

Laboratory Accreditation System Executive Committee Meeting Minutes
January 25, 2017 10:30 am
Forum on Laboratory Accreditation, Houston, Texas

1) Welcome and Introductions

Judy Morgan welcomed everyone to the meeting and asked the committee members to introduce themselves. Attendance is recorded in Attachment A.

2) Update on Committee Activities

Judy provided an update on committee activities since the previous conference. The PowerPoint presentation used for this purpose will be distributed to committee members with these minutes. She noted that, once the initial recognitions of non-governmental ABs are issued (done at this conference), future recognitions for NGABs to accredit labs to the TNI environmental standard will be managed by LASEC. This will be addressed in coming weeks, and in the upcoming revision of the LASEC charter.

Jack asked that participants submit issues they would like to see for future Assessment Forums and Mentor Sessions. He noted that small labs and new labs are a frequent focus of these groups but that issues for stable long-term labs tend to get overlooked, and that the Assessment Forum should really focus on assessment issues rather than implementation issues.

3) Policy for Method Selection

The NELAP AC asked that LASEC develop a policy to guide the ABs' decisions about "representative sampling" during laboratory assessments. While all drinking water methods must be assessed, ABs seek some guidance so that all can follow similar processes in choosing other methods for review.

Several versions of drafts have been discussed previously, but the entire issue got set aside while the revised standards modules were being reviewed. Now that standards review is largely completed, a fresh draft policy was offered for review. (see Attachment 3) The following comments were offered:

- "Representative sampling" needs to be more clearly defined, and it needs to be scalable according to the size and scope of the lab. Many individual assessors currently do this but there are no guidelines to provide consistency. Typically, 1-2 methods per technology are selected and drinking water methods are included in the representation, even as all assessors understand that all drinking water methods must be assessed. If one drinking water method for a technology was reviewed, one method for a different matrix but using that technology should still be reviewed.
- For selected methods, is "cradle-to-grave" review required or is it acceptable to review only particular aspects of the method, such as calibration, DOCs or some other aspect?
- For a small lab, different fields of accreditation (FoAs) may have the same manager, while larger labs are more likely to have different managers for different scopes (e.g., metals versus organics. It's important to look at the processes across managers as well as technologies and matrices.

- Technologies should be aligned with TNI technology codes. One commenter noted that a similar document from early NELAP cays indicated that assessments should be “fluid” depending on the lab size.
- The draft document should be provided to the AC to review to ensure that it does not conflict with individual AB’s SOPs.
- Microbiology methods should be included in any list of technologies.
- EPA representative reminded all that every drinking water method must be assessed.
- Assessors must balance their time between assessing the lab’s quality system and its methods. One commenter noted that the full quality system should always be assessed, regardless of the methods selected for review, and that this balancing helps to ensure that the selection of methods is less critical than if only methods are reviewed.
- One assessor recommended that, for a small lab, assessing all methods sometimes identifies a huge problem.
- Participants generally agreed that method-defined parameters must all be audited individually.
- The policy eventually adopted will impact the training of new assessors.
- The policy should define the minimum expectation. ABs will set specifics themselves.

Aaren Alger, Chair of the NELAP AC, offered that the reason for requesting this policy was to resolve whether all methods or some selection needed to be assessed, and possibly to define some minimum number of methods. She stressed that she does NOT want to rewrite individual AB’s SOPs about on-site assessments. She also noted that each AB defines lab size by both people and scope, but that the selection of methods for review should not be determined by time limits on the site visit.

Aaren’s comments were taken to heart, that the efforts put forth thus far to clearly define how to select “representative” methods go beyond what the NELAP AC wants or can utilize. Judy indicated that the current draft will be polished and sent to the AC for review of the draft.

4) Policy for Documenting Prep Methods

The NELAP AC had also asked that LASEC develop a policy about documenting the assessment of prep methods. While all prep methods do get assessed, some ABs accredit them specifically, naming them on the scope, while other ABs include the prep as part of assessing individual methods, and thus do not identify prep methods on the lab’s scope of accreditation.

Judy asked for comments from labs about the value of having the prep method listed on the scope. Labs did not offer many comments but the assessors present had a number of comments, as follows:

- In the site reports, a list of methods audited is included, whether prep methods as standalones or determinative methods. Most third-party assessors do this regardless of what the AB chooses to put on the certificate, so that potential secondary assessors will be able to refer to the site report and see that the prep

method(s) were in fact assessed. If a method offers a choice of preparations, the assessor goes by the lab's method SOP.

- Is it possible to assess a particular prep method that might be in multiple determinative methods?
- The reason for the current somewhat confusing status is that each combination of prep and determinative methods would require a separate PT sample, which would be incredibly burdensome to labs.
- General consensus was that combining this prep method policy with the "representative sampling" policy would be a good idea.
- One participant suggested that some document be prepared for which prep methods match which determinative methods, and ask the labs to mark which prep methods they use.
- The fundamental need is for a system to assist ABs in communications about secondary accreditations, so that the secondary AB does not have to contact the primary AB every single time.
- The lab is responsible for getting the assessor to look at the prep methods and put those into the site report.
- The AC will eventually develop a system that communicates the prep methods, and perhaps adding those to the generic application would be helpful.

Aaren, again, noted that the issue is with prep methods that were not audited, and that the AC wants a policy to describe how the primary AB can document that prep methods were audited, so that a secondary AB (which might require accreditation of prep methods) can know that the preps were in fact audited by the primary.

After discussing both draft policies, consensus was that the documentation of prep methods can be combined with the method selection policy since these are complementary activities. A revised draft will be prepared for LASEC.

5) The Generic Application

Dan Hickman asked for a few minutes to update the status of the generic application. It has been revised and upgraded, once again, to Version 3.0 which Dan calls "intuitively obvious" to use. Earlier versions required a detailed user manual which was cumbersome and unwieldy. KS, TX and several large labs are beta-testing this new version, and seem to like it.

Mobile labs are not yet included in Version 3.0. Dan will ask LASEC to find out from the NELAP AC what information needs to be included in the application to address mobile labs, and how that is submitted now. It is not clear how to incorporate this information into the generic application software until the IT Committee sees the data requirements. NOTE: this request has been received in writing from the IT Committee.

6) Next Meeting

The next scheduled teleconference meeting will be Tuesday, February 28, 2017, at 1:30 pm. Teleconference information and an agenda will be sent ahead of time.

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, 12/18	Chair (all)	Pace Analytical	Lab/FSMO	Yes
2	JoAnn Boyd	jboyd@swri.org	3 years, 12/16	StdsRev	Southwest Research Inst.	Lab/FSMO	Yes
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	No
6	Jack Farrell	aex@ix.netcom.com	3 years, 12/16	Assmt Forum, StdsRev	Analytical Excellence	Other	Yes
7	Myron Gunsalus	ngunsalus@kdheks.gov	3 years, 12/18	KS DHE	KS Lab Director	NELAP AB	No
8	Bill Hall	George.Hall@des.nh.gov	3 years, 12/16	SIRs,FAQs	NH ELAP	NELAP AB	No
9	Carl Kircher	carl.kircher@doh.state.fl.us	3 years, 12/18	SIRs, FAQs	FL DOH	NELAP AB	Yes
10	Dorothy Love	dorothylove@eurofinsus.com	3 years, 12/18		Eurofins Env't'l	Lab	Yes
11	Mitzi Miller	mitzi.miller@moellerinc.com	2 years, 12/17	FAQs	Dade Moeller, Inc	Other	Yes
12	William Ray	Bill_Ray@williamrayllc.com	3 years, 12/17		Wm Ray Consultants	Other	No
13							
14							
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	Yes
	Harold Longbaugh				Houston Lab	Lab	Yes
	Nick Straccione	nicholas.straccione@sgs.com			SGS	Lab	Yes
	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
61	Review final modules of 2016 Standard	Individual committee members per 6/28 minutes	Conclusion of full V1 review on hold pending resolution of AC issues with V1M4 & V1M1	Working to resolve concerns that led to AC rejection of individual module recommendations to accept
62	Request status update on reviews		ongoing	V2M2 edits need LASEC approval before sending to NELAP AC. Chemistry module's editorial revisions remain to be reviewed
63	Distribute draft policies	Judy	these will be addressed as time permits, once concerns about standard are resolved	Revise per discussions at conference in Houston, see minutes of 1/25/17
64	Update SOP 3-106 with "lessons learned" once the 2016 standard is in place	LASEC	"parking lot issue" -- open	Particularly, add review of committee decisions about non-persuasive comments and examine timing of multiple reviews in light of SOP 2-100 restrictions
65	Review and approve new recommendation to NELAP AC to approve technical clarification revisions to V1M1, provided by PT Expert Committee Chair to LASEC Chair on Nov. 22, 2015	LASEC	By email, ASAP – in time for December 12 NELAP AC meeting?	Revised module and revised draft LASEC recommendation sent December 4, 2016. Approved by committee vote, sent to AC for its 1/6/17 meeting
66	Gather info requirements for mobile labs from NELAP AC	LASEC	TBD	Request from Dan Hickman and IT committee

Attachment C

Policy TITLE:	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 minimum requirement and the procedure NELAC ABs will use to select the number and type 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 by all NELAC ABs. 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.

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.

Fields of Accreditation Non-specific to Drinking Water

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 on 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.

The approach to establish the methods to audit must cover the technologies and matrices in question. Various approaches in technologies may be established but typical technologies are listed below:

Select at least one method in each technology:

Volatiles GC/MS

Volatiles GC (varied detectors) E-typical types of compounds:, EDB, 8021 etc.; 8015 (GRO)

Semivolatiles GC: Pesticides, herbicides, DRO

Semivolatiles GC/MS

HRGCMS

PCBs

HPLC with varied detectors

ICP

ICPMS

GFAA or AA

CVAA

CVAF

Colorimetric

Auto analyzer

Gravimetric

Titration

Potentiometric

Conductivity

Imhof

Paint filter

Gamma Spec

Alpha Spec

Gas Flow Proportional Counter

Liquid Scintillation

If multiple matrices are accredited, such as water and soil/solids, review the technology for each one.

Method defined parameters that do not conform to a listed technology, must be audited individually. Examples are: 1664, BOD, TCLP.

In order to provide coverage of staff, one second criteria is to interview various people. Attempt to interview about 10% of the trained staff across the laboratory.

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 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

Attachment D



Policy TITLE:	Documentation of Assessment of Preparatory Methods
Policy NO.:	3-XXX
REVISION NO:	0
Program	TNI

LASEC Approved Date:	
TNI AC Approved Date:	
Policy Committee Reviewed Date:	
TNI Board of Directors Endorsed Date:	
POL Effective Date:	

I. PURPOSE AND APPLICABILITY

Each recognized TNI Accrediting Body (AB) should consider that confidence in its laboratory accreditation decisions needs to be instilled in many affected parties, inclusive of laboratory clients, officials making environmental protection and public health decisions, users of laboratory test results, the laboratory community seeking competent subcontractors, TNI AC members granting secondary accreditations, and The NELAC Institute (TNI).

Sample preparatory methods are addressed differently, by different TNI ABs. In some cases, preparatory methods are itemized on the scope of accreditation, along with the determinative methods. In other cases, the preparatory methods are not identified individually or at all on the scope of accreditation.

The purpose of this SOP is to provide a framework for how ABs document the accreditation of preparatory methods, so that each AB, granting secondary accreditations under the Mutual Recognition Policy 3-100, will be assured that the “prep methods” were reviewed and approved by the primary AB during the on-site assessment.

II. SUMMARY

Ideally, each TNI AB should attempt to accredit environmental testing laboratories for each sample preparation method, as well as for the analytical determinative method, when granting primary accreditation.

III. DEFINITIONS

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

TNI Accreditation Body as defined in Vol 2, Mod 1, and Vol 2, Mod 2

TNI 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 REGARDING PREPARATORY METHODS

Sample preparation methods are needed to convert the sample into a form suitable for the determinative method. In some cases, this process is included in the specific determinative method, but other cases, the preparation methods are secondary published reference methods that may be identified, but not extensively discussed, in the determinative methods. Approximately half of the TNI ABs accrediting determinative methods also accredit the laboratories to specific sample preparation methods.

The policy of TNI is, IF there is sufficient need for the additional accreditation system to be offered and IF the resources of the AB are sufficient to allow for competent laboratory evaluation, the AB should attempt to accredit environmental testing laboratories for sample preparation methods, as well as for analytical determinative methods. Because TNI is committed to the mutual recognition of each Primary AB's scope of accreditation bestowed on the laboratory, this policy must accommodate how a secondary AB that accredits preparation methods can be confident and assured of the laboratory proficiency using various preparatory methods from the scope of a primary AB that specifies analytical determinative methods only on their scope of accreditation. Additionally, a secondary AB that accredits only for the determinative methods needs to know how to express or limit laboratory capability and conformance for any preparation methods explicitly granted by the primary AB.

For maximum benefit to potential clients of the laboratory's services, the scopes of accreditation should clearly indicate all possible combinations of preparation and cleanup methods used in conjunction with each accredited determinative method, and for each matrix and analyte. Each combination produces different measurement quality indicators for a given analyte in a given matrix, so often not all preparation/analysis testing combinations can meet the client's data quality objectives or regulatory program requirements. Therefore, as listed or presented on the laboratory scope of accreditation, the AB needs to confirm, beyond all reasonable doubt, that each combination or permutation of the preparation, cleanup, and analytical methods meets the applicable TNI Standards for environmental measurements.

V. DOCUMENTATION THAT PREPARATORY METHODS HAVE BEEN ASSESSED DURING ON-SITE VISITS

ABs are expected to document and describe that sample preparation methods are assessed during the site visit, in a way that can be displayed explicitly, documented or otherwise accommodated in the scopes of accreditation or in the on-site assessment reports issued to environmental testing laboratories. Any of three possible scenarios will serve this purpose, or the AB may create an alternative technique for identifying which preparation methods were reviewed and approved, whether considered "accredited" or not, so long as that technique is transparent and explicit about the preparation steps addressed.

Scenario 1: Accreditation scope includes all combinations of preparation, cleanup, and analytical methods, by analyte and matrix.

A laboratory accreditation scope with this type of listing will be lengthy but will leave little doubt as to the testing capability of the laboratory and to which Fields of Accreditation are eligible for secondary TNI accreditation. The laboratory site assessment report needs to be complete enough to ensure confidence of the review of every preparation method paired with a determinative method.

This confidence must also be ensured if additional method steps are inserted, such as extract cleanups. It should not be presumed that each utilized preparation method meets the same measurement quality objectives for all determinative methods used thereafter. It should also be presumed that additional cleanup steps can significantly alter the ability to meet the measurement quality objectives.

Scenario 2: The AB's accreditation scope lists matrix, methods, and analytes, but lists preparation methods and cleanup methods individually and those are not linked to any specific determinative methods, matrix and analyte.

Most ABs that present preparation and cleanup methods on the laboratory scopes of accreditation utilize this format. The majority of samples analyzed by a particular determinative analytical method are extracted with one particular preparation method, per matrix. However, for maximum benefit and transparency to all readers of the laboratory assessment report, the preparation method(s) and cleanup method(s) should be listed with the determinative method in the assessment report. If multiple preparation methods and cleanups are performed for different chemical classes or analyte groups, then such combinations and limitations should be documented as explicitly as possible.

For this scenario, the laboratory site assessment report needs to be complete enough to show that acceptable testing performance objectives can be met for at least one determinative method that is paired with the given preparation method and/or cleanup method combination. The Primary AB should be prepared to answer any questions about how the accredited laboratory utilizes its sample preparation and cleanup methods and what performance objectives can be reasonably achieved.

Scenario 3: Accreditation scope lists only matrix, the determinative analytical method(s), and analytes, with prep methods reviewed as described in the assessment report.

The AB should be able to confirm, during laboratory assessments, that the method and analyte listed on the accreditation scope meets some defined performance criteria for sensitivity, accuracy, precision, and selectivity. When a lab seeks secondary accreditation from an AB that accredits preparation methods and the primary AB does not, the laboratory should inform the assessment team during the site assessment that this condition exists. Then, the on-site assessment report from the Primary TNI AB should list those preparation methods and cleanup methods that were observed to ensure conformance with the TNI Mutual Recognition Standards. The assessment report should note which preparatory and cleanup methods are routinely performed for each determinative method and, if appropriate, for each matrix and chemical class of analytes. The evidence used to assess those preparatory methods should be clearly identified; which may require that the laboratory SOPs be detailed enough to inform the Primary AB of the criteria that the laboratory uses to choose a particular preparation method (versus analyze the sample directly) and to clean up an extract (if cleanups are not the norm for all samples).

VI. REFERENCES

TNI Environmental Laboratory Sector Standard, Volume 2, Modules 1 and 3
NELAP Mutual Recognition Policy 3-100

NELAP On-Site Assessment Policy 3-XXX

VII. DISPUTES

Disputes between or among TNI 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 Accreditation Council.

Policy Approved Changes

Prev. Policy No.	New Policy No.	Date of Change	Description of Change
n/a	3-XXX	6/20/15	Prose draft formatted into appropriate template for policies