Summary of the NELAP Accreditation Council Meeting

April 1, 2013

The NELAP Accreditation Council (AC) met at 1:30 pm EDT on Monday, April 1, 2013, for the second of its quarterly series of assessor conversations. Attendance was not taken, except to note that FL, IL, KS, LA DEQ, MN, NH, NJ, NY, PA, TX, UT and VA, plus OK, had representatives present, as well as Analytical Excellence and Dade Moeller, Inc., both firms providing assessors on contract to several NELAP ABs. The NELAP QAO, Paul Ellingson, was also present. Most states had multiple assessors gathered in one room, which stimulated AB-internal discussions (on mute) and all participants were invited to express their opinions and current practices.

Pennsylvania's Laboratory Accreditation Program had volunteered to lead the discussion, on the topic of Internal Audits. Aaren Alger posed a series of questions and participants responded, discussing their answers and options. At the end of the session, Aaren noted that assessor responses for this topic were much more consistent than with the initial topic, traceability.

The discussion was shortened by echo problems on the teleconference line, but other than the echo, feedback at the end was positive. Another NELAP AB is invited to volunteer to lead the next assessor conversation, which will be held on June 4, 2013.

A summary of the questions and discussion follows.

Q1: As an assessor reviewing an internal audit, what do you expect to see?

- A procedure in the QA Manual or an SOP
- A schedule for internal audits
- In the Corrective Action SOP, areas to be examined
- Evidence that the internal audit was conducted – a report with sufficient information to identify the areas audited and the records reviewed
- Findings that are followed up with a corrective action process
- Evidence that the internal audit looked at method-specific activities, not "just" quality system
- A mechanism for follow-up audit to verify that the corrective action was effective
- Look for missing things, such as archiving, electronic traceability, quality functions
- Encourage use of the AB's checklists for lab internal audits
- LA DEQ noted that it does not require a separate internal audit for each mobile lab operating under a parent lab.

Q1 follow-up: Do you expect the lab to review every SOP or a representative selection? Every method or just representative ones?

- Pending response to a Standards Interpretation Request, the selection of SOPs/methods is up to the lab, unless problems are identified, then the AB would request a more in-depth internal audit
- For the annual management review, the standard specifies that all SOPs should be audited, perhaps cycling through them every couple years is sufficient
- It was noted that the standard is unclear about this issue – the NELAC standard required internal audit to cover "all elements of the management system: while the 2009 TNI standard states that an internal audit is to verify continued compliance of all elements of the management system including testing and calibration
- Consensus that the internal audit should cover all technologies for which the lab is accredited. The minimum acceptable would be one method for each technology category, then if problem(s) are identified, more reviews are needed within that category

Q2: Do you assess whether the internal audit is conducted by an "independent" person?

- It's difficult in a small lab. The report should substantiate the auditor's objectivity
- There are many labs where the Technical Director is also the QA Officer, but those typically have small scopes of accreditation
- How can the lab maintain independence or objectivity? Might it need to bring in an outsider?
- The lab staff can perform its internal audit, since even an independent (outside) auditor can be ineffective
- Any lab attempting to perform its internal audit in conjunction with an external audit is not satisfying the internal audit requirement. If someone is hired to do the internal audit, that's a "hybrid" but possibly effective, but not in conjunction with an accreditation assessment.

Q3: The lab must have an SOP, a schedule, and a follow-up plan. What do you look for as follow-up?

- A review process for non-conformances since the corrective action – a report or observation of the activity
- Delay the follow-up for a few months to see if the corrective action held or reverted to prior behaviors, as a final check
- Look at the corrective action process to verify effectiveness
- Cite the corrective action process and not the internal audit if follow-up shows continued problems
- The lab must have both a "schedule" and a "frequency" – should indicate approximate dates for internal audits to be performed, not just "annually," for instance

Q4: Would you use an internal audit report as a "cheat sheet" for an assessment?

- Yes!
- If the internal audits are stellar but the assessor finds many non-conformances, then the internal audit is clearly ineffective

Q4 follow-up: If the assessor observes a non-conformance that was identified in the internal audit, that seems to have corrective action underway, is it acceptable to mention that as an observation instead of a finding?

- In the context of a full audit, if it's a repeat finding, it should be cited but if it's a first time and seems genuinely to be in process of correction, then granting the lab benefit of the doubt is warranted.
- If corrective actions remain open for more than a year, the process is clearly ineffective and both the problem and the internal audit should be cited
- NY has a "suggestion" category in its reports as well as observation – this would be helpful if the corrective action has begun

Q5: Would you write up a lab for leaving its corrective action open for too long?

- For "critical" items, yes. What's critical? Sub-contracting to a non-accredited lab without notifying the client, for instance. Cannot be "fixed" later.
- A corrective action plan without any actual actions should be cited even if the plan seems adequate
- The internal audit should be closed out (all corrective actions complete) within a year of its being performed

Q6: What about a lab that won't provide its internal audit reports – will show the book where they are recorded but won't permit the assessor to read the book?

- That would be cited as a finding

Q7: What's the difference between a management review and an internal audit?

- Management review examines whether what they say is okay – an overview of quality system, quality metrics and complaints, more of a strategic overview for a management action plan, to determine whether the quality system fits the goals of management
- Internal audit checks whether the lab is doing what its documentation says – that actions match documents