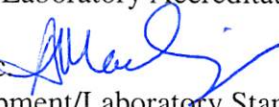




**BABCOCK Laboratories, Inc.**  
*The Standard of Excellence for Over 100 Years*



Date: September 16, 2016  
To: Ms. Felicia Marcus, Chair of the State Water Resources Control Board (SWRCB)  
Members of the SWRCB  
Ms. Christine Sotelo, Chief of Environmental Laboratory Accreditation Program  
From: Allison Mackenzie, Babcock Laboratories, Inc.   
Re: Comment Letter—ELAP Regulations Development/Laboratory Standard

As a member of the commercial environmental laboratory community, a member of the Environmental Laboratory Technical Advisory Committee (ELTAC), and as resident of the great state of California, I support California Environmental Laboratory Accreditation Program (CA ELAP) adoption and implementation of 2016 TNI Standard, Volume 1.

CA ELAP should adopt and implement the 2016 TNI Standard (Volume 1) because there is no defensible argument for modification. There are some common misconceptions about the Standard that may appear to justify modification, but I will outline in this letter why these misconceptions are precisely that and, therefore, why adoption and implementation of the 2016 TNI Standard (Volume 1) is best for CA ELAP, CA accredited laboratories, CA agencies, and CA residents.

Several states, including Florida and New York, have fully adopted and implemented the TNI Standard. As such, all laboratories—regardless of size or type—that seek accreditation within these states are subject to all applicable components of the TNI Standard. Add to this the number of states where the TNI Standard is recognized (over 25 states), the states where TNI has full reciprocity (23 states), and the number of states that are qualified as TNI Assessment Bodies (12 states). These states serve as proven and successful models for California’s laboratory accreditation program.

Opponents of full adoption and implementation of 2016 TNI Standard (Volume 1) voice concern about all laboratories being subject to all applicable components of the Standard because they surmise that the Standard’s requirements will place unmanageable strain on small laboratories and eventually force them to close. However, this has not been the experience of the aforementioned states nor has it been the experience of any of the four small laboratories who presented to ELTAC. All four of these small, 1 to 3 person laboratories have successfully implemented TNI in states such as Texas and Illinois. Further, TNI offers resources to small laboratories, such as boiler plate QA manuals and guidelines.

Full implementation of the 2016 TNI Standard (Volume 1) is best for both CA ELAP and CA accredited laboratories because it is consensus-based and nationally recognized. The TNI Standard has been developed over twenty years with input and comment from hundreds of laboratory and regulatory professionals at the federal, state, and local levels. Countless hours of time have been devoted by experts with proficiency in all areas of environmental testing—from microbiology and chemistry to whole effluent toxicity and radiological testing—to create the TNI Standard. Hundreds of professionals gather twice each year at TNI conferences to discuss, clarify, recommend, and ultimately adopt improvements to the Standard with input having been derived from multiple committees working throughout the year. Collaboration and technical



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knowledge is the power of TNI, resulting in recognition of the TNI Standard as an American National Standard by the American National Standards Institute (ANSI).

Finally, full implementation of the 2016 TNI Standard (Volume 1) is best for CA agencies and CA residents because all laboratory data used for regulatory purposes should be of known and documented quality. The fully vetted and nationally recognized TNI Standard is CA ELAP's best option if the ultimate goal of the program is to help its stakeholders ensure that the data produced by CA ELAP accredited laboratories is of known and documented quality. **Modification to the Standard is incompatible with this goal because size of population served should have no bearing on the quality and reliability of the laboratory or the laboratory's test results.**

In conclusion, adoption and implementation of the 2016 TNI Standard (Volume 1) is best for CA ELAP, CA accredited laboratories, CA agencies, and CA residents. As explained in this letter, there is no defensible argument for modification. While the concerns over implementing the Standard in its entirety are well-meaning and understandable, there is little evidence to support the validity of such concerns. In fact, the majority of evidence available indicates that small laboratories are indeed capable of implementing the full TNI Standard. The 2016 TNI Standard (Volume 1) is consensus-based and nationally recognized, which is a benefit to both CA ELAP and CA accredited laboratories. And perhaps most importantly, full implementation of the 2016 TNI Standard (Volume 1) will allow CA ELAP to meet its goal of helping its stakeholders ensure that the data produced by CA ELAP accredited laboratories is of known and documented quality.