Summary of the NELAP Accreditation Council Meeting

April 6, 2015

The NELAP Accreditation Council (AC) met at 1:30 pm EDT on Monday, April 6, 2015, for another of its series of assessor conversations. Attendance was not taken, except to note that of the NELAP Accreditation Bodies (ABs), FL, KS, LA DEQ, NJ, NY, OR, PA, TX, UT and VA, plus OK, had representatives present, as well as ANAB, Analytical Excellence, Dade Moeller, and LAB.

The AC's Chair, Aaren Alger of PA, introduced Cathy Westerman of Virginia as the moderator of the round table discussion about documentation requirements for corrective actions and common method findings, both for lab assessments. Cathy had circulated a pre-meeting request that assessors come prepared with their own contributions for those topics. (See Attachment 1.)

Cathy reviewed the reasons that NELAP holds these assessor calls and the value of building a network for assessors around which they may interact. She also acknowledged the complex work that assessors perform, and that the program managers really see only a distillation of that effort. For Virginia, she explained that method questions are a larger struggle than the application of the standard – thus the source of the second part of the discussion below.

<u>Corrective Action Plans/Documentation</u>

To set a baseline for the discussion, Cathy asked that each AB (and the contract assessors, separately) state how they review corrective action reports during the assessment process. NELAC §4.1.3 makes it plain that an "accrediting authority" can request documentation of the corrective action. For the 2009 TNI Environmental Laboratory Standard, V2M3 §6.12.6 and §6.12.7 together state that the corrective action plan must be reviewed by the AB and meet with the AB's satisfaction, and that the AB may require evidence of effectiveness of the corrective action. Here is the list of responses provided by participants:

- VA – requires the lab to provide evidence of the implemented corrective action, such as completed worksheets
- FL – each of FL's third party assessors has its own requirements, but FL does ask for documentation of corrective action for repeat deficiencies, and then verifies the corrective action at the next on-site
- KS – requires completed documentation for the corrective action, whether an SOP or training or a new form, especially when it's a repeat finding
- NJ – requires information about the corrective action and completed documentation
- NY – requires extensive documentation, such as updated procedures, copies of log book pages, and even raw data, as well as client notification of affected results. NY finds fewer repeat deficiencies when more documentation is required for the initial finding
- OR – requires a plan for the intent of the corrective action but does not always verify completion. This varies by assessor, but there will be follow-up verification at the next

site visit

- PA – has recently changed its practice. Formerly, PA required evidence of completion for the corrective action but this became overwhelming. Now, the assessor determines what documentation must be submitted but it must be more than a "plan of correction" since that minimum requirement is simply too easy to abuse. New guidance documents and fact sheets are available for labs, about this change. A root cause analysis is required in every corrective action and this is providing improved enforcement. Some labs request 60 days for their completed corrective actions in this new scheme, and PA is granting some extensions for findings that do not affect data quality
- LDEQ – requires the lab to include a corrective action plan, with text of altered language and where it will be inserted into the lab's documentation, plus a signed commitment that the lab will complete the action. If a suitable corrective action plan is not submitted on the second response, LDEQ pursues suspension of the accreditation
- UT – allows submission of a plan for the corrective action to be accomplished within 90 days of the response. Evidence of completion is required for repeat deficiencies
- OK – requires evidence of completion of corrective action to be submitted within 90 days
- Dade Moeller – assessors require a full plan plus root cause analysis and follow-up, plus whatever the sponsoring AB requires. For a finding where the data are questionable, evidence of completion is required
- Analytical Excellence – whatever the sponsoring AB requires, but typically a corrective action plan with full documentation of completion of that corrective action for all repeat findings
- ANAB – requires objective evidence of completion of the corrective action. ANAB maintains a running list of corrective actions for each lab
- TX and LAB did not respond when asked, presumably they were no longer on the call.

<u>Method Detail Discussions</u>

Participants were asked to bring their more common findings and problematic ones for this discussion.

Standard Methods / BOD

VA began with a problem that has arisen since the most recent Methods Update Rule (MUR.) SM 5210B, Section 5.C.2-2001 states, "When a bottle contains more than 67% of the sample after dilution, nutrients may be limited in the diluted sample and subsequently reduce biological activity. In such samples, add the nutrient, mineral, and buffer solutions (5210B.3a-e) directly to diluted sample at a rate of 1 mL/L (0.30 mL/300-mL bottle) or use commercially prepared solutions designed to dose the appropriate bottle size."

One accrediting body pointed out this language in SM 2510B. This language was not in the earlier (SM 18/SM 19) editions of this method and therefore is "new" to many labs now MUR compliant that jumped from SM 18/19 to the 2012 MUR-compliant revision. As such, the requirement for the nutrient/mineral/buffer solution dosing rate for sample dilutions

containing more than 201ml of sample in a 300ml bottle is a requirement frequently unknown to labs and therefore a very frequent finding. This issue has potential to impact data if not done. The discussion included comments from both ABs and contract assessors regarding its enforcement.

Second Column Confirmation for PCBs

PA noted that its assessors have had internal discussions about the requirement for second column confirmation of polychlorinated biphenyls (PCBs or Aroclors) in Methods 608 and 8082. Some of PA's NELAP-accredited labs have objected to having to perform this second part of the analysis, and Aaren asked how other ABs and assessors handle the issue. VA does not cite failure to perform the second column confirmation unless the lab's SOP specifies it because of the "should" language in the methods but notes that most labs' SOPs do require it, so the finding is written against the lab's SOP, while FL, LDEQ, OR and UT all enforce the second column requirement, and Dade Moeller's Mitzi Miller stated that several states for which their employees perform assessments require it, as well. Mitzi also noted that the second column confirmation is definitely needed when analyzing "weathered" PCB samples.

Reporting levels for Volatiles and Semi-Volatiles

Mitzi noted that, for methods 8260 and 8270, labs are being asked to lower their reporting levels into the range between the limit of detection and the limit of quantitation, a range where the primary analyte/ion may be detectable but identification of the secondary analyte(s) competes with signal noise. One solution offered by Analytical Excellence (Jack Farrell) was to resort to using peak identification ratios in the method itself. PA noted that they are not seeing this problem, but that could be an oversight and not an actual lack of occurrence.

Biannual LCR Verification

FL posed the question of how labs are interpreting the requirement to verify the linear calibration range (LCR) every six months, noting that many labs just say they work within their calibration range, although some calibrations are quadratic. One assessor noted that if the analysis is only quantifying between high and low standards for a frequently used method, there truly is no need for an LCR, while another noted that if the laboratory has a true linear range in use, then there is no problem and no need to perform LCR over the dynamic range. VA noted that they assess to the standard as written, per VA's checklist, and they find no particular problems.

LFM in Method 300 A and B

PA asked about the ranges for lab fortified matrix (LFM) in Method 300, noting that method A specifies a range of 80-120 percent while method B specifies 75-125 percent. Sections 9.4.2 and 9.4.3 specify ranges of 90-110 percent or 80-120 percent for acceptance criteria. PA has been holding its labs to 90-110 or else the result must be qualified, as being subject

to potential matrix interference. FL noted that it believes the 80-120 range is acceptable but if not within 90-110, the data must be qualified. Cathy offered to check about VA's practice.

Flame AA W/ ICP in Method 3010A

VA asked about digestion of metals by Method 2010, which states it is not applicable to silver and refers to Method 7760, which is withdrawn and replaced by Method 7000. Method 7000, however, does not address the digestion of silver. This is about prep method, and 3010 uses chloride which precipitates AgCl. Cathy has asked EPA for an answer to this question but so far, no response. FL indicated it does not accredit prep methods, *per se*, and Jack noted that few labs use flame AA now, but that for ICP, the question is how to attain the QC requirements, which should be written into the SOP. OR noted that a section of Method 200.8 also makes reference to silver ions precipitating.

Inorganic Carbon Efficiency Effect on TOC Analysis

VA noted that a question has been submitted to Standard Methods about SM 5310 A & B and the instructions in §4d to check the efficiency of inorganic carbon removal prior to total organic carbon (TOC) determination, and whether the step of checking efficiency of removal is mandated. The response from the SM committee included comments that the new revision will have updated instructions about this process. Based on the statement from SM, VA requires an annual split sample for checking efficiency of inorganic carbon removal. PA for now still requires split sample and is concerned that the Standard Method response will be problematic due to labs that continue to use old models of instruments for this determination. Cathy thanked all the participants and promised to send them a survey about the value of this call and the assessor calls in general. [NOTE: those survey questions are in the email used to distribute theses minutes.]

With no further questions being raised, Aaren thanked Cathy for moderating and adjourned the meeting.

Attachment 1

NELAP Assessor's Round Table Discussion

AGENDA:

1) Corrective Action Plans / Documentation

Let's have each AB or 3rd Party Assessor Group share their approach to documentation review for Corrective Action Plans.
The NELAC Standard and TNI Standard allow some flexibility by the AB in the approach to review of documentation.
Let's share practices regarding this review --- what do you expect a lab to submit, if anything? How rigorous is the review and/or rejection of items?

2) METHOD DETAIL DISCUSSIONS

Let's ALL bring 'to the table' 2-3 method notes regarding what you expect vs. what others expect as a discussion topic.
The 'inspiration' for this discussion is my own awareness that it's the METHOD issues, more so than the NELAC/TNI/Quality System issues, where there is most opportunity for disparity between accrediting bodies and/or assessors.
Let's compile a list of things to review, either:

- Pushbacks you've gotten from labs that you'd like to discuss
- Questions you have on a certain section for interpretation
- Common findings you find yourself communicating to labs – are these common to other ABs? (they should be!)

Clearly, this could be a lively or long discussion, or a can of worms! But if we find that's the case, we'll have our agenda for the next session.

Our purpose for having the AC Evaluator discussions is to promote consistency --- this is a great place to start!
EACH PARTICIPANT AB OR 3RD PARTY ASSESSOR GROUP SHOULD PREPARE TO DISCUSS 2-3 METHOD DETAIL QUESTIONS. PLEASE PREPARE TO HAVE THE LANGUAGE IN THE METHOD AND THE CITATION, TO SHARE VERBALLY WITH THE GROUP WHEN YOUR METHOD QUESTION IS DISCUSSED.

We'll see how many topics we get through, and decide from our progress how to address the next session [Continue the discussions? Organize topics by technology groups, etc?]
Please start now to collect your ideas for this discussion.
THANK YOU IN ADVANCE for coming "to the table" with some ideas to contribute!