Summary of the Laboratory Accreditation Committee Meeting
October 12, 2007

1. Roll call: Attendance is recorded in Attachment A.

   The regular meeting of the TNI Laboratory Accreditation Systems Committee (LASC) was called to order by June Flowers, Chair, on October 12, 2007, at 11:00 a.m. EDT.

2. Previous minutes

   Minutes from the September 14, 2007, conference call meeting, were reviewed and accepted by all members present with corrections.

3. SOP on Standards Interpretation

   The NELAP Board has not provided feedback to the LASC regarding the approval of the Standards Interpretation SOP. The inquiry form on the website can be accessed under the LASC page, but is not yet active.

4. Appeals Resolution SOP Discussion

   Suggestion was made by Dan Hickman to proceed with an SOP on Appeals Resolution. June Flowers mentioned that NELAC Chapters 1 and 6, Sections 6.10- and 6.11 defined the NELAC appeals process for AA's and AARB, and that the AB Expert Committee was beginning to prepare this SOP. Dan Hickman stated that expert committees are to write standards, not SOPs and policies, but if they have time, they can go ahead and work on this. EPA's Lynn Bradley has been assigned the Evaluation Coordinator position. This "Appeals" SOP is critical to have in place prior to the start of the evaluations. The LASC will be informed following the NELAP Board conference call to be held Monday, October 15, 2007.

5. PT Inquiry to Dual-Program States

   The PT Expert Committee is considering the frequency be changed from 2 successful analyses per year to 1 PT per year for every Field of Testing (FOT). The LASC inquired to the three states that run dual certification programs: California's Jane Jensen, New Jersey's Joe Aiello and Pennsylvania's Aaren Alger. Each of these AB's maintain 1 program for non-nelac labs that follow the EPA 1 PT/year and a 2nd program for NELAP labs that follow the 2003 standard requiring 2 PT's per year for each FOT. The inquiry made was: " do you see a comparison of pass/fail rates between the 2 programs that indicate running 2 PT's are better than 1?" The comments received via e-mail were distributed to the LASC members and briefly discussed. These 3 AB's would support a 1 PT/year frequency, however, the corrective action plan and suspension details would have to satisfy each of their current programs. There were both positive and negative potentials discussed among LASC members of the 1 year versus 2 year frequency. Further discussion will be held, and the NELAP Board will be presented with a position.

   The comments from the dual program states are enclosed in Attachment B.

6. The next meeting of the LASC will be November 9, 2007, at 11:00 am EST.

Attachment A
PARTICIPANTS
TNI
LABORATORY ACCREDITATION COMMITTEE

Member	Affiliation	Contact Information
Ann Marie Allen - present	Massachusetts, Non-nelap AB	
Jo Ann Boyd - present	Southwest Research Institute, Lab	
Lance Boynton- absent	Absolute Standards, Inc., PT	
Brooke Conner- present	USGS	T: 303-236-1877 E: bfconor@usgs.gov
Lewis Denny- present	Florida DOH, AB	
George Detsis - absent	Department of Energy, Government	T: 301-903-1488 E: george.detsis@eh.doe.gov
Dan Dickinson-present	New York DOH, AB	
June Flowers – Chairperson	Flowers Chemical Laboratories, Inc., Lab	T: (407) 339-5984 x212 E: june@flowerslabs.com
Terry Grimes- present	Pinellas County Utilities, Municipal Lab	
Dan Hickman- present	Oregon DEQ, AB	
Marvelyn Humphrey- present	USEPA Region 6, EPA	
Roger Kenton-present	Eastman Chemical Company,	
Judy Morgan- present	Environmental Science Corporation, Lab	
Jack McKenzie-present	Kansas DHE, AB	
Leyla Perez- present	Babcock Laboratories, Lab	
Dale Piechocki- present	Underwriters Laboratories, Inc., Lab	
Ilona Taunton - present	TestAmerica Analytical Testing Corp., Lab,	
Carol Batterton - absent	TNI Administrator	T: 830-990-1029 E: carbat@beecreek.net

Attachment B

Comments from Dual Program States on PT Frequency for TNI

Laboratory Accreditation Committee Minutes

This email was sent as stated in LASC Minutes September 14, 2007

From: June Flowers [mailto:june@flowerslabs.com]
Sent: Monday, October 08, 2007 1:27 PM
To: Jensen, Jane (CDPH-ELAP); aaalger@state.pa.us; Joseph.Aiello@dep.state.nj.us
Cc: Carol Batterton
Subject: PT Frequency Discussion

Hello Joe, Jane and Aaren.

I am contacting you because your States run two (dual) programs for lab accreditation.
The issue of labs performing in 2 PT studies per FOT per year was discussed at the Cambridge meeting, and that discussion continued at our last LASC conference call.

The question we have for you is do you see a comparison of pass/fail rates between the 2 programs that indicate running 2 PT's are better than 1? You may or may not have this data available, but would you be able to comment or provide feedback to our committee on this topic? The LASC has a call this Friday, and I understand there is a NELAC Board call next Monday, and PT concentrations will be discussed.

My laboratory is accredited in Potable, Non-Potable and Solid categories, so we run several PT's each year by the same technology, and the minerals and metals for DW and WW are now the same methodology. There are many labs that are accredited in a single category, so 2 PT's per year seem logical. EPA requires 1 PT per year, and most State programs follow EPA. Your States have this valuable experience evaluating NELAC and Non-NELAC labs. As TNI moves forward, our concern is whether or not the quality of lab performance is improved by analyzing PT samples more frequently.

Your reply is greatly appreciated and would be shared with the committee for discussion purposes only.
Thank you,
June S. Flowers / LASC Chairperson

The responses that follow have been approved to share with the public by these three individuals.

June,

My experience with laboratories and their performance on PT studies is as follows:

1. Labs fail PTs for various reasons: including, but not limited to, analyst error, instrument error, reporting errors, and preparation errors. Laboratories that fail for any of the first two reasons may also be reporting their regular samples incorrectly and then more PTs might be able to help them better assess their inadequacies and correct their procedures. However, if either of the last two reasons is why the laboratory is failing PTs, then it might not affect the validity of their regular samples and more frequent PTs would only help the laboratory adjust their PT procedures rather than those procedures a regular

sample goes through.
2. Many NELAC laboratories lose accreditation due to PTs not because they inaccurately analyze the PT, but because they do not meet the required NELAC PT frequency. They either try to analyze PTs too close together or too far apart. Neither of these errors would necessarily affect regular samples.
3. PTs require additional handling procedures that regular samples do not. This includes sample preparation, including dilution; special reporting procedures; and increased PT sample reviews because the laboratory's accreditation status may be affected by the results. These additional procedures keep the QA staff busy doing something that might not increase the validity of the regular samples and keeps the QA staff away from developing procedures that would make the laboratory operations better including training, internal audits, and improving current procedures.

The other side of the issue is:
1. PTs are an indicator of how a laboratory does when it is at its best and knows it's being tested. Therefore, a failure would indicate a potentially major problem because no laboratory would rationally report a PT sample with failing QC. Which means, the error is somewhere else that isn't being detected by the QC.
2. PTs are an evaluation tool used because an on-site evaluation is not practical. On-sites cannot be performed on the same frequency that PTs can be analyzed. A tested laboratory might make a better laboratory.

My experience with our laboratories is that whether or not the laboratory participates in 1 PT per year or the inordinate number that some of our NELAC laboratories participate in, the PTs are not what makes a laboratory "good". It comes from the integrity of the people working at the bench. From my experience as an analyst, it would be really easy to analyze a PT in a "non-regular" fashion that cannot be detected by anyone else. What is important is the training that the laboratory management give to their analysts and their expectations of quality work and accepting nothing but the best. Personally, I believe an on-site evaluation is a much better indicator of how a laboratory is doing than the PTs. This doesn't mean that I think we should increase the on-site frequency, but I do think that if we could change the mentality of what an on-site is, we might be able to change our laboratories' attitudes toward them. Maybe if the ABs could have an attitude that on-sites are performed on an irregular basis and if laboratories believed that an on-site could occur at any time, the bar would be raised. If at any moment an assessor could walk through your door, would you always be ready for an assessment? Maybe not, but you would probably be in a better place than if you knew you were most likely only having an on-site every 2 years with a few weeks notice. (But none of this actually answers your original question, just on my soapbox for a moment)

The question really is, "what is the minimum number of PTs that a laboratory can participate in that will assure the greatest improvement to the laboratory?" Do I know this answer? No. But my opinion is that 2 PTs per year does not a better laboratory make.

And lastly, the requirement for some laboratories to analyze multiple PTs per year (i.e.: NELAC laboratories) while other laboratories are only required to analyze 1 PT per year (i.e.: dual program states and DMR-QA programs) probably keeps the cost of PTs lower. The reason for this is that if only one PT were required per year for every laboratory, PT providers would feel a financial hit and would probably raise the cost of their PT studies to make up the difference. Therefore increasing the cost to the "1 PT per year" laboratories.

I don't know if I really helped you at all, but take my opinions for what they are worth (probably not much).

Aaren

~~~~~~~~~~~~~~~~~~~~~~~~~~~~

Aaren Shaffer Alger
~~~~~~~~~~~~~~~~~~~~~~~~~~~~

DEP-Bureau of Laboratories
Laboratory Accreditation Program
Phone: 717.346.8212
Fax: 717.346.8590
e-mail: aaalger@state.pa.us

Several of us in NJ have been thinking about this for the past couple of days. And to keep things simple the best response is that we don't have an answer. We can look at this further but we would like all involved to come up with some specific questions for us to address. We don't want to spend significant effort to provide answers that don't effectively respond to the issues being discussed by involved parties.

For instance, should we be looking at first time failures for both programs and then second time failures whether immediately following the first one or for all following studies. Should we be looking at suspensions followed by renewed accreditation and any failures after that. And so on as there can be many scenarios. And, if we're looking for some defined statistical evaluation of failure rates that may be beyond our ability.

But overall I believe that once labs are suspended for a given PT failure, when they're back in compliance they tend to remain that way for long periods of time. Which leads one to believe that 1 per year is fine. I believe that it's OK to switch to one per year but with the requirement that once a failure has occurred it would be necessary for a lab to successful analyze at least 2 follow-up samples (over a couple of months) to remain accredited.

Additionally, to look at it a different way 2 samples provide a greater opportunity for labs to be found non-compliant and for corrective actions to be initiated. Although, an effective quality system should better provide for correcting problems.

As can be seen above, I have no quick answer and I can be all over the place on this topic. And the above is a weak attempt. But I know you said you needed something by tomorrow and I didn't want you to think we were ignoring you. We are willing to work with you to pursue this further. Given our 2 tier program we may have the data necessary to answer questions. But it won't be easy and it won't be by tomorrow. Sorry about that and let us know. I won't be around tomorrow but Tom Chepiga may be able to help you with any questions.

Joseph F. Aiello, Chief
NJDEP Office of Quality Assurance

Tel: (609) 633-3840
Cell: (609) 802-1007
Fax: (609) 777-1774

Hello June,

In response to your questions, we have prepared the following:

From our accreditation perspective, the PTs are only in use to perform a quick check on laboratory performance. Such checks are limited in scope and must be reasonable and effective in its application and cost. The PTs must not over burden the State nor the lab, otherwise these PTs are no longer meeting their purpose. Successful performance in a PT study does not mean that the lab is proficient in its day-to-day performance. It means that under the conditions of the examination, the lab performed acceptably. The PTs are separate from the on-site assessments, and were never meant to substitute for on-site assessments because these two monitoring processes provide different measures of a lab. Typically, lab participation in 1 PT is sufficient, as long as stringent requirements are in place.

We have noticed differences between labs which comply with the 2 PT requirement and those that comply with the traditional 1 PT requirement. In summary, the 2 PT requirement is not necessarily better. There is too much emphasis on PTs instead of following day-to-day procedures, practices, and performing the methods correctly.

With a 1 PT requirement, a lab failing a PT study would be required to first conduct a corrective action to identify the cause for the failure, then within a six-month period the lab would be required to participate in another PT study for the failed method (which would involve analysis of all representative analytes for the method, not just the failed analyte(s)). The lab failing this second PT study for the same analyte(s) within a 12-month period would mean revocation of the lab's certificate for the method for all analytes appearing on the lab's certificate. If the lab requests for reinstatement, then it would be required to apply as a lab with a new FOA along with corrective action reports and all other requirements for accreditation of a new method.

Jensen, Jane (CDPH-ELAP)