

ACTIVITIES OF THE NATIONAL COOPERATION FOR LABORATORY ACCREDITATION (NACLA) AND THE NATIONAL CONFERENCE OF STANDARDS LABORATORIES INTERNATIONAL (NCSLI)

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Abstract – NCSLI was established in 1961 to, “promote cooperative efforts for solving the common problems faced by measurement laboratories”. NACLA was established in 1998 to coordinate laboratory accreditation activities within the United States and to serve as the U.S. link to the worldwide accreditation system. NACLA accomplishes its mission through various committees whose combined efforts lead to the evaluation of accreditation bodies (ABs) and granting recognition to ABs that are found to meet the international standard for competence; ISO/IEC Guide 58. NCSLI accomplishes its goals through the efforts of various technical committees that publish such documents as Recommended Practices, and through an accredited writing committee that produces documents for release as U.S. National Standards. The purpose of this paper is to present, in detail, the activities of these two organizations, in cooperation with the National Institute of Standards and Technology, and relate their efforts to one of the goals of the international metrology community: mutual recognition of measurements.

1. INTRODUCTION

One of the common problems, of the 21st Century, faced by measurement laboratories, and being addressed by NCSLI and NACLA, is this “mutual recognition of measurements”. The solution appears to be through the process of Laboratory Accreditation. An explanation of the accreditation environment in the United States must begin with a little history. The following paragraphs are excerpts from Laboratory Accreditation Activities in the United States [1]. That publication summarizes the accreditation scene in the U.S. in 1991. Many of these conditions are still with us. “Testing and calibration laboratories support billion dollar industries and affect the entire economic and regulatory system. Transportation systems, military systems and health care equipment rely on test data. Flawed data can result in defective products and cause financial losses, harm to the environment and serious injury or death to the user. In order to ensure the viability of data laboratories are scrutinized to validate processes and the resulting data. One method to assure the quality and accuracy of such data is through the accreditation of laboratories. Most U.S. laboratory accreditation schemes were designed to meet particular governmental or private sector needs. The U.S.

laboratory accreditation system is different from most foreign countries. The majority of foreign accreditation bodies are public organizations or organizations with some direct government involvement. There is also a growing tendency in foreign countries to run laboratory accreditation schemes in a coordinated fashion. In the United States, on the other hand, laboratory accreditation schemes are operated by all levels of government and by the private sector as well. There is no centralized coordinating body, though some coordination does take place between specific programs on their own initiative or through the intervention of other interested bodies, such as trade associations or professional societies. Requirements for laboratory accreditation programs within the federal government vary greatly by program. The requirements and scope of each program have generally been tailored to meet specific agency needs. Some programs restrict applications to state laboratories only. Some programs are open only to potential government suppliers. States administer many laboratory accreditation programs for a variety of reasons. In most cases, state and local government agencies accredit laboratories to test products regulated indirectly by requiring that such products be inspected and/or tested by an approved body. States also evaluate laboratories for other purposes, such as to assist them in enforcing federal regulations. For example states have primary enforcement responsibility for the national requirements for ensuring the quality of public water systems. In carrying out this obligation, states accredit local laboratories to test drinking water. As with federal programs, state and local requirements for laboratory accreditation vary greatly by program. Private sector accrediting bodies also administer laboratory accreditation programs for a variety of reasons. These reasons range from assisting laboratories in defending their competence in professional mal-practice matters to assisting an industry to avoid government regulation by undertaking self-policing efforts. The criteria and terminology used in private sector accreditation schemes again vary greatly among programs”.

2. NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY (NIST)

The National Technology Transfer and Advancement Act (NTTAA) signed into law on March 7, 1996, directs NIST to work with federal agencies through the Interagency

Committee on Standards Policy (ICSP) and to coordinate with federal, state and local governments, in order to achieve greater reliance on voluntary and private sector standards, and to create guidance on conformity assessment activities (including laboratory accreditation). The goal of NTTAA was to eliminate unnecessary duplication of conformity assessment activities. In 1994, the American Council of Independent Laboratories (ACIL), The American National Standards Institute (ANSI) and NIST jointly sponsored an informal Laboratory Accreditation Working Group (LAWG), to examine issues related to laboratory accreditation and recognition in the United States, and to suggest means for developing a U.S. accreditation system. In 1997 LAWG held an Open Forum at NIST to discuss the official establishment of the National Cooperation for Laboratory Accreditation (NACLA).

3. NATIONAL COOPERATION FOR LABORATORY ACCREDITATION (NACLA)

In 1998, following an open workshop held at NIST, the NACLA Interim Board voted for legal incorporation. NACLA was formed to develop and administer recognition procedures for accreditation bodies to be accepted by all NACLA parties and to provide coordination and focus for laboratory accreditation programs in the U.S. Any organization (or individual) maintaining or having an interest in or concern about laboratory accreditation in the U.S. or North America may become a member [2]. A major milestone in the development of a US national system for laboratory accreditation, emphasizing the cooperation between NIST and NACLA, was reached in July 2000 with the signing of a Memorandum of Understanding (MOU) during the annual symposium of the NCSLI, in Toronto, Canada. The agreement, NCSLI wrote, "Will enhance acceptance of accredited laboratories and promote trade within the United States and to other countries" [3]. NIST has determined after public consultation that recognition of laboratory accreditation bodies by NACLA provides a suitable alternative to direct NIST recognition under National Voluntary Conformity Assessment System Evaluation (NVCASE) procedures, and thus NIST intends to use the provisions of this MOU to ensure that NACLA recognition fulfills requirements of international agreements and arrangements. "NIST will accept NACLA recognition of the competence of laboratory accreditation bodies located in the United States to accredit testing laboratories to meet the technical requirements for their acceptance by European Community Member State governments under the Electromagnetic Compatibility (EMC) Annex of the Agreement on Mutual Recognition between the United States and the European Community. NACLA has developed and implemented a program for recognizing competent laboratory accreditation bodies through the use of accepted international standards and guides and operates in compliance with relevant national and international standards and guides. NACLA will encourage the private sector to specify the use of laboratory accreditation bodies recognized by NACLA when testing and calibration services are required to demonstrate compliance with procurement,

regulatory, trade and other requirements. NACLA will encourage laboratory accreditation bodies, including those whose services are used by the private sector to demonstrate compliance with procurement, regulatory, trade, and other requirements, to seek NACLA recognition. NACLA will work with the private sector to monitor reductions in duplicative audits and requirements, as well as savings in resources and improvements in efficiency, that result from the NACLA recognition process. NACLA will share these findings with NIST on at least an annual basis" [4]. NACLA is also a member of the International Conference on Laboratory Accreditation (ILAC). ILAC resulted from an international conference on the mutual recognition of test results convened by Denmark and the United States in Copenhagen in 1977 [1].

4. NATIONAL CONFERENCE OF STANDARDS LABORATORIES INTERNATIONAL (NCSLI)

The National Conference of Standards Laboratories (NCSL) was founded in 1961, in association with and sponsored by NIST. The purpose was to bring together those organizations that had a common interest in metrology and to promote cooperative efforts for solving common problems faced by measurement laboratories. Renamed as NCSL International in 2000, it is a professional organization with over 1500 member organizations from 45 countries. Membership represents academic, scientific, industrial and commercial organizations, government laboratories, regulatory agencies, and a broad spectrum of manufacturing companies. Among the many services available to members are: a Training Directory, a Directory of Standards Laboratories, Calibration Lab Managers Guidebook and a series of Recommended Practices (RPs). RPs include a wide range of subjects of interest to the measurement community, and can be purchased by both members and non-members. For the past several years the annual NCSL International Symposium and Workshop has included tutorials and papers on the topic of laboratory accreditation.

NCSLI is organized into more than 20 committees, each concerned with specific areas of concern to the measurement science community. Three of those committees are of particular interest to the topic of accreditation: the U.S. National Measurement Requirements Committee (USNMRC), the Accreditation Resources Committee and the ANSI/NCSLI Writing Committee. Historically, once every two years, beginning in 1982, the USNMRC has conducted a survey and published a report identifying measurement requirements in industry and government sectors. The 2000 survey included, for the first time, a section on laboratory accreditation; the report documented over seventy comments on that subject [5]. Those responses have been brought to the attention of NACLA, NIST and other interested parties. This committee, through a new forum soon to be on the NCSLI website, will continue to monitor the needs of the measurement community, including laboratory accreditation, in conjunction with the NCSLI Canadian Measurement Requirements Committee. The Centro Nacional de Metrologia (CENAM), in Mexico,

is now organizing a new measurements committee, based on the USNMRC model. The Accreditation Resources Committee is committed to providing assistance to NCSLI members who are interested in the general topic of laboratory accreditation, and/or are planning to pursue accreditation for their laboratories. To that end, following the 2001 Workshop and Symposium the committee presented a newly drafted Recommended Practice (RP-16) Practical Guide to Achieving Laboratory Accreditation, [7] to the NCSLI Board of Directors for consideration. That document has been published as a guideline, rather than an RP.

5. AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)

The American National Standards Institute (ANSI) is responsible for U.S.-based Standards Developing Organizations (SDOs) and is chartered by the United States Congress to ensure that U.S. interests are represented at all policy and technical levels within ISO and the IEC, and that the various SDOs are informed about ISO and IEC activities and given every opportunity to participate. One of the first acts in the implementation of the National Standards Strategy (NSS) was the signing by NIST and ANSI of a revised MOU, which strengthens the NIST/ANSI partnership for supporting the national voluntary standards system. Additionally ANSI is a member of the International Accreditation Forum (IAF). The ANSI/NCSLI Writing Committee is an ANSI accredited "Standards Writing Committee" acting on behalf of ANSI in developing American national standards. In 1994 this committee drafted and submitted to ANSI the document which became the American National Standard ANSI/NCSL Z540-1-1994, American National Standard for Calibration Laboratories and Measuring and Test Equipment – General Requirements [8], in 1995 the Handbook for the Interpretation and Application of ANSI/NCSL Z540-1-1994 [9], and in 1997 ANSI/NCSL Z540-2-1997, American National Standard for Expressing Uncertainty - U.S. Guide to the Expression of Uncertainty in Measurement, [10]. This is the U.S. version of the ISO Guide to the Expression of Uncertainty in Measurement (GUM). ANSI/NCSL Z540-1-1994 is the American version of ISO/IEC Guide 25, with an additional PART II, Quality Assurance Requirements for Measuring and Test Equipment (M&TE). Two actions were taken at the writing committee meeting during the NCSL International Symposium in Toronto, Canada in July 2000. The first action was to recommend, in conjunction with the American Society for Quality (ASQ) and the American Society for Testing and Materials (ASTM), the adoption by ANSI, of ISO/IEC 17025 as an American National Standard (ANS). This recommendation was accepted by ANSI and NCSLI published the standard as ANSI/ISO/IEC 17025:2000 in November of 2000 [11]. In the second action the committee recommended that ANSI reaffirm Z540-1, thus keeping it in place for another five years. There are a number of stakeholders and laboratories certified to Z540-1 who felt that a longer transition period would be needed before the full adoption of ANSI/ISO/IEC 17025

6. CONCLUSION

This paper has focused on the charters and activities of NCSLI and NACLA and their involvement in the laboratory accreditation system in the United States. NACLA and NCSLI are committed to simplifying the accreditation process in the US, without jeopardizing national trade agreements or private and public sector concerns, and improving the economic environment by increasing the confidence in laboratory results.

Among the goals and objectives of NCSLI for the 2002 – 2005 period is, "to investigate and/or develop the mechanism for contributing to Calibration Laboratory accreditation". Several other NCSLI Committees are involved in activities that affect laboratory accreditation, including interlaboratory comparisons and the interpretation and maintenance of intrinsic, derived and consensus standards.

In resolving these issues much work remains to be done by these organizations, by signatories to NACLA and others in the Metrology community. For example, the Measurement Science Conference (MSC) featured two workshops at their 2002 Conference titled "The Management Challenges of Laboratory Accreditation" and "Measurement Uncertainty by Example"; additionally there were three technical papers on accreditation. As a result of the recently released ISO 9000:2000, ISO/IEC 17025 may be revised soon. ISO/IEC Guide 58, which covers requirements for accreditation bodies, is about to become an ISO standard (17011), with some changes. Additionally, the community of Z540-1 users must be accommodated.

Laboratory Accreditation, like quality, is a moving target. Such a moving target requires management skill, cooperative efforts and perseverance.

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WEBSITES

National Institute of Standards and Technology, NIST
<http://www.ts.nist.gov>

National Cooperation for Laboratory Accreditation, NACLA
<http://www.nacla.net>

NCSL International
<http://www.ncslinternational.org>

American National Standards Institute, ANSI
<http://www.ansi.org>

International Accreditation Forum, IAF
<http://www.iaf.nu>

American Council of Independent Laboratories, ACIL
www.acil.org

International Laboratory Accreditation Cooperation, ILAC
www.ilac.org

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www.cenam.mx