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Accreditation Body Task Force Report

July 13, 2011

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Executive Summary

This report presents findings and recommended options for improving the effectiveness of TNI's National Environmental Laboratory Accreditation Program (NELAP). This effort was initiated because of events in 2010 that resulted from changes in the economy and its effect on state government funding. The report was prepared by the AB Task Force formed in June, 2010 at a TNI strategic planning meeting. The report consists of a brief introduction, a summary of the methodology employed by the Task Force, and detailed findings and recommended options. Several appendices provide supporting materials.

The Task Force developed eight specific recommended options which are summarized below, and then discussed in more detail in the Findings and Recommended Options section. For each option, the opinion of the Task Force, in terms of whether this is a short-term solution that could be implemented easily or a more long-term solution (one year or longer to implement) that might require changes to TNI's Bylaws or Standards, is provided. The Task Force has also recommended a priority for each option and a suggested leader for implementation. The Task Force recognizes that no one solution will solve the problems of every AB. Our goal was to develop multiple solutions that we believe can assist ABs.

Note: Recent events triggered by the fall 2010 elections and state economies emphasize how important the work of this Task Force has been and how important the recommended options that follow should be considered.

Option 1: Training

Have TNI develop assessor training, both for technical training and for assessment techniques. This option could be implemented in the short term, but some components may take longer.

Option 2: Administrative Support Services

Develop a number of support services (e.g., tracking proficiency test data) that TNI could provide to ABs to relieve some of their workload. This option is a long-term solution, but some elements could be implemented sooner.

Option 3: National Database

Implement the national database of accredited laboratories to enhance reciprocal accreditations. This option should be fully implemented by August 2011.

Option 4: Third-Party Assessors

Enhance the process by which NELAP-recognized ABs can use third-party assessors, especially to assess laboratories in states that do not participate in NELAP. This option could be implemented in the short term.

Option 5: Use of Assessments from Other Organizations

Use the laboratory assessments performed by the Department of Energy (DoE) or the Department of Defense (DoD) Accreditation Bodies in lieu of assessments performed by the NELAP AB. This option could be implemented in the short term.

Option 6: Sharing of Information and Resources

Develop a system so that NELAP ABs could better share information and resources. This option is a long-term solution, but some elements could be implemented sooner.

Option 7: Surveillance Assessments

Develop a process to allow the use of surveillance assessments to extend the time frame for a reassessment to beyond two years. This option is a long-term solution.

Option 8: Non-Governmental Accreditation Bodies

Develop a process to allow non-governmental ABs (also called third-party ABs) to offer accreditations that would be accepted through reciprocity by the existing NELAP-recognized ABs, especially in states that do not operate a NELAP accreditation program, or where an existing state program may be privatized. A non-governmental AB could include a separate, but closely affiliated organization, as a way to offer accreditations and other services. This option is a long-term solution.

Introduction

In June 2010 the TNI Board met in a strategic planning session. At that time laboratories and ABs expressed concerns over the ability of ABs to continue to comply with all of the requirements of the TNI Standard. Possible problems discussed included timeliness of document review, timeliness of inspections and restrictions that several NELAP states either were already experiencing or anticipated regarding their ability to travel out of state and thus offer accreditation services in non-NELAP states. Economic pressures were being felt by environmental agencies in all NELAP states as well as in the non-NELAP AB community. The Accreditation Body Task Force was commissioned by the TNI Board of Directors to identify means for TNI to assist ABs to eliminate bottlenecks and to deal with financial and personnel strains, while promoting continuation of nationally-recognized full accreditation services to laboratories.

Since the time that the AB Task Force was formed there have been initiatives in a number of agencies that would significantly change the way that state programs function. Proposals have included privatization of all or parts of state programs and limiting the scope of coverage of accreditation programs.

This report summarizes the actions that were taken by the Accreditation Body Task Force to gather information about the nature and scope of budget driven changes to programs and the options that the Task Force developed.

The Task Force determined that ABs are facing financial stress, budget cutbacks, and significant financial scrutiny of operations. The entire nation has been facing the impacts of the current economic downturn. In state government these impacts play out differently from state to state, but there are common elements. States typically have a one or two year budget cycle. Budget cuts may be made within a budget year or may not come into play until the legislature meets. Oftentimes state budgets react more slowly and recover later than the rest of the economy. State government reactions to declining revenues are usually one-size-fits all. Programs like lab accreditation may be fully funded through fees and their revenue may not be as severely impacted as general revenues, but restrictions are implemented throughout all state government programs evenly.

State AB staffs are shrinking, their travel is being restricted and their support functions are being reduced or disappearing. Since state agencies are service providers, the majority of their budget expense is related to personnel. Some states may have mandates to reduce the size of government by reducing the number of state employees. In tough times, the first action is to freeze hiring. When someone leaves a job through retirement or resignation, the position cannot be filled. After that there may reductions in force and/or reductions in pay. Travel expenses are often the target of budget cutbacks, particularly travel that is out of state. Support budgets are also cut to reduce expenditures. Privatization of services traditionally done by government is also under consideration in some areas.

The impact of budget reductions is that some ABs are not able to keep up with obligations such as review of PT data, approval of secondary (reciprocal) accreditations, scope expansions, and even timely renewal assessments and delivery of assessment reports. Review of PT data, approval of secondary accreditations, review of requests to expand scopes of accreditation, timely renewal assessments and delivery of assessment reports are all at risk.

Some ABs are being forced to restrict or eliminate their program's power to grant primary accreditation to laboratories outside their state boundaries. The state of Illinois has been forced to limit primary accreditations to laboratories inside their state boundaries. It is possible that others may have to make similar decisions. But there are also states that are not being impacted in this regard.

Possible impacts of these problems upon laboratories led the TNI Board to charter a task force to investigate what assistance TNI might provide. Any and all of these limitations on state government operations have potential impacts on accredited laboratories. The TNI Board of Directors believed that it would not be prudent to just "wait and see" and this led them to charter the AB Assistance Task Force.

Methodology

The Accreditation Body Task Force membership was chosen to have balanced representation of all stakeholders as described in the TNI Bylaws. It included accreditation bodies, laboratories and others. The Task Force met by conference call, and in person at the Savannah TNI meeting in January 2011.

AB Task Force Members

Name	Organization	Interest Group
Steve Arms* (ex officio)	Florida DOH	Accreditation Body
Susan Boutros*	Environmental Associates	Laboratory
Carol Batterton	TNI	TNI
Lynn Bradley	TNI	TNI
Bob DiRienzo*	ALS Environmental	Laboratory
Judy Duncan,* Chair	Oklahoma DEQ	Accreditation Body
Jack Farrell*	Analytical Excellence	Other
John Gumpper	ChemVal	Other
Judy Morgan*	Environmental Science	Laboratory
Jerry Parr	TNI	TNI
Matt Sica*	Maine CDC	Accreditation Body
Alfredo Sotomayor*	Wisconsin DNR	Accreditation Body
Dave Speis*	Accutest Laboratories	Laboratory

** Member of the TNI Board of Directors*

The AB Task Force took the following actions to learn more about potential problems and explore solutions.

- Conference calls with the NELAP Accreditation Council and the Laboratory Accreditation System Executive Committee (LASEC).
- Consultation with the National Forensic Sciences Technical Center (NFSTC), which has experience providing services to an accreditation community including approval of third-party ABs or and the use of third-party assessors. The Task Force sought input from NFSTC because they provide similar services and could explain how this was done.
- Review of the results of a national survey that Judy Morgan had recently completed regarding proficiency testing.
- The Task Force also solicited information from TNI ABs through two surveys that covered the topics of ability to process out of state primary applications, timeliness of

assessments, timeliness of review of PT data and training needs. Survey questions and summaries of survey results may be found in Appendix A.

- *Draft Findings and Recommendations* were presented to the membership at Savannah and subsequently to the LASEC and the NELAP Accreditation Council. Appendix B includes the presentation from the Savannah meeting with draft findings and recommendations.
- Comments from all of these sources were compiled for review and are included in Appendix C.

Comments from all of these groups were then reviewed by the Task Force and compiled into this Report to the TNI Board of Directors. On July 13, 2011, the TNI Board of Directors voted to accept this report and make it public on the TNI website.

Findings and Recommended Options

1. Training

Findings

Initial responses from Accreditation Bodies regarding training needs indicated that travel restrictions are a major factor in preventing AB's from accessing training for themselves and staff. Increasing web-based training was seen as a necessary step in addressing this concern. Training is needed both in technical areas and in tools to effectively manage an accreditation program. All web-based training should be archived to be used to train new assessors. The specific areas where TNI could assist with technical training included quality control, toxicity, radiochemistry, asbestos, and organics. The specific areas where TNI could assist with training on improving the accreditation program were:

- how to write deficiencies and track corrective actions,
- root cause analysis,
- ethics refresher training,
- professional conduct,
- managing assessments, and
- interview techniques.

Next Steps to Implement This Option

- Develop web-based technical training for assessors in 2011.
- Develop web-based training on how manage an accreditation program.
- Develop more extensive web-based training on Volume 2.
- Explore a partnership with EPA's Office of Drinking Water on wider use of their certification officer training program.

Priority: High

Timeframe: Short

Suggested Lead for Implementation: Ilona Taunton and Technical Assistance Committee

2. Administrative Support Services

Findings

There are numerous administrative activities needed to manage an accreditation program, and some of these could be outsourced to TNI to relieve duplication of efforts. Some specific areas of focus identified were:

- handling of PT data,
- application acceptance and review,
- track corrective actions to assure that they are implemented as required, and
- assessment tracking tools.

Several functions were identified where TNI could provide support at a national level, including:

- accurate information on which ABs are doing out of primary state accreditations, and
- resolution of issues that arise during implementation of the new Standard.

Next Steps to Implement This Option

- Develop a central database for laboratory applications (generic TNI application) to make the process easier.
- Develop and maintain a list of which AB can offer a primary accreditation to laboratories not located within their state.
- Develop tools to assist ABs with tracking PT data.
- Develop tools to assist ABs with tracking corrective actions.

Priority: Medium

Timeframe: Long

Suggested Lead for Implementation: AB Expert Committee and Dan Hickman

3. National Database

Findings

The lack of an operational national database hinders reciprocity and has been identified as a priority by the Accreditation Council. Implementation of the national database is required by Section 4.1.1.e of Volume 2, Module 2 of the TNI Standard and is moving forward with the database scheduled to be operational by August.

Demographic data for all laboratories in all states is expected to be entered by April 1 and the process for adding the fields of accreditation will begin. A QA test plan for the database is under development and a user's manual has been prepared.

When implementation is complete, the AB Task Force will need to determine how the national database improves review of applications for secondary accreditation.

Next Steps to Implement This Option

- Continue the implementation of the database as a high priority for 2011.

Priority: High

Timeframe: Immediate

Suggested Lead for Implementation: Dan Hickman and IT Committee

4. Use of Third-Party Assessors

Findings

Third-party assessors could help facilitate problems with accreditation, especially for assessments of laboratories located in states that are not NELAP-recognized ABs. Third-party assessors are already used by one-third of the states who responded to a recent survey. Third-party assessors are most often used for radiochemistry in the drinking water program and states often rely upon EPA's contract for this service. Use of third-party assessors will not work in all states because of issues including union labor and laws about use of third-party contractors to replace state employees. Simplification of the contract process for third-party assessors would help some states. Qualification or credentialing of third-party assessors would assist on many levels and should include development of minimum qualifications, verification of training and annual performance reviews.

Next Steps to Implement This Option

- Develop a process for TNI to qualify third-party assessors.
- Develop a model solicitation template for states to use in contracting.
- Develop a process for performance review of third-party assessors that TNI qualifies.
- Develop a service for a state to contract with TNI to obtain the use of third-party assessors.

Priority: Medium-High

Timeframe: Long

Suggested Lead for Implementation: Onsite Expert Committee

5. Use of Assessments Performed by Other Accreditation Bodies

Findings

The Department of Energy (DoE) assesses laboratories to the NELAC Standard plus supplemental requirements. The Department of Defense (DoD) manages an accreditation standard that uses ILAC-recognized Accreditation Bodies that assess labs to the NELAC Standard plus supplemental requirements.

The assessment reports from DoE and the DoD ABs could be used as a way to facilitate accreditation, especially for those laboratories located in states that are not NELAP-recognized ABs. To preserve integrity of assessment reports, it would be best if they were obtained directly from the DoE or the DoD AB with the permission of the laboratory, rather than indirectly from the laboratory. This option would not require any additional cost to the laboratory for the assessment unless additional parameters were needed for the NELAP accreditation. The state would still retain the authority to grant accreditation.

Next Steps to Implement This Option

- Explore the feasibility of partnering with DoE and the DoD-approved ABs to use their assessment reports.

Priority: High

Timeframe: Short

Suggested Lead for Implementation: NELAP Accreditation Council

6. Sharing of Information and Resources

Findings

Some ABs have developed effective systems for performing routine activities required to operate and manage an accreditation program. TNI hosts an Assessment Forum and Mentor Session at each of its semiannual meeting where ideas on specific topics are shared. APHL facilitates a laboratory assessor conference call where issues are discussed in the broader community of assessors. Some laboratories have multiple primary accreditations due to the scope of their services which results in multiple assessments from different ABs.

Next Steps to Implement This Option

- Explore the use of sharing assessors, or assessment reports, between states as a way to reduce the number of assessments for a given laboratory.
- Develop a process for sharing example form letters for AB assessments and related activities.
- Use TNI's Assessment Forum and Mentor Sessions as springboards for developing ways to share best practices among ABs.
- Work with APHL to improve the sharing of information among the state assessor group by establishing a Discussion Board comparable to the Discussion Board for the Small Laboratory Advocacy Group.

Priority: Medium

Timeframe: Short term

Suggested Lead for Implementation: LASEC

7. Surveillance Assessments

Findings

ISO 17011 allows for surveillance assessments, defined as a *set of activities, except reassessment, to monitor the continued fulfillment by accredited* [laboratories] *of requirements for accreditation.* This term is defined in the TNI Standard, but cannot be used to extend the frequency of a full reassessment due to the requirement in Volume 2, Module 3 for a full reassessment to be performed every two years. Surveillance assessments could assist ABs in managing their program as fewer reassessments would need to be performed on a two year cycle. This approach could also lead to a reduction in the cost of the program which could be passed on to the laboratories.

Some commenters supported the concept of revising the Standard to allow for surveillance assessments while others were opposed. Commenters believe there should be a formal and objective risk-based process and consistent criteria for implementing such a system.

Next Steps to Implement This Option

- Form a task force to investigate how surveillance assessments could be implemented in a formal and objective process with consistent criteria.
- Develop a model on how surveillance assessments could be used to extend the frequency of a full reassessment for more than two years.
- Use the results from this effort to develop a recommendation on changing Volume 2.

Priority: Medium

Timeframe: Long term

Suggested Lead for Implementation: Task Force with representatives from Accreditation Body Committee, Onsite Committee and LASEC

8. Non-Governmental Accreditation Bodies

Findings

Several initiatives are underway in state governments to "privatize" the state-run accreditation program and thus some alternate solution may be needed. A number of non-governmental organizations operate accreditation programs, and many of these are recognized by the International Laboratory Accreditation Cooperation (ILAC) as operating a program under ISO/IEC 17011. These ILAC ABs would likely be capable of administering a NELAP accreditation program. Such an approach would need to be developed in cooperation with the EPA Office of Drinking Water to assure compliance with 40 CFR Part 142. The state might establish an approval or recognition function and possibly allow all other actions to be done by the non-governmental accreditation body.

In initial discussions on this approach, there was a mixed response to the idea from the NELAP Accreditation Council, since to date, environmental laboratory accreditation has been considered an "inherently governmental function." State ABs were also concerned that the assessors used by these organizations are not NELAP-qualified assessors and this would introduce another element of inconsistency. Some states indicated a legislative change might be needed for them to accept an accreditation from a non-governmental AB.

However, recent developments caused the Task Force to re-consider this option and conduct a follow-up meeting with the NELAP AC. It was determined that Oregon was the only AB that would require a statutory change to recognize a non-governmental AB. A number of states would need to make a regulatory change. Philosophical issues with third-party ABs were brought up by the AC, but this Task Force believes most, if not all, of these are based on misunderstandings. A complete summary of the discussion with the NELAP AC is included as Appendix D.

There do not appear to be any serious show stoppers on use of non-governmental ABs, however, there seems to some fear that needs to be alleviated. The position of the EPA DW program (Greg Carroll) appears to be that as long as the state makes the final decision, all other parts of the certification process can be accomplished by a non-governmental party. We should survey non-NELAP states to see how using third-party ABs would impact their decision to participate in NELAP. Overall, the use of third parties appears to be more feasible than first envisioned and we need to explore this option more. States will, however, need to maintain control of decision-making in the DW program. It may be possible for TNI to approve third-parties for labs that just need a

NELAP accreditation, especially in states that are have not implemented a program. We should start small (pilot) and see how it works.

Some states might be better able to accept an accreditation from a non-governmental AB if the state had some control over the organization. This discussion led the Task Force to consider the concept of a closely affiliated organization. The Task Force sought input from NFSTC on the concept of creating a separate, but closely affiliated organization, as a way to offer accreditations and other services. This approach was used by NSFTC when the closely affiliated organization Forensic Quality Services was formed. This approach also appears feasible, if the broader solution to allow the use of non-governmental ABs is not workable, so long as separation from TNI's regular activities, such as approval of accreditation bodies, is incorporated.

Next Steps to Implement This Option

- Ensure any non-governmental ABs have the ability to operate a NELAP accreditation program according to TNI expectations, including activities such as participating in AB evaluations, payment of appropriate fees, and adhering to the requirements in Volume 2 of the TNI Standard.
- Determine if the TNI Standard (Volume 2) and Bylaws need to be clarified or revised to allow for non-governmental ABs to offer accreditations to laboratories.
- Determine if any changes are needed to the existing process by which TNI recognizes NELAP-ABs in order to recognize non-governmental ABs. Make sure this process does not duplicate efforts in the NEFAP recognition process for those organizations that offer accreditations in both programs.
- Develop a process by which a state agency can recognize a non-governmental AB to accredit labs in their state. A non-governmental AB could include an AB closely affiliated with TNI.
- Explore the feasibility of a process that would allow a NELAP AB to accept the accreditation of a laboratory that is accredited by another state-recognized non-governmental AB.
- Promote this approach to state programs that are experiencing pressure to change or privatize their accreditation program.
- Initiate a dialogue with the Office of Water to discuss this option relative to the drinking water certification program.
- If non-governmental Accreditation Bodies are not feasible, consider the establishment of a closely-affiliated AB.

- Develop a pilot program for forming such an organization and seek legal counsel on the organizational relationship of this organization to TNI.

Priority: High

Timeframe: Long term

Suggested lead for Implementation: AB Task Force

Appendix A
Surveys of Accreditation Bodies

Survey 1: AB's Current Status with Regard to Out of State Labs (OOS) Primary Applications

Survey 1 – Questions

Out of State Application Status

- Does the state accept primary accreditation applications from out of state labs and, if so, are there any restrictions?

Timeliness of Renewals

- Is the state processing renewals, including assessments, within the 2 year timeframe of the Standard?

Timeliness of New Application Processing

- How long does it take to process a new OOS application for primacy?
- Will the state accept an assessment from a former primary state and are there any limitations or conditions?

FOA's Offered Matrix/Technology

- Summary of the scope of the state's laboratory accreditation program.

Anticipated Problems

- What problems (travel restrictions, staffing, timeliness of completion of work, etc.) does the AB currently face?
- Does the AB have contingency plans for changing the lab accreditation program if budgetary restrictions continue?

Survey 1: Summary of Responses

State	Out of State Application Status	Timeliness of Renewals	Timeliness of New App Processing	FoA's Offered Matrix/Technology for details, see http://www.nelac-institute.org/accred-bodies.php	Anticipated Problems
PA	Accepting OOS apps. Not turning anyone away.	PA requires annual renewal application. Laboratories are required to submit renewal applications 60 days prior to the expiration of the current accreditation certificate. These are processed as outlined in our regulations and SOPs and are processed in a timely fashion.	Applications are processed as received. A laboratory must submit to a pre-assessment prior to scheduling an on-site assessment in order to avoid output of resources when a laboratory has not put forth the appropriate effort to be in compliance prior to the on-site assessment. When the laboratory demonstrates that it has a NELAP "quality system" on paper, an on-site assessment is scheduled.	Drinking Water Non-Potable Water Solids and Chemical	PA recently hired two new assessors and will be training these individuals over the course of the next year. This should greatly improve our ability to adhere to the regulatory requirements. If PA begins to see a significant increase in OOS applications and we foresee this could negatively impact our ability to serve the currently accredited labs, we will re-evaluate applicants
NJ	Accepting OOS & out of country apps.	Renewals are offered each year for the Jul 1 to Jun 30 accreditation year. Renewals received prior to expiration of current certificates are issued by the Jul 1 start of the new accreditation year. (Note: For nearly 100% of NELAP labs, currently meeting the Standard to have an on-site assessment as part of renewal process)	Applications for Secondary Accreditation are processed within 10 days of receipt. Applications for Primary Accreditation, when the lab is ready and qualified to be accredited, take from 2 to 5 months depending on the volume of accreditations requested. Administrative reviews are completed within 10 days with the remainder of the time given to pre-on-site assessment reviews, on-site assessment and report preparation. Additional time past 5 months may be needed depending on the quality of the lab's Corrective Action Plan.	Drinking Water Non-Potable Water Solids and Chemical Air	Based on current known conditions, no problems anticipated. When and if conditions change based on issues such as budget restraints, resource availability, volume of labs, policy switches, etc, problems will be identified.

State	Out of State Application Status	Timeliness of Renewals	Timeliness of New App Processing	FoA's Offered Matrix/Technology for details, see http://www.nelac-institute.org/accred-bodies.php	Anticipated Problems
TX	Case by case depending on location.	Renewals are completed in timely fashion. Work on renewals begins well before a certificate expires.	1. Initial administrative review happens quickly, if a complete package is submitted. If a package is incomplete, the package does not move forward until it is complete. 2. Technical review depends on the availability of assessors to review packages. After initial technical review, the pace of processing depends on the timeliness of the laboratory to respond to deficiencies identified.	Drinking Water Non-Potable Water Solids and Chemical Air Tissue	1. Adequate staffing to perform all phases of the accreditation process in a timely manner, including reviewing applications, reviewing PT results, performing assessments, reviewing reports, etc. 2. Permission to perform out-of-state assessments
LADEQ	Discouraging OOS apps, especially if 1st time app & not working on LA samples.	Running approximately 3 months behind on biennial assessments; running 1 month behind on issuing assessment reports; running 1 month behind on issuing corrective action plan responses	Running approximately 4 months behind on new application processing; running 3 months behind on making accreditation decision	Non-Potable Water Solids and Chemical Air Tissue for additional details see http://www.deq.louisiana.gov/portal/LinkClick.aspx?fileticket=ONpoRG4PiLM%3d&tabid=2925	Lack of funding to pay Accreditation Body invoice in full and delays in development of in-house database for drafting certificates and scopes of accreditation and reviewing proficiency test results Note: Below is the table for LDEQ. I understood "renewals" to refer to the biennial assessment and associated activities, so I included LDEQ's turnaround status for each of those activities. I didn't include the time to re-issue the certificates and scopes because LDEQ is implementing a new database and what normally took two weeks is taking four months. Anything the Task Force can do to help will be greatly appreciated.
LADHH	No restrictions of OSS apps.	Within 30 days of receiving application. Most within 14 days if all required documentation available	On-site within 30days of completion of application process including required PTs, staff qualification etc. for in-state labs. Out of State labs within 60 days.	Drinking Water	RFP issued for seafood testing. May need more labs.

State	Out of State Application Status	Timeliness of Renewals	Timeliness of New App Processing	FoA's Offered Matrix/Technology for details, see http://www.nelac-institute.org/accred-bodies.php	Anticipated Problems
			Note: This timeframe is dependent on getting travel approvals from superiors which can cause a delay.		
FL	Discouraging new OOS apps. Seriously considering formally restricting OOS app to SE region of US (EPA Region IV). Currently this is unwritten policy.	No problem with labs for which we are primary; some problems when we are secondary and primary is delayed (e.g., LADEQ this year	In-house processing completed in 2 weeks or less. Full processing includes assessment. About 80% are completed in 120 days or less, but this is slipping due to assessor shortages. Delays in processing secondary applications are almost always due to slowness to receive the lab's scope from the primary AB.	Drinking Water Non-Potable Water Solids and Chemical Air Tissue	1) Unless alleviated by the policy to only primary-accredit labs in Region IV, the interval between biennial assessments will grow. 2) Technical discipline assessor training may be needed. 3) Tracking PTs to analysis date will tax current staff
KS	No problem with OOS because use third- party assessors. KS doesn't get many OOS and can do more.	Currently are process renewals, including on site assessments in the required time frame	Currently are processing new applications on time. Only a few new applications have been received	Drinking Water Non-Potable Water Solids and Chemical	One of our assessors has moved to another job, leaving just one assessor available, and they will be out for some time in starting in November for family leave. We could be behind soon, as it will take awhile to hire and train a new assessor. Also, our database is not working well, and will be difficult to link to the national database. Our field laboratory program is expanding, and that is taking time away from the TNI certifications, which may be a future issue for the program, especially in light that the future governor is talking about freezing or reducing government.
NH	Will take OOS if can accommodate workload, have the necessary FOA and meet the 2 year on-site schedule	I have a schedule I try to keep (send, return, process and renew). The goal is to turn them around at the date of renewal. Some factors	I try to turn these around pretty quickly: a priority. Mostly this depends on the lab. I'm still waiting for a new lab to send me	Drinking Water Non-Potable Water Solids and Chemical	None as long as we have the current staff (2) and we stay healthy.

State	Out of State Application Status	Timeliness of Renewals	Timeliness of New App Processing	FoA's Offered Matrix/Technology for details, see http://www.nelac-institute.org/accred-bodies.php	Anticipated Problems
		affect this process. Some may even be the lab sending in the renewal application late.	all the requested documents. It has been 2 months and counting.	Rewriting rules. Will request the addition of Tissue and Air.	
CA	Will accept OOS. Have not turned down OOS. Only turned down some out of country applications.	Although there have been some delays in the past, we endeavor to meet the time lines and complete them on time	If the laboratory sends in all the needed documents on time, scheduling of onsite takes about 2 months and the rest will be done within the time lines required by NELAP – total time will be about 6 months.	Drinking Water Non-Potable Water Solids and Chemical	Some out of state travel restrictions due budgetary constraints, training new staff. If the number of out of state Primaries increase, there will be a need for additional staff/assessors.
OR	Accepting OOS applications.	Behind on renewals but having internal issues		Drinking Water Non-Potable Water Solids and Chemical Air Tissue	
VA	Yes, Restrictions: Prior to January 1, 2012, will process OOS applications ONLY for labs expressing a current practice of producing data being reported to VA's DEQ for compliance purposes; after January 1, 2012, requests from OOS labs will be accepted for labs expressing a current practice or future desire of producing data to be reported to VA's DEQ for compliance purposes. (If there is no intention to do work in VA then we have no regulatory authority to go OOS.)	Yes	60-90 days for initial application review and response (for accepted OOS applications)	Drinking Water Non-Potable Water Solids and Chemical Air Tissue	Staff restrictions will cause us to screen new OOS primary applications carefully to assure OOS applicants have a regulatory need for VA accreditation. VA will honor secondary applications if secondary has intentions to do business in VA. Contingency: Modify VA Code to increase fee structure to support additional staff and/ or cover added costs associated with OOS.

State	Out of State Application Status	Timeliness of Renewals	Timeliness of New App Processing	FoA's Offered Matrix/Technology for details, see http://www.nelac-institute.org/accred-bodies.php	Anticipated Problems
UT	Have not refused any OOS labs but may do so if staffing becomes a problem.	Yes	We process an OOS application within 30 days of receipt of the completed package. The entire process [on site, reports and corrective action review, etc.] will usually take 3 to 4 months. Secondary recognition is done from the primary's certificate. Any method listed is recognized. Prep methods will be added with a letter from the primary indicating the method was reviewed.	Drinking Water Non-Potable Water Solids and Chemical Air	Our program staff numbers were radically reduced. We will not have capacity to take on a large number [more than 10 to 15] of OOS labs as Primary AB and keep to the time lines.
NY	Still taking OOS as well as out of country apps.	Annual (New and accurate certs issued on April 1 of each year, provided lab submitted a complete application in time.)	9 months, 3 months internally, provided a complete application is submitted	Drinking Water Non-Potable Water Solids and Chemical Air	Routine assessments conducted beyond 24-month frequency. Currently, ELAP has a 70% completion rate between 08/09 and 07/10. Retirement of majority of the current assessors is expected within 5 years.
IL	**Only** renewal apps for primary OOS labs that had an on-site in 2010 **and** for which their cert expired in 2010 were renewed for one more year. Otherwise due to staffing and resource limitations, no longer accepting new primary OOS apps or apps from primary OOS labs for which current IL cert expires in 2011. **All** OOS IL primary accredited labs will have to find new state AB when IL certificate expires in 2011. Still accepting secondary OOS apps.	All renewal applications are being processed in a timely fashion as required by the NELAC Standard. See Anticipated Problems and attached e-mail regarding 2 year on-site assessment schedule.	With moratorium publically announced on accepting OOS apps no longer getting any new primary OOS apps. We were getting some prior to announcing our moratorium. Very few if any apps from new in-state labs. All such apps would be processed in timely fashion. May be a delay in performing on-site assessment for any new lab.	Drinking Water Non-Potable Water Solids and Chemical	Backlog of on-site assessment due to retirement of 1 of 2 assessors. Not able to fill vacancy. Restrictions on use of third-party (contact) assessors. Not presently receiving approval for: out of state travel for the few remaining OOS on-site assessments scheduled/due in 2010, attending TNI conferences, and to attend out of state basic assessor training course. Due to both state travel and/or financial situation/restrictions. If training of additional assessor (present staff member) goes as planned (4 supervised in-state on-site assessments by end of 2010 and attend basic assessor training course hopefully in Chicago, IL during April 2011) then backlog of on-site

State	Out of State Application Status	Timeliness of Renewals	Timeliness of New App Processing	FoA's Offered Matrix/Technology for details, see http://www.nelac-institute.org/accred-bodies.php	Anticipated Problems
					assessments should be addressed in early 2012. During this time no on-site assessments would be over 2-3 months past due. Continued uncertainty of state's financial situation and out of state travel and training restrictions. Need assistance with costs for any out of state travel, required training and attending TNI conferences. Please note we are still processing in-state renewal application, issuing of certificates and PTs studies in a timely fashion.
MN	Will accept all OOS applications. No restrictions.	Renewals are completed in timely fashion	60 days as required by state laws and rules. Actual timeline is closer to 30 days from receipt to approval. Online system requires completeness before lab can actually submit the application.	Drinking Water Non-Potable Water Solids and Chemical Air	

Survey 2: Follow Up Questions Regarding Timeliness of Assessments, PT Data Review and Training

1. Timeliness of Laboratory Assessments: Assessments Intervals

	Total # labs	# Labs assessed every 2 years	# Labs assessed at 2 – 2 ½ year interval	# Labs assessed at 2 ½ – 3 year interval	# Labs assessed at 3 year interval
IN-STATE LABS					
MN	120	100%			
CA	28	21	4	2	1
VA	30	30			
LADHH	5	2			3(State cert only)
NJ	815 (NELAP?)	224	284	207	100
PA	28*	1	8	16	0
FL	282	25	155	102	
TX	168 (82)**	49	29	3	1
KS	61	34			27
LADEQ	18	4	14	0	0
UT	50	100%			
OR ***	34 (68 assessments)	47% (32)	29% (20)	18% (12)	6% (4)
OUT OF STATE LABS					
MN	20	100%			
CA	9	5	4		
VA	7	7			
LADHH	29	2			
NJ	135	34	40	33	28
PA	8*	0	0	4	0
FL	165(111)	10	61	40	
TX	7 (0)	N/A	N/A	N/A	N/A
KS	37	7 by third-party assessors			
LADEQ	24	3	14	3	4
UT	12	100%			
OR ***	18 (30 assessments)	23% (7)	37% (11)	37% (11)	3% (1)

**3 In-State and 4 Out of State Labs were initial NELAP labs; they have not had their second assessment yet.*

*** Due to the age of the program, only about half of all laboratories have been scheduled for one or more follow up assessments. Numbers reflect those labs (in parenthesis), not the totality. That is, 82 = 49 +29 +3 +1.*

**** The above information is based on the last 2-3 assessment cycles depending on when the laboratory entered the program. It is also includes assessments that are due and have not yet been performed. This information is for the physical on-site assessment only.*

2. PT Review and Processing

	As received by provider	Within 1 month of receipt	Within 1-3 months of receipt	Within 3-6 months of receipt	More than 6 months from receipt
TIMELINESS OF PT DATA REVIEW AND PROCESSING					
MN	100%				
CA	< 1%	> 95%	< 5%	0 %	0%
VA	85%	*100%			
LADHH	100%				
NJ	80%	2%	5%	3%	10%
PA	A few	Most	A few	0	0
FL	43%	9%	30%	8%	10%
TX	40%	15%	20%	20%	5%
KS	No response				
LADEQ	2	4	8	17	69
UT	100%				
OR ***	?	?	?	?	>50%

** All data is reviewed immediately upon receipt for failed PTs. Acceptable PTs may be delayed for data entry if assessor is traveling.*

*** Due to the number of laboratories and the peculiarities of Texas due process requirements, PTs are not normally evaluated as they come in, but starting four+ months from each lab's renewal date.*

**** Difficult to tell since PTs are evaluated at the time of their annual renewal or when a lab requests a change in the scope of their accreditation. Some will be timely most will not. The information is contained in individual folders and it is non-value added at this time to go and inspect each one.*

3. Do you use third-party assessors?

State	Response
MN	Beginning 2011, we will use third-party assessors for conducting most assessments of laboratories located outside the state of Minnesota.
CA	No
VA	No
LADHH	No
NJ	No
PA	No
FL	No
TX	Yes
KS	Yes, for our out of state Primary certifications.
LADEQ	Yes, beginning Jan. 2011
UT	No
OR	Yes – For Radchem only

4. Do you foresee problems meeting internal training requirements for assessors as specified in the 2009 TNI Standard?

State	Response
MN	No. The requirements are generally the same as past requirements for assessors. We will comply with the requirements as stated in the TNI Standard but will not fully implement the accompanying, published TNI guidance.
CA	Some. Recruitment and retention of new staff who are trained may be a problem
VA	Yes
LADHH	Possibly given the budget constraints of the State
NJ	No
PA	No
FL	Cost, availability, and uncertainty as to what the new technical training requirements are, how they can be met, and whether they must be met prior to July 1, 2011.
TX	Yes, given the onrushing implementation date of TNI Standard and the limited availability and unavailability of certain training courses. See Item #6, below. It is likely contract assessors may have similar problems regarding documented training.
KS	We may, as we will have a new assessor to hire this year, and we do not have in house training for all the testing as of yet.
LADEQ	If current assessors are not grandfathered in, I foresee some problems
UT	No
OR	That will depend on the interpretation of SIR, but we are still evaluating.

5. What is your plan for meeting this requirement?

State	Response
MN	We require attendance at the USEPA Certification Officer's training course. We have specialized training for all technologies not covered under the USEPA's current training. New assessors conduct at least one co-assessment with each trained assessor employed by MDH. In our case, this means that our newest assessor performed four supervised assessments prior to leading an assessment. Assessors also lead at least one assessment under supervision of a trained assessor before performing a solo assessment.
CA	May need to make arrangements with TNI to recommend faculty for providing some training
VA	Using a combination of EPA CO's courses, Online Courses, and Internal resources.
LADHH	To send assessors to training courses.
NJ	Either through attending non-state training courses or through in-house training.
PA	PA has and will continue to develop its own assessor training programs.
FL	We have conducted assessor basic and technical training internally in the past and also have sent assessors to commercially provided training courses. We will continue to use both means as necessary and feasible.
TX	Provide training as currently available.
KS	We are planning on developing some training and seeing if we can use training developed by the other NELAP states.
LADEQ	Identify in-house Department staff to provide the training.
UT	We will continue as before with the basic training and experience as a foundation. Specific training is often done as it is available. We would like to see more offerings during the TNI meetings and online.
OR	Our Section Managers are technically competent to perform the technical training internally but will have to evaluate whether they themselves have documented training in all technologies as they are assessors too (we are likely OK of we can stick to disciplines).

6. In what areas can TNI help you meet these requirements? (X means a state indicated need)

Area	Response
Asbestos	XXXXXX
Chemistry	
Inorganics	XXXX
Non-metals	XXXX
Metals	XXXX
Organics	XXXXX
Micro	XXXX
Radiochem	XXXXXXX
Toxicity	XXXXXXXXX

7. Other Comments

State	Comment
CA	As we transition from the NELAC Standards to the TNI Standards in 2011, there are bound to be many challenges and problems. During that period there will be issues both from the laboratories and the AB's which may require immediate resolution.
VA	We have met the immediate training requirements for current staff but training future staff members without resources being made available by TNI to meet these TNI requirements may be very difficult. It is very hard to get approval for new staff members --- even harder when the up-front training expense is so excessive. DCLS believes that ALL required training, including the Basic Assessor course, should be available via internet at reasonable costs. This would facilitate hiring and training new staff as well as refresher courses for existing staff. It would also facilitate more consistency among the ABs for the training content. Currently, based on the rare availability of the EPA and Basic Assessor course, it's reasonable that an AB would have a new hire in the office and unable to perform the duties of his job for 9 or 10 months or up to a year before the required training 'becomes available'. This is unacceptable with the budget limitations that all ABs are facing.
LADHH	State budget concerns can affect plans for the accreditation program.
PA	Out of State travel to training courses is strictly prohibited if being paid by our own funds. In-State travel is only slightly looser. Web-based training would be preferable. I believe a requirement for full-blown assessments every 2 years is too frequent. TNI should re-visit the surveillance assessment option to extend the full on-site assessment to 5 years as allowed by ISO.
TX	Training for two of nine current assessors for metals and organics based on EPA drinking water certification course for chemistry (Cincinnati, OH) rather than NELAC-oriented training course. One assessor not trained for inorganics, non-metals, metals, and organics (i.e., currently only trained for microbiology).
LADEQ	At the time of the submission of this questionnaire, LDEQ has not committed to paying the $6 K accreditation body invoice, so the cost to the Department of any assistance will be a major consideration.

Appendix B
Accreditation Body Task Force:
Findings and Draft Recommendations

Judy Duncan, Chair

This is a conversion of a PowerPoint presentation given in January, 2011 in Savannah, Georgia. The presentation can be downloaded at: http://www.nelac-institute.org/meeting-presentations.php.

Mission

To identify means for TNI to assist ABs to eliminate bottlenecks and to deal with financial and personnel strains while promoting continuation of nationally recognized full accreditation services to laboratories.

Members

Steve Arms (ex officio)	NELAP AB
Susan Boutros	Small lab
Lynn Bradley	Other
Bob DiRienzo	Lab
Judy Duncan, Chair	State non-NELAP AB
Jack Farrell	Other
John Gumpper	Other
Judy Morgan	Lab
Matt Sica	State non-NELAP AB
Alfredo Sotomayor	State non-NELAP AB
Dave Speis	Lab
Carol Batterton	TNI staff support
Jerry Parr	TNI staff support

Preliminary Observations

- ABs are facing financial stress, budget cutbacks, and significant financial scrutiny of operations.
- State AB staffs are shrinking, their travel is being restricted, and their support functions being reduced or disappearing.

- Some ABs are not able to keep up with obligations such as review of PT data, approval of secondary (reciprocal) accreditations, scope expansions, and even timely renewal assessments and delivery of assessment reports.
- Some ABs are being forced to restrict or eliminate their program's power to grant primary accreditation to laboratories outside their state boundaries.
- Possible impacts of these problems upon laboratories led the TNI Board to charter a task force to investigate what assistance TNI might provide.

Task Force Activities

- Conference call with ABs
- Meeting with NFSTC to explore third-party AB process
- Review of survey data provided by Judy Morgan
- Two surveys soliciting information regarding ability to process out of state primary applications, timeliness of assessments, timeliness of review of PT data, and training needs.

Conference Call with ABs

- Two areas of concern highlighted:
  - Completion of the national accreditation database
  - Accurate information on which ABs are doing out of primary state accreditations
- Mixed response to query about TNI becoming an AB or making contract services available

Ideas from Meeting with NFSTC

- Focus was to determine how TNI could best provide services to the ABs
- One option is a fee for service model selecting two or three of the most critical services needed by the ABs. Additional services could be phased in as we determined need.
- Setting up the service as a separate business unit to account for revenue and expenditures separately is preferable. Easy to see if the venture was fiscally sustainable or not.

Ideas from Meeting with NFSTC

- Having the service partially underwritten by a grant could also help to launch the program.
- Set up a sister organization to provide the services. This approach would be preferable if TNI were offering some high risk services and needed to be insulated. At this point, TNI is only interested in offering pre-decisional activities as services.
- Seek the advice of an attorney on whether or not to set up a separate or subordinate organization. TNI could also partner with another existing organization to provide services.

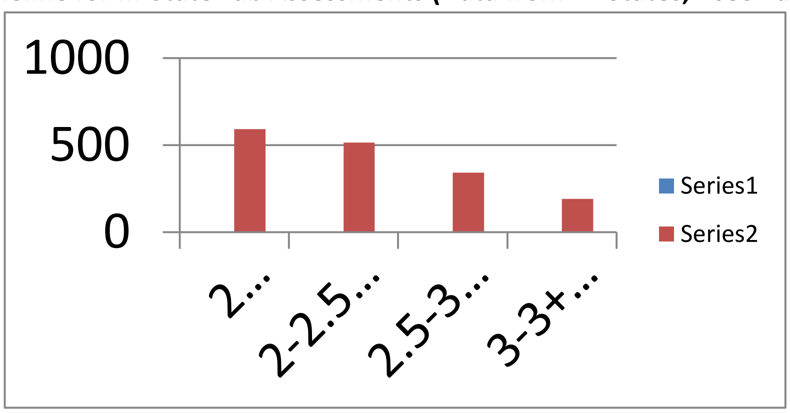
AB Survey #1: Status of Out of State Primary Accreditations and Timeliness

- Only 5 ABs indicated that they have issues with either accepting primary applications from out of state or timeliness of processing of applications for accreditation.
- IL no longer accepting out of state primaries. Existing IL OOS primaries will have to find another AB.
- There could be issues with available scope of accreditation if more states are restricted from doing out of state primaries.

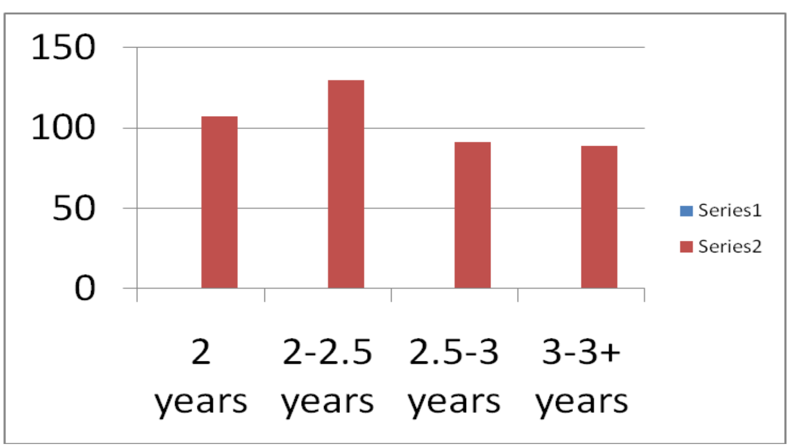
AB Survey # 2: Timeliness and Training

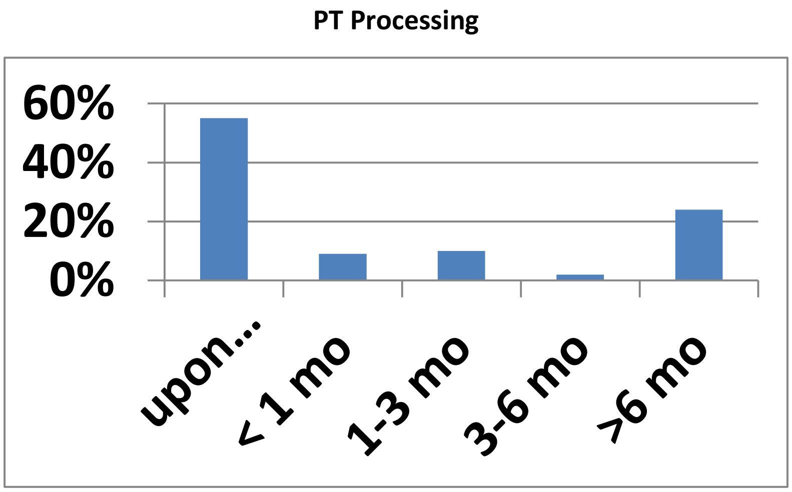
- Timeliness of primary instate assessments
- Timeliness of out of state assessments
- Timeliness of review of PT data
- Compliance with training requirements of new Standard
- 12 of 15 ABs responded to survey

Timeline for In-State Lab Assessments (Data from 12 States, 1639 Labs)



Timeline for Out of State Lab Assessments (Data from 12 States, 417 Labs)





Third-party Assessors

- 7 of 12 ABs responding do not use third-party assessors
- 2 ABs use third-party assessors for out of state assessments only
- One AB uses third-party for radiochemistry assessments

Meeting 2009 Standard Training Requirements

- 4 ABs indicated they would have no problem
- 8 ABs indicated possible problems due to budget constraints, travel constraints, availability of training, and keeping up with new staff training.

AB Plans for Meeting New Training Requirements

- USEPA certification officer training (2 ABs)
- In-house training (7 ABs)
- Arrangements with TNI (3 ABs)

Training Areas Where TNI Can Assist

- Toxicity: 9 of 12
- Radiochemistry: 7 of 12
- Asbestos: 6 of 12
- Organics: 5 of 12

Other Concerns from ABs

- TNI needs a mechanism for immediate resolution of issues that arise during implementation of the new Standard.
- All required training, including basic assessor training should be available online.
- State budget concerns will impact how ABs manage their programs.
- Out of state travel for training is prohibited. Web-based training is preferable.

Laboratory Needs / Requests

- Access to primary and secondary accreditation
- Timeliness of processing
- Applications for primary and secondary accreditation
- Renewals of accreditation
- Preparation of on-site inspection reports
- Timely review of corrective actions
- Standardization of program implementation

Key Finding

- One size solutions will not fit for all states. TNI needs to develop a range of solutions to address many concerns.

Onsite Lab Assessments

- The most immediate need is to assure that the 27 out of state labs that were previously accredited in Illinois have found a new AB for primary accreditation. TNI is contacting each lab to be sure that they have found an alternative AB for primary accreditation.

Onsite Lab Assessments: Options for Discussion

- Provide assistance to ABs in securing third-party assessors.
- Surveillance audits in alternate assessment cycles may be a solution. If a lab is doing a good job, the frequency between assessments can be lengthened. This would allow the AB to better manage their resources.
- Adjustment of frequency of assessments in the Standard may be another solution.

Assistance with Administrative Review: Draft Recommendations

- TNI should explore options for assisting with:
  - application review,
  - follow-up on corrective actions to assure that they are implemented as required, and
  - assessment tracking tools.

Third-Party Assessors: Draft Recommendations

- Simplification of the contract process for third-party assessors would help some states. Possible actions for TNI include:
  - development of a process to pre-qualify third-party assessors,
  - development of a model solicitation template for third-party assessors,
  - development of an evaluation process for selection of third-party assessors,
  - TNI could develop a service for a state to contract with TNI to obtain the use of third-party assessors, and
  - TNI could explore the use of resource sharing between states and develop model MOUs.

Third-Party Assessors: Draft Recommendations

- Qualification or credentialing of third-party assessors would assist on many levels and should include development of minimum qualifications and verification of training.
- TNI should not pursue becoming a third-party accreditor at this time.

PT Data Review: Draft Recommendations

- TNI should consider developing a process for centralized review of PT data for conformance with the Standard. Following TNI review, states can take whatever action is warranted under state programs. State responses may be different, but review criteria will be the same. This may help secondary accreditation issues.
- TNI is sponsoring a mentoring session at this meeting to explore best practices from states and the commercial sector.

National Database: Draft Recommendation

- TNI should expedite the implementation of the national database to assist ABs with secondary accreditation issues.

Training of Assessors: Draft Recommendations

- TNI needs to have web-based training of assessors up and running in 2011.
- The initial focus of the training should be in the technical areas identified.

Next Steps

- The AB Task Force will receive comments and suggestions at this meeting and by email.
- Information will be compiled into a report to be presented to the TNI Board with input from the NELAP AC and LASEC for determination of appropriate action.

Appendix C
Compilation of Comments to the AB Assistance Task Force

COMMENTS & SUGGESTIONS FROM SAVANNAH

After the presentation of Accreditation Body Task Force Findings and Draft Recommendations at the Savannah meeting, the Task Force received the following comments and suggestions:

Third-Party Assessors and/or Accreditations

- EPA DW program has always supported the use of third-party auditors, but requires that state makes the final determination. Greg Carroll will check to see if a third-party accreditation will work for the DW program.
- NY would need a legislative change to accept third-party accreditations.
- Is the information in the presentation really complete? I think the problem is worse than it looks.
- Credentialing of the third-party assessors is a good idea.
- Using the DoD reports is a good idea. Assessor qualification not so much. Labs don’t want third-party assessors because of cost.
- Need to think through assessor qualifications. At this time, only a state AB can say who is an “assessor”.
- Guidance for use of third-party assessors is a good idea.

Partnering with DoD/DoE

- Did the Task Force consider having the ABs partner with other organizations doing audits like DoE and DoD? Perhaps the ABs could audit information from these other entities. DoD and DoE are consolidating their quality manuals. They have 4 recognized 17011 ILAC ABs on contract. There are potentially 90 labs accredited by DoD and DoE.
- In a follow-up email from George Detsis: Perhaps it may make sense for certain states to possibly adopt DoECAP audits of large analytical laboratories that we audit and that service both the Federal Gov't./State interests in an effort to relieve financial auditing burdens upon certain TNI states.
- Downside might be that DoD and DoE only accredit for parameters that they need for their work. Their accreditations might not be broad enough.
- The DoD and DoE ABs can accredit for whatever the lab wants to be accredited for. They use the same standards and same PTs. The ABs in the DoD program would be open to what the lab wants and what TNI wants to do.
- Accepting a DoE or DoD audit or accreditation might would require a Standard change and maybe a legislative change in some states.

- Another advantage is that labs could get an ISO 17025 accreditation from a DoD AB. It's more bang for the buck even if it costs a little more.
- If state law prohibits use of DoD audit or accreditation, there may be a process in between that will work (like looking at records, reports, etc.)
- My lab uses multiple third-party ABs and there is more inconsistency than among states. Would like to have reciprocity with DoD.
- Third-party ABs will brief DoD labs March 28-April 1 and discuss issues. DoD ABs are held to a high standard.
- As a NELAP AB, I am more than willing to accept a DoD report. Seems like common sense. Do DoD assessors ever look at NELAP reports? PT inconsistency might be a problem. PT and assessment issue were there before the economy tanked.
- DoD ABs get good feedback from DoD. At first they went to all the assessments, now they just pick and choose which ones to go to.
- The key is oversight and review of reports, DoD reviews all reports.
- Everyone's success through this economic downturn will be based on partnering.
- Isn't using the DoD, DoE only a drop in the bucket. This is only 90 labs. We need to solve the big problem.
- DoD and DoE are a duplication of effort. We need to combine forces!

Surveillance Audits/Inspections

- Revising the frequency of assessments based on performance is a good idea. Need to have consistent criteria. Could use teleconferencing, videoconferencing for a shortened assessment cycle.
- Not a good idea to allow a lab to skip an assessment altogether. A surveillance assessment is needed.
- Where's the line between good and bad? Labs will pay more attention to their quality system if they can see a benefit like a reduced number of onsite assessments.
- Who decides if lab gets reduced assessments? It can't be based on the number of findings.
- Get away from "good lab, bad lab" terminology and establish a risk-based process to determine assessment frequency. Figure out key metrics, use that to determine frequency.
- Competence of assessor could be an issue in looking just at number of findings.
- When we don't understand the root cause, we should not get away from a two year cycle.
- This is not the time to cut back on assessments.
- Surveillance assessments will require a Standard change. There are good international models on when to do surveillance assessments. It can be a formal and objective process
- Limited scope labs should be eligible for reduced frequency of assessments.
- Concerned about assessment frequency. We need to stay focused on producing data of know and documented quality. That is our mission. We must continue to do training.
- TNI should leave assessment frequency alone.

Training

- Implement web-based training for assessors.
- We need to train assessors how to write deficiencies and how to track corrective actions. This burden can be assumed by third-party ABs.
- A root cause analysis is needed. What is the problem here, really? We need some management improvement within the AB organization. Some assessors are taught poor practices on the job. Need to help ABs learn how to manage the process.

General

- The Task Force didn't ask about report turnaround time. That's not so good. One lab waited a year to get a report after the onsite.
- The Task Force focus was on existing ABs. These same issues may be constraining other states from becoming ABs.
- Need to have a central database for lab applications (generic TNI application) to make the process easier.
- We should approach this like a business; do things that enhance 80% of the business.
- How many of the changes being considered by the Task Force will require changes to the Standard?
- We need to see which of these recommendations will get us to where we need to be most quickly.
- In order to respond to the current economic situation, can ABs agree to change/suspend the rules on an interim basis by resolution or other means? They could use this avenue on an emergency basis to get some temporary relief. Private ABs can react quickly if changes made.
- We need to keep in mind that these are hard times for labs, too.

COMMENTS & SUGGESTIONS FROM THE LAS EC

After the presentation of Accreditation Body Task Force Findings and Draft Recommendations on a Laboratory Accreditation System Executive Committee conference call, the Task Force received the following comments and suggestions:

Third-Party Assessors and/or Accreditations

- If the states have trouble getting contracts in place for third-party, why will getting an MOU in place be easier?
- The Standard sets the criteria for assessors, what does TNI view to be different for third-party, than for any assessor? Adding a middle organization, will have to be paid for and thus increase cost to the lab. Where is the cost benefit to the lab? The third-party assessors

whose rates are low for the accrediting and assessing industry outside of environmental. Adding a middle organization will only add on to current rates."

- MOUs often work better for states. It would be helpful for TNI to act as a clearing house for third-party assessors.
- Is the report is available if a third-party is used. Who is responsible for offering accreditation if the primary state will not? Would it be proper for ABs to receive reports directly from the labs since TNI does not allow labs to directly submit PT results, but rather requires submission from the PT provider?
- It might be best to only accept assessment reports from third parties rather than accepting the accreditation of third parties that were not TNI ABs.
- Accepting an accreditation decision from someone that is not a TNI AB as a slippery slope.
- Recognizing accreditations that are not a part of TNI as a slippery slope.
- Some states have not needed to use either third-party accreditors or assessors.
- Some state systems accept reports from resident states for out of state labs. If a third-party assessment was done at the request of that state then they also accept that. They do not accept third-party accreditation. The state could accept an assessment if the accreditor was recognized by TNI. States try to make sure that home states are responsible for the work within their state.
- Discussion of accepting third-party assessments should apply only to routine inspections and not to enforcement based inspections.
- TNI might have a pod of third-party assessors but keep third-party accreditation out of the discussion.

Partnering with DoD/DoD

- Someone with DoD and DoE experience should be contacted to learn of confidentiality requirements for their reports. DoD or DoE may have to be the ones to say that they could be released.
- If states could accept DoD or DoE audits then they might be used to reduce frequency of state audits.
- In light of financial stresses and cut backs, TNI should look at audits conducted by DoD and DoE in meeting AB needs. This could relieve some of the stress for big labs. TNI should look outside the box. These audits should not take the place of TNI but could reduce frequency of audits for states in reduced budget situations.
- DoE has talked about becoming a TNI-recognized AB in the past and might need to explore it further since they use TNI as a base for their program and add specifics for some aspects of radiochemical waste handling, safety, training and protection. The bottom line is that the TNI Standard is the base document and DoE needs to look at becoming an AB.

Surveillance Audits/Inspections

- The best idea of the AB TF is the idea of surveillance audits. It is unfortunate that more audit time is spent on low value items (traceability of thermometers for example) rather than high value items (thorough audit of gc/ms for example).
- Where does the 2 year + or – minus 6 months frequency in the Standard came from.
- The + or – minus 6 months is in the TNI Standard. It is part of the language attached to surveillance audits in TNI to be compliant with ISO language.
- There was discussion of the need to have a risk based decision making process for determining how to use surveillance audits at the Savannah meeting. If the right risk based criteria were developed then there would be an opportunity for saving resources.

Training

- Training for ABs on how to manage their programs efficiently would help.
- Archived training would help and so does idea sharing.
- Annual ethics refresher training should be included in training plans for TNI as well as introductory training. Topics on quality control would also be helpful.
- Example form letters for AB assessments are in some of the templates being prepared and these are helpful.

General

- Taking small steps to ease the burden is best and decisions should be made on affordability.
- The economy is tough on labs too and issues that they have raised, such as PT frequency, seem to have fallen on deaf ears at TNI.
- One of the driving forces for labs in suggesting the AB TF was what happens if states are rolling back on scope and frequency of audits.

COMMENTS & SUGGESTIONS FROM THE NELAP AC

After the presentation of Accreditation Body Task Force Findings and Draft Recommendations on a NELPA Accreditation Council conference call, the Task Force received the following comments and suggestions:

Third-Party Assessors and/or Accreditations

- Pre-qualifying third-party assessors would be very helpful.
- The AB still cannot circumvent the state procurement process.

Partnering with DoD/DoD

- The biggest issue with this is that the assessors are not NELAP-qualified assessors.
- It will introduce another element of inconsistency.
- DoD and DoE are not NELAP recognized ABs.
- Can they cover the scope that will be needed?
- Texas is conceptually open to the idea.
- States would need to have an agreement with the third-party. Cannot subpoena a DoD auditor for enforcement. Would have to rely on the lab to provide the report.
- Would rather encourage them to become an AB. This would not be as complicated.
- Don't we do the same thing now when we have dual primaries? We should look among ourselves first for help. We can audit for each other if it is necessary to avoid excessive travel.

Surveillance Audits/Inspections

- The idea has merit. We check to see if it conflicts with DW certification requirements for an audit every 3 years.
- Could just do DW assessment as the "surveillance" audit.
- At one time in DW there was a four year assessment interval. At two years, just did a records audit. This practice was discontinued, but not certain what the reasons were.

Training

- Proposals for training look like a good idea.

General

- Has the Task Force explored any options for assistance to ABs that cannot pay the TNI recognition fee?
- Has the Task Force coordinated with other groups like the Consistency Improvement Task Force? It seems like there is some duplication of effort going on.
- Just FYI, IL labs seem to be making a smooth transition. Most have found a new AB. There have not been any big issues so far.
- If you ABs don't think you need help or need to make improvements, you are wrong. He gets the sense that the ABs don't think they need help or appreciate TNI's efforts to provide assistance. The NELAP AC needs to look carefully at these recommendations. The FL legislature is looking at privatizing the FL lab accreditation program.
- The Task Force can't help us with day to day problems.
- The ABs may need to look at a different way of doing things.
- The problem is retaining staff.

Appendix D
Comments from NELAP Accreditation Bodies on the Use of Third-Party Accreditation Bodies

In order to assess the feasibility of their recommendations on the use of third-party accreditation bodies (ABs), the Accreditation Body Task Force (AB Task Force) posed four questions to the current NELAP ABs. These questions included:

- What would prevent you from accepting an accreditation issued by a non-government AB?
- Is this the result of statute or regulation?
- Could you grant mutual recognition to a lab that had been accredited by a non-government AB in another state? Why not?
- Given current economic climate and assuming that state regulations could be changed to allow it, is there a philosophical reason that we should not accept third-party ABs?
- Emphasize that non-government ABs will be going through the same evaluation process as the current state ABs.

Summary

The following ABs responded to some or all of the Task Force questions: KS, TX, PA, FL, OR, NH, LA DEQ, LA DHH, NY, and UT.

KS, NY, NH, and LA DHH have requirements in regulation that ABs have to be a government or tribal entity. With this specific regulatory language, it will not be possible for these ABs to recognize an accreditation issued by a third-party AB. PA and FL indicated that regulatory intent in their state was for an AB to be a government entity, but it is not specifically stated in regulation. They would need to seek a legal interpretation.

TX, UT, and LA DEQ could recognize a third-party AB and accreditations issued by a third-party, as long as the third-party was approved by the NELAP AC.

OR is the only state reporting statutory language that prohibits them from accepting a third-party AB. There is also an indication that EPA will not accept third-party ABs in the DW program.

Philosophical issues with third-party ABs included concerns about consistency, the perception that the “fox is watching the henhouse”, the perception that third parties are often more difficult to deal with than state agencies, and reluctance to give up state regulatory authority to third parties.

Comments Received During the NELAP AC Meeting on May 16:

- KS defines an accreditation body as a government entity in regulations.
- TX can grant secondary accreditation to any lab accredited by an approved NELAP AB.
- The intent of the PA statute was to restrict recognition to governmental ABs, but could seek legal interpretation.
- OR wants to be able to recognize DoD accreditations (using third parties).
- LA regulations would allow them to recognize a third-party AB.
- FL regulatory intent was to allow only governmental due to the language in NELAC 1.4 but the specific wording does not specify governmental.
- The approval process for third parties is not the issue for some ABs; it is the fact that they are non-government.
- NY state regulations refer to “another state AB”.
- UT can recognize “TNI accredited” lab, per administrative rule.
- EPA Region 4 has issued an opinion that DW program cannot recognize a third-party AB. The state has to issue the accreditation.

Additional Comments from ABs

Following this meeting of the NELAP AC, the ABs were asked to submit additional comments by email.

Comment received from Michelle Wade in KS:

I wanted to take the time to give you my opinion on 3rd party ABs. I would like to clarify that this is not necessarily the official view point of KS.

First officially (from our lawyer) KS would have to change their regulations to approve 3rd party ABs. I am going to suggest to Dennis that as we’re changing the regulations for the standards that we change that language as well; but, as I don’t know where we are at, or what is actually being changed at this point I can’t guarantee anything.

I personally would not have a problem with reciprocity with a 3rd party AB; assuming that the 3rd party AB was approved in the same manner as the rest of the NELAP ABs, and that they were accepted by the rest of the AC. I not only feel that they could do equally as well any state AB, but in many instances would probably outshine the state ABs as they are not faced with the same regulatory issues as the states are.

HOWEVER the recent events in Florida did have me concerned. AELA being an organization of laboratories caused me great concern with their impartiality; it seemed that the fox was deciding to guard the hen house. It just does not seem right for an organization of laboratories to certify their own laboratories.

With that thought in mind it led me to the counter argument that then is it right for Accreditation Bodies to be evaluating and approving other Accreditation Bodies? It would seem that it would be much better to have a 3rd party organization do those evaluations as well.

From a laboratory perspective, having been through both a state audit, and a 3rd party audit – I would much rather utilize a state audit team. Not only my own experience as a laboratory person being audited, but from discussing things with out of state laboratories seeking primary with KS; there were certain laboratories that would not utilize KS as a primary because they did not like our selection of auditors. 3rd parties are often considered to be more difficult than state assessors.

My biggest (and really only) concern with using a 3rd party AB would be exasperating the consistency issue. If they are perceived (and often rightfully so, for many reasons) to be more difficult just on an assessment, it would stand to reason that they would be more stricter ABs, and would therefore cause an even bigger stink than we already have.

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Comment received from Bill Hall in NH:

NH ELAP is currently following the NELAC Standards. Without looking at the standards, I believe they state that an AA (AB) is a state, federal or tribal entity.

I don't have a warm & fuzzy feeling about your request; to accept third-party AB accreditations. These entities have not made any positive moves towards NH as an accrediting authority. I'm not sure they "recognize" our work. I had a DoD assessor come into one of our labs - to look at virtually the same thing we assess. No discussions on the matter were offered by the third-party assessor. No sense of mutual recognition mentioned.

TNI seems to get ahead of itself quite often. Where is the report on the dire situation with our current ABs.? Most of what is shared is hearsay. TNI needs to come up with a formal study / report on this matter before I would even consider moving from my position.

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Comment received from Irene Ronning in OR:

ORELAP uses third-party assessors for radiochemistry and doesn't have a problem with third-party assessors meeting the assessment needs of our AB's providing they have been checked out.

However, we cannot accept third-party accrediting bodies. Our statutes that give us the authority for the program does not allow for third-party ABs. I do not like the idea because it means that we would have to give up our authority to the private, for profit, sector and I can see all kinds of possible problems with this.

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Comment received from Louis Wales LA DHH:

LADHH's regulations specify NELAP Accredited Accreditation Bodies-(State or federal government) for reciprocity therefore accreditation issued by non-government ABs would not be acceptable. This is the result of regulations.

LADHH could not grant mutual recognition to a lab accredited by a non-government AB in another state based upon the current regulations for LADHH's laboratory accreditation program. This does not mean the regulations cannot be changed but the agency sentiment is to only extend mutual recognition to other governmental agencies.

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Comment received from Steve Arms FL DoH:

Considering the recent departmental recommendations to privatize the certification program, and given the current political "atmosphere," I would find it very hard to believe that there would be any opposition whatsoever (at least internally) to our recognizing the accreditations of 3rd party ABs (i.e., non-governmental bodies), as long as they (ABs and labs) are held to the same standard as all the other players. Also, our current rules do not specify that ABs are governmental bodies, although that was probably an assumption we made at the time due to the language in NELAC 1.4.