Summary of LASEC SIR Subcommittee Meeting February 25, 2014, at 12:30 pm Eastern

The Subcommittee's conclusions on SIRs 67, 160, 171 and 180 are noted below.

Attachment 1 contains the text of SIRs discussed and the NELAP Accreditation Council's feedback on them.

SIR #67 – this is a valid SIR. Drop the first sentence, keep the second sentence and re-post for new votes.

SIR #160 – Not a SIR, previously reviewed. Letter sent to submitter already, and closed out.

SIR #171 – concern is about the source of the specification for calibration, which is only in the 2003 NELAC standard. Carl assesses asbestos and will research the source and report back at the March 25 SIR subcommittee meeting.

SIR #180 – not on the agenda but was one of three that the AC tabled until its March discussion of SIRs. It has mixed votes, even though already revised once to serve as proxy for SIRs 110, 129, 152, 166 & 180) addressing the same question (must they use only the "latest approved edition" of a method.) Judy suggests that it should be taken down and an FAQ prepared. An internet search provides no evidence that this section of the standard has ever been the subject of an interpretation by groups that do so (IEEE was the only one found.) Lynn would like to put this "on hold" and ask the AC at its next discussion about resolving the questions by use of a FAQ.

Attachment 1

Agenda for SIR Subcommittee February 25, 2014

Results from AC Discussion, November 18, 2013 are in red text

67 – multiple "against" votes but one "needs discussion" that must be addressed

SIR #67 – the "needs discussion" vote was changed, but this should be flagged for possible addition to the standard during the next revision.

Question: NELAC 2003: C.3.1 and C.3.2

The Standard states you must use the "established test method acceptance criteria" or "client data quality objectives for accuracy" when confirming the LOQ. First of all, our clients virtually never set 'data quality objectives for accuracy', they rely on the lab to set that for the methods. Second, only new methods set acceptance criteria at the LOQ. What criteria should be used, for instance, for EPA 8000-series tests, which only designate an 85-115% CCV criteria at mid-level for most methods, but usually mandate no specific criteria for LCSs? While using our lab-generated LCS criteria may work, those numbers are usually developed using mid-level spiking levels.

Many new methods state CCVs must be within 60-140% at the LOQ, while LCSs may be within 50-150% of expected values. Mid-level criteria are usually tighter.

Last, there's a problem with respect to the statement in TNI Standard (section 1.5.2.2), "The annual LOQ verification is not required if the LOD was determined or verified annually on that instrument." I have seen several LOD/MDL studies that have good precision (produces a relatively low LOD), but the accuracy is terrible (average of 250% recovery). In my opinion, being able to physically see something at extreme low levels doesn't mean you can accurately determine the concentrations at low-levels. Some range should be set like 50-150% at the LOQ for confirmation.

Response:

There is no criteria prescribed for LCS recoveries, either at a mid or low level. It is up to the laboratory to determine these criteria if they are not specified in the method or by other rule or regulation.

Webcast training on LOD and LOQ is now available on the TNI website under the Educational Delivery System tab.

160 – relatively new posting that got lost in the shuffle, has "needs discussion" requests

SIR #160 – this should return to LAS. It's a "how to" question that should be answered by the AB based on the specific details of an individual lab's circumstances.

Question: NELAC 2003: D.3-4

If when doing monthly analyst verification using positive controls, one of the analysts is not available to submit his/her results, is the acceptance criteria used to determine the validity of data affected?

Response:

The question seems to apply to D.3.2. If an analyst is unable to participate in the "group counting" effort for a month, the only change in the acceptance criteria would be due to a laboratory only having 1 microbiology analyst who performs counts. In that case, the individual analyst's counts must agree within 5% of each other. When there is more than 1 analyst involved in the "group counting", then results must agree within 10% of each other.

171 -- multiple "needs discussion" requests

SIR #171 – this is not a SIR but rather a request for permission to "qualify" data where the analysis doesn't meet the requirements of the standard. AC members are unable to identify an interpretation request in the question, but if there is one, the response needs more supporting information, so that ABs not accrediting asbestos can assess the response

Question: NELAC 2003: D.6.5.1.1(g)

Grid Openings. The magnification of the grid opening measurement system shall be calibrated using an appropriate standard at a frequency of 20 openings/20 grids/lot of 1000 or 1 opening/sample. The variation in the calibration measurements (2s) is <5% of the mean calibration value.
Request: We are accredited by NELAP for Asbestos in water by TEM. At our last audit we were deficient for our TEM grids that they didn't meet the 2s<5% requirement. We obtained grids that were certified as meeting that requirement except the data would seem to cast doubt in that statement. The company took 400 measurements and obtained the following: mean= 9098.74um, s=507.31um, 95% confidence interval= 49.87um. 2 standard deviations is about 11% which is 95%, but their 95% CI is calculated correctly and is so small because they used a lot of points, but more than 5% of the time measured results will exceed that range. My question here is: I cannot find a reference to the 2 standard deviation performance criteria anywhere except NELAC. What I am finding is that you need to determine the average grid area. The method does not even discuss establishing performance criteria. With that being said and the apparent difficulty in finding appropriate grids shouldn't laboratory established criteria be allowed as long as that information is communicated to the client and incorporated into the uncertainty of measurement calculation? If that is unacceptable would it be acceptable to measure each grid opening as it is counted and dispense with the average area

Response: Certification is not the same as calibration. In this case, the laboratory's calibration is a verification that the grid openings are adequate for their intended use. If the grid openings do not meet the requirements of 2s<5%, then they can't be used. No other means of calibration is allowed.