HISTORY AND FUTURE OF LABORATORY ACCREDITATION

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ABSTRACT

In 1978, the US Environmental Protection Agency (EPA) initiated a laboratory certification program for laboratories involved in analyzing drinking water and delegated the authority for operation of the program to state agencies. Over the ensuing years, many states expanded this program to include other environmental media. As a result of efforts that began in 1987, a National Environmental Laboratory Accreditation Program (NELAP) has been created and is now managed by The NELAC Institute (TNI). This presentation will summarize the activities leading up to the formation of TNI, describe in detail the core programs being performed by the new organization and provide information about the future of national laboratory accreditation.

INTRODUCTION

Laboratory accreditation serves multiple purposes for different constituents. In general, NELAP accreditation attests to the competency of a laboratory for conducting environmental measurements.

- For the public, NELAP accreditation promotes confidence that environmental data used to make policy decisions to protect public health and the environment are generated by laboratories with demonstrated competence.
- For data users, NELAP accreditation serves a consumer protection purpose. It provides assurance that the laboratory has been evaluated and has met accepted standards of competency established by and within the profession.
- For the profession, NELAP accreditation advances the field by promoting accepted standards of practice and advocating rigorous adherence to these standards.
- For government agencies, NELAP accreditation provides a basis to make a determination if environmental monitoring data are adequate for their intended use.
- For the laboratory, NELAP accreditation provides ongoing internal and external evaluations, demonstrates a commitment to continuous improvement, provides an effective mechanism for accountability, and enhances its reputation.

THE BEGINNING

Almost all environmental compliance, regulatory and clean-up decisions are made based on measurement information. Data of known and documented quality is critical for end users of environmental measurement data and government agencies to make accurate, reliable and cost-effective decisions to protect the public health and the environment. An important factor in improving the quality of environmental data to ensure that the data are adequate for the intended

purpose is a consistent, stringent, comprehensive and yet practical accreditation program to ensure the competency of all environmental testing laboratories and related sampling and measurement organizations in the United States.

EPA, with the states as its implementation partners, maintains requirements for the certification of drinking water laboratories as well as outlining accreditation requirements for laboratories that analyze lead in paint and asbestos. Many states independently established accreditation programs covering the analysis of waste waters, solid and hazardous wastes, and air samples. In the 1980's, the commercial laboratory community began to advocate a national accreditation program to consolidate the multiple state programs that contained divergent accreditation requirements. A national program would provide the foundation for ensuring the capability and competence of laboratories to foster the generation of data of known and documented quality. Over twenty years ago, EPA recognized the problem of uncoordinated, inconsistent and redundant state and federal laboratory accreditation programs. In a 1988 Report to Congress on the comparability of laboratory test procedures, the EPA recommended that it explore the feasibility of establishing a uniform, national laboratory accreditation program

In 1990, EPA's Environmental Monitoring Management Council (EMMC) established an ad-hoc panel to respond to the concerns from laboratories and regulators about the diverse number of state accrediting programs with different, sometimes conflicting requirements. This group was to consider the feasibility and advisability of a national environmental laboratory accreditation program. The workgroup concluded that a national program was a viable option, and recommended that EPA consult with representatives of all stakeholders, by establishing a federal advisory committee.

The Committee on National Accreditation of Environmental Laboratories (CNAEL) was chartered in 1991 under the Federal Advisory Committee Act (FACA) and its members represented the stakeholder community (federal, state accrediting programs, commercial laboratories, etc.). CNAEL was to explore the possibilities of a national program and provide recommendations to EPA concerning the alternatives for a national program as well as the implementation and administration of such a program. In its final report to EMMC in 1992, CNAEL recommended that a self-supporting national program for laboratory accreditation be established and provided recommended models and structure for the organization that would implement the program. CNAEL recommended the program consist of performance evaluation testing, combined with a laboratory process and quality assurance certification program, which would include on-site audits.

THE EARLY YEARS

In response to the CNAEL recommendations, EPA, state and federal representatives formed the State/EPA Focus Group in 1993. The participants in these meetings represented EPA program offices, state regulatory agencies, states with differing types of accrediting programs, and federal agencies that had a need to perform environmental testing. This group developed a proposed framework, modeled after the National Conference on Weights and Measures and prepared a draft Constitution, Bylaws and Standards, which were published in the Federal Register in December 1994.

On February 16, 1995, state and federal officials voted to approve an interim Constitution and Bylaws – thus establishing the National Environmental Laboratory Accreditation Conference (NELAC), a standard setting organization. The major objective of NELAC was to develop accreditation standards and adopt them so that the standards could be used to support a National Environmental Laboratory Accreditation Program (NELAP). These standards were developed by a set of standing committees, who were each responsible for a chapter of the NELAC standards.

In 1999, NELAP was established with 11 states that received recognition as NELAP accreditation bodies. The goal of NELAP is to foster cooperation among the current accreditation activities of different states and other governmental agencies and to unify the state and federal agency standards. Each of the recognized accreditation bodies must implement the NELAC standards, and must accept the accreditation of laboratories accredited by other NELAP accreditation bodies. There are currently 13 state agencies that are recognized NELAP accreditation bodies.

NELAC was structured as an association of co-regulators: EPA, the states, and other federal agencies. Stakeholder groups such as commercial laboratories, municipalities, and trade groups were encouraged to attend meetings and participate on the NELAC committees. A vote to approve standards was limited to representatives from the state and federal agencies. If a private-sector organization felt the need to provide recommendations, such consensus could only be solicited through a committee chartered under the Federal Advisory Committee Act (FACA). In 1997, the Environmental Laboratory Advisory Board (ELAB) was established under the FACA to provide consensus advice on various issues, including recommendations on the NELAC standards.

NELAC was established as a way for the national laboratory accreditation effort to begin. However, not having the authority of an act of Congress to establish an accreditation program, NELAC relied on the voluntary participation of states to implement the program. States that decide to become part of the program are expected to use one set of requirements, the "NELAC Standards."

EPA had always intended for the program to be self-sufficient. EPA followed the recommendations of CNAEL in retaining oversight of the program, but expected a graduation into autonomy. It is clear that without EPA's leadership and monetary support over the past 12 years NELAC would not have progressed beyond the conceptual stage, but lacking an anchoring Federal statute, NELAC could not presume continued funding from EPA or the Agency's perpetual management of the program.

THE TRANSITION

Two significant events occurred in the late 1990's that required changes to the original NELAC structure:

- The National Technology Transfer and Advancement Act (NTTAA) became law in March 1996. The NTTAA outlined requirements Federal agencies must implement relative to the use of private sector standards and conformity assessment practices.

Federal agencies were directed to adopt private sector standards, wherever possible, in lieu of creating proprietary, non-consensus standards.

- A revised OMB Circular A-119 was issued in February 1998. This circular established policies on Federal use and development of voluntary consensus standards and on conformity assessment activities. Voluntary standards were defined as standards that were developed by a voluntary consensus standard body (VCSB). OMB Circular A-119 further defined the attributes and functions of a VCSB, which included, among other requirements, balanced interests in the standards development and approval process.

Clearly, NELAC, in its original structure, did not meet the definition of a voluntary consensus organization. Therefore, in 2002, NELAC amended its Constitution and By-Laws to make the conference a standards adoption body only. NELAC established itself as an organization that could receive and consider standards that have been developed by standards development organizations that use a consensus process as defined in OMB A-Circular 119. The last NELAC standard was published in 2003 and implemented in 2005.

While there are many recognized voluntary consensus standard bodies (ASTM International, American Industrial Hygiene Association (AIHA), etc.), no one group came forward to develop standards specifically designed for accreditation of environmental laboratories and field activities. In 2002, a new voluntary consensus standard organization, the Institute for National Environmental Laboratory Accreditation (INELA) was formed with a mission of developing standards for NELAC and other organizations to use.

INELA was incorporated as a non-profit member organization. The membership is entitled to vote on all standards and may voluntarily participate on any committees. INELA formed expert committees that functioned like the standing committees of NELAC, but with balanced representation from all stakeholder groups. Using the NELAC standards as a template, these expert committees began the process of developing consensus standards. The first INELA standard was accepted by member vote in September 2004, but was not adopted by the organization as it did not represent any significant change over the 2003 NELAC standard. In May, 2005, INELA began the process of reorganizing the 2004 standard so that a single volume would contain all the requirements for accrediting a targeted program such as environmental laboratories, field operations, taxonomy, etc.

THE RESTRUCTURING EFFORTS

The EPA Office of Research and Development (ORD) began providing financial and staffing support from the early meetings of the State-EPA Focus Groups. The ORD funding support allowed the National Environmental Laboratory Accreditation Conference (NELAC) and the National Environmental Laboratory Accreditation Program (NELAP) to begin operations and provided direct support through August 2006. At the Interim meeting in 2000, EPA reminded the NELAC community of the recommendation in the Committee on National Accreditation of Environmental Laboratories (CNAEL) document dealing with self-sufficiency. In 2005, Lara Autry, the NELAC Executive Director announced that a series of cooperative agreements would provide support for facilitating NELAC's transition to self sufficiency. These were awarded to several groups for various tasks deemed necessary to support the future program. As a step

toward self sufficiency, Ms Autry resigned from her role as NELAC and NELAP Executive Director in August, 2006, but continued as the project manager for the self sufficiency effort.

The National Forensic Science Technology Center (NFSTC) was selected as the primary organization to assist the NELAC board in determining the structure and format of a future organization. The NELAC board selected a team of individuals, the Self Sufficiency Task Group (SSTG) to provide recommendations on a plan for self-sufficiency, and a transition strategy to ensure the continuation of the NELAC and NELAP activities until the transition was complete. The SSTG solicited input from the NELAC community during the January 2006 NELAC meeting. The suggestions from this meeting were used to develop a draft vision, mission and purpose for the new organization, and identified key characteristics that the new organization should possess. In addition, the SSTG used the input from the meetings to develop a strategy for transition into a new organization, and identified immediate, interim and final goals.
The SSTG also considered current standard setting organizations and solicited offers from professional organizations who might be interested in assisting with the NELAC self-sufficiency efforts. INELA was one several organizations that responded to this solicitation. Of the responses, INELA best fit the characteristics and criteria defined by the SSTG.

After an informal meeting between the INELA Board of Directors and representatives of the SSTG in April, 2006, The SSTG drafted a non-binding Memorandum of Understanding (MOU) for consideration and approval by both the INELA and NELAC Boards of Directors. In June 2006, both boards approved the MOU and selected five members from each organization to form a joint Partnership Planning Team (PPT) to explore the potential combination of the two organizations. The PPT developed a proposed model for the new organization and presented this to the stakeholder community at the NELAC meeting in Kansas on August 14 and 15, 2006. The PPT solicited suggestions and comments at the August 2006 NELAC conference in Kansas City and will continue to explore the options.

THE PLAN FOR TRANSITION TO SELF-SUFFFICIENCY

The presentation covered the proposed mission, values, organization, governance and structure of a transformed organization that builds on the attributes of both NELAC and INELA.
The underlying assumptions the PPT provided for moving towards a combination were:

- Combining the operations of NELAC and INELA will result in a stronger organization.
- Combining operations will allow NELAC to achieve self-sufficiency quicker.
- Combining operations is less disruptive to the stakeholder community.

The core values identified by the PPT as necessary in the transformed organization include:

- An organization that is inclusive and responsive to the needs of all stakeholders
- An organization based upon integrity and honesty
- A quality based organization that encompasses both a belief that the program is worthwhile and that quality is the underlying value for everything that is done.

The PPT recommended that the corporate structure of the organization be that of an incorporated 501(c)3, not-for-profit member organization managed by a board of directors.

At the end of the NELAC meeting, a vote was held by the government officials in attendance that overwhelmingly confirmed that the NELAC Board of Directors should continue to work with INELA on pursuing options for working together. The INELA membership in attendance at the meeting unanimously endorsed this direction as well. Based on the outcome of the NELAC meeting, the PPT continued its work with the goal of having the transformed organization operational by the next meeting of these groups in January 2007.

The PPT met by teleconference on a weekly basis and had a three-day meeting in late September, 2006 to complete their task of developing recommendations. Concurrently with this effort, the NELAC board formed a task group to develop recommendations about the governance and structure of the accreditation programs. These efforts were completed in October, 2006 at which time the recommendations were sent to the NELAC and INELA boards for their consideration and were published on both the NELAC and INELA websites in a special report titled Recommendations for Combining NELAC and INELA Operations. A meeting of the INELA and NELAC Boards of Directors and Committee chairs occurred on November 6, 2006, to consider the recommendations.

FORMATION OF THE NELAC INSTITUTE

On November 6, 2006 a giant step towards achieving the long-term goal of the environmental laboratory and monitoring communities to have a national accreditation program was realized. After years of an evolving program under the auspices of the NELAC and INELA, the respective Board of Director's took actions necessary to form The NELAC Institute (TNI).

The actions taken on November 6th to form TNI were the result of years of hard work to create a national program through NELAC, years of hard work by INELA to create a consensus process for the development of accreditation standards, and months of intense exploration by a Partnership Planning Team (PPT) representing both entities that culminated in this new organization. As reflected in the new name, The NELAC Institute (TNI) has combined the heritage of NELAC with the consensus process of INELA into one organization.

The NELAC Institute (TNI) is a 501(c)3 non-profit organization whose mission is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community. The organization is managed by a Board of Directors and is governed by organizational Bylaws. Members of the organization include individuals from laboratories, data users, federal and state agencies and anyone interested in promoting environmental data of known and documented quality.

More information about TNI is available at www.nelac-institute.org.

TNI's PROGRAMS

The NELAC Institute operates the following major programs:

- Consensus Standards Development,
- Laboratory Accreditation System,
- National Environmental Laboratory Accreditation,

- Proficiency Testing, and
- Technical Assistance.

Consensus Standards Development Program (CSDP)

The purpose of the Consensus Standards Development Program (CSDP) is to develop consensus standards for the accreditation of environmental laboratories. Accreditation standards are developed by Expert Committees using a consensus process that includes the elements of openness, balance, due process, and consensus as established by Circular A-119 published by the US Office of Management and Budget. Standards have been developed that are widely applicable, and will therefore promote a uniform national program of environmental laboratory accreditation. These standards are modular, allowing their assembly into a series of volumes, each specifically designed for a stakeholder group (Laboratories; Accreditation Bodies; Proficiency Test Providers; Proficiency Test Provider Oversight Bodies; and Field Sampling and Measurement Organizations). The standards that have been developed by this program are summarized in Table 1.

Table 1. TNI Accreditation Standards

Environmental Laboratory Sector
Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis
Module 1 - Proficiency Testing
Module 2 - Quality Systems: General Requirements
Module 3 - Asbestos Testing
Module 4 - Chemical Testing
Module 5 - Microbiological Testing
Module 6 - Radiochemical Testing
Module 7 - Toxicity Testing
Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories
Module 1 - General Requirements
Module 2 - Proficiency Testing
Module 3 – On-site Assessment
Volume 3: General Requirements for Environmental Proficiency Test Providers
Volume 4: General Requirements for an Accreditor of Environmental Proficiency Test Providers
Field Sampling and Measurement Organization (FSMO) Sector
Volume 1: General Requirements for Field Sampling and Measurement Organizations
Volume 2: General Requirements for Accreditation Bodies Accrediting Field Sampling and

It is important to note that the TNI laboratory accreditation standard differs from the EPA certification program in one very significant manner. The TNI standard is based on ISO/IEC 17025, an international standard that contains both technical and management requirements.

Laboratory Accreditation System Program

The purpose of Laboratory Accreditation System Program (LASP) is to develop a system for the accreditation of environmental laboratories that consists of the policies and procedures, interpretations, guidance documents, and any related tools used by accreditation bodies to implement a national environmental laboratory accreditation program.

In addition to developing the laboratory accreditation system, this program is also responsible for establishing a national database of accredited laboratories.

National Environmental Laboratory Accreditation Program (NELAP)

The National Environmental Laboratory Accreditation Program (NELAP) was established as a means to improve the quality and consistency of environmental data throughout the United States, Although NELAP is a national program, state governmental agencies serve as Accreditation Bodies. States, which apply to NELAP to become an accreditation body, may select to operate an accreditation program which covers all of the EPA regulatory programs or as few as one. For example, many states may select to only accredit laboratories for chemistry and microbiology under the drinking water program. Other states may select to operate a comprehensive program, which includes all types of analyses for all types of media (i.e., hazardous waste, waste water, drinking water, air, soil, etc.) under the five EPA regulatory programs [i.e., Clean Air Act (CAA), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), Clean Water Act (CWA), Resource Conservation and Recovery Act (RCRA), and Safe Drinking Water Act (SDWA)]. There is no requirement that a state incorporate any particular portion of the possible scope into its program. The scope of accreditation, the type of laboratory included under the state's program, including the regulatory or voluntary nature of the program itself, the assessment of fees, and the use of third party assessors are all options of the state.

A NELAP Accreditation Body will accept by recognition, the accreditation status of a laboratory issued by another NELAP Accreditation Body (this is called secondary accreditation). Each Accreditation Body must adopt and adhere to this principle as a condition of membership in NELAP. In accepting the accreditation status of a laboratory through recognition, the Accreditation Body assumes accreditation responsibilities as a secondary accreditation body. A laboratory seeking accreditation must apply to its home state Accreditation Body for accreditation. However, if the Accreditation Body does not offer accreditation for testing in conformance with a particular field of accreditation (matrix-method/technology-analyte/analyte group), laboratories may obtain primary accreditation for that particular field of accreditation from any other NELAP Accreditation Body.

Proficiency Testing Program

Proficiency Testing (PT) is defined as a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. The TNI PT program consists of:

- A PT Expert Committee that establishes the requirement for proficiency testing.
- A PT Board who manages the implementation of the program.
- A PT Provider Accreditor that accredits organizations as PT Providers.
- Private and public sector PT Providers that manufacture and provide PT samples and evaluate the results.

The TNI PT Expert Committee has developed standards for laboratory proficiency testing and proficiency testing samples, including: criteria for selection of the providers of the samples; protocols for the use of proficiency test samples and data in the accreditation of laboratories; and criteria for Proficiency Test Provider Accreditors (PTPAs).

The PT Board maintains a national PT program that contains the following elements:

- Fields of Proficiency Testing (analytes, concentrations, matrices and acceptance limits) appropriate for the scope of environmental monitoring performed in the United States
- Oversight of organizations that provide PT samples to laboratories to ensure these organizations are competent to do so.

Technical Assistance Program

The purpose of the Technical Assistance Program is to provide assistance to stakeholders, particularly those seeking accreditation and those who accredit. The program develops tools, training, and other resources to enable stakeholders to efficiently participate, adopt, implement and comply with the TNI standards. Specifically, this program:

- Develops tools and templates to assist laboratories and accreditation bodies with implementing accreditation programs.
- Ensures that training programs relevant to the needs of the stakeholder community are provided.
- Ensures that laboratory assessors have a forum to discuss common issues.
- Develops a mentoring program to assist both laboratories and accreditation bodies with implementing accreditation programs.
- Provides a voice and solution strategies for small organizations.

THE FUTURE

Lessons from history provide insight into key practices offering stability and growth to the new organization.

- TNI has achieved short-term financial stability, primarily through cooperative agreements with EPA and membership dues, but also through sound fiscal practices such as maintaining a small staff and virtual office with low administrative overhead.
- There is very strong stakeholder support for the work TNI is doing with more than 90% of its stakeholders believing in the programs being offered.

- Dedicated volunteers with a passion for this effort, committee structure and balance, and the expertise and experience of the organization's membership are all proven assets.
- Significant progress has been made towards implementing a new accreditation standard.
- Committees to operate the TNI programs are well established and viable.
- TNI has been accredited by the American National Standards Institute as a consensus standards organization.
- An infrastructure has been established to allow TNI to expand the program into non traditional areas of monitoring such as field sampling and measurements, stack emission testing, and taxonomy.

There are, however, recurring themes that contribute to instability and need to be addressed to ensure success.

- A true national accreditation program has not been achieved.
- Some stakeholders do not support a national accreditation program.
- No standard beyond the 2003 NELAC Standard has yet been adopted by NELAP.
- The requirements appear onerous to small laboratories.

Implementation of the New TNI Standards

The 2003 NELAC Standard has been used by NELAP-recognized Accreditation Bodies (ABs) since 2005, and as such, is very familiar to the ABs as well as the accredited laboratory community and other stakeholders. However, the 2003 NELAC standard contains language about the operation of an organization that no longer exists, contains administrative detail that does not pertain to the operation of an accreditation program, contains obsolete language from an obsolete version of ISO 17025, is very hard to read and understand by laboratories that have not been accredited, and is not recognized by the EPA as a consensus standard. The 2003 NELAC Standard is widely perceived as one of the barriers to increasing the participation of both laboratories and states in the program.

The 2008 TNI standards, which have been in development since 2003, were developed to respond to criticisms of the 2003 NELAC standard. The TNI standards were developed by a true consensus process, use the current version of ISO 17025, have incorporated ISO 17011, are organized to make it easier for a laboratory to understand the requirements, and have improved some of technical weaknesses in the 2003 NELAC standard.

TNI has begun a process by which these standards will be reviewed for suitability for use in an accreditation program, and if so, will be formally adopted for use in NELAP. The current goal would be for these standards to become effective in 2010.

National Accreditation

TNI's vision is that every organization that generates environmental monitoring data will be accredited to a consensus standard. For this vision to become a reality, a number of actions need to occur.

- TNI needs to reach out to EPA program offices and state agencies to understand their needs and concerns and then take action to address these needs and concerns.

- TNI needs to reach out to those laboratories that believe the program to be too onerous and find ways to alleviate their concerns.

To address these concerns, TNI's Advocacy Committee has taken on the task of reaching out to other organizations to understand their needs and concerns on national accreditation and bring those needs and concerns back to TNI for action. Specifically, the Advocacy committee has initiated efforts to meet with EPA program offices (e.g., Air, Solid Waste, Wastewater), other federal agencies, state agencies, and other data users to understand their needs for reliable environmental data and work to ensure the TNI program meets the needs of all data users, and to meet with trade associations representing laboratories to understand their perspectives on laboratory accreditation and work to ensure the TNI program addresses their concerns.

Small Laboratories

Many small laboratories perceive the 2003 NELAC standard has too onerous. TNI believes many of these concerns can be solved with the outreach effort that has begun, but TNI also believes more can be done to help small laboratories. TNI has already accomplished some actions to help small laboratories:

- a Quality Manual template has been developed
- templates for technical and administrative Standard Operating Procedures are being developed,
- laboratory "mentoring sessions" are now a integral component of every TNI meeting,
- several training courses and workshops to help small laboratories have been held, and
- the position of Small Laboratory Advocate within TNI has been created.

As a result of these actions, many small laboratories, including many 1 and 2 person laboratories have become accredited over the last 2 years. TNI believes much more can be done, including:

- developing more tools and guidance,
- offering web-based training,
- ensuring that all requirements in the standard are essential for data quality, and
- improving the consistency of laboratory assessments.