

**Laboratory Accreditation System Executive Committee Meeting Minutes  
July 28, 2015**

1) Welcome and Roll Call

Judy Morgan welcomed everyone to the meeting. Those in attendance are recorded in Attachment A. The minutes of June 23, 2015, were approved. Lynn noted that Kim Sandrock has resigned from our committee since she is no longer associated with the AB in Minnesota due to a realignment of duties. Also, Judy announced that she will be moving to a new position, but in the same stakeholder category, and plans to continue as Chair of this committee. She noted that the past few weeks have been “hectic” and asked for our patience during this disorganized period, which should soon draw to a close.

2) Election of Vice Chair

Choosing a Vice Chair has fallen to the bottom of our committee’s priority list, repeatedly, but finally there is room on the agenda to deal with the issue. Judy Morgan nominated Kristin Brown for Vice Chair and asked for additional nominations from participants. No additional candidates were identified. Jack Farrell seconded the nomination, and Kristin’s election to the Vice Chair role was unanimous. Congratulations, Kristin!

3) Assessment Forum and Mentor Session

Both these sessions at conference received much positive feedback, both verbally to Judy and the organizers as well as on the evaluation forms. The Assessment Forum was attended by about 80 people, and Barb Escobar is writing up a summary from her notes about the morning panel on writing findings and corrective actions, to be published with the presentations. The afternoon session about an effective QA manager was well received, also.

The Mentor Session, about writing findings (a hands-on exercise) brought many requests to have additional such sessions in the future, and a similar session on writing corrective actions will be considered. Jack moderated this session, and gave kudos to presenters Mike Shepherd and Cathy Westerman.

Lynn noted that, on the recommendation of the Advocacy Committee, TNI had offered free registration for the one day of the Assessment Forum, to non-NELAP state certification personnel (one per state.) Several individuals did so.

Members of the Assessment Forum subcommittee are Jack Farrell, Kristin Brown, David Caldwell, George Detsis, Barbara Escobar and Carol Schrenkel. Members of the Mentor Session subcommittee are Jack Farrell, Betsy Kent/Chair and Carol Schrenkel.

4) SIRs and Implementation Guidance

There was no activity in this area for LASEC attention since the previous meeting, except for the submission of a new SIR, which has been sent to Quality Systems for a response.

Members of this subcommittee are Kristin Brown, Bill Hall, Carl Kircher and Judy Morgan/Chair, with staff support provided by Lynn.

## 5) Status of Standards Review

### *Calibration Interim Standard*

This portion of Module 4 is approved and final. There was considerable discussion about specific issues that continue to concern the NELAP program, during the joint committee meeting at conference in Chicago. Four objectionable items were discussed during that session and the Chemistry Committee has proposed acceptable “technical edits” to the approved document, to address the objections. NELAP approves these changes and all concerns are considered resolved. The items and the solutions follow, as proposed by the Chemistry Chair:

#### 1. **Calibration standard RSE**

The AC requested a written document or a publicly available video presentation describing use of RSE. This is the easiest of the issues to resolve, and I will ensure that both are available.

#### 2. **Use of “Statistical Degrees of Freedom”**

After consideration, I agree that it is not necessary to mention degrees of freedom in the standard and propose the following edit:

For regression or average response/calibration factor calibrations the minimum number of non-zero calibration standards shall be as specified in the table below. ~~For calibrations not listed below, the number of initial calibration standards must result in at least three statistical degrees of freedom.~~

| Type of Calibration Curve      | Minimum number of calibration standards <sup>b</sup> |
|--------------------------------|--|
| Threshold Testing <sup>a</sup> | 1  |
| Average Response               | 4  |
| Linear Fit                     | 5  |
| Quadratic Fit                  | 6  |

<sup>a</sup> The initial one point calibration must be at the project specified threshold level.

<sup>b</sup> Fewer calibration standards and degrees of freedom may be used only if equipment firmware or software cannot accommodate the specified number of standards. Documentation detailing that limitation must be maintained by the laboratory.

#### 3. **Use of the word “may” in 1.7.2.f.iii**

The language can be revised to eliminate the word “may” without changing the intent, as follows:

Data associated with an unacceptable calibration verification ~~may~~ **shall** be reported with qualification **qualified if reported**, and **shall not be reported if** prohibited by the client, a regulatory program or regulation

#### 4. **Quantitative vs. qualitative in 1.5.2.2.1.c.i of the LOQ language**

The intent is that the results be quantitative (later in the document we note that the laboratory must develop a statement of precision and accuracy at the LOQ). So, the language can be modified as follows to clarify the intent:

c) The LOQ is verified if the following criteria are met:

- i) All results are **quantitative** (above zero and meet the qualitative identification criteria of the method e.g., recognizable spectra, signal to noise requirements, and presence of qualifier ions).
- ii) **Recovery of each analyte is within the laboratory established accuracy acceptance criteria.**

If a result from an LOQ verification sample is not above zero, does not meet the qualitative identification criteria in the method, and/or **is not within the laboratory established accuracy limits**, the problem must be corrected and the verification repeated, or the LOQ verification must be repeated at a higher concentration

The NELAP AC has replied to Chemistry that these revisions and training materials satisfy their concerns. Judy asked that all LASEC members review the calibration standard (sent on June 3 with the May minutes or available at [http://nelac-institute.org/content/CSDP/standards.php?ap3=1\\_5](http://nelac-institute.org/content/CSDP/standards.php?ap3=1_5)) and the revisions above, and be ready to make our final recommendation at the next LASEC meeting.

#### *Detection and Quantitation Standard (V1M4)*

This portion of Module 4 has now undergone a membership vote, as a VDS, so that it seems it will be available for incorporation into the final “2015 standard” after all.

The biggest question raised was whether LASEC can recommend for the new NDL definition if EPA hasn’t yet approved that change – even though the Agency is expected to publish approval, it may not happen in the same timeframe. The corollary question is, once the MDL definition is published in the Method Update Rule, why should it be in the TNI standard? However, the planned MUR is only for the Clean Water Act, and it is conceivable that each media program could have a different procedure for establishing the MDL.

Another participant noted many “little things” in this portion of the standard that will need additional explanation for most users, and that is a serious concern for eventual implementation. The prospect of needing an additional form of guidance for this section of the standard could become problematic, but since comments from the voting process have not yet been addressed, it’s too soon to know what the IS will look like.

Judy established a team to look at the LOD/LOQ VDS (which is only three pages) prior to our August 25 meeting – herself, Carl, Barbara, and Jack also said he would review if it he could make time. This team should send comments to Lynn, who will compile and distribute them to the full committee before the 8/25 meeting. The VDS can be obtained from the CSDEC status table, at [http://nelac-institute.org/content/CSDP/standards.php?ap3=1\\_5](http://nelac-institute.org/content/CSDP/standards.php?ap3=1_5) (look beside V1M4.)

#### *Radiological Chemistry*

This module got overlooked when it received final approval earlier in 2015. We need to play catch-up. Carl declared that he has participated with this committee and is satisfied with the standard. Judy will reach out to George Detsis, Joe Pardue and Nile Luedtke to seek their review and input for the LASEC recommendation.

*PT Module Reviews – V1M1, V2M2, V3 & V4*

The latest revisions to these modules and volumes, as made by the PT Expert Committee at conference, were sent to LASEC and the NELAP AC on July 23.

Judy, Carl and Mitzi have consistently participated with the PT Expert Committee and been actively involved with the revision of all the PT modules. Judy asked that anyone so inclined should review the latest changes to the PT portions of the standard and send comments to this committee. Once the language for the IS is approved by PT Expert, Judy and Mitzi will draft a recommendation for LASEC consideration.

*Microbiology Standard (V1M5) – not discussed during meeting*

Three minor comments to this module were received during the voting period, and addressed at conference as either editorial or formatting issues. Prior to completion of voting, LASEC had determined the VDS to be an improvement over the previous module and implementable, so that once the final version is available, we can craft a recommendation for this module.

6) Policies for the NELAP AC

Prior to resigning, Kim did review and edit the prep method policy, as promised. It has been passed to the manager of the MN ELAP and then to Kristin for further modification, and should be available for the August LASEC meeting.

The policy pertaining to review of analytical methods during laboratory reassessments is still pending review by an LASEC member.

This discussion raised the issue of a replacement member for Kim. Several names were mentioned, and Judy asked that committee members think of who would be a good “fit” for our group. A representative from a non-NELAP state would fill the perspective that we will lack once OK submits its NELAP application later this year and we no longer have Ann Marie Allen of MA, but any stakeholder group is acceptable, since LASEC is well balanced, now.

7) Next Meeting

LASEC will meet on Tuesday, August 25, 2015, at 1:30 pm Eastern. Teleconference information and an agenda with any other materials will be sent the week before.

Action Items are included in Attachment B.

## Attachment A

**PARTICIPANTS --TNI LABORATORY ACCREDITATION SYSTEMS EXECUTIVE COMMITTEE**

|    | NAME                         | EMAIL  | TERM,<br>End<br>Date | INTEREST                    | AFFILIATION                    | S/H<br>CATEGORY                    | PRESENT |
|----|------------------------------|--|----------------------|-----------------------------|--------------------------------|------------------------------------|---------|
| 1  | Judy Morgan,<br>Chair        | <a href="mailto:Judy.Morgan@pacelabs.com">Judy.Morgan@pacelabs.com</a>                     | 3 years,<br>12/15    | Chair<br>(all)              | Environmental<br>Science Corp. | Lab/FSMO                           | Yes     |
| 2  | JoAnn Boyd                   | <a href="mailto:jboyd@swri.org">jboyd@swri.org</a>   | 3 years,<br>12/16    | StdsRev                     | Southwest<br>Research Inst.    | Lab/FSMO                           | No      |
| 3  | Kristin Brown,<br>Vice Chair | <a href="mailto:kristinbrown@utah.gov">kristinbrown@utah.gov</a>                           | 2 years,<br>2/17     | SIRs/Assmt<br>Forum/FAQ     | UT Bur. of Lab<br>Improvement  | NELAP AB                           | Yes     |
| 4  | David Caldwell               | <a href="mailto:david.caldwell@deq.ok.gov">david.caldwell@deq.ok.gov</a>                   | 2 years,<br>12/17    | Assmt<br>Forum              | OK DEQ                         | Non-NELAP<br>AB                    | Yes     |
| 5  | Karen Costa                  | <a href="mailto:Costa.Karen@epa.gov">Costa.Karen@epa.gov</a>                               | 3 years,<br>12/17    |                             | US EPA                         | Other                              | No      |
| 6  | George Detsis                | <a href="mailto:george.detsis@eh.doe.gov">george.detsis@eh.doe.gov</a>                     | 3 years,<br>12/17    | Assmt<br>Forum              | US DOE                         | Other                              | No      |
| 7  | Barbara<br>Escobar           | <a href="mailto:Barbara.Escobar@pima.gov">Barbara.Escobar@pima.gov</a>                     | 3 years,<br>12/15    | Mentor,<br>AssmtFrm,<br>FAQ | Pima County, AZ                | Lab/FSMO                           | Yes     |
| 8  | Jack Farrell                 | <a href="mailto:aex@ix.netcom.com">aex@ix.netcom.com</a>                                   | 3 years,<br>12/16    | Assmt<br>Forum,<br>StdsRev  | Analytical<br>Excellence       | Other                              | Yes     |
| 9  | Bill Hall                    | <a href="mailto:George.Hall@des.nh.gov">George.Hall@des.nh.gov</a>                         | 3 years,<br>12/16    | SIRs,FAQs                   | NH ELAP                        | NELAP AB                           | Yes     |
| 10 | Betsy Kent                   | <a href="mailto:bkent@rcid.org">bkent@rcid.org</a>   | 3 years,<br>12/15    | Mentor<br>Sessions          | Reedy Improv.<br>District, FL  | Lab/FSMO                           | No      |
| 11 | Carl Kircher                 | <a href="mailto:carl_kircher@doh.state.fl.us">carl_kircher@doh.state.fl.us</a>             | 3 years,<br>12/15    | SIRs, FAQs                  | FL DOH                         | NELAP AB                           | Yes     |
| 12 | Mitzi Miller                 | <a href="mailto:mitzi.miller@moellerinc.com">mitzi.miller@moellerinc.com</a>               | 2 years,<br>12/17    | FAQs                        | Dade Moeller,<br>Inc           | Other                              | No      |
| 13 | William Ray                  | <a href="mailto:Bill_Ray@williamrayllc.com">Bill_Ray@williamrayllc.com</a>                 | 3 years,<br>12/17    |                             | Wm Ray<br>Consultants          | Other                              | Yes     |
| 14 | Carol Schrenkel              | <a href="mailto:CSchrenkel@suburbantestinglabs.com">CSchrenkel@suburbantestinglabs.com</a> | 3 years,<br>12/16    | Mentor,<br>Ass. Forum       |                                | Other                              | No      |
| 15 |                              |  |                      |                             |                                |                                    |         |
|    | Elizabeth<br>Turner          | <a href="mailto:eturner@ntmwd.com">eturner@ntmwd.com</a>                                   |                      | Ex Officio                  | Small Lab Issues               | North TX<br>Mun. Water<br>District | No      |

|                   |                                |  |  |                      |                                  |          |     |
|-------------------|--------------------------------|--|--|----------------------|----------------------------------|----------|-----|
| Associate Members |                                |  |  |                      |                                  |          |     |
|                   | Aaren Alger                    | <a href="mailto:aaalger@pa.gov">aaalger@pa.gov</a>   |  |                      | PA DEP                           | NELAP AB | No  |
|                   | Carol Barrick                  | <a href="mailto:cabarrick@msn.com">cabarrick@msn.com</a> ,<br><a href="mailto:Carol.Barrick@mosaicco.com">Carol.Barrick@mosaicco.com</a> |  |                      | FCC<br>Environmental             | Lab/FSMO | No  |
|                   | Myron Gunsalus                 | <a href="mailto:ngunsalus@kdheks.gov">ngunsalus@kdheks.gov</a>   |  |                      | KS Lab Accred.                   | NELAP AB | yes |
|                   | Carol Haines                   | <a href="mailto:bio.haines@gmail.com">bio.haines@gmail.com</a>   |  | Stds Rev,<br>ad hocs | Retired from EPA<br>as of 5/1/15 | Other    | No  |
|                   | Christelle Newsome             | <a href="mailto:cnewsome@c2nassociates.com">cnewsome@c2nassociates.com</a>   |  |                      | C2N Associates,<br>Inc.          | Other    | No  |
|                   | Gale Warren                    | <a href="mailto:ggw01@health.state.ny.us">ggw01@health.state.ny.us</a>   |  | SIRs                 | NY ELAP                          | NELAP AB | No  |
|                   | Program Admin.<br>Lynn Bradley | <a href="mailto:Lynn.bradley@nelac-institute.org">Lynn.bradley@nelac-institute.org</a>   |  |                      |                                  |          | Yes |
|                   |                                |  |  |                      |                                  |          |     |

**Attachment B**

**Action Items – LAS EC**

|    | <b>Action Item</b>  | <b>Who</b>                              | <b>Expected Completion</b>                                  | <b>Actual Completion / Comments</b>  |
|----|---|---|---|--|
| 42 | Craft wording for recommendation about PT modules   | Judy/Mitzi                              | Before conference in Chicago<br>Prior to August 25 meeting? |  |
| 43 | Draft memo to LASEC re needing full member attendance at meetings   | Lynn send to Judy                       | May 2015  | 6/3/15 – still needs sent to committee, or else the couple of members who never attend and are not active in AF/MS planning should receive personal follow-up? |
| 48 | Contact Kirstin Daigle about reviewing and editing the on-site assessment draft policy                            | Judy                                    | ASAP – sometime in August?                                  |  |
| 49 | Comment on the VDS as reviewed for committee recommendation purposes  | Kristin-V1M4-LOD/LOQ;<br>ESC staff-V1M5 | NLT July 5  | Still pending  |
| 50 | Highlight revisions to V1M4-Calibration, and distribute to LASEC for review, for final recommendation to NELAP AC | Judy                                    | June 26, 2015   | OBE – NELAP objections addressed at conference in Chicago (see above)  |
| 51 | Review LOD/LOQ standard   | Judy, Carl, Barbara, and Jack           | Friday, August 21, 2015                                     |  |
| 52 | Contact G. Detsis, J. Pardue and Nile Luedtke re review of rad module   | Judy                                    | soon  |  |
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