

**SUMMARY OF THE
TNI STATE PRIMACY LABORATORY ACCREDITATION TASK FORCE
MEETING**

AUGUST 2, 2011

The Task Force held a conference call on Tuesday, August 2, 2011, at 2:00 pm EDT.

Chris Armstrong, OK DEQ	Present
Kristin Brown, UT DOH	Present
Art Clark, EPA Region 1	Present
Ken Jackson, TNI (Chair)	Present
Megan Latshaw, APHL	Absent
Martina McGarvey, PA DEP	Present
Michelle Wade, KS DHE	Present
Kathryn Wangsness, AZ DHS	Present
Michael Wichman, State Hygienic lab at UI	Present

1 – Approval of Previous Minutes

Under item 3, 4th sentence “Maine and Iowa” were changed to “Maine and Rhode Island”; and in the fifth sentence “some states” was changed to “Maine and Rhode Island”. The comment on the 5th paragraph of item 3 was deleted and the text was unchanged. Art proposed acceptance of the minutes with these changes, and this was seconded by Michelle. The amended minutes were approved unanimously.

The action items from the previous minutes were considered:

Item 1. TNI cannot be an ILAC signatory because each accreditation body state would have to become an ILAC signatory. Since the TNI quality system standard is fully compliant with ISO 17025, laboratories can claim to be “ISO 17025 compliant”, but not ISO 17025 certified”.

Item 2. Art reported Rhode Island pays \$53 per hour for third party assessors, who are hired as individuals rather than an assessment organization. Some of the assessors are retirees. They are all qualified EPA Certification Officers, as required by EPA for drinking water assessments. Information from Maine was unavailable, since its certification officer has recently resigned. Michelle reported that Kansas uses third party assessors for out-of-state laboratories and the laboratories pay the assessors about \$90 – 120 per hour.

Item 3. Ken had asked the NELAP ABs to estimate the cost of accrediting a state primacy laboratory for its drinking water analytes. Depending on location, New Hampshire estimated \$2500 - \$5000, and New Jersey estimated \$15000 – 20000. Although these were the only states who responded, it is believed other states will be within these high and low limits.

2 - ELAB initiative for EPA to adopt the TNI Quality System standard for its primacy laboratory certification program

Ken shared an e-mail he received from Dave Speis. Along with Michelle and Mike he is a member of the Environmental Laboratory Advisory Board (ELAB), which has performed a detailed comparison of the new TNI quality system standard with the EPA Drinking Water Certification Manual. They found that the TNI standard focuses on a strong (ISO 17025) quality system and does not include analytical prescription while the opposite is true for the Certification Manual. Consequently, ELAB has recommended the Office of Water mandate the TNI standard for all drinking water laboratories and continue to provide technical prescription through its certification manual. It was agreed this would be a tremendous boost to the mission of this task force, but it does not include the TNI proficiency test (PT) requirement. For NELAP accreditation to be favored by primacy laboratories, the PT frequency may have to change.

3 – Discussion document “Thoughts and Questions regarding the Use of Third party Assessors”

Art had previously circulated this document (attachment 1). Since it is highly likely that accreditation of state primacy laboratories will require the use of third party assessors, it was agreed the answers to many of these questions will be required. He put these thoughts together following discussions in multiple meetings. It was stressed that the use of a 3rd party would be to do the assessment and still have the state make the final accreditation determination.

Art will send this document to the NELAP ABs for comment. Kathryn will ask Denise, the current chair of the State Assessor Forum, to send out for feedback the question of third party assessors; i.e “Would you be prepared to accept assessment reports by 3rd party assessors if the state retains the accreditation authority?” The TNI Accreditation Body Task Force report on the use of non-governmental accreditation bodies was briefly discussed, and it was agreed that, for most primacy laboratories, this would probably only be a feasible approach if the state received the 3rd party report and then retained the accreditation authority.

4 – List of Ideas for “developing an acceptable approach for accreditation of primacy laboratories in the TNI system”

This was a summary of the approaches considered to date, and had been circulated by Ken (attachment 2). Limited time permitted only a brief discussion. It was proposed to remove item 2 (at least temporarily), because it is doubtful if any EPA regions will be able to take on this task.

The options considered so far would require 3rd party assessors, and the question was raised if their use would be acceptable to the primacy laboratories. Art said EPA uses contractors to assess radiochemistry laboratories with no problems.

Option 1 may be feasible if 3rd party assessors can be hired at a relatively low cost (as with Rhode Island), and if the PT frequency can be retained at once per year. However, this would still entail a cost compared with EPA certification. Chris pointed out that, regardless of any accreditation fee, it is costly for a laboratory to set up the quality management system required in the TNI standard.

5 – Adjournment

The meeting adjourned at 3:30 pm. Ken will contact members to schedule the next conference call.

LIST OF ACTION ITEMS TO BE COMPLETED

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:
1	6/24/11	Find out if TNI could provide certification to ISO 17025.	Ken	Complete
2	6/24/11	Ask some States how much it costs them to hire 3 rd -party assessors.	Art	Complete
3	6/24/11	Ask NELAP state how much it would cost for primacy laboratory accreditation	Ken	Complete
4	8/2/11	The State Assessor Forum will be requested to ask the states if they would be prepared to accept assessment reports by 3 rd party assessors if the state retains the accreditation authority.	Kathryn	When feasible

ATTACHMENT 1

Thoughts & Questions regarding the Use of Third Party Assessors

Art Clark – 8/2/2011

I've read the AB Task Force Report and the suggestions from Scott Hoatsen and some of the responses to them. I have some thoughts and some questions for TNI, the NELAP AC and the ABs.

When the term "third party assessors/assessments" is used, I believe there are three variations:

1. The use of individual third party assessors to conduct an assessment.
2. The use of assessments performed independently by "non-NELAP" ABs such as DoD, DoE or ABs recognized by other entities (e.g., ABs recognized by ILAC¹).
3. The use of assessments performed by third party assessor organizations under contract to a NELAP AB.

Questions:

1. Would it be easier for a 3PA² to do an assessment in a "non-NELAP state" than in a NELAP state? Why?
2. DoD uses ILAC recognized ABs to assess labs according to the NELAC 2003 Standard. Would it be willing to use NELAP ABs (assuming that state regulations allowed it)?
3. Would DoE, DoD or an ILAC AB allow NELAP ABs to use its assessment reports? If so, under what conditions?
4. Would NELAP ABs allow DoE, DoD or ILAC ABs to use their assessment reports?
5. What are the costs of assessments done by NELAP ABs, DoD, DoE, ILAC ABs and others?
6. Would NELAP ABs and TNI support changes to the TNI Standard allowing the admission of non-state ABs, federal ABs and/or ABs recognized by other entities?
7. Would NELAP ABs and TNI support the use of non-NELAP ABs or non-NELAP assessors as "experts" or "assessors"? Is this practical?
8. In what ways do NELAP ABs use 3PAs? (How many NELAP ABs cannot do this?)
9. Are the scopes of DoE and DoD assessments broad enough to be of use to most NELAP ABs? How would the ABs have to supplement the DoE and DoD assessments in order to meet their needs?
10. Would DoE or DoD accept a NELAP assessor as a team member? Would his/her role be that of a full, equal team member?
11. Would the NELAP ABs accept an MOU between TNI and DoE or DoD?
12. Will DoE and/or DoD transition to the 2009 TNI Standard?
13. Would TNI, NELAP, and/or EPA accept an ILAC assessment if it followed the 2009 TNI Standard?
14. Would TNI serve as a clearing house for non-NELAP assessors to evaluate their training, qualifications and conflicts of interest?

¹ ILAC is used as an example because it has been mentioned in discussions.

² 3PA = Third Party Assessor (an individual, an organization or a government body)

ATTACHMENT 2

State Primacy Lab Accreditation Task Force, July 29, 2011

Ideas for "developing an acceptable approach for accreditation of primacy laboratories in the TNI system"

1. The "Rhode Island model", in which individual 3rd party assessors are used instead of an organization. Perhaps someone from TNI could be the assessor or work with the assessor. They should be required to have completed requisite TNI training and have the necessary experience. State retirees may be interested in doing this and would be a readily available source.
2. Have an EPA Regional Office combine with the States in that region to become an AB; e.g., Region 5 might accredit the Region 7 primacy laboratories. This would involve a voluntary group of ABs, rather than asking all of the NELAP Accreditation Council ABs to do it.
3. Ask the NELAP Accreditation Council to form an AB, using a 3rd party/parties to do all the work. That way, the AB would only have to receive and review the recommendations of the 3rd party Certification Officer. This should require minimal work by the individual NELAP ABs, but would provide accreditation by government bodies with their collective authority. Perhaps the Certification Officer could be a TNI staff member. Perhaps States such as VT, which is not a NELAP AB, but requires its laboratories to be NELAP-accredited, would be prepared to become involved.
4. Amend the TNI standard for primacy laboratories to make accreditation more acceptable; e.g., reduce PT frequency to once a year.