

Summary of the Laboratory Accreditation Body Expert Committee Meeting
Monday, August 5, 2012, at the Forum on Laboratory Accreditation, Washington, DC

Members present in the room:

Aurora Shields
Nilda Cox
Sharon Mertens
Steve Arms
Lynn Bradley

Members present on the phone:

Donna Ringel
Virginia Hunsberger
Jeff Flowers
Judy Quigley
Rebecca Pierrot

In the absence of Joe Aiello, LAB chair, Steve Arms chaired the meeting. The agenda addressed all three of the committee's assignments from the original Accreditation Body Assistance Task Force.

Administrative portions of AB duties – Generic Application

Rebecca Pierrot leads this project. She described both its background and current status to participants. A rough draft of the generic application was presented for comment at conference in Sarasota, mostly demographic data, and that presentation led to asking the individual NELAP ABs what additional information each of them needs to have included. Plans are to create an electronic application that a lab can complete once, and have the information parsed into required format(s) for any of the ABs, with the lab updating information over time as appropriate. ABs will not be required to use this generic application, but it will be designed so that labs can prepare a suitable printed version for those ABs needing a paper application in a particular format with a hand-inscribed signature and submit electronically to those ABs able to accept electronic submission.

Consideration was given to using the Minnesota Electronic Laboratory Data Operations (ELDO) system as the basis for this application but that would be more difficult than necessary and has been abandoned in favor of a standalone database. While the application will not work directly with the Laboratory Accreditation Management System (LAMS), it will use the states' Field of Accreditation (FoA) tables in LAMS as the source for selecting desired scopes for the labs.

A database development plan was begun after Sarasota, but it remains uncompleted due to the more urgent need for TNI's Database Administrator, Dan Hickman, to adapt LAMS method codes so they are usable within the context of this spring's EPA Method Update Rule (MUR.) Once the method code updates for MUR are completed, the development plan can proceed and the prototype offered to the NELAP ABs for review and updating. The database supporting this generic application will be a complex entity, due to the need to accommodate 15 different but overlapping sets of information requirements.

Comments received included the following:

- Consider making it possible to "gray out" unneeded information for ABs where the lab does not intend to apply for secondary accreditation.

- Individual state forms and fees will evolve over time, and the application itself must stay current.
- For an AB requested to grant secondary accreditation, having the scope of accreditation requested by the lab already present on the application will be a great timesaver, since secondary can only be requested for fields already accredited by the primary.
- Dan's existing work with the state AB's IT staff about LAMS data entry will help facilitate setting up the electronic communications needed between the AB and this new application database.
- One commenter demanded that all state applications be consistent. This is unlikely to happen, and is the main reason for needing such a complex database for a "generic" application.

Third Party Assessors

Jeff Flowers leads this activity, and presented the results of efforts thus far. Initially, a listing of individuals available to contract with NELAP ABs to assess laboratories and provide site reports was envisioned, and that concept grew into a full-fledged credentialing system for third party assessors (TPAs,) verifying resumes and categorizing lead assessors, assessors, and technical experts.

The potential criteria for evaluating assessors were determined to be as follows, based on extensive discussions with individuals working as TPAs. This list is re-worked considerably since the Sarasota conference.

- Years experience as an environmental assessor
- Degree(s) held (BA/BS/MS/PhD)
- Years experience in and analytical laboratory (Positions and duration)
- Training courses completed (when and where)
- Assessor training
- Technical Training Courses
- Specialized training and skills
- Refresher and continuing training courses
- Number of quality training presentations made (type and content)
- Membership in trade/professional organizations
- TNI Committee membership
- Authorship of documents related to environmental assessments
- Specialized program knowledge (TNI, NELAP, NQA-1, ISO 9001...)
- Specialized technical knowledge (organic, inorganic, radiochemistry,...)
- Specialized knowledge of software quality principles
- Current involvement with national organizations
- Completed course for NELAP assessors
- Experience conducting assessment for State accrediting bodies
- Contracts maintained and duration
- USEPA training as a certification officer for Drinking water
- Business Organization and number of years in Business
- Number of Qualified Assessors
- Geographic areas covered

- Insurances Maintained and Amounts (liability, errors&omissions, workman's comp, etc)
- Statement of Financial Stability (DB)
- Organizational Compliance with 17025 and 17011 for operation
- Number of NELAP compliant assessments completed

Comments during discussion included the following:

- A requested that TNI undertake to provide continuing education for assessors, with CEU credits, and referred to the Association of Boards of Certification as a resource for potential testing for assessors
- Some of the criteria would apply to individuals while others might apply to companies, so that contract ABs performing only the assessment part of accreditations ought to be differentiated from contract assessors
- Perhaps the model of licensing PT providers within TNI would be useful
- A new standard for assessors (qualifications, training, etc) would be needed since these items (above) are not part of the current standards
- Base criteria plus specific technical requirements for specialty areas would be needed.
OR needs a list of technical specialties available
- Concerns about whether state employee assessors and TPAs would be equivalent were raised, or whether the contract assessors would have to meet qualifications to which state employees could not be held.

The original purpose of this activity was to simplify state AB contracting with TPAs. MN noted that a list of assessors they could use as a mailing list for published requests for proposals would be an acceptable starting point.

Eventually, the suggestion was made and well received by the committee and audience, that TNI ought to begin with a simple list of individuals or ABs that wish to be known as available for TPA work. TNI might or not charge for inclusion in such a list or database, to be available on the TNI website. This straightforward task can be accomplished fairly quickly and will be helpful to ABs. Further steps can be undertaken later, or not, depending on need and resources available.

A request was made to add to the list of criteria that individuals would address in their resumes or listing applications or however it gets accomplished, a question about whether that individual or firm also performs consulting activities, which might help with conflict-of-interest decisions.

The committee agreed to discuss this once again, at its next meeting (August 21) and formulate a recommendation to the TNI Board, that the project be approved to proceed in step-wise fashion, starting with a simple list of TPA candidates that addresses the criteria noted above.

Possibly Changing the Standard to 5 Year Reassessment Cycle with Surveillance Assessments

Lynn presented the current status of the committee's further exploration of possibly changing Volume 2 of the 2009 TNI Standard to permit full reassessments every 5 years (per current Module 1) instead of every 2 years (per current Module 3.) A workgroup comprised of LAB, LASEC and the former OnSite Assessment Committee was chartered by the Board and

previously formed a recommendation against this change, in 2011. Prior to delivery of that recommendation to the original ABTF, strong support FOR the change was expressed from a few others, so that the issue was stalemated.

Next, the Board assigned LAB to consult with stakeholders further, in hopes of reaching a consensus conclusion. As part of this assignment, LAB discussed with the NELAP AC the desirability of changing the standard to 5 year reassessments with surveillance assessments (every 2 years at most) in between. That discussion resulted in the AC's consensus that it would be better not to change the standard due to potential difficulties with travel approvals (only regulatory required travel receives approval in many states) and consistency that might result. This consensus was reached, even as the AC acknowledged that the change would result in substantial resource savings for very large labs (a small proportion of NELAP labs) while increasing resource costs for very small labs (a great proportion of NELAP labs.)

One LAS EC member noted that LAS had proposed a schedule which the first workgroup considered, for surveillance assessments inbetween full reassessments, with criteria for how in-depth those surveillances might be. A way to reward "good labs" while ensuring that not-so-good labs received stronger oversight, this proposal was admittedly subject to charges of favoritism, and could create a scheduling nightmare.

Another commenter noted that actually receiving an assessment is a "reward" to a good lab, because of the training opportunities presented by the assessment. Another noted that "surveillance assessments" need to be much better defined. Another asked if, perhaps, a DoD or DOE audit could substitute for a surveillance visit, but this presents different problems to different state ABs.

An A2LA representative described its assessment schedule, using surveillance, for a newly accredited lab. This commenter also recognized that other non-governmental ABs use different programs/schedules, but that they all recognize one another's accreditations, as ILAC signatories, and do not consider the varying practices to interfere with that recognition.

- Full initial assessment, 2-people, 5-days (year 0)
- 1-person 1-day (year 1)
- 2-people, 4-days (year 2)
- desk audit (year 3)
- 2-people, 4-days (year 4)
- desk audit (year 5)
- 2-people, 4-days (year 6.)

The existing requirement that drinking water labs be assessed at least every 3 years becomes a confounding factor. One commenter suggested that these labs could have a "unique" frequency. The committee clarified that, at least initially, this proposal was designed to help the ABs, not the labs, in modifying the schedule.

The former Chair of the original ABTF asked whether the committee will recommend a change to the standard, or not, and suggested using the drinking water 3-year requirement as a

benchmark (compliance with federal regulation) while defining surveillance assessments so that use of modern electronic tools (videoconference, for example) to clarify what might be acceptable, and formalizing decision criteria about severity of findings for use in determining how exhaustive a surveillance audit should be.

The chair of the AC expressed wonderment that even thought the AC has decided it does not desire to have the current 2-year reassessment cycle changed, the conversation about whether to change continues.

The committee agreed to take this issue up at its next meeting.