The National Cooperation for Laboratory Accreditation (NACLA) Mutual Recognition Arrangement

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Abstract

Unlike most other economies around the world, the United States has within its border an estimated 40 private sector laboratory accreditation bodies, 30 local or state accrediting bodies and 31 federal accreditation bodies. By the mid 1990's it became clear that there was little acceptance of laboratory accreditation by parties in domestic and foreign markets and there was a failure to agree on common procedures and criteria upon which to base the acceptance. Laboratories were required to carry multiple accreditations to meet the needs of various clients. Users of testing services and product specifiers did not have a means to measure the competence of the laboratories. This often resulted in them establishing their own accreditation programs with their own sets of criteria, thus adding to the confusion.

NACLA was established in the "image" of other regional mutual recognition arrangements (MRAs) such as the European cooperation for Accreditation (EA) and the Asia Pacific Laboratory Accreditation Cooperation (APLAC) to make some sense out of this complexity. However, unlike other cooperations, the users, government and laboratories play a very active role in the operation and success of NACLA. This paper will discuss the NACLA operations and specifically, how these interactions work to ensure appropriate input from the affected parties, and build confidence in the NACLA recognition process.

1. Brief History

It was recognized early on that the NACLA model for recognition of laboratory accreditation bodies would have to differ in certain ways from other regional cooperations in order to address the recognition of multiple accreditation bodies from within one economy, especially with respect to the issues of conflict of interest and competition that play a role in any American business.

The first NACLA Board of Directors and its Secretariat were established in 1997. The Bylaws were also established. NACLA was incorporated as a 501c(6) organization in 1998. The first laboratory accreditation bodies applied for NACLA recognition in 1999 and three bodies, A2LA, ICBO-ES and NVLAP were recognized as NACLA MRA signatories in 2000. There are eight additional applicant accreditation bodies at some point in the NACLA recognition process.

2. The Organizational Structure

All laboratory accreditation cooperations enjoy active participation from their signatories, applicant accreditation bodies, stakeholders and laboratories at the committee level (sometimes by special invitation) but only the signatory accreditation bodies from each economy within the cooperation are allowed to vote on policy and procedure resolutions (usually in meetings of the General Assembly, made up of the signatories from each economy), and on decisions of admittance of new signatories to their MRA (in an "arrangement council meeting" of the current signatories).

NACLA is structured differently. The NACLA Board of Directors (BOD), where decisions on policies and procedures are made, consist of a balance of accreditation bodies (signatory or non-signatory), laboratories, users (specifiers) and government. The 2002 BOD consists of:

2002 Board of Directors - Executive Committee

President: Roxanne Robinson, A2LA	*(accreditor)*
Vice Pres: Louis Dixon, LTD Consulting	*(user)*
Secretary: Doug Geralde, CSA International	*(lab)*
Treasurer: Tony Anderson, NCSLI	*(lab)*
Immed. Past Pres.: Don Heirman, Lucent Tech	*(user*)

Board of Directors/Operations Council

Reinaldo Figueiredo, ANSI	*(user)*
Jo Ann Given, ASCLD	*(accreditor)*
Barbara Judge, ACIL	*(lab)*
Peter Mockridge, CAP	*(accreditor)*
Lynne Neumann, LAB	*(accreditor)*
C.P. Ramani, ICBO ES	*(accreditor)*
Richard Reitz Retlif	*(lab)*
Malcolm Smith, NCS Labs	*(lab)*
Larry Yates, Norfox	*(user)*

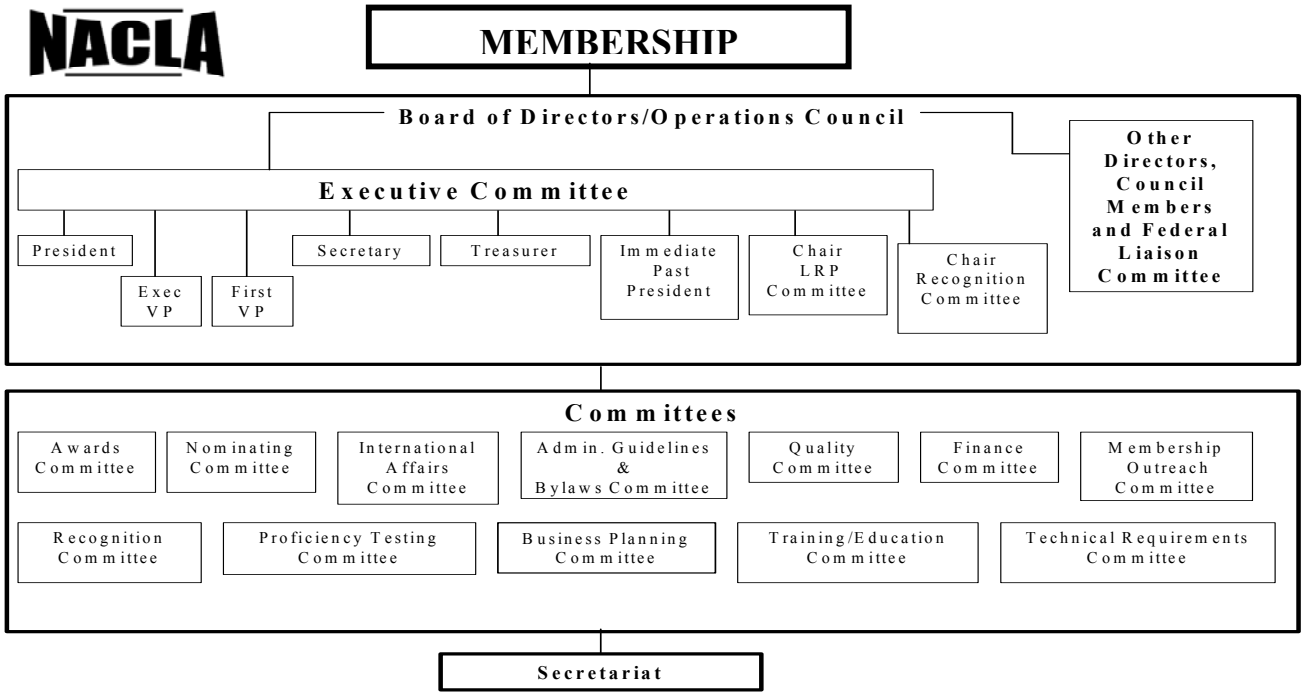
Government representatives
John Fishell, U.S. Navy
Michael Olson, FDA
Mike Rafalowski, FHWA
Mary Saunders, NIST
Dr. Ann Wiegers, Nat'l Veterinary Services Labs, USDA

Observers

Don Wilson, SCC	(*accreditor*)
Graham Cameron	(*accreditor*)

Veronica G. de Solorzano, EMA (*accreditor*)

The government representatives abstain on voting on any BOD fiduciary issues. Other than that, all BOD members have voting responsibilities. NACLA needs to fill two *user* openings with industry representation and would welcome candidate suggestions from the NCSLI membership or the readers of this paper.



NACLA Organizational Chart

At this point in time, the NACLA organizational structure [1] is quite complex but the standing committees are in the process of being combined and re-defined so that the structure is pared down and easily followed. When the simplification is complete the committees may align as follows:

Technical Committee
Quality, Technical requirements

Recognition Committee
Training/Education; Appeals

Proficiency Testing Committee

Accreditation Issues Committee
International affairs; guidelines; bylaws; finance

Public Affairs Committee
nominations; membership/outreach/website

This alignment would be more comparable to the other regional cooperations.

Unlike other regional cooperations where the standing committee chair positions are almost always filled by accreditation body representation, there is nothing to preclude the NACLA standing committees from being filled by representation from either the user, government or accreditation body membership. In fact, a concerted effort is sometimes made to ensure that the most suitable representation fills the committee chairman position. For example, NACLA thought it best to ensure that a non- accrediting body representative was chair of the Recognition Committee. This committee is responsible for establishment of the policies, procedures and requirements that the accreditation bodies must meet in order to be recognized, and NACLA perceived a conflict of interest if an accreditation body representative filled the chairman role. A government representative current chairs the Recognition Committee.

3. The Recognition Process

The NACLA recognition process is very similar to other regional co-operations. The accreditation bodies must meet the requirements of ISO/IEC Guide 58 and their accredited laboratories must comply with the requirements of ISO/IEC 17025. The process includes a visit to the applicant accreditation body by a team of evaluators. The accreditation body's headquarter operations are evaluated and their assessors are observed performing assessments.

NACLA evaluation teams can be made up of properly trained and qualified representatives from accreditation bodies, government agencies or industry. Other regional cooperations usually rely on senior accreditation body staff to make up the evaluation teams. However, including others besides the accreditation body staff on these evaluation teams allow for confidence building opportunities through active participation of regulatory authorities, industry and others that have the need to build confidence in the accreditation bodies that will be recognized. Representatives from regulatory agencies or industry groups that are interested in using the accreditation body's laboratories may also be invited by the applicant accreditation body to observe their NACLA evaluation.

As further evidence of the effort to build confidence in the NACLA recognition process, users and government agency representatives play an active role in the Acceptance Panel meeting where the decision is made on whether to invite the applicant accreditation body to sign the NACLA MRA. All attendees to the Acceptance Panel meeting are allowed to participate in the discussions surrounding the results of the applicant accreditation body's evaluation and the question and answer session that allows for clarification of any issues. At the end of the discussion period, only the signatory accreditation bodies decide whether the applicant complies with the NACLA requirements and can be invited to sign the MRA. However, once the accreditation bodies have made their decision, the other panel members are asked to vote on the issue of due process, i.e. were the approved NACLA procedures followed? A ¾ majority of the voting members must cast positive votes in order for the accreditation bodies' vote to be ratified.

NACLA has received comments that restriction of the vote by the signatory accreditation bodies to recognize the applicant accreditation body is perceived as a conflict of interest and a barrier to competitive practices. The NACLA BOD is expected to address this issue at their April 2002 BOD meeting. It is likely that the voting process to recognize new accreditation bodies will be changed so that a balanced panel of specifiers, regulatory authorities and accreditation body representatives will be voting at the Acceptance Panel meetings. NACLA intends to eliminate the "do process" vote as a requirement for recognition of the applicant accreditation body, because those responsible for that vote will have a direct role in the vote for signatory status.

4. Monitoring and Re-evaluation

As with the other regional cooperations, periodic monitoring and re-evaluation of each NACLA MRA signatory is required after recognition has been granted. However, NACLA requires that each signatory undergo a surveillance visit two years after recognition has been granted, irrespective of any other conditions that may have been placed upon the applicant as part of their recognition. This surveillance focuses on examining changes in the accrediting body's organization, their compliance with the latest issue of ISO/IEC Guide 58 and any other NACLA requirements, and their laboratories' adherence to the latest issue of ISO/IEC 17025 and the NACLA traceability policy.

All elements of the requirements for NACLA recognition are re-evaluated at least every four years.

5. Future Steps

NACLA is listening carefully to industry specifiers and regulatory agencies in order to meet their needs and build their confidence in the NACLA recognition process. Of critical importance is ensuring that the laboratory accreditation process includes any specific technical requirements that industry or the regulators might have beyond what is generically outlined in ISO/IEC 17025. NACLA's Technical Committee is the place where these specific technical requirements can be developed. For example, the Federal Highway Administration (FHWA) is presently working with interested state and federal regulators, laboratories and accreditation bodies in a NACLA Technical Sub-committee to develop specific construction materials testing requirements. Ultimately, the FHWA intends to recognize those NACLA- recognized accreditation bodies that demonstrate that their laboratories comply with ISO/IEC 17025 *and* the NACLA specific technical requirements for construction materials testing.

NACLA is also looking at the options and ramifications of possibly de-coupling the recognition process from the need to sign the NACLA MRA in order to encourage the use of such accreditation bodies by both Federal agencies and private sector specifiers. NACLA has been told that many Federal agencies have indicated that a more "vertical recognition" process, independent of the MRA but with NIST verification, would meet their needs. They fail to see the relevance of the NACLA MRA to their programs, and thus are hesitant to participate in and make use of the existing NACLA recognition process.

Also, having recognition coupled with entry into the MRA is thought by some to create impediments to accreditation bodies that wish to be NACLA-recognized. For example, some accreditation bodies -- such as those that are part of Federal agencies -- may be unable to recognize other accreditation bodies as required by the NACLA MRA. Others may be unwilling or reluctant to recognize their competitors.

NACLA is in very earlier discussions concerning this vertical recognition option and no decisions have been made. It is clear however, that NACLA must maintain ISO/IEC Guide 58 as the minimum requirements for accreditation bodies to meet and ISO/IEC 17025 as the minimum requirements for their accredited laboratories to meet.

5. Conclusion

NACLA is a fairly "young" laboratory accreditation cooperation but it has made great strides towards establish a system within the United States for recognizing laboratory accreditation bodies. Further study is needed to define the best "model" for using this recognition within the United States so that the test data generated by the accredited labs is accepted without the need for further testing and the testing laboratories can pursue accreditation from the accreditation body that best meets their needs and won't require them to maintain redundant accreditations.