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REVIEW PAPER

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Update on the activities of the National Cooperation for Laboratory Accreditation

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The nominal author describes concepts developed by both the Laboratory Accreditation Working Group and its successor, the interim board of the National Laboratory Accreditation Cooperation, which she chaired from May 1997 to May 1998. The groups were composed of individuals from both the public and private sectors representing laboratories, accreditors, and public and private sector users. Any errors in reporting are the author's alone.

Abstract The efforts to form a laboratory accreditation cooperation in the United States and North America are described, including activities of the Laboratory Accreditation Working Group and the interim board of the National Cooperation for Laboratory Accreditation. The vision, mission, and guiding principles developed by the two groups are presented, along with the operational documents, such as bylaws, the recognition document, guidance documents and the quality manual drafted by the interim board.

Key words Calibration · Global market · Guide 25 · Guide 58 · Laboratory recognition

Introduction

In 1994, the American Council of Independent Laboratories (ACIL), the American National Standards Institute (ANSI), and the National Institute of Standards and Technology (NIST) sponsored an informal Laboratory Accreditation Working Group (LAWG) to examine issues related to laboratory accreditation in the United States and to suggest approaches for developing a more coherent system. Concerned with multiple and duplicate assessments, and the lack of domestic and international recognition of accreditations, the group explored ways to achieve the goal of one assessment per laboratory in a given field of testing[1], using internationally accepted procedures that would be acceptable to all those requiring (or desiring) laboratory accreditation. LAWG participants agreed that development of a credible domestic system must be compatible with international systems to achieve international recognition of accreditation in the United States. Working toward this end, LAWG solicited input and participation from all affected parties: laboratories, accreditors, industry, and government (Federal, state and local), as well as input from those concerned with international trade issues, in a series of public meetings.

The essential need for a national approach to coordinate laboratory accreditation was put forward in challenges raised by the National Research Council (NRC) in 1995. In its study of the standards and conformity assessment procedures needed to support global trade, it stated that ".....domestic policies and procedures for assessing conformity of products and processes to standards require urgent improvement" [1]. In response to this study, Congress (in the Technology Transfer and Advancement Act of 1995; Public Law

[1] Testing includes calibration for the purposes of this paper.

104–113 [2]) charged NIST with coordinating Federal, state and local conformity assessment activities along with those of the private sector to eliminate unnecessary duplication and complexity. NIST has worked with all parties in response to this mandate by convening public meetings and discussions, as called for in its Implementation Plan [2].

In October 1995, ANSI, ACIL and NIST hosted the first of three public meetings to discuss the need for greater coordination among laboratory accreditation activities and ways for reducing the number of redundant audits. In the first meeting, numerous participants described the problems facing laboratories, accreditors and users of laboratory accreditation [3]. The second forum, on 7 January 1997, discussed the possible establishment of a National Cooperation[2] for Laboratory Accreditation (NACLA) [4]. The third, on 16 April 1998, described procedures to be used by NACLA for coordinating and recognizing laboratory accreditation activities to meet both public and private sector needs. During the three years of discussion, consensus developed that a single public/private entity was needed to coordinate laboratory accreditation activities within the United States and eventually North America. This entity must allow the needs of the various interest groups to be met, while allowing for competition among accreditors, governmental recognition, and international acceptance, based on common procedures for both accreditation and recognition of accreditation by all parties.

Consensus positions

In the three public meetings, representatives of accreditors, laboratories, and users of laboratory accreditation from industry and government agreed that a more unified national system was essential to satisfy domestic economic requirements and to facilitate trade. They also agreed that any infrastructure, to be successful, must be acceptable to all affected parties, and that a reasonable goal was to set the limit at one test for any given product of a laboratory, to be accredited by a recognized competent accrediting body whose results were accepted nationally and globally.

Building on the LAWG vision and principles, participants in all three meetings identified the following needs to be met eventually by a more formal structure:

- Manufacturers and other users must be confident that the test data from suppliers are generated by qualified laboratories that perform testing according to valid test methods and following appropriate operating procedures.
- Governments at all levels within the United States must also be confident that laboratory test data used to demonstrate compliance with regulations or procurement actions are generated by qualified test laboratories using valid methods and procedures.
- Laboratories need a single, consistently applied mechanism for demonstrating their competence in generating test data and for evaluating their quality assurance procedures, with minimal duplication of valid assessments.
- Governments, industry and other users of laboratory test data in the United States need a mechanism for ensuring their confidence in the laboratory test data supplied to demonstrate compliance with their procurement actions, regulations, or standards. They may also need evidence of the competence of a laboratory to meet particular standards and regulations in specific sectoral areas.
- Foreign governments need a means for being sure of the credibility of laboratory data from the United States. The global market requires that laboratory accreditation procedures used on both sides of a trading relationship be similar, transparent, readily available, and based on international performance guides.
- All users require a mechanism for recognizing the competence of different laboratory accreditation bodies, while competent accreditation bodies require a situation where their accreditations are reciprocally accepted across political boundaries.

Tuning the vision into reality

During the first forum, consensus emerged on a vision to reduce the problems linked with the current state of affairs. There was agreement that: (1) international standards should serve as a basis for accreditation and recognition, (2) reciprocity of competent accreditations in the United States is needed, (3) there should be international acceptance of an effective United States system, (4) high-quality accreditation and sound laboratory data must be preserved, (5) greater education of users is needed, (6) regulators at all levels (Federal, state, and local) must coordinate among themselves, (7) and that common interest and goals between government and industry must be explored. The subsequent public fora in 1997 and 1998 only solidified the agreement on these issues, and paved the way for creating NACLA.

In May 1997, an interim NACLA board was established for drafting operational procedures and devising a provisional structure for a formal entity. The interim board was selected to represent interests from laboratories, accreditors, and users in both industry and government, as well as representatives from ANSI, Mexi-

[2] NACLA was originally referred to as a council, not cooperation, but was changed to reflect NACLA's coordination mission, and to avoid confusion with other accrediting bodies.

co, and Canada. It was charged with developing the procedures and requirements needed for a more formal institution. By May 1998, the interim board had drafted bylaws, procedures for recognizing competent accreditors, a provisional quality manual, interim training procedures, and a proposed structure. The results of the interim board's efforts were reported at the May 1998 forum and, in late May 1998, NACLA was incorporated as a nonprofit coorporation in the United States.

Proposed NACLA activities

NACLA was formally established in May 1998 by the private sector, as an organization with participation by all those in the United States, both in the private and public sector, who actively support development of a system for recognizing the competence of testing and calibration laboratories, and worldwide acceptance of their test and calibration reports.

The interim board agreed that to be effective, NACLA will: (1) use agreed-upon criteria and procedures for accreditation and recognition of accreditation (following international guidelines) in the United States, (2) review uniform implementation of procedures and provide a mechanism for appeal of decisions, (3) provide for government (or appropriate industry) recognition of accreditation, (4) provide representation from the United States at non-treaty international fora, and (5) with NIST's assistance, provide means for recognition of accreditations in the United States for foreign governments. When accrediting bodies are recognized by NACLA as competent, a user will be able to select among them. Reciprocity among accreditors will be based on a common recognition by NACLA and relevant Federal authorities. The recognition process will use a hybrid assessment involving both peer assessment and participation by the authority requiring accreditation (private sector or regulatory agency). The actual evaluation will use mixed private sector/public sector teams. The NACLA interim board also agreed on the following vision, guiding principles, and mission for the organization.

The vision

The NACLA's vision is one of a United States laboratory accreditation system that includes a cooperative relationship between the public and private sectors and achieves the following:

1. For the testing laboratory: a single accreditation in a given field of testing, with worldwide recognition of the laboratory's competence.
2. For the user: a test performed once, with worldwide acceptance.
3. Accreditation based on uniform criteria intended to ensure that a laboratory is qualified to provide data of consistent quality.

Guiding principles[3]

- Realize the vision: universal acceptability of the results of any valid test or calibration performed by a competent laboratory accredited by a NACLA recognized accreditor.
- Eliminate duplication and inefficiency in the current laboratory accreditation process and enhance the United States competitiveness in domestic and global markets.
- Develop a comprehensive and rigorous domestic system, using appropriate domestic and international guides and standards, for recognizing competent laboratories, both government and private sector, to promote acceptance of their results by domestic and foreign regulators and product purchasers.
- Exercise appropriate government oversight at the Federal, state, and local levels to ensure satisfaction of regulatory requirements[4].
- Achieve recognition by the United States government when such recognition is necessary for a laboratory's accreditation to be accepted by other foreign governments.
- Allow participation of all parties in the laboratory accreditation scheme including consumers, laboratory customers, testing laboratories, accrediting bodies, and organizations (both public and private sector) that require accreditation in the United States.
- Apply appropriate domestic and international guides and standards for accreditation and recognition, and adapt them to meet the special requirements of Federal and state regulatory bodies or particular user's needs[5].
- Ensure that all laboratories (i.e., manufacturer's, third-party independent, and government) are equally eligible to apply for accreditation, and that equivalently rigorous procedures are used to accredit each laboratory in a given field‹fn›Some regulatory agencies may limit acceptance of accreditation for mandated programs to third party or independent laboratories.[6].

[3] These principles were developed for presentation at the second forum, but have been modified slightly to serve as principles for the NACLA structure.

[4] Does not imply setting regulatory requirements.

[5] Some agencies may need to specify additional requirements for specific regulatory requirements and purposes.

[6] The word "council" was subsequently changed to "cooperation" to reflect NACLA's coordination mission, and to avoid confusion with other accrediting bodies.

- Ensure formulation of and adherence to appropriate ethical principles and standards of conduct in all NACLA operations.

Mission

The NACLA mission is to develop and administer common accreditation procedures that can be accepted by all NACLA parties; to provide coordination and focus for laboratory accreditation programs in the United States, and to serve national and international needs in laboratory accreditation.

NACLA's objectives are to bring together the various parties who require accreditation, who perform accreditation, and who are accredited, and to develop and administer common accreditation procedures that can be accepted (regardless of accreditor) by different authorities requiring accreditation. The active participation by government agencies in NACLA committees and with the liaison committee to the NACLA board should ensure that regulatory needs are met without multiple or duplicate accreditations of laboratories, while the active participation by both accreditors and laboratories will facilitate their input into the development and implementation of technically sound, realistic procedures for accreditation.

Composition

NACLA is a nonprofit coorporation that is envisioned as a partnership of public and private organizations with an interest in laboratory accreditation. Participants include industrial firms and associations, standards organizations, accreditors, laboratories and laboratory associations, government agencies (federal, state and local), and other interested parties.

Authority and responsibility

In time, NACLA will be empowered to act on behalf of its participating organizations, as well as to be, both nationally and internationally, the United States entity for coordinating laboratory accreditation activities, and develop and represent the United States' positions for regional and international laboratory accreditation organizations. Procedures for representing the United States' positions are still being developed; however, it is hoped that government agencies will fully participate in the development and use of NACLA coordination activities and recommendations in carrying out their regulatory and other governmental responsibilities.

Organizational structure

Membership

Membership is open to all interested parties who subscribe to the NACLA vision, principles and protocols through a formal application process.

Board of directors

The Board is the policy making and governing body of NACLA. It is made up of a balanced representation from laboratories, assessors, users, and other stakeholders. The Federal sector is represented formally through a Federal Liaison Committee.

Operations committee

The Operations Council, the technical arm of NACLA, will be responsible for overseeing the recognition process for accreditors, dealing with standards and assessment issues, operational procedures and other technical matters. It must have broad representation from a balance of affected interests.

Secretariat

The Secretariat is responsible for implementing Board decisions and coordinating the Operations Committee's activities. Until the Board appoints a permanent secretariat, NIST is acting as interim secretariat.

NACLA operations

Accreditation standards

Relevant national and international standards, such as ISO/IEC Guide 58 for accreditors, ISO/IEC Guide 43 for proficiency testing, and ISO/IEC Guide 25 for laboratories, are the primary procedures used by NACLA participants. In consultation with the relevant stakeholders, including regulatory authorities, additional procedures for a specific sector may be required.

Assessment of accreditors

The Operations Committee will coordinate audits and reviews of accrediting bodies (accreditors) according to the detailed operating procedures for recognition developed by the interim board. The NACLA review

team for assessment of a private-sector accrediting body will have a majority of private-sector accreditors; a review team for a government accreditor will have a majority of accreditors from the government sector.

Appeals process

A full-scale appeals procedure will be developed by the Operations Committee and submitted for NACLA approval.

NACLA interface with regulators and other government bodies

NACLA, with the assistance of NIST as chair of the Federal Liaison Committee, will actively work to achieve the goal of Federal agency acceptance of NACLA procedures, functions, and decisions. As applicable, participating Federal agencies are encouraged to work toward harmonizing their accrediting and recognition requirements and practices with those of other public and private sector entities to the extent that their unique underlying regulatory and public health laws allow. While special procedures may be needed and developed for a particular sector, these should be applied consistently throughout that sector. NIST is working with the Office of Management and Budget on guidance for Federal agency participation in NACLA to meet requirements set forth by the National Technology Transfer and Advancement Act (Public Law 104–113 [2]) to minimize duplication and overlap in conformity assessment activities in the United States. NIST is also considering use of the National Voluntary Conformity Assessment System Evaluation (NVCASE) program as appropriate to provide United States government backing for the recognition process.

Conclusion

NACLA is intended to provide a means for addressing and solving the widely recognized problems created by overlap and duplication in laboratory accreditation. It is a means for eliminating unnecessary overlap and duplications of laboratory accreditation which are currently burdening the laboratory community, and preventing worldwide acceptance of laboratory accreditation and test data from the United States. The three open meetings revealed a strong consensus for resolving these problems through a reasonable structure for coordinating activities and recognizing the competence of qualified accrediting bodies in the United States and ideally throughout North America. The interim board has developed the key documents for operating an organization which can meet national needs and set priorities. The full NACLA organization and Board of Directors will agree to these documents, and begin operations in late 1998.

References

1. National Research Council (1995) Standards, conformity assessment and trade into the 21st century. National Academy Press, Washington, D.C.
2. Public Law 104–113, 104th Congress (1995) The National Technology Transfer and Advancement Act of 1995. 15 USC 3701. Washington, D.C. Collins BL (1997) The National Technology Transfer and Advancement Act – Plan for Implementation. NISTIR 5967. NIST, Gaithersburg, Md.
3. Leight WG, Galowin L (1996) Proceedings of the Open Forum on Laboratory Accreditation at the National Institute of Standards and Technology, 13 October 1995. Special Publication 902. NIST, Gaithersburg, Md.
4. Jablonski JS, Leight WG (1997). Report on the Open Forum on Establishment of the National Council[7] for Laboratory Accreditation (NACLA) at the National Institute of Standards and Technology. NISTIR 6008. NIST, Gaithersburg, Md.