# Summary of the NELAP Accreditation Council Meeting June 4, 2018 1:30 pm Eastern

#### 1. Introductions

The NELAP Accreditation Council (AC) met at 1:30 pm on Monday, June 4, 2018. The minutes of May 7, 2018, were approved. Those present are listed in Attachment 1.

The outstanding email votes on the May meeting's recommendation to renew the recognitions of KS, LA DOH and UT resulted in fourteen yes votes for each AB, with the individual ABs abstaining from voting on their state's renewal. All three renewals are thus approved.

## 2. Nominations for NELAP AC Vice Chair

In accordance with the NELAP General Operations SOP 3-100, nominations for Vice Chair of the Council were again on the agenda. There were no additional nominees. Paul Bergeron was nominated at the May 7 meeting, and the election will be held at the July 2 meeting.

### 3. Standards Review and Adoption

Aaren reviewed the history thus far, and asked for comments on the individual modules of the standard. There were no comments or concerns about any of the modules. When she reached V1M4, Aaren noted that the guidance documents are still pending, and also brought up discussion of the FL rulemaking which retains some language about demonstration of capability from the 2003 NELAC standard (see item 4 below, for that discussion.)

While the NELAP Standards Acceptance SOP 3-103 states that the Council will set an implementation date two months after adopting a new standard, Lynn recommended including a clause in the motion to adopt the 2016 TNI standard, specifying that an implementation date will not be set until all required guidance documents are approved. SOP 3-103 does not make allowance for this circumstance because it was not envisioned at the time of the latest revision. Review of the chemistry guidance documents awaits arrival of the revisions requested by TNI's Policy Committee, and with both LASEC and the NELAP AC needing to review and approve them, two months is an unreasonably short time.

Carl moved and Paul Bergeron seconded that the Council accept the TNI ELS Volume 1 entirely but with the understanding that the AC will not set an implementation date until all required documents are approved. Carl then amended his motion to include Volume 2, and Paul accepted that amendment with a renewed second. All present voted to approve the motion, and the remaining four ABs will be asked to vote by email. NOTE: as of Friday, June 8, three of the four absent ABs have voted to approve, also.

## 4. Florida Notice of Proposed Rule

On May 30, 2018, FL published a Notice of Proposed Rulemaking that essentially adopts the 2016 TNI standard. There is a 21-day comment period, and if no comments are received, the proposal becomes final 20 days later. The rule itself is at <a href="https://www.flrules.org/gateway/View">https://www.flrules.org/gateway/View</a> Notice.asp?id=20469248

Several individuals outside of the AC have expressed concern that FL proposes to retain a few items from the 2003 NELAC standard, under which it has been operating for many years.

The one item that could be substantive involves requiring an annual documentation of continued proficiency when a lab has not run samples during the previous year for that method, matrix, and analyte. Carl noted that this requirement applies only to labs receiving primary accreditation from FL. There were no adverse comments from the Council members about retaining this requirement, and several members noted that their state has also added limited additional requirements to the standard, over the years.

# 5. Decoupling Policy POL 3-102

An updated version of the document was provided, with the "interim oversight" portion removed, but an additional concern arose, that the definition of the NELAP AC refers to representatives "appointed by the state." Participants agree that it should be "appointed by the AB" and in fact, that wording is what is used in the TNI Bylaws to describe NELAP AC. Also, the definition for a NELAP AB was the same as that for the AC; this error needs to be corrected as well. These changes will be made and the document returned for approval at the July meeting.

## 6. PTRL Guidance

This document was provided by the PT Expert Committee, and is essentially material that was intended to be part of TNI's updated Small Lab Handbook, but that committee realized that it should be freely available to all users of the standard and not only those purchasing the Handbook. Policy Committee reviewed the document on June 1 and found that it qualifies as guidance and imposes no new requirements. After a brief discussion, Aaren asked that Council members review the document and bring their feedback to the July meeting. The following comments were provided by email, prior to the meeting:

1) Needs page numbering (Page X of Y)

2) On 2<sup>nd</sup> page, the "\*Caution" paragraph is linked by the asterisk to the bulleted note above it. Therefore, the phrase "(third bullet above)" can be removed as is not needed is confusing.

3) General / minor edit suggestion for throughout the document: instead of referring to an analyte "being spiked into" a sample, state instead (more simply) that the analyte is "present". For example, the "Caution" paragraph on 2<sup>nd</sup> page would read: "... runs the risk of reporting a false negative when the analyte may be present in the PT sample. If an analyte is present in a PT sample, reported result of

..." ("Being spiked" can communicate that the lab is doing some spiking.)

4) Suggest this sentence of the "\*Caution" paragraph on 3<sup>rd</sup> page be made **bold**, as it is one of the key points in the document: "**If an analyte is** <del>spiked into</del> **present in a PT sample, any result reported with a less than "<", as a non-detect, or a zero value is scored as not acceptable.**"

5) Example 4's summary, bottom of  $3^{rd}$  page, which says "Report <7.0 ug/L or the numeric value of <5.2 ug/L." is contradictory to the same data in Example 6 in the middle of the  $4^{th}$  page where it says "Lab reports 5.2 ug/L" as Acceptable. I believe the "<5.2" in Example 4 should read "5.2" without a less than sign. [Before seeing the contradiction I was not comfortable with telling a lab that if they got a 5.2 they had to report it as a <5.2 in the circumstance of Example 4. I was happy to see clarity to my concern in Example 6.]

6) The NOTE in the middle of the 4<sup>th</sup> page reads, "As defined, the PTRL is the lowest acceptable concentration for an analyte when that analyte is spiked into a PT sample. Therefore, if an analyte is spiked into a PT, any numerical result, including zero, that is reported below the PTRL will be evaluated as not acceptable, as that

numerical result will be below the acceptance limits." I worked with a situation last week where I observed that <u>the ACCEPTABLE RANGE</u>, in two different PT studies for a single analyte, went below the PTRL. Specifically, I was working with a situation regarding Aluminum in Solids. In this case the PTRL in the table is 250 but the acceptance range which is calculated from performance statistics of participating labs went down to 100 and 102 (two different studies). Whether this is common, a fluke, or a mistake on the part of the PTP, I don't know [and don't have resources to determine] but the examples I have demonstrate that statement in the Note of this document is incorrect at this time.

### 7. Lessons Learned Document from LASEC with CSDEC Response

LASEC prepared this document after its experience reviewing the multiple modules of the 2016 revision of the standard. It was first shared with CSDEC, and that group's feedback is included in the version shared with the Council. Lynn explained some of the struggles that LASEC had with the reviews, and then the fact that several critical issues were not identified until they were brought to the NELAP AC confounded the entire process.

There was some discussion about whether the ANSI process actually serves the state regulatory bodies, but no conclusions. CSDEC's comments are clear that that group believes the changes already made to the standards development process are adequate to address shortcomings identified in NELAP, but there is no way to alter the fact that committee feedback can only occur in the form of comments by individuals.

Aaren requested that all AB representatives read the document, and share their thoughts either by email or at the July meeting, so that the Council's feedback can be added in, before the final version is offered to TNI's Board of Directors.

#### 8. New Business

There was no update on the checklists for the 2016 standard.

Cathy raised a suggestion that the Council approach TNI's Advocacy Committee with a proposal to somehow include access to training events in the annual fee that is paid by NELAP ABs. There was general agreement to pursue this idea, and a more formal request will be forthcoming.

It looks like at least thirteen AB representatives will be attending conference in New Orleans, in August.

#### 9. Next Meeting

The next meeting of the Council will be Monday, July 2, 2018. An agenda and any documents will be sent in advance.

### Attachment 1

STATE	REPRESENTATIVE	PRESENT
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