

TNI Stationary Source Audit Sample Expert Committee Teleconference Minutes on August 31, 2009

Participants:

Committee members

Maria Friedman
Richard Swartz
Ray Merrill
Jack Herbert
Mike Schapira
Gregg O'Neal
Michael Klein
Stan Tong

Associate members

Shawn Kassner
Mike Miller

Guests

Frank Jarke
Josh Wyeth
Jeff Lowry

Discussions:

The meeting was called to order at 2:03 PM EDT. Welcome was extended to new guest (present at this time), Josh from Wibby (Provider). Josh introduced himself and provided a short brief re. his qualifications and interest to participate in the SSAS Expert Committee.

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

Maria confirmed the spreadsheet/documents for today's meeting (sent to all on 8-28-2009), and also forwarded earlier an email from Dan Tholen re. today's main topic (Appendix A of the Provider VDS).

- 2) Review and approval of minutes from teleconference on August 24, 2009

Stan pointed out a typo in the sentence re. the discussions on retests for failed audit samples (page 4, 3rd paragraph from bottom, 1st sentence): the word "chance" should be replaced with "change."

Gregg motioned to accept the minutes with the proposed change; Stan seconded. Motion carried.

- 3) Chair Update

Since EPA has extended provision of free audit samples until January 1, 2010, the SSAS Expert Committee has more time to discuss Appendix A. Thereafter, the three SSAS Standards will still be finalized and the committee will continue to work on its other

projects (e.g., SSAS Central Database and the Guidance Document for Participants). When EPA finalizes the proposed rules to the CFR, the committee will also have to review/modify the SSAS Table. Later on, the committee may also be charged to oversee the TNI SSAS Program (TBD).

- 4) Review comments to Appendix A in Provider VDS (see Appendix comments spreadsheet)

Maria asked if anyone has comments to Dan's email. Shawn replied he agreed with Dan's suggestion to drop Appendix A from the Provider VDS. If needed, Providers can refer to the homogeneity and stability guidance procedures in the appendix in Volume 3 of the Environmental Laboratory Sector. No matter which program the Providers are following, they will test for homogeneity and stability, and conduct verification the same way.

Maria suggested the committee can write a separate guidance procedure to ensure that audit samples are affordable and since that was the basis of Ray's proposed changes to Appendix A. Stan thought it would be more cost effective for Providers to be working from one guidance procedure. Mike Miller pointed out that quality is quality, achieved through a uniform standard. The Providers must have a consistent approach to prove the quality of their products. The prospective Providers to the SSAS Program are all experienced in making standards and they have already proven quality in their products and services.

Gregg asked if the current homogeneity and stability procedures being proposed as reference are less stringent than the EPA's requirement. Mike Miller did not think the EPA is doing any of these testing right now. However, if they do, the proposed guidance procedure will provide a huge improvement. Stan mentioned that current audit samples are periodically tested and there are available data going back through the years. Shawn did not think there are standard criteria for the current procedures; Stan confirmed. Therefore, the guidance in Appendix A of Volume 3 sets up the standard.

Maria reiterated that the reason we are still in discussion of Appendix A is because of the concern that the procedures stated therein may raise the cost of audit samples. Will referencing the appendix in Volume 3 have a detrimental effect on cost of audit samples? Shawn pointed out that those procedures are called "guidance." If so, then Jack said that contradicts the idea that those procedures can be the standard. Shawn further attested that Providers go out of their way to ensure adequate verification, homogeneity, and stability testing are performed on PT samples and it will be the same for audit samples. Jack noted that PT batches are larger; Shawn replied not necessarily so. Providers look at sales information to determine the size of batches they produce. Ten to thirty may be typical at times, per Shawn.

Maria noted the main differences between PT and audit samples: a) PT batches are larger, audit sample batches are smaller, b) PT samples are ordered in advance, audit samples are ordered on an as-needed basis. Shawn said it is a question of quality and not economics. If a national PT program can be run through Volume 3 Appendix, then the audit sample program can run through it as well. Maria replied we do not want to jeopardize quality but the question on economics remains. Jack added that permitting agencies would not want to burden Facilities with the extra cost of audit samples, if they're cost prohibitive.

Gregg suggested referencing Volume 3 Appendix in the Provider VDS now but letting the Committee reserve the right to write its own guidance procedure later. Mike Schapira asked if Volume 3 requires Providers to use the same methods used by the laboratories. Shawn replied that Providers use more rigorous methods that have higher precision. Mike Schapira expressed concern that if that was so, then interferences may affect methods differently. Shawn replied that if the audit sample was properly designed, then there would be no issues with the methods used in the laboratories.

Jack said he liked Gregg's suggestion and moved to accept Gregg's suggestion. In the meantime, Ray joined the call and was briefed on the current discussion. He had also read Dan's email and had no objection to drop Appendix A from the Provider VDS but have it as a separate guidance procedure. Jack and Mike Schapira said that introducing a second set of guidance confuses the issue. Ray disagreed and noted that there are differences in the two programs that it is appropriate to have separate guidance procedures. Mike Schapira requested Ray to explain the differences between the two guidance procedures. First, Ray pointed out that if Appendix A stays in the Provider Standard, then it cannot refer to soil and water samples; second, keeping Appendix A as written gives the appearance of requiring certain procedures regarding testing of manufacturing lots. Ray added that, after speaking with Dan and a PT Provider, he understood that alternatives are acceptable. Though, he still believes that leaving Appendix A as-is in the Provider VDS would be misleading. Then, Gregg noted that it will also be misleading if the Provider VDS references Volume 3 Appendix. Ray said it will depend on how we reference it. He suggested referencing Volume 3 Appendix but also saying that our own guidance is being developed. Maria suggested use of the same language used to indicate replacement of ILAC G-13 with ISO/IEC 17043 when approved (see Provider VDS, Section 5.1.3). Shawn argued that we cannot reference a document that does not exist. ISO/IEC 17043 is at least in draft form now; the committee's guidance procedure is not even in draft. Shawn also thought that TNI no longer accepts guidance documents. However, Maria said that such mandate does not apply to the SSAS Expert Committee (and for that matter, to the SSAS Program). Maria mentioned the Committee can hold off publishing the SSAS Standards until a replacement to Appendix A has been written.

Ray suggested that instead of referencing Volume 3 Appendix, the Committee can write in the Provider VDS that any homogeneity and stability procedures (note that verification procedures are already stated in the Provider VDS) used must be approved by the Provider Accreditor. Ray's main concern is the relevancy of Volume 3 Appendix. At this time, Jeff Lowry (from ERA) joined the call and asked why Ray would want to write a different procedure. Quality has to be tested always. The audit sample acceptance criteria are already tight. Do we want less stringent limits? If so, that would not be quality. Ray explained that the main issue between the PT and the SSAS Programs is that PT lots have many samples of the same concentration while an audit sample lot may have a range of concentrations and, hence, why we need changes in procedures.

Jack noted that if Providers have different procedures, then there could be differences in cost and quality. Ray replied that the Provider Accreditor will be the normalizing factor. It is also up to the Providers to use the most cost effective procedures.

Based on these additional discussions, Gregg modified his motion to leave it up to the Provider Accreditor to approve the homogeneity and stability testing procedures that the

Provider will use, and drop Appendix A from the Provider VDS. Ray asked if the Committee can still write a separate guidance procedure later, if needed; answer was yes. To this effect, Gregg modified his motion again to add that provision.

Maria will send out the proposed new language to the Provider VDS, to satisfy the motion. Voting will be via email.

Next teleconference is on September 14th, 2:00 PM EDT.

Meeting was adjourned at 3:30 PM EDT.