



September 15, 2016

Jeanine Townsend, Clerk to the Board
State Water Resources Control Board
P.O. Box 100, Sacramento, CA 95812-2000

RE: CA ELAP decision to incorporate the TNI 2016 Standards

Dear Ms. Townsend:

I am an experience chemist who works as a consultant and has a great deal of experience working with small laboratories implementing NELAP-compliant quality systems. I am based in Utah and I want to add my support to ELAP's decision to use the TNI 2016 Standards as the basis of their program.

As you may be aware, the State of Utah was approved as a NELAP AB ("Accrediting Authority" at that time) in the first round of approvals when the NELAC process first began recognizing ABs and accrediting laboratories. At that time there was a great deal of push back from the state laboratory association with much angst and many dire predictions, *e.g.*, "It will cost way too much money", "All the small labs will be forced to go out of business", "This is only applicable to the big commercial labs", etc.

Was it different than the previous system? Yes, absolutely. Did all the dire predictions come true? No, absolutely not. And now, years later, virtually all of the laboratories that were in the state before the implementation of NELAC are still there. One exception is a laboratory that closed its doors because they were erroneously told by someone, not associated with the State AB, they would need to hire a full-time QA person. In the ensuing years, other very small laboratories have come on line and been accredited into the program. There has been some attrition, but, curiously, most of the attrition has been due to closing and consolidation of commercial labs, a process that is reflective of the nation as a whole. In spite of the predictions, the small municipal and improvement district laboratories have continued performing their work and are, in the opinion of most of the community, better for the upgrade. Those that loudly predicted the failure of the community have quieted almost completely now that they know what the system really entails. Are there still complaints? Yes, but no one is advocating throwing out the whole system any more.

In my company's work, we have provided Quality Manager services and consulting to a number of small labs, as well as large labs, in Utah and other places throughout the US, including California. In Utah specifically, these include a one-person, four-method wastewater lab, a two-person, one-method drinking water lab (where the two people are county environmental scientists who run the lab part time), and a four-person, 30-method commercial lab. All of these laboratories are now operating in compliance with the TNI standards and are not "overburdened" by the requirements.

The reason that the labs are not overburdened is because the requirements are scalable. The laboratory that had only one method also had only one document. I use the past tense because that lab has recently decided to double their scope to two methods. The quality manual and analytical SOPs are all contained in the same document and address all of the things that the standard requires for this lab, but not a host of additional things.

Fine tuning these types of documents required some training and experience and a bit of fumbling around at the time. However, as a NELAP community, we have taken that experience and channeled it into the aids that, as ELAP points out, are available from TNI. With the support you are offering to your community, I am confident that any lab regardless of size or scope that commits to the Standards will be able to successfully implement them, to the ultimate betterment of the entire California environmental laboratory community.

The ISO-styled self-inspecting quality system is a boon to any lab that implements it thoroughly and I assume that is the primary reason that ELAP was considering a Standard with a quality system. It requires laboratories to actually know what they are doing at all levels and to work to identify and correct their own issues. This is a huge positive difference from the former model of "follow the method and wait for the auditor to tell you when you're wrong".

There are many benefits to using the TNI 2016 Standards over the other options that were considered, including the quality improvement requirements, pathways to adapt methods to specific situations, clarifications of when traceability is required, requirements to understand customer needs, and, perhaps most importantly, ready availability. One of the other benefits to the laboratory community of this more mature standard that has not been discussed much is in consistency of application of those requirements. Under the previous model, the laboratory was held captive to the whim of the auditor. The TNI community helps the laboratory when the auditor is wrong. Just this afternoon, I had a question from a person that stemmed from a non-NELAP auditor "finding" several years ago. The questioner was confused about a current laboratory process because it went against the finding. They assumed the auditor had correctly cited a requirement that isn't a part of any method or system I know. In truth, the auditor was wrong. While this happens from time to time, in the NELAP system there are ways to pursue and right these kinds of errors. A correction process for assessors is glaringly absent from systems without a community-supported consensus Standard.

So, I wish to add my experienced voice to support ELAP's decision to recommend adoption of the TNI 2016 Standards. It is currently the best option for a laboratory accreditation standard and community that this country has to offer. Additionally, I would like to add that it is clear from my experience with small wastewater and drinking water laboratory's across the country, as well as large laboratories, there is no need to remove additional "burdensome" requirements from the Standard as all of the requirements are scalable to the type of laboratory in which they are used. I recommend adoption of the entire standard and joining of the entire CA ELAP community to the greater TNI community.

Thank you for allowing me to weigh in. I would be happy to discuss this further, if it would be helpful.

Sincerely,

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