

**Joint Meeting -- Laboratory Accreditation Body & OnSite Assessment Committees
Tuesday August 16, 2011
Bellevue Environmental Measurement Symposium**

Committee members present:

LAB: Sharon Mertens, Lynn Bradley, Rebecca Pierrot, Steve Arms, Art Clark

OSA: Nilda Cox, John Gumper

Lynn Bradley facilitated the meeting. She opened by explaining the reason for a joint meeting, that TNI seeks to join these two committees, and then asked the individuals present at the committee table to introduce themselves and state which committee they belong to.

Merger of LAB and OSA committees

Sharon provided some background about the proposed merger and the process for accomplishing it.

Both committees will need to vote to merge, and the Consensus Standards Development Executive Committee will need to approve the merger. No votes have occurred yet, and there was no quorum for either committee at this meeting. Still, there was a joint teleconference meeting in July, where the concept was discussed, and historically, there were a few joint meetings during development of the 2009 standard.

The AB Assistance Task Force (AB/TF) assigned specific ones of its recommended options to one or the other of these committees – administrative support, third party assessors, and surveillance assessments (this is where the modules are opposite.)

None of the meeting participants (audience) expressed opposition to merging these groups.

Administrative Support and a possible uniform application for labs

The LAB Committee had already requested and received a go-ahead from the Accreditation Council to pursue creation of a single application for labs, before the AB/TF made its recommendation. This goal has long been set and awaited, by the laboratory community.

While a prototype is not yet created, there would be substantial administrative savings to ABs in having an electronic application that is connected to the LAMS database as well as the states having e-applications now.

First steps are to inventory the current applications, for what information is presently collected. The ABs will be involved with this process as well as the application development, and a strong suggestion was made that the AC needs to be consulted to determine which tools is a priority.

Comments were that similarities in existing applications ought to be identified, and the goal should be not to disrupt state AB efforts, so the eventual product will likely not be mandatory. It was noted that from the NELAC standard, the application components

were prescriptive, but many ABs have added things. The Fields of Accreditation will likely be the most variable.

TNI's database administrator, Dan Hickman, suggested employing multiple phases – demographics, then methods/analytes, then other data.

Another commenter suggested coordinating with NEFAP, to see if their materials are helpful.

Other administrative functions were suggested for assistance – PT tracking, assessment tracking (corrective actions), and that the AC ought to be consulted about its priorities. The suggestion was made that a formal requirements document might be created before beginning with the application development. Dan indicated that the PT database is already underway.

Third Party Assessors

Art presented the issue of third party assessors, since he is involved with this issue as the AC liaison to EPA in addition to the LAB committee and the State Primary Lab Accreditation Task Force (SPLATF, staffed/led by Ken Jackson.) Art hopes to find a way that will satisfy the ABs as well as the state certification programs, for both qualifying third party assessors and third party ABs as well as enabling the NELAP state ABs to recognize or at least utilize the assessments of others. (NOTE: each of these issues was a recommended option of the AB/TF.)

Art requested responses to the questions he formulated from initial committee meetings about this topic. Those questions are presented here:

1. Would it be easier for a 3PA¹ 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?

¹ 3PA = Third Party Assessor (an individual, an organization or a government body)

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?

Several state ABs commented on whether/how they utilize third party assessors. One participant noted that the TNI standard defines “consultancy” in a way that may ease restrictions on utilizing third party assessors, but that will not apply to fee-for-service arrangements. Having pre-qualification of third party assessors by TNI might be beneficial, and the “consultancy” issue will need to be addressed when setting up third party arrangements. Also, non-state assessors will have difficulty in obtaining the drinking water certification training.

Dan noted that the AB/TF recommendations are tools for use if desired, not requirements. Still, they may benefit all stakeholders, particularly if TNI can ease the ABs ability to use new tools.

Another commenter suggested that it’s important to ensure, when comparing costs, the comparisons are made with “fully loaded” employee versus contract staff costs. Florida noted that “fully loaded” costs are incorporated into its accreditation fees.

At the end of the session, MN noted that they are establishing a contract for third party assessors and that other ABs can utilize this vehicle as a no-cost way to access third parties.

Surveillance Assessments

Steve Arms presented this issue. He noted that ISO 17011 allows surveillance assessments but that V2M3 of the current TNI standard specifies that reassessments will be 2±½ years, which negates any possible value of surveillance assessments.

Steve asks how should we (eventually) designate when surveillance assessments could be done, and does NELAP even want to use surveillance assessments? Internationally, surveillance assessments might be a check-up on a new AB, or just a partial assessment. Regardless, for them to be used by NELAP/TNI, a revision to the current (2009) standard will have to be accomplished.

A representative of L-A-B stated they use a 3 year cycle, with 2 surveillance assessments (annual). The first surveillance in section 4, management, and the second, section 5, technical. The third year is a full reassessment.

The L-A-B commenter noted his understanding that A2LA does surveillance assessments after the first year for newly accredited labs, but then uses a 2-year assessment cycle without surveillance, and that it’s likely that ACLASS and Perry Johnson do the same as A2LA (but not confirmed.)

John Gumpfer noted that ISO 17011 requires a full assessment every 5 years, and that the issue is whether TNI chooses to relax its current standard to permit surveillance assessments in-between, and also that it was the understanding of the OSA committee that full assessment every two years was a demand from the NELAP program. He suggested consulting documents in the ILAC community about risks of surveillance assessments.

Nilda expressed concerns about sacrificing the NELAP/TNI goal of data quality, in order to use surveillance. Further discussion focused on the fact that, given the 4 items required by ISO 17011 for surveillance assessments, there would only be a 1/3 reduction in time needed, and that it might not be cost effective to use them. Rebecca pointed out that, from the lab's perspective, surveillance assessments help maintain a good relationship with the assessor and the AB. Another commenter noted that the assessor who conducted the full assessment ought to be the one conducting the surveillance.

Then there was discussion about off-site surveillance – an interview, document review, reviewing internal audits of the lab as it monitors itself? And how these techniques can sustain the confidence of the lab community and trust that the lab's quality management system is functioning.

Another point made was whether there should be a financial incentive for “substantially compliant” labs. If this route were chosen, it is important to have objective criteria.

Another point made was that, if some ABs use surveillance and some do not, how does that “flexibility” impact consistency among ABs?