

Summary of the TNI NELAP Board Meeting April 6, 2009

1. Roll call

The NELAP Board met at 12:30 PM CST on April 6, 2009. Those members in attendance are listed in Attachment 1.

2. Minutes

Minutes from the 3-16-09 meeting were reviewed. Steve arms noted that he made the motion under item #6 where there was a questions mark. The minutes were approved for posting with this edit.

3. Update on renewals

First round:

CA –CA under review by team, due April 11

FL –approved

Second round:

IL- Team reviewing response to technical review. Question on agenda today. Dan Hickman granted a 30 day extension to the evaluation team to review the response.

LADEQ – Repose to technical review submitted.

OR – Draft report from the onsite is in preparation. Labs for shadow observations have been selected.

TX – Onsite scheduled for April 20, lab shadow scheduled for April 30

New applications:

VA application has been submitted.

4. Documentation Requirements

Paul Ellingson submitted the issue below for NELAP Board consideration:

The NELAC standard in many cases gives specific requirements for accreditation. In question are to what extent do the procedures need to be documented in the Quality manual. If an AB incorporates by reference the 2003 NELAC standard into rule, what additional written procedures must the AB have to meet 6.3.2.1.3 of the standard?

6.3.2.1.3 Accrediting Authority's Quality System

b) The quality system shall be documented in a quality manual and associated written quality procedures and shall be made available for use by the staff. The quality manual shall include at least the following:

- 7) the policies and procedures established to maintain document control for documents required by the NELAC standards;
- 8) the policies and procedures to implement the accreditation process;**
- 9) the policies and procedures for dealing with appeals, complaints and disputes by laboratories; and
- 10) the policies and procedures for dealing with reports of questionable laboratory practices.

Evaluation Team

At a minimum the team feels that the NELAC standard should be incorporated into the Quality manual with specific procedures defined and detailed as appropriate. The team feels that the Quality Manual lacks detailed documentation on how the AB runs their accreditation program and how they comply with NELAC Standards.

Specific areas in question include:

- PT failures – Evaluation of failures, suspending or revoking accreditation
- Mobile laboratories
- Suspension and revocation
- A general need to provide more detail on how the program is run (i.e. NELAC states defines when suspension or revocation needs to happen, the Quality Manual needs to define how that suspension will take place).

Accreditation Body

From the Technical Review, the AB believes that the NELAC standard in many cases gives the specific requirements for accreditation and no additional information is required in the Quality manual. In the initial response to the evaluation team for the technical review the AB indicated that by incorporating by reference the standard into state rule, that there was sufficient detail listed in the standard and that in many cases there was not a documentation requirement.

After extensive review and discussion of this issue, the NELAP Board recommended that the evaluation team ask the Accreditation Body for more detailed documentation of their procedures in those specific areas where they had concerns. The Board believed that in some cases just referencing the standard may be appropriate, but not in all cases.

5. LASC recommendation for new TNI standards

Dan presented the LASC recommendations in the LASC Attachment 2 table for discussion beginning at No. 2 under AB Expert committee, p. 25.

| LASC Recommendation # | NELAP Board Response | Comments |
|---|----------------------|----------|
| AB Expert Committee | | |
| 2. V2:M1 –4.3.5, 5.7.3b, 6.3.2 Seems to be for ABs that have more than one person on the staff but this is not always the case | No objection | |

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|---|--------------|--|
| 3. V2:M1 -7.6.2"Accreditation Body shall appoint" – many state ABs don't have this authority. | No objection | |
| 4. V2:M1 –7.7.3 Need a guidance document or perhaps an additional "Note" in the standard to refer to specific policies and SOPs that put specific timelines on the renewal process. | No objection | |
| 5. V2:M1 –7.7.1"Surveillance on-site assessments" needs to be defined | No objection | |
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The Board went back to review previous responses to items # 1, 3, 4, 7, 10, 12, and 24 under the PT Expert Committee section.

Texas had comments that were not previously considered and needed to be discussed. Texas advised the NELAP Board that they would have to veto Item #3 as currently written. Texas is uncomfortable with an “appeals process” that is outside of the state’s due process statutes and regulations.

Texas is also concerned with the requirement that labs must use unaccredited PT providers if sample cannot be obtained from an accredited provider. This is definitely a “no” vote for Texas and could be a veto.

Texas objects to the requirements for experimental PTs. The comments reflect that experimental PTs are no longer required, but the website still indicates that they are. This is a veto issue for Texas.

6. SW 846

Dan Hickman reminded the group that the NELAP board still owed the TNI Board a response on how they would resolve the issue of accreditation for SW 846 method updates. Joe Aiello indicated that he was supposed to be meeting with ELAB and OSWER on this issue. Joe will call Dave Speis to determine the status of those meetings. This issue will be on the agenda for the next meeting.

8. Next meeting

The next meeting of the NELAP Board will be April 20, 2009. Agenda items at the next meeting will include:

Update on renewals
SW 846

Attachment 1

| STATE | REPRESENTATIVE | PRESENT |
|-----------|---|---------|
| CA | George Kulasingam T: (510) 620-3155 F: (510) 620-3165 E: gkulasin@dhs.ca.gov | Yes |
| | Alternate: Jane Jensen jjensen@dhs.ca.gov | |
| FL | Stephen Arms T: (904) 791-1502 F: (904) 791-1591 E: steve_arms@doh.state.fl.us | Yes |
| | Alternate: Carl Kircher carl_kircher@doh.state.fl.us | |
| IL | Scott Siders T: (217) 785-5163 F: (217) 524-6169 E: scott.siders@illinois.gov | Yes |
| | Alternate: TBA | |
| KS | Jack McKenzie T: (785) 296-1639 F: (785) 296-1638 E: imckenzi@kdhe.state.ks.us | No |
| | Alternate: Dennis L. Dobson 785-291-3162 ddobson@kdhe.state.ks.us | Yes |
| LA DEQ | Paul Bergeron T: 225-219-3247 F: 225-219-3310 E: Paul.Bergeron@la.gov | |
| | Alternate: Cindy Gagnon E: Cindy.Gagnon@la.gov | Yes |

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| LA DHH | Louis Wales T: (225) 342-8491 F: (225) 342-7494 E: lwales@dhh.la.gov | Yes |
| | Alternate: Ginger Hutto ghutto@dhh.la.gov | |
| NH | Bill Hall T: (603) 271-2998 F: (603) 271-5171 E: whall@des.state.nh.us | Yes |
| | Alternate: Jeanne Chwasciak jcchwasciak@des.state.nh.us | |
| NJ | Joe Aiello T: (609) 633-3840 F: (609) 777-1774 joseph.aiello@dep.state.nj.us | Yes |
| | Alternate : TBD | |
| NY | Stephanie Ostrowski T: (518) 485-5570 F: (518) 485-5568 E: seo01@health.state.ny.us | Yes |
| | Alternate: Dan Dickinson dmd15@health.state.ny.us | |
| OR | Dan Hickman T: (503) 229-5983 F: (503) 229-6924 E: hickman.dan@deq.state.or.us | Yes |
| | Alternate: Raeann Haynes haynes.raeann@deq.state.or.us | |
| PA | Aaren Alger T: (717) 346-8212 F: (717) 346-8590 E: aaalger@state.pa.us | Yes |

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|----|---|-----|
| | <p>Alternate: Bethany Piper bpiper@state.pa.us</p> | |
| TX | <p>Stephen Stubbs T: (512) 239-3343 F: (512) 239-4760 E: sstubbs@tceq.state.tx.us</p> <p>Alternate: Steve Gibson jgibson@tceq.state.tx.us</p> | Yes |
| UT | <p>David Mendenhall T: (801) 584-8470 F: (801) 584-8501 E: davidmendenhall@utah.gov</p> | Yes |
| | <p>Alternate: Kristin Brown kristinbrown@utah.gov</p> | |
| | <p>Program Administrator: Carol Batterton T: 830-990-1029 or 512-924-2102 E: carbat@beecreek.net</p> | Yes |
| | <p>Evaluation Coordinator: Lynn Bradley T: 202-565-2575 E: Bradley.lynn@epa.gov</p> | Yes |
| | <p>Quality Assurance Officer Paul Ellingson T: 801-201-8166 E: altasnow@gmail.com</p> | Yes |