

Summary of the NELAP Accreditation Council Meeting

April 21, 2014

1. Roll Call and Approval of Minutes

The NELAP Accreditation Council (AC) met at 1:30 pm EST on Monday, April 21, 2014. The minutes from April 7, 2014, were approved. Judy Morgan, Chair of LAS EC, joined the group for discussion of several difficult SIRs. Jerry Parr joined the call towards the end, responding to an on-the-spot invitation to do so. Those members and guests in attendance are listed in Attachment 1.

2. Action Items Pending

- Prepare and issue new certificate to MN for renewal date 4/22/14, to expire August 12, 2016. A copy of the certificate will be sent to the EPA Regional office when available.
- Prepare and issue new certificate to LDEQ for renewal date 9/10/13, to expire November 16, 2015; PA will notify the Regional Office once copy of certificate is available.

3. Evaluation Team Recommendation to Renew MNELAP's NELAP AB Recognition

The recommendation of the team was delivered to Aaren by the Lead Evaluator, Donnell Ward, and circulated to the AC prior to this meeting. Steve Arms moved, and Donnell seconded, to accept the team's recommendation to renew the Certificate of Recognition for MN ELAP.

During the formal discussion after the motion, Steve inquired whether the AC's practice is to have all corrective actions (CAs) fully implemented prior to recommending renewal or if submission of an acceptable plan and timeline to fulfill the corrective actions is sufficient. Steve explained that this issue is under discussion with the Non-governmental AB workgroup. Donnell noted that some of MN's CAs have a plan with a final date for accomplishment, and Aaren stated that it generally been left to the professional judgment of the evaluation team, where a plan would be acceptable for minor CAs but if it's something "major" the team might want to see evidence.

All 10 ABs present voted yes on the motion, and IL (Scott Siders) had emailed his "yes" vote prior to the meeting, noting that he would be unable to be present. The remaining three ABs will be polled by email. NOTE: as of April 22, 2014, these remaining three ABs have all voted "yes."

4. SIR 180

This SIR is "proxy" for five SIRs all concerning the perception that a lab is required to use the "latest version of a method" for analyses, unless it is not possible or inappropriate to do so, and has had several responses rejected by the AC as being either vague or unenforceable.

Judy had prepared a discussion draft that was distributed prior to the meeting, with relevant information. Working with the LAS EC's SIR Subcommittee, Judy carefully researched ISO definitions and usage of the terms "standard" and "test method," and learned that ISO does not use the term "method." Based on ISO Guide 2 (1996 version, updated in 2004), "standard" is a "driving document" or the underlying authority of a program, and definitely does NOT refer to analytical methods in the ISO usage. Our (TNI) confusion comes from decades of experience with the terms standard and method as they relate to the publication, **Standard Methods for the Analysis of Water and Wastewater**, and the method versions that are published and/or promulgated by the various EPA programs.

She proposes to prepare a new SIR response that explains the ISO definitions and clarifies that the language of the TNI standard, based on ISO 17025, does not address method selection at all, and also to ask that Quality Systems Expert Committee clearly define the terms being used, in its active revision of Volume 1, so that this misunderstanding is not perpetuated in the next version of the TNI Standard. AB representatives present agreed that this is a sensible approach.

Steve noted that future revisions of the standard should also include some clarification that ABs accredit individual methods and method SOPs, while ISO 17025 does not address accreditation for specific methods.

5. SIR 200

This SIR recently received its two-week notice for voting purposes, and that resulted in review and reconsideration then ultimately, withdrawal of SIR 200 from the voting process. The question concerns whether a lab's Quality Manager (QM or QAO) is considered "key personnel" and then whether the lab's primary AB must be notified of a change to the QAO.

The requirement to notify the AB of a change in "key personnel" (including the QM) resides in V2, which the labs are not supposed to need or be required to purchase. Also, "key personnel" is nowhere defined. Most ABs have addressed the notification requirement in policy or regulation, but some others have not and do not enforce the requirement because it is not part of V1 and thus they cannot require that it be done.

Additional clarification emerged during the discussion. V1M2 4.1.7.2(e) states that if the Technical Supervisor (or Technical Director, TD) is absent for more than 35 days, the lab must notify its AB, but does not actually address a replacement of the individual. V1M2 4.1.7.1 does state that a QM may also be the TD – a provision not in the ISO language but added as a "note" for the small lab's benefit. Thus, if the QM is so stated to be equivalent to the TD, then the same notification requirement should apply, but it was only during this conversation that we all realized this notification was only about absence, not replacement.

This is the part that can be clarified through an interpretation. Cathy offered to send Judy the language from Virginia's regulations, about the notification requirement, since that might be helpful in crafting some part of the SIR response.

The V2M3 7.0 (a-f) requirements to notify the AB need to be added to V1 and Quality Systems Expert Committee has already been asked to include that in its active revision of

the standard.

Participants also noted that EPA publication 815-R-05-004 (Manual for the Certification of Laboratories Analyzing Drinking Water), Chapter III section 13.4 requires that the lab to notify “the appropriate Certifying Authority” within 30 days of “major changes in personnel, equipment, or laboratory location.” “Major change in personnel” is therein defined as loss or replacement of the lab supervisor or the unavailability of a specific analyst to perform analyses for a particular parameter which only that analyst conducts.

6. Use of Back-Up Lead Evaluator for FL and Possibly LA DEQ

Last fall, when Jerry Parr met with the AC to discuss the two new contract Lead Evaluators (LEs,) part of that conversation addressed whether the back-up person (Paul Ellingson) should lead both the KS and FL evaluations, since Michelle Wade had just resigned from KS and was going to be working as a contract assessor for FL. At that time, the AC decided that Paul should lead the KS evaluation, but deferred its decision about FL. Since the FL renewal letter needs to go out in June, it was time to make that decision.

Also, Paul Bergeron has raised his concern that one of the other contract assessors used by LDEQ has stated its intention to object to Michelle leading the LDEQ evaluation because that would presumably give her access to additional information about the other contract assessors which might give her an advantage when writing proposals for contract assessor work with LDEQ and other ABs.

Discussion initially covered the types of information that an evaluator might see about contract assessors, and whether that same information could be obtained through Freedom of Information Act (FOIA) requests by any individual. Consensus was that the actual contracts, as required submission for the evaluation documentation, don't contain information about the qualifications, credentials or performance of the assessors, but that such information might be accessible during reviews of lab files, and that obtaining the same information through FOIA would likely NOT occur in timely fashion although it should be possible to do so.

At this point, Lynn contacted Jerry and asked him to join the call for the discussion. Aaren explained to him what had been discussed thus far.

Earlier, it was not clear that Michelle would be working for other ABs as an assessor, but now that is so. The current LE contracts do not address other work. Paul Ellingson has not worked as an assessor since leaving UT employment, to our knowledge, so he will not have that potential conflict of interest.

Information about assessor qualifications presumably remains confidential only during the selection and contract award processes. Participants discussed whether possibly confidential information could be redacted from the contracts when submitted for the renewal applications, or withheld during file reviews during the evaluations, but this was deemed impractical, time-consuming, and not a viable solution. ABs using contract assessors perform assessor appraisals as part of their contract oversight and the feedback forms from labs are a normal part of the lab files, whether the assessor is an employee or a contractor.

There is presently nothing in either of the LE contracts to address conflicts of interest. The plan was to address these on a case-by-case basis as they might arise between the LE and an individual AB, and then accommodate by assigning the back-up LE when needed. Having a different LE for all evaluations for ABs using contract assessors could become prohibitively expensive.

Jerry suggested that possibly an amendment to the LE contract would be appropriate, to somehow prevent overlap between working as both an assessor and an evaluator.

Lynn noted that the decision about FL needs to be made quickly but that the other ABs using contract assessors are not scheduled for some months yet, so that there is ample time to sort out the potential complainant's issue. The AC decided by consensus that Paul E. should lead the Florida evaluation. NOTE: Both LEs have been so notified.

One participant raised the possibility that perhaps the AC should re-visit the use of a contract LE for future cycles of evaluation, due to the growing complexity of confounding issues with the use of a contract LE.

7. Next Meeting

The next AC meeting will be the May 5, 2014, Assessor Call, led by Aaren and PA ELAP, on the topic of supervisor qualifications and the Technical Director position, covering how to evaluate transcripts and related issues. A "hold the date" announcement has already been sent and a reminder with materials needed for the discussion will be sent the week before the call

The next "regular" meeting of the AC will be on Monday, June 2, 2014. An agenda and teleconference information will be sent out before the meeting. There being no SIRs presently needing discussion, the tentatively scheduled May 19 meeting is cancelled.

Attachment 1

STATE	REPRESENTATIVE	PRESENT
FL	Stephen Arms T: (904) 791-1502 F: (904) 791-1591 E: steve.arms@flhealth.gov	Yes
	Alternate: Carl Kircher E: carl.kircher@flhealth.gov	Yes
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	No
KS	N. Myron Gunsalus ngunsalus@kdheks.gov 785-291-3162 Fax: (785) 296-1638	Yes
	Alternate: Rudy Ghijsen rghijsen@kdheks.gov 785-296-6198	Yes
LA DEQ	Paul Bergeron T: 225-219-3247 F: 225-325-8244 E: Paul.Bergeron@la.gov	Yes
	Altérnate: TBD	
LA DHH	Donnell Ward T: E: donnell.ward@la.gov	Yes
	Alternate: TBD	
MN	Lynn Boysen E: lynn.boysen@state.mn.us	Yes
	Alternate: Susan Wyatt T: 651.201.5323 F: E: susan.wyatt@state.mn.us	No
NH	Bill Hall T: (603) 271-2998 F: (603) 271-5171 E: george.hall@des.nh.gov	Yes

	Alternate: TBD	
NJ	Joe Aiello T: (609) 633-3840 F: (609) 777-1774 E: joseph.aiello@dep.state.nj.us	No
	Alternate : Rachel Ellis E: rachel.ellis@dep.state.nj.us	No
NY	Stephanie Ostrowski T: (518) 485-5570 F: (518) 485-5568 E: seo01@health.state.ny.us	No
	Alternate: TBD	
OR	Gary Ward T: 503-693-4122 F: 503-693-5602 E: gary.k.ward@state.or.us	No
	Shannon Swantek T: 503-693-5784 E: Shannon.swantek@state.or.us	Yes
	Included for information purposes: Scott Hoatson T: (503) 693-5786 E: hoatson.scott@deq.state.or.us	No
PA	Aaren Alger T: (717) 346-8212 F: (717) 346-8590 E: aaalger@pa.gov	Yes
	Alternate: Yumi Creason E: ycreason@pa.gov	Yes
TX	Alice Colt T: 512-239-3927 Alice.Colt@tceq.texas.gov	No
	Ruthie Wedig Ruth.Wedig@tceq.texas.gov	Yes
UT	Kristin Brown T: 801-965-2540 F: 801-965-2544 E: kristinbrown@utah.gov	No
	Alternate: Robert Aullman T: 801-965-2541 F: 801-965-2544 E: raullman@utah.gov	No
VA	Cathy Westerman T: 804-648-4480 ext.391 E: cathy.westerman@dgs.virginia.gov	Yes

	Alternate: Ed Shaw T: 804-648-4480 ext.152 E: ed.shaw@dgs.virginia.gov	No
NELAP AC PA and EC	Lynn Bradley T: 540-885-5736 E: lynn.bradley@nelac-institute.org	Yes
EPA Liaison	Marvelyn Humphrey T: (281) 983-2140 E: Humphrey.Marvelyn@epa.gov	Yes
Oklahoma	David Caldwell David.Caldwell@deq.ok.gov	Yes
Guests:	Judy Morgan, Chair, Laboratory Accreditation Systems Executive Committee, jmorgan@esclabsciences.com Jerry Parr, TNI Executive Director, jerry.parr@nelac-institute.org	