

Summary of the NELAP Accreditation Council Meeting

May 5, 2014

The NELAP Accreditation Council (AC) met at 1:30 pm EDT on Monday, May 5, 2014, for another of its quarterly series of assessor conversations. Attendance was not taken, except to note that FL, KS, LA DEQ, MN, NY, PA, TX and VA, plus OK, had representatives present, as well as ACLASS, Dade Moeller and Shepherd Technical Services.

Aaren Alger, Chair of the AC, led the discussion. The topic concerned evaluating the qualifications of the Laboratory Supervisor, also referred to as the Technical Manager or Technical Director. Lab Supervisor (LS) is the term used in Pennsylvania regulations, and will be the term used in this summary for that reason. Before the meeting, Aaren had distributed some documents in pdf format, including parts of the PA application form that address the LS and sample correspondence with labs about apparently un-qualified LS personnel. The pdf format does not lend itself to incorporation into Word documents, so those are not included in this summary.

Initially, applications for PA primary accreditation named LSs either having no qualifications or without documenting the qualifications. To help labs better understand and comply with the requirements, PA developed a form with instructions that requires providing the area(s) supervised, the person's education and whether they are a "replacement" or "alternate," plus the amount of experience working in relevant analytical disciplines and if applicable, the Operator Certification license number. This form must be signed by the laboratory's designated representative and also attested to, by the individual whose information is being submitted as a proposed LS.

There is also a corresponding review form used by assessors, with a required review by a second assessor, also. PA does not require this information from labs applying for secondary accreditation, but accepts the decision of the primary Accreditation Body (AB) without further review.

Aaren then asked how other ABs handle the issue. She answered a question about additional state requirements by explaining that PA's requirements are essentially those of the TNI Standard, except for using different terminology – LS instead of Technical Manager/Director and "Field of Accreditation" instead of "technologies."

OK asked about non-US education and how that is addressed. PA had sought direction from its Civil Service Commission on this issue, and the response was that the LS must have a degree from an accredited institution and that the transcript must be translated by a certified organization, if not in English. She noted that the requirement for having attended an accredited organization is PA-specific and not in the Standard itself, but some other ABs also require it. One other AB has also imposed that requirement after spotting "diploma mill" credentials in an application. The suggestion was made that perhaps the standard should be amended to specify "degree from an accredited institution."

Also, the number of “lab supervisors” seems to be expanding. Previously, there was one person as the “lead” supervisor, but now it’s common for each field of testing to have its own LS. This expands the approval and tracking responsibilities for an AB considerably. Aaren asked how other ABs handle this issue.

MN, FL, and NY indicated that they accept multiple LSs. Both VA and TX noted that all LSs were initially grandfathered but as turnover occurs, they’ve instituted processes to maintain identification of the LS. VA and KS do not presently require transcripts but NY, FL, TX and OK do require transcripts. LDEQ and MN require credentials in their applications but verify the qualifications of the LS during the on-site.

Since transcripts often contain Social Security Numbers, virtually all ABs now require that the SSNs be blacked out prior to submission, or have a mechanism for doing that prior to filing the documentation.

Appeals to an AB’s decision that an LS is not qualified occur with some regularity. The EPA Certification Manual permits a Certification Officer to waive the education requirement if experience is deemed equivalent, but the TNI standard does not provide for this. PA noted that it will sometimes give “provisional approval” to an LS pending receipt of “confirmation of education,” and then allow one or two semesters for that person to complete the needed courses. PA’s Advisory Committee opposed the waiver-for-experience option for approving LS candidates.

VA noted that **they currently had an inquiry from a lab about whether they would** accept an LS for a micro lab with qualifying coursework but no degree. **Comments were made by other ABs regarding the requirement for a BS degree or a two-year degree depends on what tests the lab is performing.** VA noted that the *EPA Drinking Water Manual* allows an AB to make those exceptions based on its judgment **but that the NELAC/TNI standard does not make those exceptions.** VA noted that the “minimum sixteen semester hours” as written in the standard includes both bio and micro and is thus vague.. NY noted it requires one micro course. For a treatment plant, the micro qualification can be the operator’s certificate or a two-year degree with a micro course.

Aaren next asked how “experience” is evaluated, and stated that PA requires hands-on experience with a particular technology for two years (minimum twenty-one months), so that the LS is capable of providing guidance and support to analysts. She noted that data review is not considered the same as actual bench experience performing the analyses, for evaluating experience. FL noted that two years’ experience, where the lab performed only a few samples for that field of testing, would not be adequate, but that it requires “regular experience” and that if samples are truly scarce, it will consider proficiency testing samples and demonstration of competency analyses as part of the required experience.

FL inquired how other ABs handle the situation where more than one laboratory has the same LS (*i.e.*, one person overseeing multiple locations.) PA requires the lab to provide a “plan of oversight” where the LS must be on-site at least once every 16 days. PA regulations require departmental approval for an LS serving more than one location, and the 16 day timeline is

also in regulation. NY noted that, for day-to-day operations, this effectively leaves some facilities without an LS. LDEQ noted that this is addressed in V1M2 of the standard, and that it considers the operating hours of the lab, the area served and the accuracy of the lab's operations, and may try to discourage the practice.

Aaren inquired how other ABs handle secondary accreditations, with respect to the naming, tracking and approving of LSs. PA has begun confirming all LSs with the primary AB due to a criminal case in that state where one LS signed all fraudulent or erroneous reports, and to ensure that all PA LAP correspondence is going to the correct individual. VA and FL keep a record of direct reports but rely on the primary AB and do not confirm with the primary. NY does not always contact the primary AB but welcomes inquiries about labs where it is the primary.

FL noted that it often finds unreported LS changes or replacements from inquiries originating with secondary accreditations. LDEQ spot-checks secondary applications, but welcomes inquiries. LDEQ also has its Electronic Document Management System (EDMS): Electronic Document Management System available on the internet through the hyperlink; the URL is <http://www.deq.louisiana.gov/portal/ONLINESERVICES/ElectronicDocumentManagementSystem.aspx>

FL inquired whether assessors check LS credentials during the on-site, and stated that FL assessors do so, including asking during the opening conference whether there have been changes in the key personnel. PA, NY and TX verify the credentials with the application, prior to the on-site, but TX also checks to verify that the LS is actually doing the work. Shepherd Technical Services and Dade Moeller both confirmed that they check to verify that the designated LS is performing the work. Participants noted that this represents a good practice that all should consider adopting.

That concluded the portion of the call devoted to Laboratory Supervisors.

With time remaining, Aaren asked permission to bring up a different topic, about how ABs handle the requirement that the designated Quality Assurance Manager/Officer (QAM or QAO) have training in the laboratory's QA system, per V1M2-4.1.7.1(d) and how the ABs evaluate that training.

Dade Moeller replied they look for formal training or in-service training from the previous/out-going QAM, or else ISO training or routine in-service training of QA personnel in the laboratory. VA requires documented training, and the requirement may be met by reading the QA Manual and the standard or by some other form of quality system training.

PA asked if any AB approves QAM. Apparently not, but PA requires identification of the QAM and requires notification when the designated person changes. LDEQ both requires identification and verifies the QAM's credentials.

FL asked whether any ABs have restrictions on the LS also serving as the QAM. TX replied no, and NY allows one person to serve both roles. PA allows this practice but if it is a large

commercial lab, they strongly discourage it. LDEQ does allow this but requires a justification. FL noted that it allows the LS to serve as QAM where staffing is limited, but wryly remarked that staffing is always limited.

Shepherd Technical Services asked how do the ABs interpret the language of the standard (V1M2 4.1.5 (i) and also the NELAC Standard) that requires the QAM to be a member of the lab staff. PA does not evaluate whether the QAM is "staff" but operates under the presumption that if the individual is paid, they are "staff." LDEQ permits contracting the QAM position but finds that practice not to work out well.

There were no further questions, and the call was adjourned.