TNI Stationary Source Audit Sample Expert Committee Teleconference August 24, 2009

Participants:

Committee members: Maria Friedman Richard Swartz Ray Merrill Jack Herbert Mike Schapira Gregg O'Neal

Associate members: Shawn Kassner Mike Miller

- 1) The meeting was called to order at 2:06PM EDT.
- 2) Approval of August 17 Minutes: Ray moved to accept the minutes as written, Gregg seconded. Motion carried.
- 3) Questions for the Chair: Mike S. asked if any new members for the SSAS Expert Committee would be forthcoming. Maria replied, "not yet." She is not e-mailing prospective members as they cannot vote. Ray mentioned it would be good for them to participate anyway to provide their input.
- 4) Review of the VDS, V1M1 (Providers), Appendix A:

Per Ray, A.2.vi refers to the RPD of recovery.

Shawn said Providers can propose alternative test methods for homogeneity and verification testing.

Editorial note: section numbers below refer to sections as they are named in Ray's proposed Appendix A draft.

Maria, referring to section A.2(d)(iv) "prepare a single test portion for each sample," asked if that would diminish the test. Ray said that you need to have two samples at different concentrations. Is two a better measure? He took it out because you do a precision test in section A.1, which is repeatability. Changing the requirement in A.2 to one test portion may save money.

Gregg asked if samples are verified after they've been sealed and ready to ship. Ray said yes – see A.2(b).

Maria asked why "be treated exactly like..." had been deleted from section A.1(a)(i). Could it be added to the end? Ray said he left it out because you would then need to use the reference method. Providers can use better methods for this testing. Example – Method 6 or 8, Ray's preferred method is better than that in the CFR.

Maria announced that comments will be allowed via e-mail until close of business today.

5) Review of VDS V1M3 (Participants), Figure 1 (TNI SSAS Program Information Flows)

The committee discussed revised figures that had been distributed to the committee via e-mail. Jack asked about the differences. Ray said that some arrows needed double heads; he made that correction. We should split the 2 figures, pre-test, and post-test (this comment was previously made).

Jack said that sometimes Facilities will want to be the main communication outlet. If there is a failure, Facilities are responsible. Ray mentioned that the dotted line in the figure meant that the Facility can be represented by another party.

Gregg said Laboratories should be able to talk to the Provider, cut out uninformed middle man.

The committee discussed who is responsible to fix a failure: it depends on the particular circumstance.

Jack said the figures are basically OK. He had no major comment. Maria said we are not voting on the figures anyway as this was previously voted on.

6) Resume review of Internal Comments, Provider tab, line 56, Section 11.2

Maria said it was unclear from the San Antonio meeting what the outcome was on this comment due to conflicting notes, so we would discuss the section today.

Shawn expressed to Mike S. that he disagrees with the comment, although he understands Mike's point. Just running it again does not help if you do not know the true value.

Mike S. replied that we need to look at how we are setting up this Program. We need to set up something that clearly states how to react when something goes wrong, e.g., failed audit samples. Do we want to say you're out of luck when you fail an audit sample? What do we then do with the field samples. We can't have field samples thrown out just because an audit sample fails.

General Discussion: If the audit sample fails then the Regulator has to make a decision about the field samples, they are not just automatically thrown out. If the audit sample fails, hopefully we can re-run the sample again if it is still blind.

Maria said that if there was a failure, the Regulator can still accept the field samples and the stack test.

Mike S. said it's no good if it's not a blind audit during a 2nd chance run. Ray said if the audit was a failure, and you have a true value, you may find a simple math error and the Regulator would then accept the audit and the field results as valid. If there is a larger issue, then the audit may be a failure, and the field results may or may not be valid.

General discussion: In the current EPA system the Laboratory never gets true values. Early discussion was to improve the program by reporting audit sample true values to the Laboratory, so they can do corrective action if needed. There was also some discussion about hold times. Maria said that due to the time frame of receiving analytical data, Laboratories may not be able to analyze a failed audit sample again, because the hold time may be expired.

Shawn said that when results are published to required party, within 3 days, everybody is going to get an answer.

Mike S. said that audit results can be submitted prior to final report (this is way it should be). Shawn agreed.

Mike S. said that the Laboratory measures the catch weight of material in the field sample. They do not get the sampling volume. Ray pointed out that with this Standard, that will change. Mike S. said that the Laboratory data may be meaningless without the sample volume. Jack asked if the Laboratory would get the sample volume with the new Standard.

Mike S., regarding the issue of submitting the audit results with the stack test results, said he will not have the stack test results in the correct units because he does not get the sample volume.

Ray asked, if there is a failure, do Regulators need stack test data as well? Jack replied yes, they would.

Jack said that if the Laboratory doesn't present evidence they made a mistake then he's just got two different results. Others: Then make regulatory decision based on that.

Gregg asked, where we're going, you just get one shot on the audit? Shawn replied yes.

Ray pointed out that a mistake made on an audit sample might not necessarily be made on the field samples.

Shawn said he wants to get all information back to the Laboratory as quickly as possible, including the true value of the audit sample. That way the Laboratory can use the audit sample as a QA sample and figure out what problem is.

Mike S said he agrees with Shawn, but he's not excited about the idea of not having a 2nd chance to run the audit blind.

Shawn said the Regulator could possibly give a 2nd chance.

Maria said that the SSAS Central Database might be changed if needed to include pass/fail results of 2nd analyses.

General discussion: Comment field in the SSAS Central Database can also explain what happened. There would need to be a supplemental upload to the database so that pass/fail results can be changed if necessary.

General Discussion: After the Laboratory gets the true value, is evaluation of audit sample complete? Maybe not. Depends on specific situation. Once value is known, it's not a blind audit sample any more.

Shawn said that SSAS is not an anti-fraud program. Ray agreed with Shawn, while Jack disagreed. Gregg said it had the potential to act as an anti-fraud program.

The committee discussed the use of QA samples for audits, and how they differ from PT samples. The values of QA samples are known to labs when they order them. The true values of PT samples are not known to labs when they order them. Agencies do not accept QA samples as audits.

Shawn said that if the Laboratory just re-runs a blind audit sample, they can't find where the problem is. Mike S. replied that they go back to the very beginning and re-run the whole thing. They try to figure out where the problem was. Re-analyses are performed all the time.

Gregg's opinion was that having a 2nd chance means you have a blind audit again. If you already know the value, then it's not a blind audit, just a QA sample used to fix problems. Regulations are geared toward having an audit.

Ray asked what's best for Laboratories: giving a 2nd chance to pass, or having the true value to aide with QA? Said Jack, if the Laboratory knows they failed, they know a lot. The committee discussed to what extent the Laboratory knowing they had failed an audit sample, but not knowing the true value, gave them an advantage in a 2nd chance analysis. Jack suggested that if the Laboratory fails an audit sample, they can order a QA sample to see where the problem was.

The committee then discussed how fast new audit samples would be supplied in the event a Laboratory needed to analyze a 2nd audit sample.

The committee discussed whether a chance was needed in the VDS as written to address the possibility of retests of failed audit samples. It was mentioned that a representative of the Laboratory stakeholder group, Maria, had been on the committee from the beginning. Maria's view was that the consequences of a failed audit sample with regard to any need for a retest was a matter that fell to Regulators to decide, and outside the scope of the Standard. Gregg said that changing the Standard for retests would be good for corrective action for laboratories, but Ray pointed out that changing now would be a major change to the Standard.

Maria reminded the committee that if the SSAS Program is not working as written, it would be modified according to the 2-year revision schedule. There is also the expedited Tentative Interim Amendment process when changes of an emergency nature are required, however those changes would also need to go through TNI's Consensus Standard Development Board.

Mike Miller said that he agreed with Shawn: the original audit sample result is the result; how field test results relate to the audit samples is a regulatory question, and should not be a part of the SSAS Program.

Gregg agreed with Mike Miller, but added that additional audit samples should be able to be sent out.

Richard concurred with Mike Miller and Shawn, stating that the subject of the proposed change is beyond the purview of this Standard.

Richard moved to consider the comment non-persuasive. Gregg seconded, and the motion carried.

7) Closing Discussions

Maria said she would send the final spreadsheet of comments with the updated VDS to the committee, with review and comment needed back to Maria by close of business 08-25-2009. Afterward, she would forward the VDS to Jane for final formatting and posting on the website. Also, the committee was requested to submit any comments on Ray's revision to Appendix A of the Provider VDS by close of business 8-24-2009.

The meeting was adjourned at 3:43 PM EDT.