WILLIAM RAY CONSULTING, LLC

September 16, 2016

Jeanine Townsend, Clerk to the Board
State Water Resources Control Board

To the Members of the State Board

COMMENTS ON THE PROPOSED ADOPTION OF NEW ELAP STANDARDS

William Ray Consulting provides these comments which are based on over 43 years' experience on both sides of the issue. These include over 8 years as a laboratory director of a certified laboratory and over 9 years as a certification officer for the Colorado River Regional Water Quality Control Board, ELAP and the prior drinking water laboratory certification program. I was the State Board's Quality Assurance Program manager for over 18 years and currently sit on 3 committees associated with TNI (1 as a full member, 2 as an associate member).

Comments

ELAP states it intends to adopt The NELAC Institute (TNI) 2016 standard as the standard for the certification of environmental laboratories. In a letter dated September 1st of this year, Christine Sotelo Chief of ELAP to ELTAC members, stated the adoption of the TNI standard would provide the following benefits

- Standards applicable to a broad scope of environmental laboratories
- Readily available educational and training resources from TNI
- Basis for sound enforcement

However these supposed benefits do not take into account the extensive additional work necessary for compliance without demonstrated benefit in data quality, an incomplete data quality system, the differences in type of laboratory used as the model for TNI's standard versus the most common laboratory currently certified by ELAP, the increased costs born directly by the laboratory and through increased fees, and the continued problem of ELAP's inability to conform to the protocols necessary for enforcement actions.

Many of these concerns are not recent or specifically due to ELAP's action. In 2006 the American Water Works Association (AWWA) expressed the same concerns in a letter to

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Benjamin Grumbles, Assistant Administrator for Water at US EPA. The letter states that AWWA did not believe that NELAP standards were beneficial for the vast majority of laboratories providing compliance data under both the Safe Drinking Water Act and the Clean Water Act and provided these points

1. The quality of laboratory testing will not necessarily improve as a result of adopting NELAC standards.
2. "A single standard for all labs" will not meet the needs of all projects/programs.
3. NELAC will increase cost for all labs; NELAP certification can be at least three times more expensive than typical state certification.
4. Small-utility labs may be forced to close due to the added expense of NELAP; these labs are essential to the long-term, robustness of the utility's treatment facilities.
5. Some states have standards in place (e.g., California's ELAP), which are similar to NELAC, consequently any marginal benefit of adopting NELAC is even smaller in these states.
6. State labs are currently certified by EPA; certification by another state agency and reciprocity such as in NELAC can create a conflict of interest.

For your review, a copy of the faxed letter (difficult to read) and the draft letter are included with this submission.

Extensive additional work without demonstrated data quality improvement

The basis for the 2016 standard is the international standard ISO 17025. ISO 17025 is the standard for all types of testing and calibration laboratories. As such it is very broad in its requirements. In order to create relevance and to be more specific in detailing the requirements for environmental testing laboratories TNI added to the ISO 17025 language. The result is the creation of the NELAP standard.

ISO 17025 and NELAP requirements can be summed up as trust nothing, verify everything. NELAP has added the need to document every step in order to demonstrate compliance. For example in both the Quality Systems General Requirements (Module 1, section 5.5.13.1.e)) and the Microbiology Testing module (Module 5, section 1.7.3.7.b).iii) requires the testing and verification of glassware volumes. In Module 1 the testing is only done once, but in Module 5 testing is done quarterly. Both sections would require the testing be documented. However the work requires the creation and

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tracking of correction factors or the discarding of the glassware, does not account for analyst error when making volume measurements, and in several cases does not improve data quality over what it would be if it were not done.

Incomplete data quality system

The standard cannot lead to improved data quality as it is not a complete data quality management system. The standard is merely a bunch of procedures that set up the framework for a data quality management system but it lacks data quality objectives. The standard even allows the reporting of poor quality data as long as the laboratory marks it as such. Since the laboratory can submit poor quality data and the State Agency Partners have not established data quality objectives or exclusion preventing the reporting of poor quality implementing the standard will not improve data quality. EPA has describe in both its Requirements for Quality Management Plans (QA-R2) and Requirements for Quality Assurance Program Plans (QA-R5) that there be a systematic process called the Data Quality Objectives (DQO) process critical to achieving desired data quality and places the development of DQOs as first. To operate without them and assume that some form of procedure is sufficient is unacceptable.

Standard is not applicable to the most common laboratory certified

The 2016 TNI standard is the latest in a line of NELAP standards dating back to 1999. The majority of laboratories participating in the initial drafting of the 1999 standards were participants in EPA's Contract Laboratory Program (CLP) as well as other medium and large commercial laboratories who wished an easier path to interstate commerce. These laboratories brought with them their experiences from CLP work and from the multitude of individual state requirements. CLP and most interstate commerce involved technically advanced work mostly relating to the analysis of samples for metals and organics. These laboratories were self-contained including ancillary functions such as control over hiring/firing and procurement.

When discussing the issue of the relevance of the standard to small laboratories most within the TNI community believes a small lab is 2-4 full-time lab people. They were amazed when presented with the current situation in California where a small laboratory is one that is one part-time person who also operates the treatment plant. Several TNI Accrediting Body states (Virginia, Texas, and Oregon) do not have this problem as they created a separate program for these labs (Virginia) or exempted those

labs from certification (Texas and Oregon). No such effort is being considered in this proposal.

There is no recognition for lab functions not the responsibility of the lab, i.e., employment and procurement. The standards require control over these functions which those in the government sector cannot exercise. As example, Module 1 section 5.2.7 stipulates there be data integrity training which may include ethics training. The standard requires that some form of signed documentation showing an employee's participation and understanding of their obligations. The standard states that the employee should know that violations could lead to immediate termination. In many cases, laboratory work is done by treatment plant operators who work under a union agreement where such work is part of their job description. If a worker refused to sign the required documentation the standard can place the laboratory in the position of not allowing the employee to conduct the analyses otherwise stated in the agreement. The employee's right-to-work is abridged by this standard.

Increased cost

Some make the argument that the purchase of the standard is a burden as compared to the current standard which is available free of charge. However this is not different than other situations where the laboratory must pay for required procedures. Several approved methods mandated by EPA and the State are purchased from consensus setting bodies such as Standard Methods. But in this case laboratories have other sources for approved methods that are free, such as from USEPA.

There is no other source of the standard as it is the sole property of TNI along with the guides and much of the training. The international organization responsible for ISO 17025 is very protective of its copyright and has sought relief when their standard was used without their permission – and appropriate payment. The same can be said for TNI. This means that a single purchaser could not obtain the standard from TNI and reproduce it or could they use any of the guide or template materials to create generic copies of documents.

ELAP has stated that there are readily available educational and training resources from TNI. However this does not account for the costs associated by the laboratory whether born directly or because ELAP adds the cost to the fees. Examination of the TNI website shows several training webcasts on various subjects. The cost for non-members ranges from $35 to $250 per person. TNI training in the standard is usually given at one of the

semi-annual meetings where the costs per person can range from $300 - $400 for the event however the cost of travel to the event (usually held out-of-state) and the potential that the course is in addition to the event costs significantly raise the price. Most available training in the standard given outside of the semi-annual meetings is given by companies outside of California and the cost per event can be in the neighborhood of $8,000.

Cost for the standard is $176 per person although there is a network version priced at $320. Manuals and guides are $250 for the QA manual template, $190 for the Small Lab Handbook, and $10 for SOP templates.

If ELAP were to make these available they would have to pass the cost onto the laboratory in the form of fees.

The standard does not lead to sound enforcement

Although more detailed standards makes it easier to describe the desired action it still does not reduce any of the effort necessary to conduct effective enforcement. Effective enforcement is about knowing the standard and the many ways a laboratory could comply with the standard. ELAP has demonstrated for many years and even up to the present that it does not know how to conduct proper enforcement actions. It has failed to collect sufficient evidence to show violations, cannot describe how an action or inaction was a violation and even cannot relate its current standards to proper actions. It has even taken action without consideration for proper due process.

Sincerely yours,

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