and confidentiality statements are included with every assignment for evaluators.

4.3.2 The NACLA Secretariat maintains in secured files all confidential records on the application, evaluation and recognition of applicants. The

Executive Director at the direction of the Board of Directors/Operations Council controls access to these files and designates who else has access to these files. Documents necessary to convey information about recognized accreditation bodies and their scope of recognition are not confidential. An applicant or recognized accreditation body may request in writing that the Secretariat release an evaluation report to a specifically identified party.

4.3.3 The NACLA Code of Ethics assures every member of NACLA abides by the NACLA Bylaws and their respective elected and/or appointed position. It also assures financial obligations by personnel, officers, directors, and members are understood and transparent to all members of the organization.

4.3.4 NACLA conducts evaluations in an impartial and objective manner. NACLA participates in the devolvement of evaluation procedures and the development of sector specific technical requirements in an impartial and objective manner. All NACLA operations are carried out in a non-discriminatory manner.

4.4 LIABILITY

4.4.1 NACLA carries adequate insurance to cover the activities of the organization.

4.5 DOCUMENT CONTROL: NACLA controls documents to ensure proper review, approval maintenance and availability.

4.5.1 Records are maintained at the secretariat for each applicant and recognized accreditation body including application, correspondence, evaluation reports, corrective action responses, recognition letters, scopes of recognition, invoices and payments.

4.5.2 Records are also retained for the Board of Directors/Operations Council, the Executive Committee, each committee, council and the organizations financial and legal documents.

4.5.3 Records are maintained in a secure and confidential manner by the Secretariat. The NACLA records control procedure governs the disclosure of confidential information.

4.5.3 Records are retained at least five years (seven years for financial records and indefinitely for legal incorporation documents) and are made available as appropriate.

4.6 FEEDBACK

4.6.1 Feedback about the quality of NACLA's operations is encouraged and welcomed. One of the key functions of NACLA is the evaluation of accreditation bodies. NACLA makes a special effort to obtain feedback from evaluated bodies about the performance of the evaluators.

4.6.2 NACLA offers all stakeholders the opportunity to provide feedback to the Board of Directors/Operations Council at the NACLA Forum and feedback links on the NACLA website.

4.7 COMPLAINTS

4.7.1 NACLA recognizes the importance of promptly and effectively responding to all complaints. All complaints are brought to the attention of the NACLA Secretariat or other appropriate NACLA officer. All complaints are recorded for the acknowledgment of receipt recording the facts and date of the complaint.

4.7.2 The Executive Committee is notified of the complaint and is responsible to decide the nature of the facts. The Executive Committee will choose the appropriate actions to remedy the complaint and follow-up to communicate that remedy to the complainant.

4.7.3 Depending on the facts of the complaints against a Recognized Accreditation Body may include the Recognition Council Chair and the general Recognition Council to vote on the appropriate action for the recognized AB.

4.8 CORRECTIVE AND PREVENTATIVE ACTION

4.8.1 Corrective and/or Preventative Action(s) requests can result from feedback, complaints, internal audits, management reviews, and meeting minutes. All requests for corrective or preventative actions will be recorded and maintained by the Secretariat. The Secretariat will forward all requests to the Executive Committee for review and designation of the appropriate person(s) responsible for completing the action. The Executive Committee will review each completed corrective action and preventative action for effectiveness of implementation. Following completion, the Secretariat will report the results at the NACLA Board of Directors/Operations Council meetings providing a summary of each investigation and result.

4.9 INTERNAL AUDIT

4.9.1 The quality system is audited in accordance with a pre-determined schedule to determine whether quality activities and related results comply with the documented quality system described or referenced within this Quality Manual. Where appropriate and practical, all internal auditor(s)

shall be trained persons not ordinarily involved in the activities being audited.

4.9.2 The results of the internal audit are recorded together with details of any corrective actions planned to be and/or actually taken. Necessary corrective and preventive actions (including revisions to the Quality Manual, Procedures or any quality documentation) are approved by the appropriate authority.

4.10 MANAGEMENT REVIEW

4.10.1 The NACLA management review is comprised of two types of review: (1) on-going reviews during regular Board of Directors/Operations Council and Committee meetings and (2) a formal annual management review. The on-going reviews focus on quality-system issues discussed during Board of Directors/Operations Council and Committee meetings. The yearly management review is a complete review of the quality system including this Manual and related policies procedures; it usually takes place during the last NACLA Board of Directors/Operations Council meeting of the year.

APPENDIX A

NACLA STRUCTURE

