SUMMARY
TNI CHEMISTRY EXPERT COMMITTEE MEETING

April 3, 2019

The Chemistry Expert Committee (CEC) held a conference call on Wednesday, April 3, 2019. Committee Chair Valerie Slaven led the meeting. The agenda for the meeting is presented as Attachment 1.

1. Roll Call

Valerie Slaven, Consulting Services (Other) - 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, Neptune (Other)	Present
Max Patterson, UT DOH (AB)	Absent
Charles Neslund, Eurofins (Lab)	Present
Colin Wright, Florida DEP (Lab)	Present
Calista Daigle, Quality Consulting (Other)	Absent
Chad Stoike, ALS Global (Lab)	Present
Robert Wyeth, Program Administrator	Present

Associate member Nicole Cairns was also present. A quorum was present and the meeting commenced.

2. Approval of March 6, 2019 Meeting Minutes

After a few minor editorial corrections, a motion to approve was made by Deb and seconded by Colin. With a unanimous vote the minutes were approved and will be posted. Meeting minutes were submitted to William for posting.

3. Standard Interpretation Requests (SIRs) – CEC responses

The following SIR's (297, 282, 339, and 340) were addressed again (consistent with last Months assignments) during the meeting, and proposed responses were discussed and approved.

- SIR 297 Response (Attachment 2)
  Previously addressed by the committee; new response was presented by Valerie. Request concerned if DOC specific to every method, matrix and analyte. The revised response was discussed; minor modifications

were made and subsequently approved by the committee. The motion to approve was made by Eric, seconded by Chuck. The response was approved unanimously and was forwarded to Lynn Bradley on behalf of the LASEC/AC.

- SIR 282 Response (Attachment 3)
  This SIR addresses the use of MS data to supplement a failing LCS. CEC response is that in no case would an MS be used to supplement a failing LSC. Eric prepared and presented the CEC response. After discussion and minor modifications, a motion was made by Deb, seconded by Chuck and unanimously approved by the committee. The response was forwarded to Lynn Bradley on behalf of the LASEC/AC.

- SIR 339 Response (Attachment 4)
  Relates to use of ongoing DOC, after timely and continued use by the lab, PT/LCS as an acceptable substitute for an IDOC. Committee consensus was that this substitution is only acceptable if the analytes for which accreditation is being sought is contained within the ongoing DOC data. The response was prepared and presented by Deb. After discussion and minor modifications, a motion was made by Jay, seconded by Collin and unanimously approved by the committee. The response was forwarded to Lynn Bradley on behalf of the LASEC/AC

- SIR 340 (Attachment 5)
  Concerns the MDL process; the SIR seeks clarification on when to verify at or below the LOQ and when to use the same spiking concentration as in the original study. The response was prepared and presented by Collin. After discussion and minor modifications, a motion was made by Chad, seconded by Chuck and unanimously approved by the committee. The response was forwarded to Lynn Bradley on behalf of the LASEC/AC

4. **Discuss Cathy's comments on the guidance document**
   Cathy Westerman submitted via e-mail, additional comments and a question on guidance document 3-109 created by the CEC. An excerpt from the e-mail dated March 20, 2019 is presented in attachment 6. Valerie has not responded as of this

date. The committee felt a response from the committee should be tabled until all comments are received from the LASEC/AC as other comments are not necessarily expected but may be presented. If no additional comments/questions are received by the May conference call, a response to Cathy will be prepared.

Valerie advised committee members that the May call will include discussion of the SIR spreadsheet, the internal audit and Cathy and/or other LASEC/AC comments received on the guidance document. Following conclusion of those activities, the committee would begin discussions of modifications to the DOC issues highlighted in the SIRs. Val also reported having received AB comments regarding DOC in addition to those in the SIRs. She will share those AB comments with committee members.

The CEC meeting adjourned at 3:15 PM ET on a motion by Deb and seconded by Jay. The next CEC conference call is scheduled for May 1, 2019 at 2:00 PM ET.

Attachment 1

CEC Meeting Agenda

April 3, 2019

1. Roll call
2. Review March minutes
3. Review SIR responses
4. Discuss Cathy's comments on the guidance document

Attachment 2

SIR 297

Standard	2009 TNI
Volume and Module (eg. V1M2)	V1M4
Section (eg. C.4.1.7.4)	1.6.2 and 1.6.3
Describe the problem:	Are the DOC requirements in V1M4 sections 1.6.2 and 1.6.3 specific to each Matrix-Method-Analyte combination for which a laboratory seeks or maintains accreditation? The language implies that they are, and because laboratories are accredited by Matrix-Method-Analyte, should be, but it is not explicit enough to preclude another interpretation. (Richard Burrows is aware of the issue and is expecting the SIR.)
Comments:	Section 1.6.2 is specific to the matrix-method-analyte combination as illustrated by the references to analytes in 1.6.2.2.a and "all parameters" in 1.6.2.2.d. Therefore, if no other analysis is performed for a matrix-method-analyte combination within a 12 month period, a new IDOC would be required per the last sentence in 1.6.2.
Response(updated):	Section 1.6.2 (IDOC) is specific to each matrix-method-analyte combination. Section 1.6.3 does not state that it is specific to each matrix-method-analyte combination. In fact, given that the standard allows the use of an LCS or PT samples which are not required to contain every compound according to the standard as acceptable forms of DOC it cannot be said that the standard requires ongoing DOC to be matrix-method-analyte combination specific. In addition, the standard states that it is the responsibility of the laboratory to document a procedure describing the ongoing DOC and its adequacy per 1.6.3.1. There are accreditation bodies that currently require ongoing DOC to be matrix-method-analyte combination specific implying that they do not see the standard as written as adequate then it is the laboratories responsibility to document an adequate procedure for ongoing DOC.
Response to comments:	The standard does not require ongoing DOC to be matrix-method-analyte combination specific however we have expanded and clarified the response to the best of our ability and do intend to revise the DOC section of the standard in the next revision. The input from the ABs has already been requested and received on this and continued input will be sought so that the standard can be modified to a procedure that is believed to be adequate by the ABs in the next revision.

Note: This is really a questions about the 2016 standard not the 2009.

Attachment 3

SIR 282

To the Chemistry Committee from LASEC SIR Subcommittee:

We tried to write Implementation Guidance for this SIR, as it was determined not to be a valid SIR back in 2014 when it was submitted. We learned from Silky that the language goes back to the early NELAC Standards but that the way it's now been put into practice is now what the old Quality Systems Committee intended when they wrote the language. Apparently, the language has been carried forward for two decades now, without really being examined.

Please coordinate your response with the Quality Systems Expert Committee. For this one, normal timeframes have long since been abandoned. Thank you!

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M4
Section (eg. C.4.1.7.4)	1.7.3.2.3 and Note
Describe the problem:	The language in the note under Section 1.7.3.2.3 is as follows, "The matrix spike may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS" seems to indirectly indicate that an analyte in the MS which meets the LCS acceptance criteria may be used in place of the same analyte in the LCS that does not pass the LCS criteria. In short, if an analyte in the LCS fails the LCS acceptance criteria can you use the same analyte from the MS instead if it meets the LCS acceptance criteria. My interpretation is that this is not the intent of the note in this section of the standard to allow this however I have received questions from several sources regarding the applicability of the above requiring further explanation. I look forward to your response.
Committee Comments:	The MS is "used in place" meaning an LCS is not analyzed. The MS cannot replace a failing LCS. This note will need to be clarified in the upcoming revision of the standard. It is assumed that if a sample matrix can pass which is a worst case scenario, then a clean matrix should be able to as well. This is why the MS limits must be as stringent as the LCS. It should also be noted that this was originally

	intended for use in small waste water labs that only analyze a single waste stream.
Response:	The language "used in place of" is interpreted to mean that the batch does not contain an LCS. The quality of the data is being evaluated with an MS instead of the LCS. However, if an LCS is present in the batch, it must be analyzed and evaluated to assess the quality of the data, independent of the results of a MS. The committee will clarify the wording of this section in next revision of the Standard.

Attachment 4

SIR 339

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M4
Section (eg. C.4.1.7.4)	1.6.1 c)

Describe the problem:
1.6.1.c)In cases where an individual has prepared and/or analyzed samples using a method that has been in use by the laboratory for at least one (1) year prior to applying for accreditation, and there have been no significant changes in instrument type or method, the ongoing DOC shall be acceptable as an initial DOC. The laboratory shall have records on file to demonstrate that an initial DOC is not required.

Question: Would like clarification on the wording in this section. Is the section saying that if a lab applies to add accreditation for a method the lab has been performing in house for at least one year, the analyst performing the test can submit an On-going DOC for accreditation rather than an Initial DOC? The wording almost suggests that the analyst does not need an IDOC for a test method the lab has held certification for over one year, only an On-going.

Thank You

Committee Comments:

The Standard does allow applying for accreditation for a method in the limited case of a method "the lab has been performing in house for at least one year" without the performance of an Initial DOC. Please note that Section 1.6.1.c) does not say "a test method the lab has held certification for [*for*]over one year".

The Committee agrees that the requirements and clarity for Initial and Ongoing DOC are unsatisfactory, and has already slated these sections for revision in the next version of the Standard. Suggestions are welcome.

Response:

The question has been posed in two parts, and is answered accordingly. For the first question, if the individual has been performing the method, preparing and analyzing samples, and meets all the laboratory requirements for an Ongoing DOC (Section 1.6.3), the Standard allows substitution of an Ongoing DOC for an Initial DOC. It should be noted that the requirements for an Ongoing DOC (Section 1.6.3) include any one of five approaches, one of which is "another" Initial DOC.

Section 1.6.1.c) is not relevant to the second question, in which "the lab has held certification for over one year". This posits a situation in which a new analyst is being trained for an already-accredited method; these requirements are set in Section 1.6.2 (the Initial DOC).

Attachment 5

SIR 340

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M4
Section (eg. C.4.1.7.4)	1.5.2.1.2

Describe the problem:
40 CFR 136 Appendix B (3) (a) "During any quarter in which samples are being analyzed, prepare and analyze a minimum of two spiked samples on each instrument, in separate batches, using the same spiking concentration used in Section 2." If the variation in the spiking concentration is used to calculate the MDL (MDLS = t(n −1, 1−α = 0.99)Ss), and the lab uses the MDL to calculate a LOQ (maintaining that the LOQ ≥ the lowest calibration concentration), this may not be "a spike at or below the LOQ" as prescribed in TNI V1M4-2016 §1.5.2.1.2 because the concentration value does not play a role in calculating the MDL (DL). It seems the TNI ongoing verification definition differs from 40 CFR. If the lab were to use a concentration at or below the LOQ, this would not always satisfy 40 CFR 136 Appendix B (4) (b) "Include data generated within the last twenty four months, but only data with the same spiking level." The lab seeks clarification on when to verify at or below the LOQ and when to use the same spiking concentration as in the original study. Thank you.

Committee Comments:

Response: The TNI requirement does differ from the EPA MDL procedure in that it requires that the spikes used for the ongoing verification of the MDL be "at or below the LOQ." The EPA MDL procedure has no limitations for the spike concentration used in the initial determination and ongoing verification, other than they be at the same concentration. The LOQ should therefore be set at the concentration of the lowest calibration standard or the concentration of the spiked samples used to determine the MDL, whichever is greater. This will ensure that the spike concentration is at or below the LOQ and that the ongoing verification can be carried out using spikes of the same concentration as the initial determination, as is required by the TNI standard.

As addressed in guidance document 3-109, it should be noted that a new initial MDL study would be required if the spike concentration of previous MDL studies was above the LOQ and the LOQ cannot be raised to match the previous MDL spike concentration.

ATTACHMENT 6
Except from Cathy Westerman e-mail to Valerie Slaven dated Wed, Mar 20, 2019 at 2:46 PM reference 3-109 guidance document

Hi, Val,

I have reviewed the revised LOQ document and had a couple of minor comments and one question. I thought I'd send this directly to you rather than "via" the AC. Our next AC meeting is 4/1, so if you have a comment or response for my question I can share it with the AC at that time, if it seems relevant to do so.

"Quick Notes": 1. Page 3: minor typo in the "terms in the calculation" box, 3rd line (spelling of 'blanks') 2. Page 5: there's an extra page break (a blank page) 3. Page 7: I think there's a typo in the middle paragraph, which begins with the word "Typically, ...". Was the sentence that starts with "This would be of no value ..." intended to say "... and most labs will not select ..."? 4. Page 8 (page number is covered by a text box I believe): I personally see no value in the last phrase on that page, "... although some labs incorrectly applied one" (speaking of a quantitative criterion.) A lab should not be called "incorrect" for applying a criterion which was above and beyond what was expected [in my opinion], and, "incorrect" or not, I don't see where this document needs to speak to, or criticize, previous practices.

"Question": 1.

On page 12, the added text to the first paragraph: I understood the paragraph before the additional text was added. The new text really confuses me. Can you comment on that text? Is the committee saying that if a lab doesn't analyze various sample types then the EPA method requirement (stated in the previous sentence) does NOT have to be met? I'm very confused by this paragraph now.

I admittedly gave this a "quick read" but these are my only comments. I've cc'd Jay Armstrong since we had a quick discussion about my question and I let him know I'd be sending you a question. I've cc'd Aaren and Lynn to involve AC folks with my feedback, but also "keep it simple" for now. :)

Thanks for looking this over.

Cathy