Laboratory Accreditation System Executive Committee Meeting Minutes
September 22, 2015

1) Welcome and Roll Call

Judy Morgan welcomed everyone to the meeting. Those in attendance are recorded in Attachment A. Minutes from July 28 and August 25 were approved. Lynn noted that we have another Associate Member, Kirstin Daigle of TestAmerica. Kirstin was formerly Chair of the committee, but became inactive for a while and has now returned.

2) Assessment Forum and Mentor Session

Jack reported that the workgroup had a good teleconference the previous week, and has a tentative agenda and plan for conference in Tulsa. They have asked that the order of sessions be modified to have the Mentor Session follow the Assessment Forum so that the Mentor Session can delve more deeply into an Assessment Forum topic. They also plan to involve David Caldwell heavily, so that the sessions can focus on helping OK labs comply with OK regulations, since at that point, OK will be undergoing the NELAP AB evaluation process. The tentative agenda is in Attachment C.

Planners asked that all committee members consider and suggest new presenters for the various topics, particularly small laboratory folks, so that the "same old" faces don't continue to appear at every conference.

One participant asked that planners consider replacing the term "root cause" with "causal effect" or some similar alternative phrase, since many people seem to dislike "root cause."

Jack asked that LASEC prepare a summary of the Chicago Assessment Forum from Barbara's notes, and make that available as guidance for Assessors and QA staff.

3) SIR Subcommittee

The subcommittee did not meet this month, but one action was taken. In response to a "two-week notice" email issued to the NELAP AC (per its Voting SOP 3-101, for SIRs that have incomplete voting but do have approval by the required two-thirds majority), an AC representative suggested that SIR #132 (as approved) actually conflicts with the wording being incorporated into the revised standard, and therefore #132 should not be published.

After due consideration, Judy agreed with this position as well as the suggestion that the issue can only be clarified by actually defining certain types of volumetric glassware. It is established policy that definition language cannot be added through the SIR process, as that would actually expand the standard itself rather than "interpreting" it, so SIR #132 will be withdrawn and the submitter notified that the issue cannot be addressed through a SIR. This notification will also include a short paragraph apologizing for the prolonged delay and explaining that only upon extended discussion did we realize where the problem lay.

Judy agreed to verify the status of this issue with the Quality Systems Expert Committee as its revision of V1M2 is underway.

4) Status of Standards Review

Calibration Standard – revision of sections 1.7.1-1.7.2 of V1M4 is now complete, and a draft recommendation was offered for LASEC approval that includes development of the agreed-upon guidance for Relative Standard Error calculations. Other agreed-upon technical edits have already been made and the correct version of the standard is posted in the status table. A copy of this draft recommendation is included in Attachment D, below.

Several participants raised new objections to this version of the Calibration Standard, despite what we believed to be a successful resolution to its contentious history. One offered the opinion that it is neither auditable nor implementable. For specific issues, first, the language in correction 2 (in the draft recommendation) was noted to be inconsistent with one AB's current practice, and could lead to endless re-running of CCV samples. Second, while there were no adverse comments about removing the reference to "statistical degrees of freedom," one participant objected to the examples stopping at quadratic, even though the standard had no prohibition against using other calibration models.

The chair asked for a vote, since a quorum was present. Kirstin moved and Barbara seconded that the recommendation be adopted. With 8 people present, there were 5 aye votes, one nay and two abstentions. Since the five votes to approve are actually less than half of the committee (current membership is 14 full members plus one ex officio), Judy asked that the vote be kept open and completed by email to the rest of the committee.

PT Modules (V1M1 and V2M2) – Judy stated that many comments were submitted during voting on the Interim Standards, that closed on August 21. Thus, it is premature to formulate a recommendation for the PT modules, despite what we discussed at earlier committee meetings.

5) On-Site Assessment Policy for the NELAP AC

Kirstin had added material to the formatted statement from the LAB Expert Committee, and this becomes the working draft policy for LASEC. She explained that she sought to create a document that could establish consistency among ABs, meet the intent of the ISO standard and provide some guidance for the ABs about how to use their resources. The discussion draft is included as Attachment E, below.

While it might be ideal to review all methods in a lab's scope of accreditation – and the EPA Drinking Water program has set a clear expectation that all drinking water methods must be assessed – that is an impractical workload. ISO 17011 allows for assessment of a selection of methods but does not set parameters for making that selection. As a first issue, if we establish a baseline of the minimum requirements for review of a method (assessment), we will then have a common understanding upon which to estimate the workload and establish a practical attainable selection process. Then secondarily, we need to decide whether to set requirements for method review, for instance based on technology or some other criteria, or establish a proportionate requirement, perhaps on a sliding scale that depends on the lab's scope?

Comments made during discussion included the following:

- the “shoulds” and “shalls” in the draft policy will need to be made consistent and preferably mandatory
- the goal is consistency across the NELAP ABs -- this consistency is particularly important where several ABs have only 1-2 assessors doing all the work, while other ABs can send 3-5 assessors to large labs for a week
- sampling is acceptable but probably not for drinking water or initial accreditations, only for reaccreditations and surveillance assessments
- document and data review off-site may be used to supplement the on-site method reviews
- should raw data be reviewed for some subset of assessed methods? Other aspects subject to review are method SOPs, PT results, demonstrations of competency, MDLs, LOD/LOQ establishment and interviews with the analysts
- much of the method information can be reviewed prior to the site visit, as the assessor can request data packages, audit reports and PT results for off-site review
- if all methods are reviewed, then a sampling of “pieces” should be examined, but if a sampling of methods is to be reviewed, then all aspects of the method should be examined, including traceability of standards.

Barbara, Jack and Judy offered to send sample pre-audit letters to Kirstin (and LAS) to help in formulating a review scheme. We also discussed what an appropriate level of detail for a policy document might be, since the policy document sets expectations rather than describing actual practices, and that some additional information might need to go in an accompanying procedure instead. Participants agreed that a procedure might become necessary, but to focus on the policy aspects first.

6) Next Meeting

LASEC will meet on Tuesday, October 27, 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, End Date	INTEREST	AFFILIATION	S/H CATEGORY	PRESENT
1	Judy Morgan, Chair	Judy.Morgan@pacelabs.com	3 years, 12/15	Chair (all)	Environmental Science Corp.	Lab/FSMO	Yes
2	JoAnn Boyd	jboyd@swri.org	3 years, 12/16	StdsRev	Southwest Research Inst.	Lab/FSMO	No
3	Kristin Brown, Vice Chair	kristinbrown@utah.gov	2 years, 2/17	SIRs/Assmt Forum/FAQ	UT Bur. of Lab Improvement	NELAP AB	Yes
4	David Caldwell	david.caldwell@deq.ok.gov	2 years, 12/17	Assmt Forum	OK DEQ	Non-NELAP AB	No
5	Karen Costa	Costa.Karen@epa.gov	3 years, 12/17		US EPA	Other	Yes
6	George Detsis	george.detsis@eh.doe.gov	3 years, 12/17	Assmt Forum	US DOE	Other	Yes
7	Barbara Escobar	Barbara.Escobar@pima.gov	3 years, 12/15	Mentor, AssmtFrm, FAQ	Pima County, AZ	Lab/FSMO	Yes
8	Jack Farrell	aex@ix.netcom.com	3 years, 12/16	Assmt Forum, StdsRev	Analytical Excellence	Other	Yes
9	Bill Hall	George.Hall@des.nh.gov	3 years, 12/16	SIRs,FAQs	NH ELAP	NELAP AB	Yes
10	Betsy Kent	bkent@rcid.org	3 years, 12/15	Mentor Sessions	Reedy Improv. District, FL	Lab/FSMO	No
11	Carl Kircher	carl_kircher@doh.state.fl.us	3 years, 12/15	SIRs, FAQs	FL DOH	NELAP AB	Yes
12	Mitzi Miller	mitzi.miller@moellerinc.com	2 years, 12/17	FAQs	Dade Moeller, Inc	Other	No
13	William Ray	Bill_Ray@williamrayllc.com	3 years, 12/17		Wm Ray Consultants	Other	Yes
14	Carol Schrenkel	CSchrenkel@suburbantestinglabs.com	3 years, 12/16	Mentor, Ass. Forum		Other	No
15							
	Elizabeth Turner	eturner@ntmwd.com		Ex Officio	Small Lab Issues	North TX Mun. Water District	No

Associate Members							
	Aaren Alger	aaalger@pa.gov			PA DEP	NELAP AB	No
	Carol Barrick	cabarrick@msn.com, Carol.Barrick@mosaicco.com			FCC Environmental	Lab/FSMO	No
	Kirstin Daigle	Kirstin.daigle@testamericainc.com			TestAmerica	Lab	Yes
	Myron Gunsalus	ngunsalus@kdheks.gov			KS Lab Accred.	NELAP AB	Yes
	Carol Haines	bio.haines@gmail.com		Stds Rev, ad hocs	Retired from EPA as of 5/1/15	Other	No
	Dorothy Love	dorothylove@eurofinsus.com			Eurofins Env't'l	Lab	Yes
	Christelle Newsome	cnewsome@c2nassociates.com			C2N Associates, Inc.	Other	No
	Gale Warren	ggw01@health.state.ny.us		SIRs	NY ELAP	NELAP AB	No
Program Admin. Lynn Bradley		Lynn.bradley@nelac-institute.org					Yes

Attachment B

Action Items – LAS EC

	Action Item	Who	Expected Completion	Actual Completion / Comments
42	Craft wording for recommendation about PT modules	Judy/Mitzi	After comments from IS voting are reviewed and addressed?	
43	Draft memo to LASEC re needing full member attendance at meetings	Lynn send to Judy	May 2015	6/3/15 edits re-sent to Judy at new email
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; ESC staff-V1M5	NLT July 5	Still pending
51	Review LOD/LOQ standard	Judy, Carl, Barbara, and Jack	Friday, August 21, 2015	Awaiting feedback from JoAnn
52	Contact G. Detsis, J. Pardue and Nile Luedtke re review of rad module	Judy	soon	All but Detsis are actually on the expert committee. OBE.
53	Contact Quality Systems Expert Committee about the issue of SIR #132	Judy	ASAP	
54	Send sample pre-audit letters to Kirstin	Barbara, Judy, Jack	ASAP	
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58				

Attachment C

Tentative Agenda for Assessment Forum and Mentor Session in Tulsa

Monday 1/25 Afternoon:
Assessment Forum – Preparing to be TNI Compliant

1pm-1:10 pm	Intro
1:10 pm-2:15pm	Training on Regulations – David Caldwell Changes to be expected for Oklahoma Standard coverage of MDLs and PTs
2:15pm -3pm	Panel discussion on How to Comply & What are the Pitfalls in Accreditation -- New state labs, Oklahoma labs, Jack, David, Someone from Virginia, Minnesota, maybe Cathy Westerman and Lynn Boysen
3pm-3:30 pm	Break
3:30pm-4:30pm	Continue Panel Discussion
4:30 pm-5pm	Close-out, Evaluations and Future topics

Tuesday 1/26 Morning:
Assessment Forum – Preparing for TNI Assessments

8:00am – 8:15am	Intro
8:15 am-	How to Perform Effective Internal Audits 20-30 minute presentations - 2-3 QA Officers (e.g. Dorothy Love, & someone from small lab too) – David will make possible suggestions of a QA officer from an OK lab.
10:00am-10:30am	Break
10:30 pm	Mock Assessment Interviews – Patty Snyder
11:00am-12pm	Corrective Action Process with Top Audit Findings -

Tuesday 1/26 Afternoon:
Mentor Session – How to do a Corrective Action/Root Cause Analysis

1pm-1:10 pm	Intro
1:10 pm-3pm	Panel Discussion on How to perform CARS… (Jack, David, Kristen, and more).
3:00pm-3:30pm	Break
3:30-4:30pm	Work through Root Cause Analysis on some of the Common Findings found in the earlier Assessment Forum.
4:30 pm-5pm	Close-out, Evaluations and Future topics

Attachment D

Draft Recommendation of LASEC to NELAP AC
TNI Standard V1M4 Sections 1.7.1-1.7.2, September 2015 (aka the Calibration Standard)

The LASEC has reviewed the Calibration Standard (V1M4 §1.7.1-1.7.2) and in accordance with the LASEC Standards Review for Suitability SOP 3-106, is providing the recommendation to adopt this new version of the subject standard, with the following condition:

> Guidance on the use of Relative Standard Error is needed, so that the ABs can share it with their laboratories to aid in consistent implementation of this standard. We understand that the Chemistry Expert Committee will provide this guidance in the form of both a written document and a publicly available video presentation (such as YouTube) describing use of RSE. We will ask that these will be provided to the NELAP AC for review prior to being finalized.

As agreed during the Joint Committee meeting at conference in Chicago (July 16, 2015), the subject version (now posted to the website) includes two editorial changes made after the final vote of approval, as follows:

1) The term "Statistical Degrees of Freedom" was removed from the standard in §1.7.1.1.e, since it is confusing and susceptible to a variety of interpretations. The Chemistry Expert Committee replaced the language with 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[b]
Threshold Testing[a]	1
Average Response	4
Linear Fit	5
Quadratic Fit	6

   [a] The initial one point calibration must be at the project specified threshold level.
   [b] 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.

2) The word "may" in 1.7.2.f.iii was replaced with language to make the handling of unacceptable calibration verifications mandatory instead of optional, 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

Attachment E

Policy TITLE:	**On-Site Assessment of Analytical Methods**
Policy NO.:	**3-XXX**
REVISION NO:	**0**
Program	**NELAP**

I. PURPOSE AND APPLICABILITY

Each recognized NELAP Accreditation Body (AB) understands that confidence in its accreditation decisions needs to be instilled in many affected parties, inclusive of laboratory clients, officials making environmental protection and public health decisions, users of analytical data, the laboratory community seeking competent subcontractors, NELAP AC members granting secondary accreditations, and The NELAC Institute. The principle of recognition is also a fundamental concept in a national environmental laboratory accreditation program.

This policy establishes the expectations NELAC ABs to follow during the assessment of test methods during the NELAC accreditation process, so that all parties to the NELAP Mutual Recognition Policy 3-100 and all other stakeholders may be assured that equivalent practices between NELAC ABs are followed regarding the extent to which test methods are reviewed and how.

This policy applies to the assessment of all NELAC fields of accreditation, regardless of regulatory program.

II. SUMMARY

The policy establishes the responsibilities of NELAP ABs for the review of test methods during on-site assessments for purposes of NELAC accreditation.

III. DEFINITIONS – need to identify items belonging in this section

All definitions are incorporated by reference to maintain consistency within the TNI organization.

NELAP Accreditation Body as defined in Vol 2, Mod 1, and Vol 2, Mod 2
NELAP Accreditation Council as defined in the TNI Bylaws ~~2010, as amended~~
Standard as defined in Vol. 1 Mod. 2
Conformity Assessment Body as defined in Vol.2 Mod. 3
Primary Accreditation Body as defined in Vol. 2 Mod. 2
~~Secondary Accreditation Body as defined in Vol. 2 Mod. 2~~

IV. RESPONSIBILITIES OF A NELAP ACCREDITATION BODY FOR INITIAL ASSESSMENT AND REASSESSMENTS

The EPA OGWDW requires that all drinking water test methods for which the laboratory holds or seeks NELAC accreditation be assessed individually at each on-site assessment. Therefore, all NELAC ABs must comply with this EPA requirement when the NELAC AB performs initial and all reassessments.

For the initial assessment of the laboratory for non-drinking water fields of accreditation, the NELAP AB should review each analytical method associated with each field of accreditation for which the laboratory seeks NELAC accreditation. However this recommendation may be impractical based on the scope and complexity of the laboratory's application for accreditation. For initial assessments; the NELAB AB should review a representative number of test methods to assess competency using the following guidelines: INSERT GUIDELINES AFTER DISCUSSION – See next page for discussion notes.

For reassessment; those assessments performed at intervals of two years plus or minus six months, the NELAP AB should review a representative number of methods to assess continued competency using the following guidelines: INSERT GUIDELINES AFTER DISCUSSION

During test method review, each NELAC ABs should minimally review the following items:

1. Test Method Standard Operating Procedure (SOP): The NELAC AB should compare the laboratory's SOP to the reference method for compliance and to ensure any SOP modifications to the reference method are listed in the SOP with justification for the modification.
2. Method Validation Data: The NELAC AB should review the validation data for the test method as defined by the laboratory's quality system.
3. Proficiency Testing Results
4. Traceability of Reference Materials
5. Equipment Maintenance Records

The NELAC AB Assessor should interview the analyst(s) that routinely performs the test method. The NELAC AB should select the analyst for interview from initial and on-going demonstration of proficiency records. During the interview the NELAC AB Assessor should review test method setup in the data acquisition software, the laboratory's LIMS system or whichever platform is used the by laboratory. The assessor should review instrument data for initial calibration, instrument performance checks and quality control for compliance to the test method SOP. The assessor should verify nonconformance is handled in accordance with the test method SOP. The assessor should ask the analyst to show them the analytical process from start to finish ascertaining the analyst has a solid understanding of the test method and associated laboratory systems and procedures.

LASEC DISCUSSION POINT: Language from V2M3 Below provided for LASEC reference. Also please have a copy of Appendix 1 of this document handy for reference during discussion. An issue with this policy, appendix 1 and the standard is that none of the documents establish the min requirements for test method review during the assessment. To meet the intent of the policy (to instill confidence in stakeholders and ensure equivalent practices are followed by all ABs (this policy must first establish min requirements for the process of method review; then we can determine what constitutes a representative number of methods that need to be assessed. I have inserted language for the test method review process to prompt discussion.

6.3.5 *ISO/IEC 17011:2004(E), Clause 7.5.6*
The accreditation body shall establish procedures for sampling (if applicable) where the scope of the CAB covers a variety of specific conformity assessment services. The procedures shall ensure that the assessment team witness a representative number of examples to ensure proper evaluation of the competence of the CAB.

NOTE: Accreditation bodies should establish procedures for selecting systems, methods and analytical activities that will be observed during an on-site assessment based on the accreditation scope and complexity of the CAB to be assessed. Assessors should strike a balance between thoroughness and practicality while determining the extent to which CABs meet this Standard. The examination of the systems, processes and procedures of the CAB should give a general sense of its past and present capabilities to perform work of known and documented quality.

6.9.2 *ISO/IEC 17011:2004(E), Clause 7.7.3*
The assessment team shall witness the performance of a representative number of staff of the CAB to provide assurance of the competence of the CAB across the scope of accreditation.

V. RESPONSIBILITIES OF A NELAP ACCREDITATION BODY DURING SURVEILLANCE ASSESSMENTS AND EXTRAORDINARY ASSESSMENTS.

According to Section 6.13 V2M3, NELAC ABs should have procedures and plans in place for carrying out surveillance on-site assessments and surveillance activities. The surveillance on-site assessments and surveillance activities are to be performed by the NELAC AB between the initial assessment and the reassessment and between each reassessment thereafter.

If the NELAC AB performs surveillance on-site assessments then the AB should include at least X method review as part of the on-site assessment.

According to Section 3.7 V2M3, NELAC ABs should perform extraordinary assessments when there is a complaint against the laboratory, changes in laboratory ownership, key personnel, scope of accreditation or other matters that may affect the ability of the laboratory to fulfill accreditation requirements.

If the NELAC AB performs an extraordinary assessment effort due to a complaint about the laboratory's compliance for a test method then the NELAC AB must review the test method as part of the assessment. If the extraordinary assessment is performed in order to add to the laboratory's scope of accreditation; then the NELAC AB should follow the same guidelines set in this policy for initial assessment.

VI. REFERENCES

TNI Environmental Laboratory Sector Standard, Volume 2, Modules 1 and 3

VII. DISPUTES

Disputes between or among NELAP accreditation bodies relating to this policy shall be resolved according to the appropriate TNI policy or procedure.

VIII. EFFECTIVE DATE

This policy becomes effective on, and remains in effect until amended or revoked by the TNI NELAP Accreditation Council.

Policy Approved Changes- Need to update when revision is complete.

Prev. Policy No.	New Policy No.	Date of Change	Description of Change
n/a	3-XXX	6/20/15	Policy paragraphs approved by LAB Expert Committee edited and formatted into appropriate template for Policy documents, for transmission to LASEC for further review and recommendation to the NELAP AC