SUMMARY
TNI CHEMISTRY EXPERT COMMITTEE MEETING

November 6, 2019

The Chemistry Expert Committee (CEC) met by teleconference at 2:00 PM ET on November 6, 2019. Chair Valerie Slaven led the meeting.

Roll Call

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

Gail Warren, Farid Ramezanzadeh and Nicole Cairns, associate committee members were also present. Paul Junio CSDEC chair and Mike Delaney were guests on the call. The Agenda for the meeting is presented in Attachment 1. With a quorum present the meeting proceeded.

September and October Meeting Minutes

The September minutes were presented for committee approval. With no comments or suggested changes Jay motioned to accept the minutes and after a second by Max the motion was unanimously accepted. The October minutes were presented and after no discussion, Max motioned to accept and was seconded by Colin. With an abstention by Jay, the motion passed unanimously. Both sets of minutes were forwarded to William for posting.

Review of Committee Roster

The committee roster attached below was presented and reviewed. As Shawn was now employed by Pace, a Lab and Calista may also be affiliated with a lab, the question of balance/lack of dominance was raised. Val will address Calista for clarification of her status.

At this juncture it was decided that regardless of the immediate outcome of this review process, the first action should be to attempt to attract new members before excusing any current members as each has been a valued committee member.
The roster was corrected to list Deb as an Independent Consultant as Phoenix no longer exists.


Copy of Committee Membership Chemistr

SIR Spreadsheet

The SIR spreadsheet was presented and approval by the committee was sought. On a motion by Jay and second by Chuck with a unanimous vote of the committee members present the SIR response was approved. This approval was noted as "for the record" as it was necessary for Bob to finalize and submit the document to meet established deadlines.

Discussion of DOC feedback for the AC and where to start with DOC revision

A copy of the collection of responses received is again presented in Attachment 2. The committee collectively reviewed and discussed the comments from the AC. Val asked the committee what were the overriding DOC issues of concerns in these comments as interpreted by the committee members. The initial inputs focused on the concept of "another approach", use of PTs, precision and accuracy of the DOC process, the issue of analytes without spikes, the required documentation by ABs, and the differing requirements of ABs in the process for IDOC and on-going DOC (CDOC).

An additional concern of the committee was the inconsistency of the existing standard's language relative to the individual analysts and the laboratories accreditation via DOC by method/matrix and analyte. Also the capability of those individuals who are involved in sample preparation as opposed to analysis was raised as a fundamental issue.

It was suggested that the overall DOC issue is one where continuing input and involvement of ABs is critical to a successful modification of the standard.

After lengthy discussion, Val requested that each committee member prepare a list of requirements and the process related to analyst IDOC and CDOC and what requirements are necessary the laboratory for IDOC and CDOC to meet AB accreditation requirements.

Paul volunteered to review the ISO 17025 requirements regarding demonstration of competence and report back to the committee during the December call.

The meeting of the committee was adjourned at 2:40 PM ET on a motion by Max and a second by Colin. The next scheduled meeting of the committee will be by teleconference on Wednesday, December 4, 2019 at 2:00 PM ET.

Attachment 1

CEC call November 6th

Agenda

1) Review of September and October Minutes
2) Committee Roster Review
3) SIR Spreadsheet Review/Approval
4) Discussion of DOC feedback from the ABs and where do we start with DOC revision

   Discussion questions

   a. What do the ABs think needs to change?
   b. What is working for the ABs?
   c. What are labs currently doing?
   d. Are there other approaches we should look at?(from methods or other programs)
   e. Should the method/lab and the analyst have separate clearly listed requirements?
   f. What happens if a person is only responsible for part of a procedure?
   g. What is needed to really show if a person is competent on an analysis?

Attachment 2

Good morning, Val,

Sorry to have not responded sooner. I've cc'd the whole group so that anyone else can chime in if they don't agree or want to comment further.

The only part of the DOC section we have struggled with in VA is the phrase in V1M4 1.6.2.2 "It is the responsibility of the laboratory to document that other approaches to initial DOC are adequate." For example, we've had labs "document" [by writing in their QA manual] that running a PT sample is an adequate substitute for the DOC as described in the Standard.

I don't have a problem with some flexibility within the Standard in this area; we've communicated to labs who feel they have a 'better idea' that their process needs to address *both precision and accuracy for us to agree that another approach is "adequate"*.

My recommendation would be to change that sentence to something along the lines of, "It is the responsibility of the laboratory to document that other approaches to initial DOC *address both precision and accuracy in an equally effective manner*, to be considered adequate."

We have found the rest of the DOC section to be clear and have no other concerns or requests.

Thank you for the hard work of you and your committee!

Cathy

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Cathy Westerman, Manager, Laboratory Certification Group
Department of General Services (DGS) / Division of Consolidated Laboratory Services (DCLS)
Office: (804)648-4480 x391
600 N. 5th Street, Richmond, VA 23219

Initial Demonstrations of Capability:

*Has to follow any reference method prescribed procedure (more stringent standard).

*Has to be performed before an analyst runs the method solo.
*The paperwork / form has to be completed in a timely fashion.

On-Going Demonstrations of Capability:
*Has to be performed / documented once per year.
*Four LCSs or PTs (if available for the analyte) may be used. The lab's approach has to be documented in their quality manual or an administrative SOP.
*The paperwork / form has to be completed in a timely fashion.

Bill Hall
NH ELAP
(603) 271-2998

I would prefer that the option to "document that other approaches to initial DOC are adequate" be removed. This only opens the door for a lab to do something that is possibly crap and then makes it harder for the AB to enforce. Possibly replace this statement with one that says something like "if the approaches listed in items XX – XX are not possible, then the laboratory shall develop and document an alternate initial/continuing DOC procedure that addresses both precision and accuracy of the method."

Our State regs require documentation of the IDOC/CDOC to be the following:
(i) An identification of the analysts involved in the preparation or analysis, or both.
(ii) The sample matrix.
(iii) The analyte, class of analyte or measured parameter.
(iv) An identification of the test method performed.
(v) An identification of the laboratory-specific standard operating procedure used for analysis, including revision number and effective date.
(vi) The dates of preparation or analysis, or both.
(vii) The summary of analyses, including results.

The actual IDOC and CDOC shall meet the following requirements:

(vi) An initial demonstration of capability for each method that relates to the employee's job responsibilities has been performed. The initial demonstration of capability requirements are as follows:

(A) An initial demonstration of capability is required prior to the use of any method.

(B) An initial demonstration of capability shall be completed each time there is a change in instrument type, personnel or method.

(C) An initial demonstration of capability must include all sample preparation and analytical steps contained in the method.

(D) If the method or State or Federal regulations specify a procedure for the initial demonstration of capability, that procedure shall be followed;

otherwise, an initial demonstration of capability shall be performed as follows:

(I) The analyte shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified in the method. If the method does not specify a concentration, the concentration must be in the lower half of the calibration range or at or below the maximum contaminant level for Safe Drinking Water Act compliance testing, whichever is lower.

(II) At least four aliquots of the quality control sample shall be prepared and analyzed consecutively according to the method. The preparation or analysis, or both, may occur on a single day or over the course of multiple days.

(III) Using all of the results, calculate the individual recovery, the mean recovery and the standard deviation of the mean recovery for the population sample in the same units used to report environmental samples. When it is not possible to determine mean and standard deviation, such as for presence-absence and logarithmic values, the environmental laboratory shall assess method performance using criteria from the method or other established and documented criteria.

(IV) Compare the information from subclause (III) to the corresponding acceptance criteria for precision and accuracy in the method. If the method or regulation does not specify acceptance limits, the % Relative Standard Deviation must be less than 20%. To be considered acceptable, an initial demonstration of capability must meet all acceptance criteria.

(E) When a method has been in use by an environmental laboratory prior to January 1, 2005, and there have been no changes in instrument type, personnel or method, the environmental laboratory shall have records on file to demonstrate that an initial demonstration of capability is not required.

(F) The laboratory shall retain all data necessary to reproduce the initial demonstration of capability.

(G) The work cell as a unit shall meet the following requirements:

(I) When a member of a work cell changes, the new work cell shall demonstrate capability by means of acceptable quality control performance checks on four consecutive batches. The acceptable performance shall be documented. If any quality control performance check within the four consecutive batches following the change in personnel fails to meet acceptance criteria, an initial demonstration of capability shall be completed.

(II) If the entire work cell is changed, an initial demonstration of capability shall be completed.

(vii) A demonstration of continued proficiency by at least one of the following every 12 months for each method that relates to the employee's job responsibilities:

(A) Another initial demonstration of capability.

(B) Acceptable performance of blind performance samples (single blind to the analyst).

(C) Successful analysis of blind proficiency test samples on a similar test method using the same technology (for example—GC/MS volatiles by purge and trap for EPA Methods 524.2, 624 or 5030/8260 would require documentation for only one of the test methods).

(D) At least four consecutive laboratory control samples with acceptable levels of precision and accuracy as required by the initial demonstration of capability described in subparagraph (vi).

(E) Analysis of at least ten authentic samples with results statistically indistinguishable from those obtained by another trained analyst. The samples must include samples free of the analyte of interest and samples containing the analyte of interest at measurable concentrations.

Ms. Aaren S. Alger | Laboratory Accreditation Program Chief
Department of Environmental Protection | Bureau of Laboratories

PO Box 1467 | Harrisburg, PA 17105
2575 Interstate Dr. | Harrisburg, PA 17110
Phone: 717.346.8212 | Fax: 717.346.8590
www.dep.pa.gov

Michele Potter, NJ

I'd also add that the section needs to have language that addresses DOCs (initial and continuing) must be performed for every analyte that the laboratory possess or seeks for accreditation. We've had labs think for the continuing DOCs that if they use a PT to meet this requirement that they only have to do the analytes in the PT – there needs to be clarity that if a PT is used for the continuing DOC that any analytes not included in the PT that are fields of accreditation must have a DOC performed in accordance with another alternative procedure. It should also be clarified that if a PT is used for continuing DOCs that the PT must actually be acceptably analyzed – again we've had labs try to use a failed PT for a CDOC and it would be much easier to enforce if the standard came right out and said when PTs are used they must be evaluated as acceptable in order to meet CDOC requirements. And would also like it clarified that if a PT is used only the main analyst performing that PT is allowed to use it for their DOC, all other analysts performing that analysis must determine a DOC by an alternate procedure… and for the record, I don't really like labs being able to use a PT to meet DOC requirements; to me those are two different requirements but we work with it…

Dear Lynn and AC Members,

Our FL Administrative Code Rule has always required laboratories to “maintain analytical performance … for those analytes and test methods with which they have been certified or are seeking certification.” The 2016 amendments clarified that this means IDOC or CDOC for each matrix-method-analyte annually. This also reconciles the TNI V1M4 language about what “ongoing DOCs” mean in Section 1.6.3.

Please let me offer a one-person opinion (Vanessa is free to add something, of course) on IDOCs and CDOCs.

The IDOC requirements in Section 1.6.2 are okay as written, but please feel free to offer improvements if any are needed.

Section 1.6.3 is the one that I really thought was insufficient, although it would have been perfectly fine if our NELAP accreditation system only went to the test method level and did not specify “analytes” (which of course we have to do for the SDWA and CWA regulations). The minimum that I would like to see, in order to have confidence in the laboratory’s certification for EACH accredited matrix-method-analyte, would be at least one of the following for each matrix-method-analyte annually:

+ Another IDOC
+ An acceptable score on a PT sample for the corresponding FoPT matrix-method-analyte where the Assigned Value for the analyte was at a nonzero quantitative value.
+ MDL redetermination or verification (and hopefully accuracy & precision targets are met despite the low concentration value used)
+ Sample duplicate pairs for at least 2 samples (if the analytes are not spikable; this would be very useful for TCLP, Paint Filter Liquids, or other methods if both positive/detect and negative/nondetect results are included and compared)
+ Batch method blanks and LCSs that include each analyte (including the Aroclors) at least once in the year and processed under all prep/analytical method steps and assessed against acceptance criteria
+ Same samples (at least 2 samples) analyzed by at least 2 analysts and getting “equivalent” results (also useful if both positive/detect and negative/nondetect results are included and compared)

Thank you for letting me contribute my two-cents. Sorry for the delay in responding.

Yours truly,

Carl Kircher
904-791-1574