THE NELAC INSTITUTE STRATEGIC PLAN 2007-2012 Chartering a New Direction

November 9, 2007

MISSION STATEMENT

The purpose of the organization 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.

VISION STATEMENT

All entities generating environmental data in the United States will be accredited to consensus national standards.

ORGANIZATIONAL HISTORY AND PROFILE

The Drinking Water Certification Program was established in 1978 and was followed two years later by federal regulations, which triggered the start of unprecedented growth in environmental laboratory testing.

The efforts to establish a national laboratory accreditation program began in the 1980s. Between 1980 and 1984, the Environmental Protection Agency's (EPA's) Contract Laboratory Program (CLP), the first de facto national accreditation program, was established as were some state accreditation programs beyond drinking water. Commercial laboratories began advocating for a uniform approach to accreditation and, in 1987 in a report to Congress, EPA recommended the consideration of a national accreditation program. In 1992, the Committee for National Accreditation of Environmental Laboratories (CNAEL) issued a report recommending the formation of a national accreditation program. The model for the National Environmental Laboratory Accreditation Conference (NELAC) was created by an EPA/State Focus Group in 1993 and its first bylaws were adopted in 1995. NELAC was established as an unincorporated organization of Federal and State officials that performed three major activities:

- the **development** of uniform accreditation standards to be used by all states that voluntarily decide to participate in the program,
- the adoption of these standards for use in state programs, and
- the **recognition** of state agencies as Accrediting Authorities (AAs) to administer the program within their state.

The first NELAC Standards were adopted in 1998 and the first AAs were recognized in 1999. By 2001, 655 laboratories had been accredited to the NELAC Standard.

In 2002, NELAC decided to no longer develop accreditation standards and instead decided to rely on standards developed by consensus standards organizations. That same year, the Institute for National Environmental Laboratory Accreditation (INELA) was formed by a small group of interested individuals. INELA was incorporated as a non-profit organization with the primary purpose of developing consensus-based accreditation standards.

In 2004, supported by an EPA cooperative agreement, NELAC began to explore options for the long-term sustainability of the organization. In 2006, INELA and NELAC agreed to

combine operations and form The NELAC Institute (TNI). Under TNI's umbrella, all activities previously performed by either NELAC or INELA were assumed, and several new activities to include advocacy, technical assistance, and a laboratory accreditation system were undertaken. In 2007, TNI elected its first Board and began strategic planning.

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 a new accreditation standard.
- Expert committees are well established and viable.
- ANSI accreditation of TNI as a consensus standards organization has been applied for and is pending.
- Policies on standards development and committee operations have been established.
- A series of successful meetings have been held since the first meeting of the Forum on Laboratory Accreditation was held in 2004.

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.
- Efforts to harmonize the TNI standards with EPA program needs may affect our mission.
- Adequate financial support is difficult and may not exist.
- Potential conflicts of interest are possible from the interconnected group of active participants.
- Special interest groups may be trying to impede progress.
- TNI lacks an established program for the recognition of Accreditation Bodies and no standard beyond the 2003 NELAC Standard has yet been adopted.
- There also is a perception that the 2003 NELAC Standard is too onerous for small laboratories.
- TNI does not yet have a well-defined business plan.

CORE STRATEGIES

The following four overall strategies will govern the goals and objectives for The NELAC Institute (TNI) over the next three to five years. Table 1 appended to this plan indicates the TNI program, committee, or board that is responsible for each of the numbered goals in each strategy.

- Strategy 1: Establish and maintain a national program for the accreditation of environmental laboratories and other organizations directly involved in the generation of environmental monitoring data. In order to achieve its mission, TNI must have a viable national accreditation program. The goals to accomplish this strategy are:
 - 1.1 Establish an effective national program for the accreditation of environmental laboratories.
 - 1.2 Establish and maintain a national proficiency testing (PT) program to support a national environmental laboratory accreditation program.
 - 1.3 Develop policies, procedures, and tools to assist with the implementation of a national environmental laboratory accreditation program.
 - 1.4 Finalize and implement all accreditation standards that are currently under development.
 - 1.5 Expand the program into non-traditional areas of environmental data collection.
- Strategy 2: *Increase participation*. Only 12 States are currently participating as recognized Accreditation Bodies. Some states are participating without being Accreditation Bodies by incorporating the NELAC Standard into their regulations, by requiring laboratories to be accredited, or by recognizing NELAC-accredited laboratories. A true national program is one where every state participates in some fashion. Only about 20 percent of the laboratories performing environmental analyses in the United States are currently accredited to a national standard. A true national program is one where every laboratory is accredited. Thus, this strategy is to increase participation in a national program by both states and laboratories. The goals to accomplish this strategy are:
 - 2.1 Develop an effective system for having states participate in a national program without having to become Accreditation Bodies.
 - 2.2 Develop materials and provide assistance to states and laboratories to make it easier for them to participate.
 - 2.3 Promote the benefits of accreditation to states and laboratories, advocate for stronger support of accreditation from data users, and persuade data users to make accreditation mandatory.
 - 2.4 Develop new accreditation standards that meet the needs of states and data users, while removing burdensome requirements for laboratories that are not essential for data quality.
- Strategy 3: Provide conferences that are beneficial to the environmental community and enhance TNI's mission. Experience has shown that face-to-face meetings are essential for TNI committees to interact and further their progress. These meetings are also a source of revenue to support the organizations infrastructure. The goals to accomplish this strategy are:

- 3.1 Hold a semi-annual Forum on Laboratory Accreditation.
- 3.2 Co-sponsor the National Environmental Monitoring Conference.
- 3.3 Conduct other regional conferences and workshops.

Strategy 4: *Establish infrastructure to ensure TNI's future success*. TNI has adequate short term funding to accomplish its short terms goals, but does not have a plan in place for long-term sustainability. The goals to accomplish this strategy are:

- 4.1 Attract and retain qualified paid and volunteer staff for all services and activities.
- 4.2 Increase the operational and management efficiency and effectiveness of TNI.
- 4.3 Acquire stable, long-term financial resources to support TNI programs and their growth.
- 4.4 Develop and maintain an effective Board of Directors.

PROGRAM GOALS AND OBJECTIVES

Strategy 1:

Establish and maintain a national program for the accreditation of environmental laboratories and other organizations directly involved in the generation of environmental monitoring data.

Goal 1.1 Establish an effective national program for the accreditation of environmental laboratories.

Objectives:

- By January 2008, adopt and implement the national PT program developed by the PT Board.
- By February 2008, implement a credible and efficient system for having states be recognized as Accreditation Bodies.
- By December 2008, adopt and implement all policies and procedures needed for a national environmental laboratory accreditation program.
- By January 2010, adopt and implement an approach that allows for states to participate in a national program without becoming recognized Accreditation Bodies.
- Adopt and implement the new TNI laboratory accreditation standards within two years of their approval by the membership (target date is August 2010).
- By January 2012, adopt and implement an approach that allows for effective accreditation of different types of laboratories.

Goal 1.2 Establish and maintain a national PT program to support a national environmental accreditation program that contains the following elements:

- Fields of Proficiency Testing (i.e., analytes, concentrations, matrices and acceptance limits) are appropriate for the scope of environmental monitoring performed in the United States.
- All organizations providing PT samples to laboratories are recognized as competent to do so.

- By December 2007, implement all policies and procedures necessary for operation of a national PT program.
- By December 2007, ensure that an oversight program is in place for PT providers that ensure that the providers are competent to operate environmental PT programs.
- By December 2007, ensure that Fields of Proficiency Testing are appropriate for their intended use.
- By January 2008, implement a process to periodically evaluate the effectiveness of the PT provider oversight program and the Fields of Proficiency Testing.

Goal 1.3 Develop policies, procedures, and tools to assist with the implementation of a national environmental laboratory accreditation program.

Objectives:

- By August 2008, develop procedures to be used by the NELAP Board in implementing a national accreditation program.
- By January 2009, implement a national database of accredited laboratories.

Goal 1.4 Finalize all accreditation standards that are currently under development.

Objectives:

- Finalize standards for Field Activities, Accreditation Bodies, and On-site Assessment by August 2007.
- Finalize standards for Proficiency Testing and Quality Systems by August 2008.

Goal 1.5 Expand the program into non-traditional areas of environmental data collection.

- By December 2008, identify an approach for the accreditation of field sampling and measurement organizations.
- By August 2009, establish a process that will allow the TNI approach to accreditation to be expanded into other areas such as taxonomy, ambient water quality monitoring, or emission testing.

Strategy 2: Increase participation.

Goal 2.1 Develop an effective system for states to participate in a national program without having to become Accreditation Bodies.

Objectives:

• By January 2009, develop an affiliate/associate program for states.

Goal 2.2 Develop materials and provide assistance to states and laboratories to make it easier for them to participate.

Objectives:

- Develop tools to assist laboratories and states.
- Conduct regional conferences and workshops.

Goal 2.3 Promote the benefits of accreditation to states and laboratories, advocate for stronger support of accreditation from data users, and persuade data users to make accreditation mandatory.

Objectives:

- By January 2008, establish a Speaker's Bureau and develop a plan for promoting laboratory accreditation at national and regional meetings.
- By August 2008, publish a White Paper quantifying the benefits of laboratory accreditation.
- By January 2009, develop a plan for Federal Agencies to require all environmental monitoring data from their contract laboratories be generated by NELAC-accredited laboratories.

Goal 2.4 Develop new accreditation standards that meet the needs of states and data users, while removing burdensome requirements for laboratories that are not essential for data quality.

- 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.
- Meet with trade associations representing laboratories to understand their perspectives on laboratory accreditation and work to ensure the TNI program addresses their concerns.
- By August 2010, harmonize the TNI accreditation standards with the EPA drinking water certification program.

- By August 2010, modify/improve the TNI accreditation standards so they are acceptable for use by all states.
- By August 2010, modify/improve the TNI accreditation standards so they meet the needs of data users.
- By August 2010, develop an approach to the accreditation standard that recognizes the differences in laboratories and the scope/complexity of work they do for obtaining their respective accreditation under this program and eliminates requirements that are not essential for data quality.

Strategy 3:

Provide conferences that are beneficial to the environmental community and enhance TNI's mission.

Goal 3.1 Hold a semi-annual Forum on Laboratory Accreditation.

Objectives:

- Improve processes for conference management.
- Expand participation in the Forum.

Goal 3.2 Co-sponsor the National Environmental Monitoring Conference (NEMC).

Objectives:

- Improve processes for conference management.
- Seek additional funding opportunities.
- Expand participation in NEMC.
- Improve the technical aspects of NEMC.

Goal 3.3 Conduct other regional conferences and workshops.

Objectives:

• Explore opportunities for managing regional workshops.

Strategy 4: Establish infrastructure to ensure TNI's future success.

Goal 4.1 Attract and retain qualified paid and volunteer staff for all services and activities.

Objectives:

- Increase level of activity for Executive Director to full time.
- Add one staff person (i.e., a contractor) to assist with Accreditation Body evaluations.
- Develop a long-term plan to take on those functions that are currently supported by EPA assistance agreements.
- Improve the system for encouraging volunteer work on committees.
- Ensure a pool of volunteers is available for committees.
- Evaluate the Executive Director's performance on an annual basis.

Goal 4.2 Increase the operational and management efficiency and effectiveness of TNI.

Objectives:

- Increase the effectiveness of TNI.
- Maintain fiscally prudent operations.
- Produce timely, accurate financial reports.
- Improve the functionality and appearance of the TNI website
- Provide routine communications/information to TNI members.
- Establish a Policy Committee to ensure policies have been implemented for all key activities.
- Establish an on-going evaluation process for all programs.

Goal 4.4 Acquire stable, long-term financial resources to support TNI programs and their growth.

Objectives:

- Explore external funding options.
- Develop internal sources of funding.
- Develop a budget for the operation of TNI programs and a plan for cost recovery.
- Maintain an awareness of potential funding opportunities and respond to such opportunities as they arise.

Goal 4.5 Develop and maintain an effective Board of Directors.

- Ensure the Board is representative of all stakeholders.
- Increase the capability of the Board.

Table 1: Summary of Goals and Responsible Program or Committee

Goal	Responsibility
1.1 Establish an effective national program for the accreditation of	NELAP Board
environmental laboratories.	
1.2 Establish and maintain a national PT program to support a national	PT Board
environmental laboratory accreditation program.	
1.3 Develop policies, procedures, and tools to assist with the	LASC
implementation of a national environmental laboratory accreditation	
program.	
1.4 Finalize and implement all accreditation standards that are currently	CSD Board
under development.	
1.5 Expand the program into non-traditional areas of environmental data	CSD Board
collection.	
2.1 Develop an effective system for having states participate in a national	LASC
program without having to become Accreditation Bodies.	
2.2 Develop materials and provide assistance to states and laboratories to	TAC
make it easier for them to participate.	
2.3 Promote the benefits of accreditation to states and laboratories,	AC
advocate for stronger support of accreditation from data users, and	
persuade data users to make accreditation mandatory.	
2.4 Develop new accreditation standards that meet the needs of states and	CSD Board
data users, while removing burdensome requirements for laboratories that	
are not essential for data quality.	
3.1 Hold a semi-annual Forum on Laboratory Accreditation.	CPC
3.2 Co-sponsor the National Environmental Monitoring Conference.	CPC
3.3 Conduct other regional conferences and workshops.	CPC
4.1 Attract and retain qualified paid and volunteer staff for all services	BoD
and activities.	
4.2 Increase the operational and management efficiency and effectiveness	BoD
of TNI.	
4.3 Acquire stable, long-term financial resources to support TNI	BoD
programs and their growth.	
4.4 Develop and maintain an effective Board of Directors.	BoD

NELAP Board: National Environmental Laboratory Accreditation Program Board

PT Board: Proficiency Testing Board

LASC: Laboratory Accreditation System Committee CSD Board: Consensus Standards Development Board

TAC: Technical Assistance Committee

AC: Advocacy Committee

CPC: Conference Planning Committee

BoD: Board of Directors