



January 26, 2017

Ms. Christine Sotelo, Chief
Environmental Laboratory Accreditation Program
State Water Resources Control Board
P.O. Box 100
Sacramento, CA 95812-0100

Dear Ms. Sotelo:

On January 23, 2017, The NELAC Institute (TNI) held a panel discussion at the annual Forum on Environmental Accreditation to discuss challenges that small laboratories may have in implementing the TNI standard. Panelists included representatives from a municipal laboratory, consultants with experience assisting laboratories with compliance, and a representative from a commercial laboratory with extensive knowledge of TNI's quality systems requirements. Over 150 people attended and participated in this session, including many from small laboratories. Many of these small laboratories have been accredited to the TNI standard and are willing to share the experience.

The panelists were given a list of topics, many of which were gleaned from the California stakeholders list of Proposed Modifications to TNI Volume 1. The panelists were asked to discuss ways a laboratory could meet the requirement and/or if they thought the requirement presented a major obstacle for small laboratories. Most participants in this session have implemented and maintained accreditation.

We have summarized some of the key comments from that discussion in the attachment.

In addition to the specific issues discussed, a number of general themes and suggestions emerged during the session. These thoughts included:

- We encourage the California program to minimize changes to the TNI standard. The standards as currently written have been shown to be fully achievable for small laboratories and modifications could impact data quality and result in confusion in implementation.
- All panelists in the Small Laboratory session encouraged small laboratories to align current business practices with the TNI requirements. It is not necessary to make the requirements of the standard more complicated than necessary.
- Similarly, we do not believe that it is necessary to delay implementation of any of the requirements. The laboratories should make an initial effort to meet the requirement for

laboratory improvement and compliance. If the assessor determines that improvement is needed, allow the laboratory adequate time to achieve conformance.

- The California program should recognize that training and attitude for the assessors is just as important as for the laboratories. Panelists agreed that the assessment process should be a learning experience and not adversarial.
- The panelists also agreed that the most successful laboratories are the ones who reach out to others for information. The California program should encourage labs to share information and learn from each other.

We hope that this summary will be useful to the California program as an outreach and assistance tool for small laboratories. The resources TNI offers are designed to support the full implementation of the TNI standard as written. Please feel free to contact me if you would like to follow up on any of the ideas presented here.

A handwritten signature in black ink that reads "Jerry Parr". The signature is written in a cursive, flowing style.

Sincerely,
Jerry Parr
Executive Director

cc: Steve Weisberg
Expert Panel

- Jordan Adelson
- Stephen Arms
- Lara Phelps
- David Speis

Small Laboratory Quality Systems Challenges

Issue: The TNI standard is vague and lacks detail on how to accomplish the requirements.

In previous versions of the standards, TNI received criticism that the standard was too prescriptive. The current version of the standard uses language from ISO/IEC 17025 which is purposely less prescriptive. The less prescriptive style allows the laboratory to design their own system in a way that meets their needs. Not every laboratory operates the same way and there may be multiple ways to comply with the standard. Panelists were in agreement that small laboratories will often tend to “over-think” some requirements and make compliance more difficult than it is. One panelist observed that many small labs are often already meeting most of the requirements of the standard, but just do not realize it. Training will be a key component for the laboratories to help them recognize options for meeting the requirements. Training is also a key component for state assessors so that they, too, understand that the laboratories may not all meet the requirements the same way. We are aware that the California program has committed to extensive training for laboratories and assessors. Panelists did not feel that this aspect of the TNI standard presented a major obstacle for small utility laboratories.

Issue: Fear of revocation of accreditation based on findings that have “little to do with data quality”, e.g. documentation that laboratory personnel are free from undue influence, procedures for protecting customer information, documenting purchasing process.....

Panelists observed that requirements like those listed above may appear to have little to do with data quality, but one has to view each of these pieces in the context of the entire program. The TNI mission talks about ensuring that laboratories that produce data of “known and documented quality”. Documentation requirements like those listed above create a historical record that can be used in the future to determine if the data are reliable. These requirements do not make the data better or worse, they make the data defensible. One panelist compared the process to pulling straws out of a haystack. If you start pulling out straws, the whole haystack will eventually fall down. Yes, there is paperwork and many small laboratories are concerned about the resources to keep up with the paperwork. However, as previously noted, training and compliance assistance can provide laboratories with tools to simplify the process.

As far as revocation of accreditation based on failing to meet documentation requirements, panelists noted that in most cases, it takes multiple repeat failures over many years with no attempt by the lab to resolve the issue to bring about a revocation of accreditation. Revocation is usually carried out at the management level and the assessors only provide observations.

Issue: Section 4.1.7 (d) contains the requirement to “have documented training and/or experience in QA/QC procedures and the laboratory’s quality system”. What does this mean? What is expected of the lab?

The panelists agreed that many laboratories fear this requirement because they try to make it too complicated. Most people will have adequate experience and training if they consider conferences, webinars, creating manuals, and on the job training. One panelist suggested that the individual just write down what they have done. Panelists did not agree that this requirement should be delayed until

after CA ELAP provided training. A better option is for assessors to identify any issues surrounding the requirement and allow the laboratory adequate time to comply. One panelist also noted that he has rarely seen an assessor cite a failure to meet this requirement.

Issue: Section 4.1.7.2 (e) Leave of Technical Manager

California stakeholders have noted that the section of the TNI standard dealing with leave of the Technical Manager differs from the current California state regulation. They believe the California regulation is more stringent and should be used instead. Panelists did not agree that the California requirement was more stringent and noted that if carried to the full extent, the regulation could lead to an unqualified person being in the technical manager position for 180 days. Options that panelists had seen for complying with this requirement included subcontracting out the samples during an extended absence or hiring a temporary technical manager. If lack of a degree was the main reason there was no one to back up the technical manager, panelists suggested asking the accreditation body to grant an exception until a replacement could be found or the director returns. There are provisions in the TNI standard for exceptions.

Educational and technical requirements for technical managers have been a concern historically for some small laboratories. Panelists and participants agreed that a degree was not essential in all cases. Panelists agreed that TNI should re-visit this requirement in future revisions of the standard.

Issue: Managing Union Staff

California stakeholders believe that many of the requirements in the TNI standard cannot be implemented where staff analysts belong to a union. They believe this is particularly true where specific training is required and when disciplinary actions are needed. All of the panelists had experience working in laboratories where analysts were a part of a local government union or private sector union. While they agreed that having union staff does create an extra step in the disciplinary process, they did not believe it was an insurmountable obstacle. The key in their experience had been finding a way to harmonize the training requirements and performance expectations in terms of the union contract, and coordinating the human resources office that is already familiar with the union rules. For example, if a union employee was prohibited from signing an attestation that he (she) attended training, have another non-union employee sign for them acknowledging attendance. In most cases, panelists felt that the fear of dealing with union staff was a lack of experience and understanding of the process. In many cases, local governments already have processes in place for dealing with training and performance of union employees. All that needs to be done is to follow those procedures.

Issue: Establishing QC limits

Section 5.9.3 requires laboratories to establish QC limits. California stakeholders have asked why they cannot use the QC limits in the methods, and what is to prevent a lab from setting QC limits so broad they always pass? Also, what is to prevent an auditor from telling a lab their limits are too broad and make the lab use limits that are not realistic? In response to these concerns, panelists noted that the standard requires use of QC limits if they are included in a method. If there are no limits specified in a method, permit or regulation, then the laboratory is expected to develop a reasonable limit based on statistically determined factors and documenting the process used to determine the limits. Whatever QC limits are set, the laboratory will want to make sure they can pass PTs, which should prevent a lab from setting an unreasonably wide limit.

Issue: Section 4.14.5 (c) Internal audits are too much work

Panelists commented that internal audits are a useful and important tool for managers to know when operations are drifting off course. If internal audits are done routinely and correctly, they should result in fewer findings when the lab is assessed. It is essential to follow up with the corrective action process after the audit. Panelists agreed that the external assessment will serve as validation of the internal audit and corrective actions.

Panelists suggested that to minimize workload, the laboratory can do pieces of the audit at various times during the year and not all at once. Once again, the point with this requirement is to be able to prove that the data are of known quality through documentation.