TNI Stationary Source Audit Sample Expert Committee Teleconference for February 28, 2011

Attendance:

Maria Friedman, Chair	Committee member	present
Michael Klein	Committee member	present
Gregg O'Neal	Committee member	present
Michael Schapira	Committee member	present
Jim Serne	Committee member	present
Richard Swartz, Vice-chair	Committee member	present
Stanley Tong	Committee member	absent
Mike Hayes	Committee member	present
Jane Wilson	Program Administrator	present
Shawn Kassner	Associate member	present
Mike Miller	Associate member	present
Ty Garber	Associate member	absent
William Mills	Associate member	absent
William Daystrom	Guest	present

1) Double-check receipt of documents to be referenced in this teleconference

Maria asked the committee to confirm receipt of the documents emailed February 25, 2011 and the minutes emailed by Jane on February 26, 2011. All confirmed receipt.

2) Review and approve minutes from teleconference on February 14, 2011

Maria asked for any comments on the minutes from February 14, 2011. Richard motioned to accept/ as written with a second from Mike Schapira. All were in favor of the motion.

3) Chair Update

Maria thanked Gregg for continuing to work in outreach to new contacts for the SSAS database. There are now over 75 contacts entered in the database. Outreach will continue at events like the Source Evaluation Society (SES) meeting, which is coming up in March. Shawn asked if the number of contacts is one per agency or organization. Maria noted that for now, TNI is just gathering names, and the committee will look at the composition of the contacts later.

Maria received confirmation from A2LA that the existing mutual recognition between provider accreditors (PAs) is based on the organizations' accreditations being traceable to signatories to ILAC. Mutual recognition directly does not exist between the accreditors and TNI does not mandate it. The question about managing the addition of interferents is still pending with A2LA regarding how this could be approached by the PAs.

For documentation of the original SSAS table creation, Maria has received some data from Carl Kircher and Maria has sent it to Candace as examples of what was done. Maria will update the committee pending Candace's review and response.

Maria also noted the deletion of the provision about labs not sending audit samples to other labs for verification testing, as raised by Valgena Respass of Enthalpy during the Feb 2 SSASEC meeting in Savannah.

4) Continue discussion re. EPA comments to TNI SSAS Standard

Row 2 – Discussion completed on this issue.

Row 3 and 6 – These topics are both related to the mutual recognition issue. Maria proposed language to resolve the EPA comment. The participants agreed with Maria's proposed language. Maria added she will send the proposal to EPA first to see if it resolves their concerns.

Shawn asked about the qualifications to address an issue using a TIA and Maria feels these issues qualify since they are necessary for compliance to the new EPA rule. Gregg asked if TNI could institute something that would supersede the committee's resolution. Maria added that TNI could take some action in the future, but that might not mean that the standard has to be changed based on the proposed wording. Maria motioned to accept the proposed language and Richard seconded, All were in favor of the motion.

Row 5 – The interferents topic hasn't moved forward, as Maria is still waiting to hear from A2LA to determine next steps. Maria is proposing the committee consider Michael Klein's proposal to delete the addition of interferents until more information is available. Gregg asked if it's really a big sticking point since nothing on the SSAS table has an interferent yet. Maria noted the committee can wait for A2LA and then respond to EPA or move forward on its own. Richard agreed it is appropriate to delete the use of interferents to get the program on line and come back to it in the future.

Gregg noted that leaving it in might be easier that trying to add it back in later. He added that the standard just allows for it, and it is not a requirement. If an interferent is there, it will be evaluated to verify the equivalent difficulty. Shawn noted the provider is responsible to demonstrate that its sample designs represent an equivalent challenge. The group discussed how the PAs will implement this. Shawn explained that the PA is responsible for this verification in the PT world. This is done for soil samples today, given they have interferents in the soil matrices. Maria noted there is consistency in implementation when there is only one provider accreditor, but the providers can use different accreditors and the accreditors are not required to have the same checklist.

Jim S asked if including an interferent in an audit sample is the same as coming up with a new audit sample design. Making an audit sample with an interferent available would allow for data to be gathered from labs using it as an audit. Gregg doesn't want to see it excluded from the standard at this time. Richard added that it would probably be the regulatory agency would drive whether the interferent is present in the audit sample or not. Mike Schapira noted that the PA just has to verify that the new audit sample design represents a valid test.

Maria suggested looking at the sections in the standard related to this issue to see if a proposal can be developed that will address EPA's comments. The EPA question is how the PA will verify the challenge is equivalent when an interferent is present – would the same interferent be present for audit samples supplied by different providers, etc.

Gregg suggested the PA will have criteria for making this determination. How does the presence of an interferent move the audit sample results – it can't be compared to a clean sample. Jim thought this should be doable if the interferent is something that would be expected from the stack. With the stack sample, the lab will attempt to address the interferent, eg, use methods that will remove the interferent, etc. The lab would be analyzing a sample closer to what they would get in the field and in a similar matrix. It was noted that putting interferents in samples may shift the acceptance criteria. This could be viewed as similar to setting up a new kind of audit sample. Michael Klein stated that an audit sample with an interferent should not be considered a new audit, nor should it have different acceptance criteria. Also it was noted that not all providers might use the interferent. There should have to be more than one provider available for those samples. The EPA rule requires two providers must be available for each sample type, but one may add an interferent and one not. In order to ensure audit samples are similar between providers, an interferent, if allowed, should be noted on the SSAS table. Jim noted that a procedure has not been defined for creation of new audit samples.

Gregg wanted to make sure that the committee doesn't take action that would limit the development of the SSAS program. Jim suggested drafting a procedure for developing new audit samples. The committee would like to keep the door open to developing new audit samples but will need to develop this new procedure relatively quickly. Shawn suggested a subcommittee could develop this. Testers and labs could work on this outside of compliance samples/regulatory arena, and analyze samples with interferents as QC samples.

Maria outlined an explanation to EPA for keeping interferents in the TNI standards. The issue of equivalent difficulty can be ensured within the framework of the standards. Maria will draft a proposal and email it to everyone. Any change to the SSAS standards may mean a change for the PAs for their checklists, so they will need to review any changes.

The options are to delete the provision for interferents or provide an explanation for retaining it to EPA. There may be some revisions that would emphasize the requirements for equivalent challenge. Shawn explained the addition of interferents is up to the provider and is not something that is done without justification – typically there is a regulatory or commercial need. Providers make the assumption that many labs would be analyzing the same samples and providing data. Jim S thought that labs should also be able to analyze for the interferent, although it wouldn't be typical to do this unless the lab wants to determine the potential impact on target compound. Using the SSAS table to control the use of interferents is another option.

Maria will ask for a vote on her proposed explanation. She will note that the interferent does not need to be reported (but the lab can analyze for it if they desire). She will also send the resolution to EPA if possible.

Next Steps

Maria stated the committee needs to go back to the audit sample template to see if updates are needed based on past meeting discussion. Richard will meet with the regulators on this, picking up from the January 24th discussion. He will include William on the call.

Next meeting of the SSAS EC will be March 14th, 2:00 EDT.