

Laboratory Accreditation System Executive Committee Meeting Minutes Forum on Laboratory Accreditation, January 16, 2013

1) Session Opening Remarks

The meeting began with introductions of Committee members on the podium and the telephone. Attendance is recorded in Attachment A, with notation of whether the individual was present on the podium or by teleconference. Kirstin Daigle chaired the meeting by telephone, with Judy Morgan moderating in-room commenters.

Kirstin noted that LASEC is seeking new members, since many of the current membership need to rotate off the committee after serving two consecutive terms, since TNI was formed. Lynn noted that the Executive Director has determined that November 2013 will be the deadline for ending second terms, since that is the sixth anniversary of TNI's formation. Kirstin also noted that she will need to step down as Chair sometime later this year, due to increased responsibilities in her professional position.

She then explained the role of the "balanced" Executive Committee in supporting the laboratory sector accreditation programs – reviewing standards and developing policies and procedures for the state-based Accreditation Council (AC) with a group formulated of representative stakeholders. As an Executive Committee, LAS EC is not required to be formally "balanced" as are the Expert Committees for development of standards, but LAS EC does strive for diverse representation.

No further comments have been received on the December 14, 2012, minutes. The minutes are considered approved and will be forwarded to the webmaster for posting.

2) Revisions to the Standards Interpretation SOP 3-105

Kirstin had circulated a revised draft of SIR SOP (3-105) based on our December 14, 2012, meeting, and the first half of this meeting was devoted to discussing and editing that draft. It was also projected onto a screen so that participants could read and comment on it.

Kirstin described the changes made, based on December's comments, as she walked through a general outline of the SOP, and noted that she had revised a few items as a result of discussions with outside parties about a submission that was deemed not to be a valid interpretation request. These latter were that the committee to which the request is referred will be asked to identify the corresponding section of the "other" standard (whether the NELAC standard or the 2009 TNI Environmental Laboratory Sector Standard [ELSS],) and noting that the interpretation process is not designed for dispute resolution.

Noteworthy discussion points as the committee progressed through the SOP document are captured below.

- a. We should formally document the criteria for the decision to accept a submission as a valid request to interpret a section of the standard, rather than the current informal process of having the LAS and AC chairs review and decide. This gatekeeper review also determines to which committee the request should be addressed, since having each

expert committee review each request would be overly burdensome to the committee structure.

- b. LAS EC intends to review all interpretations before they are offered to the AC for its decision about implement-ability of the interpretation.
- c. Although the SIR process is not intended to resolve disputes between a lab and an Accreditation Body (AB), or between assessors, or other disputes, if the question posed does not indicate that it arose from a dispute and otherwise seems a valid request, then the interpretation will be referred to the appropriate committee.
- d. The SIR process is not a substitute for the appeal process of an individual AB. By default, the AB is correct. If an interpretation differs from the AB's position, the SIR outcome is not retroactive.
- e. While the committee asked to provide interpretation of a cited section of the standard is not expected to provide an exhaustive review of the entire standard or existing TNI (NELAP, in this case) policies, it is important that the committee ensure that its interpretation does not create a new inconsistency within the standard.
- f. After some back-and-forth about definitions being added in section 5.2 of the SOP, it was agreed that the criteria for what constitutes an acceptable (or valid) interpretation request should be placed on the website, on the submission page for SIRs. There may be separate criteria for the Field Activities program and the Environmental Lab program, or not – this needs to be worked out between the two programs.
- g. Consensus of the discussion was that the outcome of all submissions need not be published, but only those resulting in actual interpretations of the standard.
- h. An appeal process for the interpretation (when published) needs to be included in the SOP, with an appeal requiring a submitted rationale for appealing. A suggestion for this was to have the entire LAS EC handle appeals. Should the appeal demonstrate that the published interpretation created a conflict with another section of the standard, then LAS EC should facilitate addressing that conflict.
- i. Considerable and heated discussion about the AC's role in reviewing and accepting final interpretations occurred, yet again. Careful thought and word selection may be needed in both this SOP and the AC's voting SOP (SOP 3-101) to convey that the AC's role is to ensure clarity of wording for implement-ability and enforceability of the final interpretation, not to be able to simply dislike an interpretation and return it. The improvements to the standards development process may also ease concerns in this area, as ABs are more involved and provide input about implement-ability and enforceability in earlier developmental stages of the standard rather than being given an "adopt it or not" decision once the standard is finalized. Eliminating the "veto" voting option for SIRs in the AC's voting SOP will be most helpful in relieving this concern, and the LAS EC will work with the AC to accomplish this.
- j. It will be important that the revised standards development SOP ensure that expert committees address interpretations of the previous standard, when preparing a revised or upgraded standard. Some sort of "secretariat" function in TNI may help ensure this occurs.
- k. A flow chart of the final agreed-up procedure was requested, as part of the SOP. Lynn agreed to prepare this.

3) Request from NELAP AC for Advice on Addressing Changes to AB Operations

After the break, with a small amount of follow-up for the SOP, Kirstin outlined the issue and committee members began discussing how to respond to the NELAP Accreditation Council's (AC's) request for consensus recommendations on how to address changes to an AB's operations that might require a full evaluation outside of the normal 3-year cycle. This arises from the possibility that one or more ABs may shift to use of a contract accreditation body making recommendations for accreditation to the state. The language from the 2003 NELAC standard addressing this issue was reviewed, as the

likely basis for preparation of a policy and possibly an accompanying SOP for the AC. There is no requirement for notification of changes in the 2009 TNI Standard.

Discussion points are captured here:

- a. Who receives notification – in NELAC, it was the “NELAP Director,” a position that no longer exists. Likely this will be the AC Chair and the Program Administrator, or if it’s the Chair’s AB, then the Vice Chair would be notified. The PA could seek advice from the most recent Evaluation Team about the extent of change and possible impacts.
- b. Define “key personnel” for whom a change requires notification – likely does NOT include assessors. [NOTE: what if there are only 2 assessors and one departs – this is a substantive change, whereas losing 1 assessor of 5 or 10 would not be.]
- c. What types of changes would require notification – legislative changes affecting the “authority to accredit,” for sure.
- d. Changes that affect “the ability to carry out” accreditation activities, including inspection authority and delegations and also contracting activities, should be notifiable.
- e. Organizational changes, such as signature authority for certificates, placement of the AB within the larger organization, and a change in the number of personnel or assessors would be worthy of notification.
- f. Regulatory changes would warrant notification, but not changes to guidance or SOPs.
- g. Contracting changes warrant notification – how contractors are used as well as their numbers, perhaps
- h. Changes to web address or physical address warrant notification but not re-evaluation.
- i. Notification within 30 days seems reasonable.
- j. The AC should be consulted to learn how urgently this policy and SOP are needed.

4) Next Steps

The LAS EC will be in transition for the coming months, with changes to membership prior to November 2013 as well as the hand-off to a new Chair. The SIR SOP can likely be finalized with another 1-2 meetings. The draft policy and SOP about notification of AB changes may take a similar amount of time.

5) Next Meeting

The next meeting of the LAS EC will be Wednesday, February 6, 2013, at 1:30 pm Eastern time. The agenda will be the further revisions to SIR SOP 3-105, the AC-requested recommendations for handling changes to an AB’s operations, and reviewing a pilot set of SIR interpretations from the Quality Systems Expert Committee.

Action Items are included in Attachment B.

Attachment A

PARTICIPANTS
TNI LABORATORY ACCREDITATION COMMITTEE

Member	Affiliation	Present?
Ann Marie Allen (Jan 2007) T: 978-682-5237 x333 E: ann.marie.allen@state.ma.us	Massachusetts, Non-NELAP AB	Yes/telecon
Aaren Alger (2009) T: 717-346-8212 E: aalger@pa.us	Pennsylvania DEP, NELAP AB, Accreditation Council Chair	No
Jo Ann Boyd (Jan 2007) T: 210-522-2169 E: jboyd@swri.org	Southwest Research Institute, Lab	No
Carol Barrick (Jan 2009) T: 813-361-6911 E: cabarrick@msn.com , Carol.Barrick@mosaicco.com	Mosaic, LLC, Lab	no
Kristin Brown (Jan 2010) T: 801-965-2540 E: kristinbrown@utah.gov	Utah Bureau of Lab Improvement, NELAP AB	Yes
George Detsis (Jan 2007) T: 301-903-1488 E: george.detsis@eh.doe.gov	Department of Energy, Government	Yes/telecon
Dan Dickinson (Jan 2007) T: 518 485-5570 E: dmd15@health.state.ny.us	New York DOH, AB	No
Kirstin Daigle, Chair (Jan 2012) T: 802-660-1990 E: Kirstin.Daigle@testamericainc.com	TestAmerica, Lab	Yes/telecon
Terri Grimes (Jan 2007) T: 727-582-2302 E: tgrimes@co.pinellas.fl.us	Pinellas County Utilities, Municipal Lab	Yes/telecon
Carol Haines (Aug 2012) T: 360-871-8878 E: Haines.Carol@epa.gov	EPA Region 10 Laboratory	yes
Roger Kenton (Jan 2007) T: 903-237-6882 E: rogerk@eastman.com	Eastman Chemical Company, Lab	Yes/telecon
Judy Morgan (Jan 2007) T: 615-773-9657 E: jmorgan@envsci.com	Environmental Science Corporation, Lab	yes

Mitzi Miller (Jan 2011) T: 509-531-0255 E: mitzi.miller@moellerinc.com	Dade Moeller & Associates, other	yes
Julia Sudds (Jan 2010) T: 951.653.3351 E: jsudds@babcocklabs.com	E.S. Babcock & Sons, Inc., Lab	no
Lynn Bradley T: 540-885-5736 E: lynn.bradley@nelac-institute.org	TNI Program Administrator	yes
Guests:		

Attachment B**Action Items – LAS EC**

	Action Item	Who	Expected Completion	Actual Completion / Comments
2	Work on references for SIRs in 2009 SIR database.		Establish date at next meeting.	Is this still needed?
12	Talk to Aaren about NELAP AC representation on LAS EC.	Kirstin	3-12-12	Was this done?
13	Publicize that LAS is seeking new members. Check with the absentees about their preference for remaining on the committee.	Kirstin	October 2012	Publicizing completed -- TNI newsletter article, 10/15/12
16	Draft revisions to SIR SOP 5-101 (renumbered to SOP 3-105)	Kirstin	10/17/12	First round revisions circulated 10/23/12
18	Final draft revisions to SIR SOP	Kirstin	Prior to 12/1/12	
18a	“	“	Interim revision discussed at conference	
19	Draft policy and SOP regarding notifications to AC of AB changes	?	Confer with AC Chair on timing	
20	Recruit new members, especially ABs, and a new chair	All members	Late summer 2013	