TNI Stationary Source Audit Sample Expert Committee (SSAS)
Meeting Summary

November 18, 2019

1. Roll call and approval of minutes:

   Chair, Tom Widera, called the TNI SSAS Executive Committee meeting to order by teleconference on November 18, 2019, at 2:30pm Eastern. Attendance is recorded in Attachment A – there were 6 committee members present. Associate(s): Mike May. Guest(s): Stan Tong and Eugene Chen.

2. SOP 6-100

   LOQ Discussion

   The Committee started a conversation about LOQ at the end of the last meeting. Sherri prepared the information below to help with additional conversation:

   7.4 How this ASRL relates to method Limits of Quantitation (LoQ) expected in environmental laboratories for various analytical technologies that are in routine use.

   M13 - It is the responsibility of the user of this test method to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to performing this test method.

   M26 – It is the responsibility of the user to establish appropriate safety and health practices and determine the applicability of regulatory limitations before performing this test method.

   M26A - Mass concentration of applicable absorbing solution blank, µg halide ion (Cl−, Br−, F−)/ml, not to exceed 1 µg/ml which is 10 times the published analytical detection limit of 0.1 µg/ml.
   Detection Limit. A typical analytical detection limit for HCl is 0.2 µg/ml.

It is the responsibility of the user to establish appropriate safety and health practices and determine the applicability of regulatory limitations before performing this test method.

M29 – Section 13 lists instrument & in-stack detection limits

EPA DW Method 300.0 - MDLs must be established for all analytes, using reagent water (blank) fortified at a concentration of two (6)to three times the estimated instrument detection limit.

TNI definition of LoQ: [LoQ must be >DL, Lab must document how it determines LoQ]
re: PT reporting - For chemistry analyses, if the laboratory's Limit of Quantitation (LOQ) is below the PTRL, they may evaluate results to their normal LOQ.
If a mandated test method or applicable regulation includes protocols for determining quantitation limits, they shall be followed. The procedure used for determining the LOQ shall be documented by the laboratory. The laboratory shall select an LOQ for each analyte, consistent with the needs of its clients, and greater than the DL.
The LOQ must be at or above the lowest corresponding calibration standard concentration with the exception of methods using a single point calibration.

Sheri noted that she is opposed to the term LOQ. She thinks it is a holdover from the water methods. None of the methods described above discuss LOQ. The TNI definition of LOQ is dependent on the laboratory (see above). Mike S. noted that an accredited lab sets the LOQ at their lower standard. Sherry noted that they calibrate starting at their Detection Limit because that is the lowest point they report to. Mike S. noted that his lab would report something below their lowest standard and J Flag it as an estimate. They detected it, but below their standard. They would have detected it in the MDL study. All labs do this differently. TNI says you must have a procedure to set the LOQ and it must be documented. Sheri thinks LOQ is meaningless.

Sherri thinks the Committee needs to look at Detection Limits (DLs) when setting up ranges for audit samples and not LOQs.

Mike S. thinks reporting the DL is how low your instrument can see something, but it is not where you would want to be reporting audit samples. It is not a reliable number. You want to run the audit sample closer to your LOQ where you are really calibrated. You can't quantitate effectively at the DL. The MDL is where you can detect the compound on your instrument, but not necessarily be accurate with your number. The LOQ is where you've calibrated the range and the curve is good in this range. Putting your first standard at the DL level questions the integrity of the data.

Sheri commented that they do list an LOQ and it is 5x the DL. She would like the group to agree on a multiplier. There is nothing that says how to set an LOQ. Michael S. noted that the accrediting agencies don't let people just do anything. Whatever you are calibrating to … that is your range. The low standard is the LOQ.

Sheri noted that Oregon requires the calibration to be lower than the LOQ if the lab will report below the LOQ.

Gregg noted that EPA would say you have to bracket whatever you are looking for. The lower calibration point has to be less than the sample concentration being reported.

If the term LOQ is not used, what could be used? Mike S. doesn't want to bring DL into it. He would prefer to keep LOQ or to state using values that the lab can report as a reliable number.

Mike S. noted that auditors were not OK with his lab originally determining the LOQ to be 2-5 times the MDL. They said the LOQ is the low standard in the curve and is a point where the data can be reported reliably.

Tom commented that if you leave the statement as written and use the TNI definition for LOQ, it gives different labs and auditors their right to the different options expressed in today's meeting.

Sheri suggested that the ASRL needs to be greater than the lowest calibration standard typically seen in environmental laboratories. Then remove the LOQ language. This allows you to end up with the bracketing.

The lab is expected to calibrate around the audit sample range defined by the provider.

Tom noted that once the pilot study is done and the Committee determines what the acceptance ranges are going to be. For Air it is 2 standard deviations. The ASRL will be the assigned value – whatever the absolute lowest concentration is. If the lowest value is 1 and the range is 10%, the ASRL will be 0.9. The statement is there to ensure the ASRL is not going to be so low that the methods can't see it. Mike K. noted that we are going to vote on the data generated by this SOP as a Committee, and everyone will be making sure this doesn't happen.

Some of the methods include different techniques with different detection limits. Tom noted that the Mass Spec limits are 10x lower than ICP. Tom suggested that they request labs participating in the pilot study to report their LOQ or DL. There was agreement to do this. The purpose of the pilot study is to figure out how low the audit samples can be made.

Sheri said she'd be good to leave LOQ if information is added about how the ASRL relates to DLs and LOQs. She also wants the labs to provide DLs, LOQs and analytical technique with the data they turn in. A note was added that these items are needed. Mike S. and Katie were good with too. Tom commented that the DL information is useless because no one should be reporting down to the DL. You can't quantitate down at that level. Getting both the DL and LOQ is helpful because labs determine their LOQs differently. It will help when the Committee looks at all the data.

Section 7.4: No changes needed.

Section 7.5:
- In section 7.5.1 – Change 10 to 20 valid data points.
- In section 7.5.4: Audit sample acceptance limits are consistent with laboratory control limits in the reference method, if available, for test method accuracy.
- In section 7.5.5: ASRL is consistent with the requirements of Section 7.3.

Additional Discussion:
- Should there be a requirement for the lab to discuss any modifications to the method when they report the data? Perhaps there can be a box to check that the sample was prepared per EPA protocol. If not, describe. Make sure you are using the appropriate dilution ratio as described in the instructions received from the provider.

3. DRAFT Letter to EPA

The Committee reviewed the DRAFT letter prepared by Sheri based on the list and discussion at the last meeting. The Committee updated the letter and produced a Final DRAFT for review in Attachment D.

4. New Business.

- None.

5. Action Items

The action items can be found in Attachment B.

6. Next Meeting

The next meeting will be December 2, 2019 at 2:30pm Eastern. Ilona will send out a Webex invitation the day of the meeting.

Action Items are included in Attachment B and Attachment C includes a listing of reminders.

Tom adjourned the meeting at 3:35pm Eastern.

Attachment A

Participants
TNI
Stationary Source Audit Sample Expert Committee

Members	Rep	Affiliation	Contact Information
Tom Widera (2020) CHAIR **Present**	Other	ERA (Provider)	twidera@eraqc.com
Ilona Taunton, Program Administrator **Present/Recording**		TNI	Ilona.taunton@nelac-institute.org
Ed MacKinnon (2022) **Absent**	Other	TRC Env Corp (Stationary Source Tester)	emackinnon@trcsolutions.com
Gregg O'Neal (2020*) **Present**	AB	NC DAQ	gregg.oneal@ncdenr.gov
Katie Gattis (2020) **Present**	Lab	Element One Inc.	katie.strickland@e1lab.com
Michael Klein (2020*) **Present**	AB	NJ DEP	michael.klein@dep.nj.gov
Michael Schapira (2021*) **Present**	Lab	Enthalpy Analytical LLC	Mike.schapira@enthalpy.com
Sheri Heldstab (2022*) **Present**	Lab	Chester LabNet	sheldstab@chesterlab.net

Attachment B

Action Items – Stationary Source Audit Sample Expert Committee

	Action Item	Who	Date Added	Expected Completion	Completion
2	Find out which group in EPA is helping the Microbiology FoPT Subcommittee crunch numbers for limits.	Ilona	2/12/18	3/19/18	Need to hear back from Jennifer Best.
9	Prepare general summary of what the committee plans to change in the current Standard and why. First DRAFT.	Tom	4/23/18	5/21/18	In progress.
10	Send ideas on Storage Condition issue to Tom so he can summarize them for an agenda item in July.	All	6/18/18	7/15/18	
15	Provide Ilona with notes from New Orleans meeting so August minutes can be completed.	Tom	10/15/18	TBD	
18	Update SOP 6-100 based on review during meeting.	Tom	1/22/19	2/24/19	In Progress
22	Provide list of states that offer accreditation in Air.	Tom	7/22/19	8/6/19	In Progress

	Action Item	Who	Date Added	Expected Completion	Completion
23	Contact Advocacy to see if they have a list of states with air accreditation.	Ilona	8/6/19	8/19/19	
24	Prepare DRAFT letter to send to the TNI Board regarding need for continued SSAS activity.	Tom	8/6/19	8/19/19	
25	Get CRA form posted on the TNI website.	Tom/ Ilona	8/6/19	8/19/19	
26	Look for older tables that were used to calculate the original limits	Tom	8/26/19	TBD	
28	Prepare DRAFT letter to the Board and CSDP EC. Send for email comment.	Sheri	10/7/19	10/14/19	
29	DRAFT letter to EPA regarding SSAS program. Distribute to Committee (and Jerry Parr) for comment.	Sheri	11/13/19	11/15/19	Complete

Attachment C

Backburner / Reminders
Stationary Source Audit Sample Expert Committee

	Item	Meeting Reference	Comments

Attachment D: DRAFT Letter to EPA

Comments on Stationary Source Audit Program; Notification of Availability and Request for Comments

November xx, 2019

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The NELAC Institute (TNI) is a 501(c)(3) non-profit organization whose mission is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community.
TNI manages a Stationary Source Audit Sample (SSAS) program that includes the following components:

- Recognition of Audit Sample Providers
- Recognition of Audit Sample Provider Accreditors
- Maintenance of a central database for testers to report their data.
- A system whereby regulators can access data from testers,
- A system where participants can see their own data, and
- A SSAS table that contains methods, analytes, concentration ranges, and acceptance criteria for audit samples.

TNI also manages a Consensus Standards Development Program. TNI is accredited by the American National Standards Institute as a voluntary consensus standards organization and fully conforms to all requirements in OMB circular A-119. TNI's Stationary Source Audit Sample Expert Committee is one of 10 expert committees in this program and develops consensus standards for this program.
TNI offers the following comments in response to the notice published on September 11, 2019.

The greatest obstacle to Providers is that Stationary Source Audit Samples are far more labor and time intensive than Proficiency Test (PT) samples. As a result, most PT Providers are not willing to devote their resources to becoming an Accredited Audit Sample Provider.

The problem then becomes the EPA's definition of "commercially available". Due to the lower demand for Source Audit Samples than for PT samples, redefining "commercially available" to possibly encompass just one accredited provider would be a reasonable rationale for proposing an alternate definition of "commercially available". A change in the definition which allows for only one Provider would be in keeping with many State accreditations which mandate that a PT be analyzed if one is available from any vendor, even when only one vendor sells the PT of interest.

The Committee suggests that a caveat be added to the definition of "commercially available" to acknowledge the rarity of audit samples and AASPs. One idea for this caveat is a statement similar to the following: "Should only one AASP produce a given audit sample, the audit requirement would remain in force, and the facility or its designee must still obtain an audit sample. The single AASP providing the audit would not be allowed to raise their prices on any audit sample for which they are the sole Provider by more than [some factor] per year to avoid the possibility of artificially inflating the prices for their product."

In addition, the Committee believes that the audit program would be more robust if the allowable concentration ranges for several method/analyte combinations were lowered. This would create audit samples that better reflect the concentrations found in the field samples and thus provide a better representation of the data being submitted. The SSAS Expert Committee is currently working on a Standard Operating Procedure to lower the concentration ranges and allow for new method/analyte combinations to be added to the Stationary Source Audit Sample Table (SSAS Table).

The Committee is of the opinion that audit samples increase the legal defensibility of the data associated with them, and we are working towards making it less onerous for a new Provider to join the program so that the program can resume its mandatory status, as it is currently voluntary at the Federal level.