Summary of the NELAP Accreditation Council Meeting October 1, 2012

1. Roll call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 1:30 pm EDT on Monday, October 1, 2012. Minutes of the September 17 were approved. Those members in attendance are listed in Attachment 1.

2. Action Items Pending

- Prepare certificates and distribute to ABs where recognition has been renewed
- Approving SIR recommendations from the workgroup; transmitting back to LAS EC.
- Follow ABTFII addressing NGAB option
- Final Response to Complaint from ACIL pending completion of evaluation process for the AB
- Policy Committee Review and request for revisions to Voting SOP (3-XXX)

3. Renewal of Recognition for TX

A motion to accept the TX Evaluation Team's recommendation for renewal of recognition for Texas as a NELAP Accreditation Body was offered by Paul Bergeron, seconded by Michelle Wade. With TX recusing itself, the remaining 12 ABs present voted yes; the two absent ABs voted by email, yes.

4. MN Request for Scope Expansion

Susan Wyatt had requested by email that MN be approved to expand its Fields of Accreditation to include asbestos in drinking water, noting that immediate approval was urgent due to EPA Region 5's new requirement for MN's state primacy agreement with the Agency. Susan noted that MN plans to use the NY program's assessment team and assessment reports for this particular testing, as allowed under the NELAC standard which remains in force for both ABs at present (2003 NELAC 6.3.2.1.4, Mutual Assistance Agreements.) She also noted that applicant laboratories without NY NELAP accreditation would not be permitted to apply for this field of accreditation until such time as MN can have in place third party assessors qualified to assess asbestos (TEM) in drinking water. MN will include this test in the FoA for which it will apply for renewal of recognition, next month, but needs to be able to accredit for it sooner.

Although MN was unable to participate in this call, sufficient information was available, supplemented by Stephanie Ostrowski's input about the NY program and its asbestos accreditations, for a decision to be made. The Lead Evaluator for NY's evaluation last year, Scott Hoatson, was asked by Lynn if there were any concerns about NY participating in this arrangement, and he had no adverse comments.

NY recognizes only its own accreditation for asbestos and lead/Pb, also, because they believe they require more rigorous assessment of the testing. Several other ABs noted that they grant secondary accreditation for asbestos based on NY accreditation.

Michelle Wade moved to accept MN's request to add asbestos in drinking water to its fields of accreditation; Steve Gibson seconded. There were 12 yes votes and one abstention from participants; by email, one yes vote arrived and MN recused itself from the vote. The motion passed.

5. Quarterly Assessor Discussions

PA agreed to participate with VA in the first of the AC's series of discussions with NELAP assessors, on December 3, 2012. Cathy inquired whether it would be acceptable for VELAP staff to use an online survey tool (survey monkey) to gather information about baseline knowledge and current practices of the participating assessors, with respect to the chosen topics, in advance of that session. There was no objection; all agreed this might lead to a more fruitful discussion during the time available. The topics will likely be chosen from the list previously offered, as follows:

- Internal audits
- Management reviews
- Specific methods: BOD, PCBS, etc.
- Training files
- Demonstrations of capability
- Document control
- Thermometer calibrations
- Traceability of standards and reagents
- Writing findings (immediate, repeat, etc.)
- TNI 2009 challenges and tips
- Equipment logbooks
- Sample receipt logs

6. QAO Discussion about Interim Accreditations

Paul Ellingson had earlier circulated a brief survey about the current use of interim status for laboratory accreditations, based on concern that arose during the evaluation process. The survey results may be found in Attachment 2, below.

Interim Accreditation was addressed in the NELAC standard but is not addressed in the TNI Environmental Laboratory Sector Standard. Because it is still being used, Paul sought input from the AC about how to move forward with handling it for evaluations.

Discussion points included:

The NELAC standard required noting interim status in LAMS but not on the certificate VA and PA note interim status on the certificate, when it's used; TX and OR use the same certificate for all; LA DEQ notes interim status in the cover letter and the scope of accreditation; and IL notes it in the cover letter.

Since not all states note interim on the certificate, there are likely instances where interims have been accepted for secondary accreditation, unknown to the secondary state. This issue needs to be addressed when the standard is revised. [NOTE: the LAB Expert Committee has been so advised. There are several cases where use of interim status should be appropriate, such as for a new AB or if an AB drops out of the program and the

lab needs to transfer its accreditation to a different AB.1

Paul's conclusion was that, since some ABs are accommodate Interim accreditations and others do not, it need not be an issue during the evaluation process. As for impact on mutual recognitions, if an AB has an issue with another AB using interim status for whatever reason, then it becomes the initial AB's responsibility to deal with it. No one present raised objections to handling the issue in that fashion until it can be incorporated into a revised standard.

7. Consideration of Revising AC Operating and Descriptive Documents

Lynn had asked about a Mutual Recognition SOP that surfaced during rehabilitation of the Policy Committee's work that had been approved in 2009 by the AC but never undergone final adoption by the Board. This led to Aaren sharing a document she had created that might be the basis for a charter, and discussion of the NELAP Board Operations SOP also. Prior to this meeting, Lynn had distributed all those plus the Voting SOP, which has pending feedback from Policy Committee.

Since most participants were not prepared to discuss how the AC might revise or reshape these fundamental documents, Aaren requested that all look them over and be prepared to discuss at the AC's November 5 meeting.

8. Standards Interpretation Requests

Aaren sent email and a spreadsheet on September 20, sharing her further thoughts after the September 17 discussion of SIRs, and asking that each AB representative be prepared to discuss their concerns about particular SIRs at the November 5 meeting (SIR numbers are in the "next meeting" section below.) Lynn also identified the numbers for some newly posted SIRs in the voting website, that will be hidden among the historical backlog, and asked AB representatives please to vote on those -- SIR numbers 111 thru 121 and also 26, 52, 67, 71, 98 and 132.

Lynn agreed to review the voting site to have accurate counts for the October 15 meeting.

9. Next Meeting

The next AC meeting will be Monday, October 15, 2012, at 1:30 pm EDT. A confirmation with teleconference information and an agenda will be sent the week before. The agenda will focus on addressing the backlog of SIRs, with specific discussion about these:

- #85—NY and NH both voted "needs discussion" all other ABs voted to "approve" the SIR
- #115, 122—NH voted "needs discussion" all other ABs voted to "approve" the SIR
- #137—OR and IL voted "needs discussion" all other ABs voted to "approve" the SIR
- Possible discussion and a vote on whether the veto cast for SIR # 104 is persuasive based on information provided in comment by MN.

Items not related to SIRs will be addressed at the AD's November 5 meeting, including:

- Further developing plans for the quarterly or bi-monthly NELAP Assessor discussions
- Discuss documents and possible revisions for old policy and SOP to make them current and usable
- Other items that may arise.

Attachment 1

STATE	REPRESENTATIVE	PRESENT
CA	Fred Choske 510-620-31745 F: <u>510-620-3471</u> E: fred.choske@cdph.ca.gov	yes
	Alternate: Dave Mazzera : 510-449-5600 E: david.mazzera@cdph.ca.gov.	no
FL	Stephen Arms T: (904) 791-1502 F: (904) 791-1591 E: steve_arms@doh.state.fl.us	No
	Alternate: Carl Kircher E: carl kircher@doh.state.fl.us	No
IL	Scott Siders T: (217) 785-5163 F: (217) 524-6169 E: scott.siders@illinois.gov	no
	Alternate: Janet Cruse T: 217-785-0601 E: Janet.Cruse@illinois.gov	yes
KS	Michelle Wade E: MWade@kdheks.gov Ph: (785) 296-6198 Fax: (785) 296-1638	yes
	Alternate: N. Myron Gunsalus ngunsalus@kdheks.gov 785-291-3162	no
LA DEQ	Paul Bergeron T: 225-219-3247 F: 225-325-8244 E: <u>Paul.Bergeron@la.gov</u>	yes
	Altérnate: TBD	
LA DHH	Donnell Ward T: E: donnell.ward@la.gov	yes
	Alternate: TBD	
MN	Susan Wyatt T: 651.201.5323 F: E: susan.wyatt@state.mn.us	no

	Alternate: Stephanie Drier	no
	E: stephanie.drier@state.mn.us	
NH	Bill Hall	yes
	T: (603) 271-2998	
	F: (603) 271-5171	
	E: george.hall@des.nh.gov	
	Alternate: TBD	
NJ	Joe Aiello	no
	T: (609) 633-3840	
	F: (609) 777-1774	
	E: joseph.aiello@dep.state.nj.us	
	Alternate : Rachel Ellis	Yes – authorized to
	E: rachel.ellis@dep.state.nj.us	vote for this meeting
NIX	Stanbaria Ostrovalii	Yes
NY	Stephanie Ostrowski T: (518) 485-5570	res
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	Alternate: Dan Dickinson	No
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OR	Gary Ward	Yes
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	Shannon Swantek	no
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	Included for information purposes: Scott Hoatson	No
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PA	Aaren Alger	Yes
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	Alternates Durana Duralhalder	Ne
	Alternate: Dwayne Burkholder E: dburkholde@state.pa.us	No
TX	Steve Gibson	Yes
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	Alternate: (temporary)	yes
	Melissa Peters-Kelly	
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	Alternate: Kristin Brown	No
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VA	Cathy Westerman	Yes
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	Alternate: Ed Shaw	no
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	Lynn Bradley	Yes
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	Marvelyn Humphrey	No
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	E: Humphrey.Marvelyn@epa.gov	
	Paul Ellingson	yes
QAO	T: 801-201-8166	
	E: altasnow@gmail.com	
	Oklahoma:	no
	David Caldwell	

Attachment 2

Results of the Survey on Interim Accreditations

Part A

Does your AB use Interim Accreditation?

Yes - 6

No - 3

Comments from Yes Votes

Has been used when travel restrictions do not allow onsite inspection of the laboratory. PT's and documents are reviewed (SOP/IDOC/etc.)

Rarely; and only in instances when we are unable to perform a site visit for an addition within a field of technology the laboratory already has certification for but all other documentation has been provided.

[State Rule] allows for Interim accreditation – but not used commonly in practice (personally I don't like it)

It is used <u>sparingly</u>. It is 'required' in our regulation if [State] cannot schedule a site visit within 90 days of the laboratory's application being complete. Our GOAL is not to allow these circumstances to occur which make it a regulatory requirement.

Comments from No Votes

None

If your AB does use Interim Accreditation does it use it for new labs coming into the program?

Yes - 4

No - 2

NA - 3

Comments from Yes Votes

It is used for out of state laboratories when travel restrictions do not allow onsite evaluation- good for 1 year max- site visit must be done within the year. Sparingly, as noted above.

Comments from No Votes

We did to enable us to process the applications and get the laboratories who had previously been accredited by Illinois into our system. HOWEVER – the on-site assessment had been completed, and the laboratory was working on documentation for corrective actions. Interim accreditation was granted to allow them time to complete those corrective actions.

If your AB does use Interim Accreditation is it used when reassessment schedules cannot be met (every two years \pm 0.5 years)?

Yes - 1

No - 5

NA - 3

Comments from Yes Votes

None

Comments from No Votes

None

Part B

If another AB uses Interim Accreditation for new laboratories coming into their program, would that affect your ABs recognition of these labs?

Yes - 4

No - 5

Comments from Yes Votes

If the lab's certificate indicates an interim accreditation, we would not be able to recognize it.

It depends on the depth of the interim review/decision. If the primary 'accredits' the lab we could accept it.

If the site visit had been completed and the laboratory was working on documentation for a corrective action plan (as noted above) that would be an exception.

Comments from No Votes

This is based on the NELAP 2003 standards

I don't like the concept, personally. However, since my regulation allows for it – this would not change my ability to recognize

We would accept this use; we would be accepting 'in good faith' that the AB has taken all available measures to identify that the lab has established a quality system and that the site visit will be done in a timely manner.

If another AB uses Interim Accreditation because it cannot meet reassessment schedules (every two years \pm 0.5 years), would that affect your ABs recognition of these labs?

Yes - 4

No - 5

Comments from Yes Votes

I don't think it was ever intended for this purpose.

Since my regulation only allows state recognition if the other state 'meets or exceeds [our] requirements' – this would be a lower standard and would be an issue with recognition.

But this would be more of a concern than above. This indicates that the AB is not performing up to the standard.

Comments from No Votes

This is based on the NELAP 2003 standards

Acceptable as long as it is consistent with the adopted standards.

Again, we would be acting 'in good faith'. Would hope that all ABs would use as sparingly as possible.

Other Comments

Please describe any concerns you have about the use of interim accreditation

This can certainly be mis-used by an AB. Its 'value' is that it gives the lab 'rights' to do its business while the AB manages workload. The AB has a significant responsibility to do all in its power to assure that an accredited lab has met the quality system requirements of NELAC/TNI and that INTERIM is used sparingly.

Interim accreditation indicates to me that the AB has confidence that the laboratory will be able to become accredited following initial full accreditation process.

I have personally (in only 4 years in my position) have discovered two labs that submitted applications, but upon a surprise visit – were not labs. (i.e., empty rooms). So, I am not in support of granting any form of accreditation to a lab that has not been seen and reviewed in full. I must admit to you that my responses are off the cuff and subject to change. We have the ability

to grant Interim accreditation by regulation - but I am not comfortable with the concept. If pushed to accept recognition of Interim from another AB - I would likely need to seek legal guidance to ensure I met [State] requirements.

Currently we do not have a way of informing the public that a laboratory's accreditation is in interim status. We track this information in our own database. Under the 2003 Standard the general consensus (we believed) was that a laboratory who was granted interim status was not to be treated differently than a laboratory who had been granted full recognition. [State] law makes no provision for it. Our concern would be that if a lab is granted interim accreditation, and then ultimately does not qualify for "full" accreditation, what then? It would have to be revoked, which is an onerous legal process.

Other accreditation bodies do not recognize the use of interim accreditation so laboratories seeking accreditation from [us] are limited in the use of the accreditation outside [state]. Interims may become necessary if states have travel restrictions that affect the certification of laboratories that are primary to that state and those laboratories must select a new primary AB.