



August 28, 2016

Ms. Christine Sotelo, Chief
California ELAP
1001 I Street, 13th Floor
Sacramento, CA 95814

Dear Ms. Sotelo

Thank you for contacting The NELAC Institute (TNI) requesting information about our organization and the resources we have available to assist laboratories. We have prepared this letter to tell you a little more about TNI, but more specifically, how TNI can assist your program during this transition time.

In the late 1990's the US Environmental Protection Agency (EPA) began an effort working with many state agencies to establish a National Environmental Laboratory Accreditation Program (NELAP) to address the proliferation of state programs and the diverse nature of laboratory assessments performed by the individual states. This group soon realized that EPA could not be the manager of this effort since EPA has no statutory authority to accredit laboratories other than in the drinking water program. That realization gave birth to The NELAC Institute (TNI), a nonprofit 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. This organization is made up of all stakeholders, including regulators, labs and the vendor community. A listing of our current Board of Directors is attached.

To accomplish this mission, TNI created three core objectives:

- Development of consensus standards to be used by the states in implementing accreditation programs,
- Peer recognition of participating state agencies by a thorough evaluation of their ability to operate an accreditation program, and

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- Establishment of a Proficiency Testing program whose goal is to ensure laboratories receive an equal challenge when analyzing PT samples.

TNI has been very successful in achieving these objectives. Thirteen states participate in the program as recognized Accreditation Bodies and many more states participate indirectly by accepting a NELAP accreditation in lieu of their own. Over 1600 laboratories throughout the US have been accredited to the TNI standard and the program is viewed as rigorous, but fair.

During this process TNI has worked collaboratively with EPA in general and the Office of Water specifically, to ensure TNI's efforts are aligned with EPA goals for the quality of environmental data. At this time, the only formal ties between TNI's NELAP and EPA are a Board liaison position, held by Lara Phelps, and a liaison role held by an EPA regional staff person to the NELAP Accreditation Council, the NELAP governing body. However, many other EPA employees participate as volunteers on one of TNI's committees.

Over the years, TNI has expanded its basic focus into new areas such as field sampling and measurement, training courses, and template documents to assist laboratories in building their quality systems. Our goal in the process has been to continually support our mission of improving environmental data quality.

We have been very interested in the recent developments in California to reinvent your program and congratulate you and the ELAP staff on your remarkable progress to date. Now that you are getting close to a decision on which standard to use, we would like to inform you of the resources TNI has that could help both ELAP and California laboratories, implement the TNI standard. Many of our resources are available for free. TNI is also prepared to offer substantial discounts on various templates and recorded webcasts to ELAP.

One of the key organizational elements of TNI's structure is an educational component. TNI strongly believes that removing the perceived barriers to accreditation through education is necessary to create a truly national environmental laboratory accreditation program. This educational component consists of the following elements:

- A Quality Manual template designed to make it easy for laboratories to develop their own Quality Manual. Many laboratories have indicated preparation of this document is the most resource intensive effort they undertake.
- Other templates for various administrative and technical Standard Operating Procedures.
- Mentor sessions at each of our meetings where laboratories can meet and discuss how they addressed a particular requirement. For example, at our meeting in southern California in August 2016, one of the mentor session topics was electronic records. The presentations from these sessions are archived on the TNI website for free download.
- The Small Laboratory Advocacy Group, an on-line bulletin board where individuals can post questions related to laboratory accreditation.
- Downloadable webcasts on a variety of topics in the TNI standard. Each of these is 2-3 hours long and focuses on a particular topic, e.g., management reviews, in detail. Over the next year, TNI plans to greatly expand this list to include every section of the TNI standard.
- A checklist laboratories can use to conduct an internal audit.
- A list of consultants to help laboratories become accredited.

- Regional workshops where TNI staff and volunteers train laboratory staff on how to get accredited.
- Standards Interpretation Requests (SIRS) are posted answers to questions regarding the interpretation of the Standards.

We believe we can provide extensive support in assisting ELAP in implementing your program and would like to discuss how we can become a strong partner in more detail. Appended to this letter are two examples of specific activities where TNI could help. We know we are very early in the process but we are work with you to customize an educational program that meets the needs of your state and assist you in other ways to make the implementation phase of this effort soother. Please feel free to contact me if you need additional information or want to visit further about TNI.

Sincerely,

A handwritten signature in cursive script that reads "Jerry Parr".

Jerry Parr
Executive Director

TNI Board of Directors

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TNI Example Proposal for Providing a Quality Manual Template to Small California Laboratories

The TNI Quality Manual Template is a Microsoft Word document designed for laboratories to help prepare a Quality Manual in compliance with the TNI Standard. The prefabricated sections of the Quality Manual follow the ISO 17025 outline, but are completely fluid so that you can put sections, examples, links or references anywhere. The template includes helpful notes, examples and text that can be edited to match each laboratory's particular circumstances. It can be used by a laboratory to create a Quality Manual from scratch or ideas and sections can be used to update a current Quality Manual.

TNI charges its members \$115 for this document and \$230 for non-members. TNI could make this document available to ELAP at a substantial discount to the TNI member rate.. TNI proposes ELAP provide this document for free to "small laboratories." ELAP could define what constitute a small laboratory, but a maximum of 5 individuals seems appropriate.

TNI would also conduct a webinar on how to use the template and make it, and the subsequent webcast free to all those that receive the template.

<p>Note: TNI always has a discounted prices for its services and products to encourage individuals to join TNI.</p>

TNI Example Proposal for Providing Laboratory Accreditation Workshops

TNI has assisted many other state agencies by holding workshops throughout the state when the state was in their implementation phase. The discussion below is just one of many models that could be considered. This option would require a 6-12 month implementation schedule. TNI would propose to have 3-5 basic workshops scheduled geographically apart to minimize driving distance for the attendees. The agenda for these workshops is shown below.

AGENDA FOR BASIC WORKSHOP

DAY ONE

9:00 – 9:15 am	Welcome and Introductions
9:15 – 9:45 am	Overview of the Process and the ELAP Regulation
9:45 – 10:00 am	Break
10:15 – 12:00 pm	Understand the Requirements
12:00 – 1:00 pm	Lunch on your own
1:00 – 3:00 pm	Understand the Requirements
3:00 – 3:30 p.m.	Break
3:30 – 5:00 p.m.	Getting Ready: Information Collection and SOPs

DAY TWO

8:15 – 10:00 am	Getting Ready: Quality Manual Preparation
10:00 – 10:15 am	Break
10:15 – 10:30 pm	The Application Process
10:30 – 12:30 pm	The Assessment

About six months after the initial workshops, TNI would hold 2-3 additional two-day workshops with the topic being Advanced Quality Systems. We have found that laboratories need about 6 months to fully grasp all the requirements, and at about this time, additional questions come into play. The agenda for this advanced class is shown below.

Day One	Day Two
8:30 Role of the QA Manager	8:00 Sample Handling
9:00 Data Integrity Plan	8:30 Reporting Results and Data Review
11:00 Document Control	9:00 Analysis of PT Samples
11:30 Corrective Action	9:30 Initial Test Method Evaluation
1:00 Records	10:30 Quality Control Procedures
1:30 Internal Audit and Management Review	1:00 Frequently Asked Questions
2:30 Analyst Proficiency	2:00 How to Implement the Quality System
3:00 Measurement Traceability	Questions and Answers
3:30 Instrument Calibration	

Pricing for the Workshops

There are two options for how TNI would recover costs. The first option would be for TNI to take on all responsibilities for costs and charge the attendees a registration fee. TNI would be responsible for all costs including facility rental, labor and travel.

Under the second option, ELAP would be responsible for the costs, including labor and travel for the speakers. ELAP could then choose to offer the workshops for free.

Based on previous experience, TNI would like to have 2-4 speakers for each workshop. TNI can count a hundred or more individuals qualified to present the information. Some of these individuals would provide their time for free. Others would not. When we have done these in past, we prepared presentations that could be given by any of our volunteers. We then recruit additional paid speakers to fill in where necessary.