

Report on the NELAC Self Sufficiency Strategic Plan

By

**National Laboratory Accreditation Conference (NELAC)
Board of Directors – Self-Sufficiency Task Group (SSTG)**

**Presented
To
NELAC Board of Directors**

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Introduction

This report was prepared by the National Environmental Laboratory Accreditation Conference (NELAC) Self-Sufficiency Task Group (SSTG) appointed by the NELAC Board of Directors and in collaboration with the National Forensic Science Technology Center (NFSTC). The purpose of this report is to provide recommendations to the NELAC Board of Directors regarding the development of a plan for the self-sufficiency of NELAC and the National Environmental Laboratory Accreditation Program (NELAP) and to ensure the continuation of NELAC and NELAP during the period of transition to the new self-sufficient organization. This report also documents and summarizes the work done by the SSTG and NFSTC in support of the recommendations provided to the NELAC Board of Directors.

History

In 1991, in response to the concerns of environmental testing laboratories regarding the burden of complying with the requirements of multiple accreditation programs, the Committee on National Accreditation of Environmental Laboratories (CNAEL) was chartered by the United States Environmental Protection Agency (EPA) to explore the need and advisability of a national accreditation program. The CNAEL recommended that a self-sufficient national program for laboratory accreditation be established. This recommendation ultimately resulted in the formation of NELAC, a voluntary association of state and federal officials, in 1995. NELAC's two major functions were to develop accreditation standards through consensus and adopt them by voting on them at annual meetings. In 2001, NELAP (National Environmental Laboratory Accreditation Program) was established for the implementation of those standards. There are now 13 state agencies recognized by NELAP as accrediting authorities and voluntarily implementing laboratory accreditation programs.

In 2002, NELAC amended its Constitution and By-Laws to make the conference a standards adoption body only. NELAC receives and considers standards that have been developed by any standards development organization that uses a consensus process.

Currently, NELAC and NELAP are directed by EPA staff and funded by EPA although self-sufficiency remains the ultimate goal. At the end of the annual NELAC meeting in August 2006, the director of NELAC/NELAP will resign from those duties but continue as project manager for the self-sufficiency effort.

In 2005, the SSTG was formed and given the task of advising the NELAC Board of Directors regarding a plan for NELAC/NELAP self-sufficiency. EPA provided assistance through a cooperative agreement with the NFSTC to facilitate this process.

Process and Research

The SSTG began their work by soliciting input from the NELAC members and stakeholders during the NELAC interim meeting in Chicago (January 2006). Additional input was requested via e-mail from a list of current and past NELAC participants.

Direct input was requested from the NELAP Accrediting Authorities Committee (AAC) during a conference call conducted March 20, 2006. The SSTG also requested information from the NELAC Proficiency Testing Board (PT Board).

From the input provided and the information gathered, the SSTG: 1) developed a draft vision, mission and purpose; 2) identified the necessary characteristics of a new organization; 3) outlined a timeline and a communication strategy; and (4) identified a potential structure for a new organization.

The SSTG reviewed options available for establishment of a not-for-profit entity. The SSTG took into consideration the resources needed to establish a new organization from scratch versus partnering with an already existing professional organization. The SSTG determined there were three areas to research before making a final recommendation on incorporating a new organization:

- Research incorporating independently as a new organization;
- Research collaboration with the Institute for National Environmental Laboratory Accreditation (INELA), a non-profit standards development organization; and
- Determine if there are any other organizations which might meet the SSTG criteria.

On behalf of the SSTG, the NFSTC solicited offers from relevant professional organizations interested in assisting with the NELAC self-sufficiency efforts. The solicitation was posted April 19 on the NELAC website and emailed directly to

stakeholders. It was a vehicle to inform organizations representing the environmental laboratory testing community that the SSTG was open to offers of assistance. Organizations were invited to submit a statement of interest by May 20, 2006. In its statement of interest, the organization was asked to outline its qualifications for providing assistance to NELAC.

The SSTG was primarily interested in organizations possessing the characteristics identified by the SSTG for a proposed new organization. A number of additional criteria were also considered when reviewing the responses to the solicitation, including but not limited to: 1) common goals/mission; 2) similar constituencies; 3) experience with NELAC and the NELAP recognition program; 4) fiscal independence; 5) the value of their assets; and 6) the potential “fit” with the new organization.

The SSTG received five responses to the solicitation: Institute of National Environmental Laboratory Accreditation (INELA), Environmental Resource Associates (ERA), Analytical Excellence, Inc. (AEX), American Council of Independent Laboratories (ACIL) and Association of Public Health Laboratories (APHL).

The INELA Board of Directors offered assistance and extended an invitation to meet with the SSTG members as early as April 10, 2006. To gather additional information, a meeting was held between representatives of the SSTG and INELA in Austin, Texas, on April 27, 2006.

At an SSTG meeting held in Florida, May 24-25, 2006, and a teleconference held on June 6, 2006, the SSTG reviewed the responses to the solicitation. The SSTG requested NFSTC to respond to ERA, AEX, ACIL and APHL. NFSTC contacted these organizations and informed them that although the SSTG considered them stakeholders in NELAC and looks forward to working with them in the future, the SSTG did not have a clearly defined role for them at this time.

The SSTG reviewed the offer from INELA and determined that INELA was an organization that met most, if not all, of the SSTG criteria for the solicitation. The SSTG also took into account the feedback received from NELAC members and participants during the Chicago conference in which a strong desire was expressed for wide participation of all stakeholders in the new organization. Members and participants also expressed the need for consensus based standard development within the new organization.

On May 25, 2006, the SSTG met briefly with INELA’s Executive Director, Mr. Jerry Parr, to set up a June 5, 2006, teleconference between the SSTG and INELA to obtain additional information on potential collaboration. At the June 5, 2006 teleconference, the SSTG completed its review of the information provided by INELA, comparing the purpose, characteristics, products, services, activities, infrastructure, and constituency the SSTG proposes for the new organization to those of INELA. On June 6, 2006, the SSTG met by teleconference and agreed to recommend the exploration of a partnership between NELAC and INELA.

A non-binding Memorandum of Understanding (MOU) was drafted and submitted for approval to both the INELA and NELAC Boards on June 14 and 15, 2006, respectively. The SSTG recommended that the Boards of INELA and NELAC form a joint partnership planning team to explore the options for combining INELA and NELAC.

The NELAC Board of Directors and the INELA Board of Directors approved the MOU and each selected five members from their respective organizations to comprise the partnership planning team, which began work immediately.

The MOU establishes an exploratory period of up to six months for good-faith negotiations toward a potential combination of the two organizations. During this period, each organization may inform its constituents that this exploration is underway. At the end of the above-authorized period, if not sooner, the partnership planning team will submit its report and recommendations to the full boards of each organization.

The SSTG research was completed by June 15, 2006, when the SSTG made its recommendation to the NELAC Board of Directors.

Vision, Mission and Purpose

Based on input from the NELAC membership and stakeholders, the SSTG has written draft Vision, Mission and Purpose statements. These are working draft statements for use by the SSTG during the planning process. These statements can be refined as the planning process continues and additional information is available.

Draft Vision: *Provide a truly national laboratory accreditation system*

Draft Mission: *Foster the generation of environmental data of known and documented quality to assist efforts towards protecting and improving human health and the environment.*

Draft Purpose: *Promote Professionalism in the field of environmental analysis through Quality, Leadership and Training*

Characteristics

The SSTG has identified some of the characteristics of the new organization. In order to do business, the new organization must be a legally identified (i.e., incorporated), not-for-profit entity with programs based on consensus, national/international standards. The new organization will offer products and services in addition to engaging in activities relating to its purpose (see Figure 1).

Promoting professionalism through quality will include identifying and addressing needs for performance standards, for training and education, and for data/information. It will also include maintaining programs for the recognition of accrediting authorities and for the accreditation of laboratories.

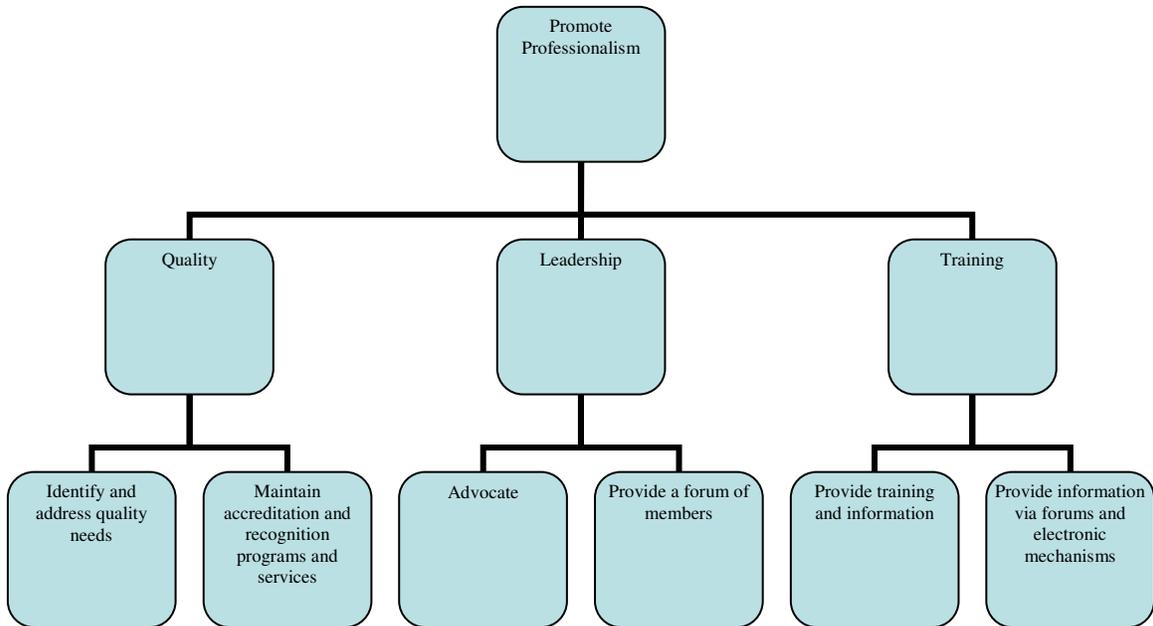
Promoting professionalism through leadership will include advocating for a national accreditation system and support for the program, as well as providing a forum for members to exchange information and discuss questions related to accreditation standards for laboratories.

Promoting professionalism through training will include providing training to program evaluators, laboratory assessors, testing professionals; providing mentoring support to states and laboratories; and providing information via forums, meetings, publications, and electronic media.

Products will include a laboratory accreditation program, a proficiency test provider accreditation program, and a national database.

Services will include the recognition of laboratory accreditors, the recognition of proficiency test provider accreditors, and the administration of the database.

Figure 1: Purpose of the Organization



Timeline

The SSTG has determined a timeline for transition into self-sufficiency that is divided into three basic segments: immediate, interim, and new governance. The following describes the focus of each of these time segments.

Immediate (Prior to August 2006)

This is the time segment until the conclusion of the August 2006 meeting in Kansas City, when the NELAC/NELAP Director leaves office. The SSTG met with the NFSTC facilitator May 24-25, 2006. The SSTG focused on gathering information, formulating a recommendation to the NELAC Board of Directors, drafting an outline of the strategic plan (focusing on the structure of the new organization), and implementing a communication strategy.

The goal of the communication strategy is to provide information to the NELAC membership prior to the August 2006, meeting in Kansas City. This should allow the NELAC membership to be prepared to discuss and vote at the meeting. The SSTG provided information and its recommendation to the NELAC Board of Directors and the NELAC Committee chairs via a teleconference facilitated by NFSTC on June 15, 2006. The SSTG:

- Presented the basics of the plan,
- Requested the NELAC Board of Directors confirm the SSTG recommendations in the plan;
- Requested the NELAC Board of Directors adopt the recommendation of signing an exploratory MOU with INELA.

NFSTC developed a PowerPoint presentation to be used for that teleconference. Committees and boards chairs will be instructed to provide the information to their committees prior to the Kansas City meeting. If requested by the chairs, representatives from the SSTG will meet with the Accrediting Authority Review Board (AARB), the PT Board, Standard Review Committee (SRC), the Membership and Outreach Committee and the AAC.

If the plan is affirmed by the NELAC Board of Directors, the NFSTC will provide information to the NELAC membership using a range of communication mechanisms:

- Web site. NFSTC will provide information to be posted on the NELAC web site approximately 45 days prior to the NELAC meeting in Kansas City (July 1, 2006).
- Direct mailing. The NFSTC will email information to NELAC stakeholders, using contacts provided by the NELAC director and the attendance list from the Chicago meeting (July 1, 2006).
- Web Conferences. The NFSTC will develop and schedule up to four informational presentations to provide information to NELAC stakeholders. Where possible, the presentations will be scheduled approximately once per week in the month of July, using a web based service that will allow “attendees” to view a PowerPoint presentation while connected to a teleconference. The announcement of the teleconferences will be made via the emailed information to stakeholders. Attendance will be on a “first-come” basis.
- Presentation at the August 2006, NELAC meeting scheduled for Kansas City. An explanation of the events which have created the timeline and determined the SSTG priorities and recommendations will be presented.

Interim (August 2006 to January 2007)

This is the time from the departure of the NELAC/NELAP Director (August 2006) until the establishment of the new organization, projected for January 2007. The focus will be on the continuation of the NELAP program, establishing a new organization and governing board, and identifying an Executive Director.

By August 2006, Lara Autry will identify the primary duties she performs in her capacities as the NELAC/NELAP Director. The SSTG recommends these duties/tasks be assigned to the NELAC Board or other committees during the interim period:

- NELAP Director. Under the current structure, the Accrediting Authority Review Board (AARB) serves in an advisory capacity to the NELAP Director on programmatic issues. The NELAP Director works with the NELAC Board to carry out her duties and establish policy for NELAP. As an interim plan, the SSTG proposes the AARB assume the programmatic duties of the NELAP Director and the NELAC Board of Directors assume oversight of those duties. In addition, the NELAC Board will assume the responsibility for NELAP policy with advice from the AARB. Administrative assistance will be provided by NFSTC within the limitations of the cooperative agreement. Extensions have been granted to all current Accrediting Authorities. As a result, no evaluations are anticipated prior to October 2007.

- NELAC Director. Under the current structure, the Proficiency Testing Board (PT Board) oversees the functions of the PTOB/PTPA and reports directly to the NELAC Board. The NELAC Director performs functions that primarily support the NELAC Board. During the interim time period, the SSTG proposes the NELAC Board of Directors continue its oversight of the PT Board while assuming the other duties of the NELAC Director. Administrative assistance will be provided by NFSTC within the limits of the cooperative agreement.

New Governance (After January 2007)

This is the time segment beginning with the establishment (i.e., incorporation) of the new organization (January 2007). The focus during this period will be on issues relating to the implementation of the new organization.

Proposed Organizational Structure

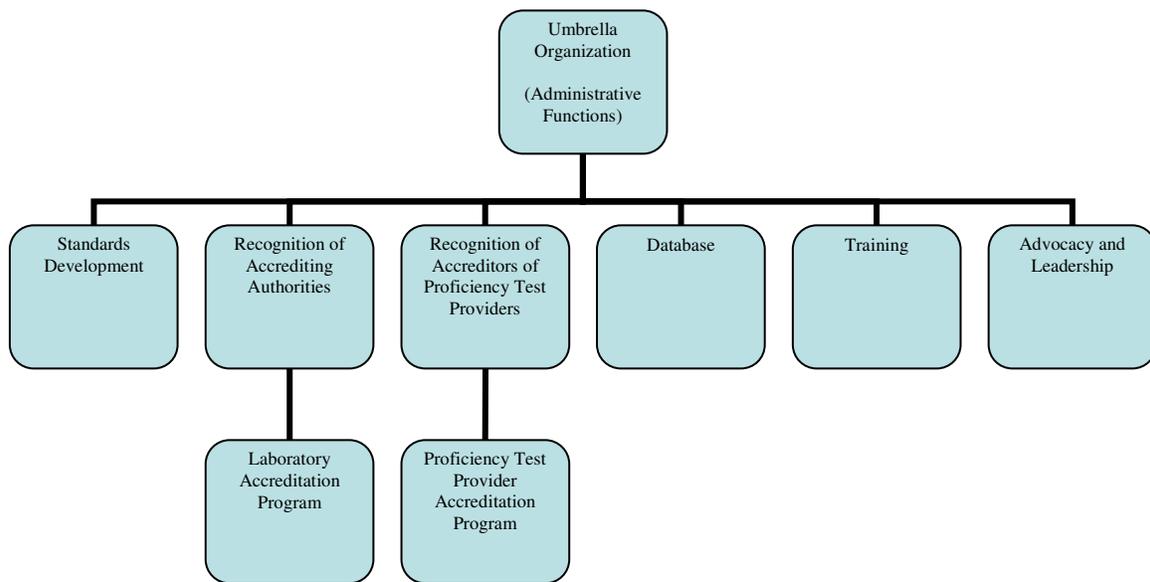
Umbrella Organization. The SSTG considered an organizational structure based on establishing an “umbrella” organization having distinct programs/sections operating under the umbrella (see Figure 2). The umbrella organization would provide administrative oversight and coordinate the functions of the programs/sections.

The SSTG is recommending that research be conducted to determine options for establishing an umbrella organization. Possibilities include a membership organization having other organizations as members, individual members, or a combination of both. The primary responsibilities of member organizations would be to select a governing board, act on by-law changes and approve business ventures

The governance of the umbrella organization would be the responsibility of a policy-making Board of Directors and an Executive Director. The mechanism for the selection

of the Board of Directors will be recommended after research on the type of membership organization has been completed. The Executive Director would be an individual contractor responsible for executing the policies of the Board of Directors. The SSTG recommends developing a job description and statement of work for an Executive Director based, in part, on the job duties identified by the current NELAC/NELAP Director.

Figure 2: Possible organizational structure



Standards Development. The SSTG met with Dr. William Tilstone about the National Cooperation for Laboratory Accreditation (NACLA) and models for international standards for laboratory accreditation programs. Dr. Tilstone is Deputy Executive Director of NFSTC and President of the Executive Committee of NACLA. Several ISO models were presented which use ISO Standard 17025 with amplification documents for laboratory accreditation programs. The SSTG recommends research of consensus models for standards which will meet the OMB Circular 119 and how these might be used by Accrediting Authorities (AAs) having a regulatory arm.

Recognition of Accrediting Authorities. The SSTG discussed several models for the organizational structure for NELAP. One option is to establish some form of self-governance by the AAs. The SSTG recommends conducting research to determine if there are external bodies suitable to evaluate AAs. Due to the complexities of the issues involved (e.g., state sovereignty and regulatory functions), the SSTG recommends the inclusion of the AAC in the development of a governance structure for the AA recognition program. The NELAC chair, Aurora Shields, requested the participation of

the AAC in this process during a conference call conducted June 6, 2006. The NELAC Chair, Aurora Shields, and the NELAC Director, Lara Autry, will schedule a face-to-face meeting for the NELAP Accrediting Authorities Committee (AAC) at the Kansas City meeting for this purpose. NFSTC will facilitate this discussion.

The SSTG recommends development of the strategic plan relating to NELAP during the interim period (August 2006 to January 2007).

The SSTG recognizes that non-AA states and other stakeholders need to have a mechanism available to provide their comments on a proposed governance structure for NELAP. The open self-sufficiency session scheduled for the Kansas City meeting will provide a venue for these comments. NFSTC will facilitate this discussion. Additional growth possibilities will be considered after the incorporation of the new organization (January 07).

Preparation for training of evaluators of accrediting authorities has begun. With NFSTC facilitation, the regional evaluators have developed a plan for training in preparation for the summer 2007 evaluations. As part of this process, the evaluators are reviewing the checklists and other materials used during evaluations, and updating them to the 2003 NELAC Standard. The regional evaluators have scheduled a meeting at Kansas City (August 2006) to review the documents and the training course. The materials will then be submitted to the AARB for approval in preparation for training to be offered at the winter 2007 meeting. NFSTC will coordinate that training.

The SSTG researched some of the cost associated with the current practice of using regional and state evaluators to conduct reviews of the accrediting authorities. EPA provided information on staffing cost spent by EPA during past evaluations. Travel expenses should also be estimated. The SSTG also recommends that the AAs provide any additional information they might have relating to this topic.

The SSTG proposes that an Executive Director oversee the evaluation process, to include identifying and assigning evaluation teams. This will require the review of the NELAC standard, policies and procedures to determine the changes which might be necessary before submitting recommendations concerning the evaluation process.

Recognition of Accreditors of Proficiency Test Providers. The Proficiency Testing vendors are accredited by a Proficiency Testing Oversight Body/Proficiency Testing Provider Accreditor (PTOB/PTPA) which is overseen by the PT Board. Currently, there is only one PTOB/PTPA and there is no charge for NELAC recognition of approximately 10 PT vendors. The PT Board meets to review the accreditations awarded by the PTOB/PTPA, to monitor the PT program, and to collect data for determining acceptance criteria. It also conducts an on site evaluation of the PTOB/PTPA every 2-3 years using volunteers.

The SSTG researched some of the cost associated with this program. SSTG obtained information from the NELAC PT Board on the estimated cost used for the PT Board

functions. In addition a database may be necessary to collect data for the determination of acceptance criteria. The SSTG also recommends researching the use of non-volunteer PTOB/PTPA evaluators, training for these evaluators, and external mechanisms which might be available for oversight of the PT program and/or determination of acceptance criteria. A review of the NELAC standard, policies and procedures will be required to determine the changes which might be necessary to maintain the PT program.

Database. This will require additional discussion and coordination of resources.

Training. One of the primary mechanisms to promote professionalism through training is through a meeting/forum. Currently, there are two NELAC meetings each year. Beginning in January 2007, the SSTG is proposing the new organization host only one meeting per year. This is due to a number of factors: the expense and time needed for NELAC to host a forum, the expenses incurred by attendees participating in two such forums every year, and the difficulty attendees have in justifying/obtaining agency approval for two forums each year.

The purpose of the annual NELAC meeting should include: business planning and conducting board business; conducting a membership meeting; conducting committee meetings and providing committee reports to the membership; obtaining membership/stakeholder input; providing training and information to members; hosting technical presentations; and exchanging information. The budget for this meeting should be separate from the organizational budget. The SSTG recommends the fees be set to generate income; i.e., to cover expenses plus a given percentage (10% has been used in the budget provided).

The SSTG recommends that options to a second annual meeting be explored. Possibilities include workshops on specific topics and scheduling board/committee meetings in conjunction with other national/regional meetings relevant to the environmental laboratory testing community, where it would be likely to have board members already scheduled to attend. The SSTG considers the website and other electronic media as potential mechanisms for providing information to the membership. The Membership and Outreach Committee is researching these options and will provide recommendations in the future.

Advocacy and Leadership. The SSTG recommends considering mechanisms which might be used to link data quality to NELAP accreditation. The SSTG recommends working in partnership with EPA program offices to encourage program acceptance of laboratory accreditation as a mechanism to ensure data quality. The SSTG also considers outreach efforts to non-NELAP states another significant element to accomplishing the organization's vision of a national accreditation system.