**SSAS Committee Meeting – October 16, 2017**
**Attendance:**

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| Tom Widera – Chair<br>ERA (Provider) | Committee member | **Present** |
| Vacant – Vice Chair | | |
| Ed MacKinnon<br>TRC Env. Corp. (Stationary Source Tester) | Committee member | **Present** |
| Gregg O'Neal<br>North Carolina DAQ (State Government) | Committee member | **Present** |
| Katie Gattis<br>Element One, Inc. (Laboratory) | Committee member | **Present** |
| Michael Klein<br>New Jersey DEP (State Government) | Committee member | **Present** |
| Mike Hayes<br>Linde (Cylinder gas provider) | Committee member | **Absent** |
| Paul Meeter<br>Weston Solutions (Tester) | Committee member | **Absent** |
| Michael Schapira<br>Enthalpy Analytical, LLC (Laboratory) | Committee member | **Present** |

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| Jim Serne<br>TRC Env. Corp. (Stationary Source Tester) | Associate member | **Present** |
| Maria Friedman (Laboratory) | Associate Member | **Absent** |
| Sheri Heldstab<br>Chester Lab Net (Laboratory) | Guest | **Present** |
| Marge Heffernan<br>Alliance Source Testing (Tester) | Guest | **Present** |
| Stan Tong<br>EPA – Region IX (Federal Government) | Guest | **Present** |
| James Haynes<br>Golden Specialty | Guest | **Present** |

**Call to Order:**

Tom Widera began the meeting at 2:07 EDT. A quorum was present.

**August 2017 Minutes Review:**
Minor edits noted and corrected. Michael Schapira motion to approve, Katie Gattis seconded. All approve (Michael Klein abstained).

Sheri Heldstab revisited an issue from the August meeting, noting a conflict between V1M3 §4.4.1 (which does not require the same calibration for audits as test samples) and V1M1 §8.2 (which requires the lab to attest to using the same calibration). Decision to revise V1M1 §8.2 to specify analyzing per V1M3 as part of revisions to modules. Question about whether TNI requires this language to be more specific. Answer was no, but this will go out for public comment and any issues could be addressed then.

**Discussion of $H_2SO_4$ (RM8) Audit Sample Integrity Issue:**

Tom Widera led a discussion about the reason why the September call was canceled; namely so that a Committee Member only call could be conducted to discuss a $H_2SO_4$ (RM8) Audit Sample Integrity Issue that the Provider ERA had. The issue centered on 5 manufacturing lots of audits manufactured on the same day in April 2016. A lab had reported low volume on an audit that was shipped. A second, replacement audit was sent and this one also had low volume. An investigation ensued and it was determined that a number of audits had low volumes (ERA guarantees a minimum of 14 ml). Further investigation noted a higher than normal failure rate for these samples. Per V1M1 §10.1.3, ERA was required to begin a review of these audit samples. Low volumes and high failure rates were an issue with these 5 lots, with the audit bias being high. All of these audits were invalidated (43 audits), pass or fail. The closed session meeting was called to develop recommendations for ERA. Tom had a call with the TNI Consensus Standards Committee who told him that the Expert Committee should send a letter to ERA's Accreditor (A2LA) with recommendations and allow the Accreditor to take any action. Every tester who received one of the faulty audits was sent a letter explaining the issue. ERA opened a "CAPA" or Corrective Action, Preventative Action" investigation to find a root cause and how to prevent it from happening again. Tom Widera will recuse himself (as an ERA employee) for the recommendations to A2LA.

Marge asked if there was any feedback from the regulated community. Tom responded that so far, either the faulty audit did not impact the compliance status and the test was accepted, or a new audit was sent and meet acceptance criteria so again, the test was accepted. ERA has not heard back from about a third of the affected projects. The two regulators on the call were asked to offer opinions; Michael indicated that he would review on a case-by-case basis, but that the facility should not be penalized for issue and Gregg indicated that he would just discount the audit in reviewing the test report.

Tom Widera reviewed and analyzed archived samples from all past $H_2SO_4$ lots. Failure rates were at historical levels (~18%). He also checked the levels for lots in stock and all were normal. Based on this, he felt the issue was limited to the 5 lots from April 2016. Gregg questioned if the historical 18% failure rate indicated a stability issue for this type audit and said no based upon stability checks done at the expiration date.

Although the root cause analysis was not complete, ERA believes the issue was evaporation of the samples causing an increase in the actual concentration of the sample and subsequent high bias compared to the listed "actual" concentration. Once A2LA reports back to Tom (as the Chair of the Committee), he will share the information with the rest of the Committee.

**Method 8 Sub-Committee:**

A discussion was started about reviving the Method 8 Sub-Committee that was looking the high failure rate for these audits. Tom Widera had looked at all ERA Method 8 audits for a reason (Specific lab? Method bias? Limits too tight? Concentration based? Other?). This information can be used by the Sub-Committee. Mike Schapira was head of this Sub-Committee and will continue. It was asked whether the Sub-Committee would like input from labs and the answer was yes. Additional members were sought if anyone had interest (don't need to be on the Expert Committee to be on the Sub-Committee).

**Updating V1M1 (continuing where left off last time, after §8.2):**

Picking up with the issue about how often an audit sample can be sent. Tom mentioned it was primarily for certain types of audits, HCl and metals, where only 3-4 labs were doing the bulk of the samples which was not anticipated when the program started. Discussed the Interim adjustments, where the module was revised to allow the same audit batch to be sent to a lab up to 8 times in a year, as long as it was not sent to the lab consecutively or more than once a month. It was mentioned that this has eased the burden of

providing enough different batches some but not nearly enough and the past discussions were summarized again. With unique identifiers and enough randomness, the labs don't know what concentrations they are getting. Mike Schapira suggested focusing on this and requiring enough overlapping batches so that labs can't guess at the concentration. Michael Klein mentioned the issue of specifying the number of batches a Provider needed in a specific range as being problematic for ranges where the Providers don't get orders. Gregg questioned how many does one need to ensure randomness? Tom mentioned that most audits are in the bottom third of the SSAS table, but that could change, so there are issues with putting a hard number based on this, and splitting the SSAS range into thirds (as discussed in the past) with hard numbers in each will result in many wasted audits to be disposed in the areas where few are ordered. Michael Klein suggested a hybrid approach, where areas of few orders would use the old language and areas of many orders would use newer language being discussed, and the areas would be revisited periodically. Discussion followed on supply and demand of audits and how to word restrictions on numbers and the need for randomness to prevent guessing of concentrations. Tom mentioned having enough at certain intervals to make guessing impractical. Katie suggested getting rid of numbers language in §8.3(f) and having enough batches at least 10% apart to accomplish this. Move this discussion to the Design Section of V1M1 (§6). How to accomplish this with language was discussed. Gregg questioned if Accreditors had input or were ever consulted on this issue and Tom replied no regarding A2LA.

Discussion ensued on how the SSAS Program language originally came from PT Sample language, but the numbers of samples are not the same, so not analogous. Sheri mentioned that she agreed with Katie and that with enough overlap, even getting the same samples over and over, they would not be sure it was the same one. Mike Schapira mentioned that we can't remove the numbers without adequate replacement language. Tom mentioned we needed to balance the need for having enough samples in the ranges where audits are ordered without having too many in the ranges where they are not ordered, plus maintain the integrity of the program. Tom will reach out to A2LA to see if they have any suggested language. Katie mentioned that the variety in batches should be proportional to the demand. Sheri talked about language based on tracking trends in orders over the prior 6 months. Tom reiterated the need for language to capture this and the need for quantification. Sheri said that she would try to draft some language. Others were asked to send along any suggested language.

Continuing to next Sections:

- Section 9 – No issues or comments noted.
- Section 10 – No issues or comments noted.
- Section 11 – Mike Schapira suggested combining §11.1.1 with §11.1.1.1 since there is no §11.1.1.2. It was agreed to make this change. Katie suggested changing §11.2(f) where it says Lab "or" Tester to "and". It was agreed to make this change. It was also discussed about having pre-printed forms to be sure to include everything. There was a further discussion of a conflict between the language in §11.1.1.1 with that in §8.1, but it was determined that the former dealt with after samples were received and the latter dealt with before samples were sent, so that's why they are different, and this is OK.

This ended the discussion of V1M1. Tom will do a mock-up of all the approved changes for discussion and a vote.

Next: November 13, 2017 at 2 pm Eastern
Meeting Adjourned 3:31 pm Eastern

**Next Minutes Author:**
November – TBD based on who was skipped. Otherwise, Mike Schapira.