

# Laboratory Accreditation

Richard B. Pettit  
Primary Standards Laboratory  
Sandia National Laboratories  
Albuquerque, NM 87185

## ABSTRACT

Accreditation can offer many benefits to a testing or calibration laboratory, including increased marketability of services, reduced number of outside assessments, and improved quality of services. Compared to ISO 9000 registration, the accreditation process includes a review of the entire quality system, but in addition a review of testing or calibration procedures by a technical expert and participation in proficiency testing in the areas of accreditation. Within the DOE, several facilities have recently become accredited in the area of calibration, including Sandia National Laboratories, Oak Ridge, AlliedSignal FM&T; Lockheed Martin Idaho Tech. Co., and Pacific Northwest National Lab. Recently, representatives from these and other DOE facilities throughout the U.S. formed a DOE Accreditation Committee under the sponsorship of the DOE Technical Standards Program. This committee will hold its first open meeting on September 23-24, 1998 at the National Institute of Standards and Technology in Gaithersburg, MD. with the goal of developing procedures for sharing and coordinating information within DOE on accreditation issues.

At the national level, a new non-profit organization was recently formed called the National Cooperation for Laboratory Accreditation (NACLA). The goal of NACLA is to develop procedures, following national and international requirements, for the recognition of competent accreditation bodies in the U.S. NACLA is a voluntary partnership between the public and private sectors with the goal of "a test or calibration performed once and accepted world wide." The NACLA accreditation body recognition process is based on the requirements of ISO Guide 25 and Guide 58. A membership drive will begin some time this fall to solicit organizational members and an election of a permanent NACLA Board of Directors will follow later this year or early 1999.

# Laboratory Accreditation

## Introduction

The need for laboratory accreditation of testing and calibration laboratories is becoming increasingly important and is being driven by both regulatory requirements and national and international requirements in the marketplace. In the future, laboratory accreditation may become a requirement for corporate survival. Accreditation is defined as “a procedure by which an authoritative body or person is competent to carry out specific tasks. [1] Compared to ISO-9000 registration, accreditation includes a review of the entire quality system supporting the laboratory, but it also includes two very important and distinguishing additional requirements: First, it includes a the review of the testing or calibration laboratory’s procedures by a technical expert to ensure that the process, equipment, environment, uncertainties, etc. are correct for the results claimed. Secondly, the testing or calibration laboratory must participate in proficiency testing in the areas where it is seeking accreditation. In many cases, the proficiency testing is coordinated by the accreditation body that is performing the accreditation, but it may also be a joint effort that is coordinated by a series of laboratories that have been, or are, seeking accreditation. These additional requirements ensure that the laboratory is performing its job correctly and that its results are compatible with other laboratories.

The purpose of this paper is to discuss accreditation activities within the Department of Energy (DOE), especially the formation of a DOE Accreditation Committee under the Technical Standards Program and the recommendation that all DOE calibration and testing laboratories adopt the international ISO Guide 25 “General Report for the Completeness of Testing and Calibration Laboratories.” In addition, the activities of a new organization, called the National Cooperation for Laboratory Accreditation (NACLA), are discussed which has the goal of recognizing competent accreditation bodies in the US and developing international recognition of the US accreditation program.

## DOE Accreditation Activities

Within the DOE, several facilities have recently become accredited in the area of calibration, including:

- Sandia National Laboratories’ Primary Standards Laboratory;
- Oak Ridge Metrology Center;
- AlliedSignal Federal Manufacturing & Technology Metrology Lab. in Kansas City, MO;

- Idaho National Engineering and Environmental Laboratory Standards and Calibration Laboratory in Idaho Falls, ID;
- Pacific Northwest National Laboratory in Richland, Washington.

Additional information of the scope of accreditation for these laboratories can be obtained from the National Institute of Standards and Technology (NIST) National Voluntary Laboratory Accreditation (NVLAP) home page at <http://ts.nist.gov/ts/htdocs/210/214/214.html>. Recently, representatives from these and other DOE facilities throughout the U.S. formed a DOE Metrology Committee under the sponsorship of the DOE Technical Standards Program. The objectives of the DOE Metrology Committee are to promote a coordinated metrology program for DOE, provide a network for sharing information and resources, and encourage high-quality, cost-effective metrology services for DOE Programs. The committee meets once a year and at the current time has three working groups in the areas of Communication, Uniformity, and Resources.

The Uniformity Working Group has recommended that DOE adhere to the requirements of ISO Guide 25 for all calibration and testing laboratories within DOE. This will provide uniformity within DOE and bring DOE into alignment with national and international standards. Before reaching this recommendation, the Working Group surveyed 30 DOE metrology laboratories concerning their current requirements. Most laboratories currently comply with ANSI/NCSL Z540-1-1994 "Calibration Laboratories and Measuring and Test Equipment – General Requirements" or ISO Guide 25. Note that ISO Guide 25 is currently under revision as DIS 17025, which will become an ISO Standard and that ANSI/NCSL Z540-1-1994 is based primarily on ISO Guide 25.

A second Working Group is focusing on Resource issues. The group has developed a web site for the committee at <http://www.doe.gov/metrology/mchome.html>. The site includes information on committee members, a point of contact at each DOE laboratory, and position papers. In the near future, a metrology capabilities database for all DOE laboratories will be added. The Communication Working Group is focusing on establishing a program to educate DOE customers and sponsors on the importance and need for metrology capabilities within DOE on a broad front. The group is establishing a process to develop and approve Position Papers from the Metrology Committee. Additional information on the activities of this group can be obtained from the web site or by contacting J. R. Wayland (505) 845-9771 [jrwayla@sandia.gov](mailto:jrwayla@sandia.gov).

An additional DOE-wide committee addressing accreditation issues has recently been formed. The group will hold its first open meeting September 23-24, 1998 at NIST, Gaithersburg, MD. Called the DOE Accreditation Committee, it is also sponsored by the DOE Technical Standard Program and has as its goal coordinating and relaying information within DOE on accreditation issues. Contact Dr. Sal Scarpitta, Brookhaven National Laboratories (516) 344-9771 for further information on the September workshop. The workshop will develop a DOE Accreditation Committee Charter and Bylaws and form Working Groups in three areas, including Communications; Accreditation Related Activities within DOE; and Interfacing with External Accreditation Activities.

## NACLA

Currently, there are over 150 accreditation bodies in the United States, representing agencies from the private sector, federal governments, state governments, and local programs. [2,3] These programs are not coordinated since they were developed to address specific needs in specific areas. The programs differ in administration, scope of the standards, approval process, etc. A more coordinated approach to the US situation is needed because there is no recognized national system for accredited laboratories; thus many laboratories must undergo multiple accreditations. [4] In addition, only a few accreditation bodies are recognized internationally, so that the tests or calibrations from accredited laboratories are not accepted in foreign countries. [5]

The issues at the national level were addressed in an Open Workshop held at the National Institute of Standards and Technology (NIST) on January 7, 1997. [6] After the Workshop, the National Cooperation for Laboratory Accreditation (NACLA) was established in order to address those issues. NACLA is a voluntary partnership between interested public and private sectors with the goal of coordinating the accreditation of laboratories in the U.S. The goal of NACLA is “a test performed once and accepted world wide.” An interim board of directors was formed in April 1997; after one year of operation, the interim board developed a processes for the recognition of accreditation bodies. At the present time, I am a member of the interim board representing the DOE through the sponsorship of the DOE Technical Standards Program Office.

The NACLA recognition process is based on international guidelines, specifically ISO Guide 25, “General Requirements for the Competence of Calibration or Testing Laboratories” and ISO Guide 58, “Calibration and Testing Laboratory Accreditation Systems – General Requirements for Operation and Recognition.” In addition, accredited laboratories must follow all elements of other required standards and relevant regulatory requirements that are needed to obtain accredited status. The recognition system proposed by NACLA provides an assessment of accreditation bodies by “teams” with representation from accreditors, as well as from other interested parties – such as government agencies, testing and calibration laboratories, and industry. The approval process also involves a Recognition Committee that also has representation from all parties. This type of “team” oversight process provides the necessary confidence building opportunities through active participation by regulatory agencies, industry and others that have a need to have confidence in the NACLA recognized accreditation bodies. In addition to the recognition process, the NACLA interim board has developed an organizational structure, operating committees, and operational procedures, including by-laws, administrative guidelines, and a quality manual. While many of these documents are still under development, many can be obtained from the NACLA web sight listed below.

An Open Forum was held at NIST on April 16, 1998 to present the current status of NACLA and discuss the proposed recognition process. The Open Forum was attended by 125 representative from accreditation bodies, federal and state agencies, industry, testing/calibration laboratories, and other interested parties. Following a discussion of the

NACLA process for the recognition of accreditation bodies, the by-laws, and the quality manual, the general consensus expressed by attendees was to proceed with the incorporation of NACLA. President Fred Grunder, representing American Industrial Hygiene Association (AIHA), proceeded with the incorporation using a law firm in Washington, D.C. Almost all of the members of the interim board have agreed to transfer to board members of the new organization. Federal agencies will participate on the new Board of Directors as liaison members. In addition federal employees will serve on all NACLA committees along with other NACLA members.

A membership drive will began sometime this fall to solicit organizational members. Soon there after, a nominating committee will develop a slate of candidates for election to a permanent NACLA Board of Directors by the fall of 1998. A full NACLA membership meeting will be held later this year or in early 1999. The slate of candidates will represent all stakeholders (government, accreditors, laboratories, industry, and other interested parties) in the NACLA process.

Additional information can be obtained from NIST/NACLA home page at <http://ts.nist.gov/ts/htdocs/210/nacla/index.htm> or by contacting Richard B. Pettit, (Sandia) at (505) 844-6242, Fred Grunder (AIHA) at (703) 849-8888 or Cathleen Trail (NIST) at (301) 975-4462.

## **Summary**

Laboratory accreditation has become a very important issue at the national level and is being driven by international/national standards and requirements, and the marketplace. At the present time, the United States has very diverse accreditation programs that are represented by over 150 accreditation bodies. A new organization, called NACLA, has been formed in order to provide for the recognition of competent accreditation bodies through a voluntary partnership of private and public sectors. NACLA will provide a focus and coordination of laboratory accreditation programs in the US (and eventually North America), in order to serve national needs in accreditation. The DOE Technical Standards Program has recently formed two committees, the DOE Metrology Committee and the DOE Accreditation Committee, in order to interface with these national activities and to provide a focal point within DOE for metrology and accreditation information and issues.

## References

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3. Helen Gillespie, “Lab Accreditation is All Over the Map,” Today’s Chemist at Work, pp. 48-54, March, 1998.
4. Belinda L. Collins, “Laboratory Accreditation: The Need for a National Infrastructure,” Calibration Laboratory, pp. 18-22, November/December, 1996.
5. Klaus Brinkmann, “How to achieve World-Wide Mutual recognition of Calibration and Test Results – or: Who Accredits the Accreditor?,” Accred. Quality Assurance, Vol. 2, No. 5, pp. 224-233, July 1997.
6. Janice S. Jablonski and Walter G. Light, “Report on the Open Forum on Establishment of the National Council for Laboratory Accreditation (NACLA) at the National Institute of Standards and Technology January 7, 1997,” NISTIR-6008, March, 1997.