SUMMARY
TNI CHEMISTRY EXPERT COMMITTEE MEETING

December 4, 2019

The Chemistry Expert Committee (CEC) met by teleconference at 2:00 PM ET on December 4, 2019. Chair Valerie Slaven led the meeting.

Roll Call

Valerie Slaven, Consulting Services (Lab) - Chair	Present
Jay Armstrong, VA DGS (AB)	Present
Paula Blaze, NJ DEP (AB)	Present
Eric Davis, Austin Water Utility (Lab)	Present
Deb Gaynor, Independent Consultant (Other)	Present
Shawn Kassner, Pace (Lab)	Present
Max Patterson, UT DOH (AB)	Absent
Charles Neslund, Eurofins (Lab)	Absent
Colin Wright, Florida DEP (Lab)	Absent
Calista Daigle, Quality Consulting (Other)	Present
Chad Stoike, ALS Global (Lab) – Vice Chair	Present
Robert Wyeth, Program Administrator	Present

Nicole Cairns, Gail Warren and Terrell Maske, associate committee members, were also present. Paul Junio CSDEC chair was a guest on the call. The agenda for the meeting is presented in Attachment 1. With a quorum present the meeting proceeded.

November Meeting Minutes

The November 6, 2019 minutes were presented for committee approval. The minutes will be amended to include the inadvertent omission of the last page of Attachment 2. With this change Deb motioned to accept the minutes and after a second by Chad the motion was unanimously accepted. Minutes will be forwarded to William for posting on the website.

ISO 17025 regarding DOC

Discussed Paul's comments on 17025; ISO language vague on DOC but definitions of competence are relevant and need to be considered in development of the revised language in Module 4. ISO language avails committee of considerable flexibility in DOC language.

Much of the current "DOC" language in ISO will be addressed in Module 2. Module 4 and other modules need to address the "how" of determining initial and on-going DOC.

Conclusion at this point was that ISO 17025 would not alter the committee's current approach to standard's modifications. True issue will be the harmonization with various state AB requirements.

DOC

Valerie initiated the discussions by stating that ISO is essentially about analyst competence. Module 4 needs to address both lab and analyst competence (being termed as initial and on-going DOC) and the differences between the two. She suggested that lab IDOC could be considered to be their method validation.

Further stated that the committee should address and decide, in the following order, on criteria/requirements for:

1. Initial lab DOC
2. On-going lab DOC
3. Initial analyst DOC
4. On-going analyst DOC

The discussion should focus on the requirements for these items; not where in the standard they will ultimately be presented.

The issue of instrument specificity was then brought up and has never been addressed in the standard. DOC, in committee opinion, would be required for instruments utilizing different technologies (i.e., Lachat vs. Seale, HP vs. Varian instruments, etc.); software differences were not thought to be technology differences although this is arguable. Suggested that DOC is method specific and if different instruments, analyst would need DOC's on both or some minimal evidence of competence/comparability.

Suggested that from an AB perspective that SOP's are the driver; if different SOP's are used then separate DOC's would be required. Issue raised was that for methods like 8270, a lab will only have one SOP used on different instruments, platforms, and even with utilization of different approaches such as SIM or LVI.

Further suggested that other operational requirements (calibration, etc) verify capabilities of lab and analyst; also noted that this type of evidence of competence is not noted in the standard.

Real issue is whether or not DOC's by method, as is the current approach, is sufficient to insure competence however measured. Does the committee need to address this?

What should a lab have in place before they should be accredited:

1. DL
2. LOQ
3. DOC
4. PT (where available; what if not available?)
5. Method validation (Note: validation performed consistent with the standard provides initial DOC for analyst)
6. More??(accuracy and precision?)

Performance of DOC for analytes for which analysis has not been done in a year; do they stay on lab certification? What is impact on lab and analyst initial and/or on-going DOC and how should standard address this issue?

One opinion was that since accreditation is by analyte, something (what?) must be done annually…. Or just do a new initial if needed?

Standard now says "prior to or on receipt of samples" DOC must be in place or re-done for the lab (any analyst would fulfill this need)….should be case for initial and on-going requirement.

Therefore (?); initial DOC for the lab is covered by DL, LOQ and method validation (all analytes?). For on-going lab DOC DL and LOQ processes can be used but need some means of support for all analytes (PT doesn't work as all analytes not present). PTs will work for what is present in the PT but not all analytes. Pointed out however that labs have all analytes available as standards and a procedure could be made up to fulfill an annual requirement if we modified standard to require it but would only have to be completed by one analyst representing the lab. Lab could also develop and document their own process to demonstrate their ability to show method/analyte competence.

Question was raised of precision and accuracy requirements. Standard currently addresses both precision and accuracy in the initial DOC but only accuracy in the on-going DOC. Committee felt this approach was acceptable.

Lab competence (DOC) should be contained within method validation and not specifically under DOC…DOC should be for analyst only as per definition in Module 2.

Regarding analyst, initial DOC shows accuracy and precision, on-going is only precision as standard is currently written…is this the committee's intent?

For analyst to show competence, what should be required (what about prep people?). Should we differentiate between techs and analysts? Include all parts of process and techs are shown competent in the DOC results.

1. Calibration
2. Precision and accuracy (minimum number of 3)
3. Blanks
4. Sensitivity
5. Selectivity

If a set (not defined) of analysts prepare matrix/method/analyte specific DOC materials and results are acceptable, all member of the team have a passing DOC.

DOC should include a list of requirements including reading SOP/Method, familiarity with terminology (?, how judged), documentation of above criteria, training records, other thoughts?

Valerie asked committee members to focus thoughts on analyst requirements for continued discussion on both initial and on-going DOC.

The meeting of the committee was adjourned at 3:30 PM ET on a motion by Shawn and a second by Deb. The next scheduled meeting of the committee is Wednesday, January 1, 2020. The meeting has been rescheduled due to the holiday for 10:00 AM ET on January 8, 2020.

Attachment 1

CEC call December 4th

Agenda

1) Review of November Minutes
2) Review Paul Junio's comments on ISO 17025 language pertaining to DOC
3) Continue DOC discussion
    a. Does the Laboratory need to demonstrate competency (method validation?, ongoing?)
        i. If so what should be required? (list review)
            1. Initial
            2. Ongoing
    b. What is required for an analyst to demonstrate competency? (list review)
        i. Initial
        ii. Ongoing