Laboratory Accreditation System Executive Committee Meeting Minutes
October 27, 2015

1) Welcome and Roll Call

Judy Morgan welcomed everyone to the meeting. Those in attendance are recorded in Attachment A. Minutes from September 22 were approved.

2) New Member Vote

In response to Judy's email about this committee's need for members who can participate in our meetings, in order to have a quorum so that we can effectively address our standards review responsibilities (and other activities), Carol Schrenkel asked to be moved into the Associate Member category. This left two open slots, one for an AB stakeholder and the other for a LAB stakeholder. The AB stakeholder slot remains unfilled for now, but the earlier of the two Associate Members who applied to be full members, Dorothy Love, was nominated for membership. Jack moved and Kristin seconded that her nomination be approved, and the vote was unanimous. Welcome, Dorothy!

2) Assessment Forum and Mentor Session

Barbara discussed the updated agendas for both meetings in Tulsa. Two of the planned presenters will need to be replaced, for the Assessment Forum, and Betsy Kent will be unable to attend but it looks as if Barbara will attend after all. See Attachment C for current draft agenda.

George offered to provide a presentation from the recent DOE meeting, about common findings during lab assessments, and how sometimes the initial findings are repeated in later assessments. This could be used as part of the broader issue of common initial findings, and the importance of management system reviews in preventing recurrences of findings.

3) SIR Subcommittee

The subcommittee met immediately prior to the full committee meeting, and approved three "recycled" SIR interpretations from Quality Systems Expert Committee to be posted for vote by the AC.

Three clarifications were discussed as well. Two are "on hold" pending final revisions to the QS module (V1M2) of the standard and the third already has a rough draft completed.

4) Status of Standards Review

Outline for Guidance for the Calibration Standard – The Chair of the Chemistry Expert Committee offered an outline for the agreed-upon guidance for Relative Standard Error calculations, in early October. While waiting for the LAS meeting, the Chair asked that the NELAP AC also consider that guidance and whether they had any comments.

Participants in this LASEC meeting offered the following suggestions in addition to the NELAP AC's comments (which are the last of the list.) It was generally well received and there were no adverse comments.

- A presentation on the choices of calibration models would be helpful,
- Recommended criteria and requirements for selecting a calibration model are needed,
- The guidance should recommend that labs provide a justification for choosing to use the more exotic calibration models,
- The guidance needs to include an explanation of the usefulness of RSE as well as actual examples of how RSE is used, in order to demonstrate that using RSE improves the analysis rather than being just one more calculation to make, since labs may not know how best to apply RSE to the analytical process,
- Since most labs have not been exposed to RSE, it needs to be explained in "plain English" and made understandable, not by repeating language of the standard or an advanced chemistry text but words that an analyst in a small lab who is unfamiliar with it will be able to readily comprehend,
- The examples need to encompass categories such as inorganics, wet chemistry and metals, not just organics, and lastly,
- The AC's recommendations were to "keep it simple" and to have the language of the guidance reference the related section of the standard, in order to be absolutely clear that the guidance is an illustration of the standard and not somehow to become an addition to the standard.

These suggestions will be returned to the Chemistry Expert Committee.

Participants expressed a strong preference to have a SEPARATE guidance document for the Detection and Quantitation sections of V1M4, since combining that with calibration is likely to be more confusing than clarifying.

Judy also noted that we would like to have a panel of small labs to review the guidance document for comprehensibility, and the perhaps TNI's Small Lab Advocate, Elizabeth Turner, can identify members for a focus group for this purpose? Also, the possibility of presenting the guidance in a future Assessment Forum was mentioned.

Judy will present LASEC's recommendation about the Calibration Standard to the NELAP AC at its November 16 meeting.

<u>Other Parts of the Revised Standard</u>

Judy noted that Quality Systems (V1M2) and Microbiology (V1M5) modules are presently open for voting, and that the PT Expert Committee is still addressing comments from the most recent vote on Interim Standards.

The Radiological module can be approved and a recommendation statement for LASEC approval will be drafted for the November meeting.

5) On-Site Assessment Policy for the NELAP AC

Kirstin described how she approached the revision presented for committee review at this meeting. With feedback from the September meeting, she updated the title but not any of the definitions yet, and did a bit of research on models for representative sampling (selecting methods) in order to revise the policy further. See Attachment D for the current draft revision.

Discussions of this second revision brought improved clarity on what the committee wants the policy to address, as well as praise for Kirstin for her efforts and progress in tackling this very difficult issue. Specific comments follow:

- The types of methods need specifically to mention that microbiology methods are included
- Every initial lab assessment should cover 100% of methods
- Reassessments can appropriately cover some selection of methods chosen from each of the technologies named in the standard and possibly sub-categories of those technologies (such as semi-volatile organics,) as well as "prep methods." (NOTE: from V1M3 §4.2.4: Technical disciplines applicable to the environmental sector include microbiology, toxicity testing, inorganic non-metals, metals, organics, asbestos, radiochemistry, and field activities.)
- The introductory portion of the policy should include a statement about the need for a comprehensive assessment of each lab's quality system, and note that this policy addresses only the selection of test methods to be assessed.
- For non-drinking water methods, an assessor might review 1 to 10 methods in a day
- One participant asked that the title be revised to "minimum requirements for assessment of test method selection" but after discussion, the group agreed that the title proposed, "Minimum requirements for test method selection for assessments" is the appropriate wording, since a policy would not provide procedures for the actual assessment.
- There needs to be an instruction that SOPs be linked to test methods
- For reassessments, the actual selection of methods should be also informed by the previous assessment findings, to ensure that effective corrective actions were implemented
- The NELAP AC has requested this policy to ensure consistency in the selection of methods to be assessed
- A lot of useful and relevant material may be found in Appendix C of Chapter 3, in the 2003 NELAC Standard
- State assessments have varied widely, over the years, in the number of assessors and time spent in the lab, so that consistency will be welcomed by the labs as well as the ABs.

Kirstin believes that this policy cannot be created until the ABs agree on what a "test method audit" actually is. However, a policy is not the appropriate document to specify those procedural details, but a procedure could be developed to accompany the policy.

At this point, the allotted meeting time was over. Kirstin indicated that she will take the comments back and again refine the draft policy, and thanked participants for helping clarify what they believe the policy should address, and how.

6) Next Meeting

LASEC will meet on Tuesday, November 24, 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	Yes
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	Dorothy Love	dorothylove@eurofinsus.com			Eurofins Env't'l	Lab	Yes
13	Mitzi Miller	mitzi.miller@moellerinc.com	2 years, 12/17	FAQs	Dade Moeller, Inc	Other	No
14	William Ray	Bill_Ray@williamrayllc.com	3 years, 12/17		Wm Ray Consultants	Other	No
15							
Ex Officio							
	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
	Christelle Newsome	cnewsome@c2nassociates.com			C2N Associates, Inc.	Other	No
	Carol Schrenkel	CSchrenkel@suburbantestinglabs.com	3 years, 12/16	Mentor, Ass. Forum		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
Guests – Steve Arms		Steve.Arms@flhealth.gov					

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	Sent Sept 18, 2015
48	Contact Kirstin Daigle about reviewing and editing the on-site assessment draft policy	Judy	ASAP – sometime in August?	Kirstin actively drafting POL 3-XXX
49	Comment on the VDS as reviewed for committee recommendation purposes	Kristin-V1M4-LOD/LOQ; ESC staff-V1M5	NLT July 5	Comments submitted by individuals during voting period
51	Review LOD/LOQ standard	Judy, Carl, Barbara, and Jack	Friday, August 21, 2015	Awaiting feedback from JoAnn OBE – voting now open, please review and vote!
53	Contact Quality Systems Expert Committee about the issue of SIR #132	Judy	ASAP	SIR withdrawn, may become a clarification.
54	Send sample pre-audit letters to Kirstin	Barbara, Judy, Jack	ASAP	?
55	Draft recommendation for Rad module, for November meeting	Lynn/Judy	November 18	
56				
57				
58				

Attachment C

Tentative Agenda for Assessment Forum and Mentor Session in Tulsa
– October 20 version

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* Panelists: New TNI labs/Oklahoma: David from OK, ~~Cathy Westerman from VA~~ and ~~Lynn Boysen from MN~~ & Jack Farrell representing third party
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- 9:30 am	How to Perform Effective Internal Audits 15 minute presentations – 3-4 QA Officers/Lab Managers Presenters: Barbara Escobar from Pima County, Star Yuan from OK Municipal Labs, Utah QA Officer (suggested by Kristin)…others?
9:30am-10:30am	Break
10:30 am-11am	Mock Assessment Interviews – Patty Snyder/Jack Farrell
11:00am-12pm	Panel on *Common Assessment Findings for Initial and Seasoned Laboratories* Panelist: David from OK, Mike Shepard third party, George Detsis from USDOE, ~~Cathy Westerman from VA~~, ~~Lynn Boysen from MN~~.

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 Initiate Effective Corrective Action Reports*. Panelists: Michael Shepard, third party, David from OK, Kristen from UT.
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 -- Jack Farrell and panelists
4:30 pm-5pm	Close-out, Evaluations and Future topics

Attachment D – Revised Draft of On-Site Assessment Policy

Policy TITLE:	~~**On-Site Assessment of Analytical Methods**~~ **Minimum Requirements for Test Method Selection for Assessments**
Policy NO.:	**3-XXX**
REVISION NO:	**0**
Program	**NELAP**

LAB Approved Date (unformatted version, see Appendix 1):	6/16/2015
LASEC Approved Date:	
NELAP AC Approved Date:	
Policy Committee Reviewed Date:	
TNI Board of Directors Endorsed Date:	
POL Effective Date:	

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~~ minimum requirement and the procedure NELAC ABs ~~to follow during the~~will use to select the number and type of ~~assessment of~~of test methods to include in assessments 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 for the selection of test methods for assessment is followed ~~between~~ by all NELAC ABs~~ are followed regarding the extent to which test methods are reviewed and how.~~ This policy does not establish procedure requirements for test method review by NELAC ABs. Minimum requirements and guidelines for test method review are specified in SOP XXXX.

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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 expects NELAC ABs to assess each drinking water test method for which the laboratory holds or seeks NELAC accreditation with each on-site assessment. Therefore, all NELAC ABs shall comply with this EPA expectation and assess each drinking water test method during each initial assessment and each subsequent reassessment.

The following sections apply to test method review for non-drinking water fields of accreditation.

Ideally, the NELAC AB would assess each test method associated with each field of accreditation for which the laboratory seeks NELAC accreditation. However this recommendation may be impractical based size and complexity of the laboratory scope of accreditation. For the initial assessment and reassessment of the laboratory for non-drinking water fields of accreditation the NELAC AB shall review a representative number of test methods to assess competency associated with each field of accreditation for which the laboratory seeks or maintains NELAC accreditation.

With representative sampling the NELAC AB shall select a subset of tests methods to assess that accurately reflects the non-drinking water scope of accreditation.

For example, a laboratory's non-drinking water scope of accreditation includes 100 test methods, 50 of which are inorganic test methods and 50 of which are organic test methods. In this case, a representative sample for test method review might include 20 test methods, 10 inorganic, 10 organic.

Rarely are the variables of the population so evenly balanced. In which case, the NELAC AB shall use purposive sampling to ensure the representative sample is evenly balanced between the variables.

With purposive sample the test method review quotas shall be set to match the profile of the non-drinking water scope of accreditation.

For example, the non-drinking water test methods listed on a laboratory's scope of accreditation are categorized as 70% organic and 30% inorganic. Thus the test methods selected for review during the assessment shall match this profile.

The number of test methods selected for review shall be based on the size of the non-drinking water scope of accreditation and the profile using the following guidelines:

LASEC Discussion: I set the set value so that test method review represents 20% of the scope regardless of scope size. I chose a fixed guideline, in which case the larger the scope of

accreditation, the more methods are reviewed. This is contrary to the ideal by the LAB committee in Appendix 1 that all methods be reviewed. The ideal is more likely to be achieved the smaller the scope so I think the set value should be set so that the smaller the scope, the more methods reviewed. The set value can be fixed or variable and it can be whatever the LASEC decides. Whatever the set value, the formula used to determine the size of the representative, purposive sample is the same and is a consistent objective, process.

# of Non-Drinking Water Test Methods	Set Value.
100+	5
51-99	5
26-50	5
11-25	5
1-10	5

To determine the number of test methods to review by each variable (organic and inorganic). The NELAC AB shall multiply the review quota (established by the profile) by the number of test methods then divide this result by the set value. Round up (or down- I rounded up in these examples – this is why bullet 4 is 22%)

For example, the test methods in a laboratory's scope of accreditation for non-drinking water methods are profiled as 60% inorganic and 40% organic:

- If the number of non-drinking water methods for which the laboratory seeks or holds accreditation is 110; a purposive sample for test method review includes 13 inorganic methods and 9 organic methods. (22 Total = 20% of non-drinking water scope)

- If the number of non-drinking water methods for which the laboratory seeks or holds accreditation is 83; a purposive sample for test method review includes 10 inorganic methods and 7 organic methods. (17 Total = 20% of non-drinking water scope)

- If the number of non-drinking water methods for which the laboratory seeks or holds accreditation is 45; a purposive sample for test method review includes 5 inorganic methods and 4 organic methods. (9 Total = 20% of non-drinking water scope)

- If the number of non-drinking water methods for which the laboratory seeks or holds accreditation is 23 a purposive sample for test method review includes 3 inorganic methods and 2 organic methods. (5 Total = 22% of non-drinking water scope)

- If the number of non-drinking water methods for which the laboratory seeks or holds accreditation is 10 a purposive sample for test method review includes 1 inorganic methods and 1 organic methods. (2 Total = 20% of non-drinking water scope).

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

According to Section 6.13 V2M3, NELAC ABs shall 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 shall include include at least X method review as part of the on-site assessment.

According to Section 3.7 V2M3, NELAC ABs shall 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 shall 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