

**SUMMARY OF THE
TNI CHEMISTRY EXPERT COMMITTEE MEETING**

OCTOBER 18, 2017

The Committee held a conference call on Wednesday, October 18 2017, at 2:00 pm EST. Chair Valerie Slaven led the meeting.

1 – Roll call

Francoise Chauvin, NYC DEP (Lab)	Present
Eric Davis, Austin Water Utility (Lab)	Present
Deb Gaynor, Phoenix Chemistry Services (Other)	Present
Shawn Kassner, Neptune (Other)	Absent
Scott Siders, PDC Labs (Lab)	Absent
Valerie Slaven, Consulting Services (Other)	Present
Gale Warren, NYSDOH (Accreditation Body)	Absent
Colin Wright, Florida DEP (Lab)	Absent
Ken Jackson, Program Administrator	Present

Associate Committee Members present: Nicole Cairns; Reed Jeffery; Chrystal Sheaff

2 – Previous Minutes

The minutes of October 4 were not considered through lack of a quorum.

3 – Voters' Comments on the V1M4 Voting Draft Standard (VDS)

Voting was complete on October 15, 2017. Twentyone comments were received from fifteen voters. In the absence of a quorum, a final decision on the comments could not be made, but there was a preliminary discussion of all comments.

Removal of sample preservation in detection limit spikes, but not in the limit of quantitation (Sections 1.5.2.1.1; 1.5.2.2; 1.5.2.2.1)

Five voters made this comment. The standard had originally required sample preservation to be included in both the detection limit (DL) and limit of quantitation (LOQ) determinations. However, EPA removed sample preservation from its MDL, so the Committee had done likewise. In the standard, sample preservation had been left in the LOQ determination in error. Francoise felt that sample preservation should have remained, and asked why EPA removed it. Val said the problem was with interferences caused by some of the preservation methods, affecting a few analytes. On discussion it was agreed that preservation should be removed from the DL to be consistent with EPA, only because many preservation methods are inadequate. For consistency, it should also be removed from the LOQ. The Committee will place this in the parking lot for the next revision cycle if EPA fixes the preservation issue. Meanwhile, this would be addressed in the guidance document.

Reporting samples with qualifiers if in a batch with failing LOQ verification (Section 1.5.2.2 b).

The commenter stated this cannot apply to drinking water, where EPA does not allow qualified data. The Committee agreed, but it is explicit throughout the TN standard that EPA requirements must be followed if more stringent. This will be emphasized in the guidance document. Francoise suggested referring to a statement in the calibration section.

The laboratory's normal acceptance ranges for recovery should not be applicable because by definition concentrations below the Reporting Limit have significantly higher variation and therefore will fall outside acceptance limits derived from higher concentrations (Section 1.5.2.2.a).

The Committee commented that nowhere does it say a laboratory must use its normal acceptance limits.

Any definition of DL should allow the use of the lowest standard on the curve as the DL (Section 1.5.2.1.1).

The Committee disagreed. If a method requires sample preparation, this will result in a very different DL. Francoise commented this would also conflict with the calibration section of the standard.

If there not 20 points available or established yet for the method being performed for an LOQ, would the arbitrary 70-130% be applied as is done per SW-846 or is there additional guidance that can be provided to make these sections clear for all laboratories. (Sections 1.5.2.2 d; 1.5.2.2.1 c2)

The Committee agreed. There is a need to address what normal guidance limits would be. This should go in the guidance document. A lot of methods have recommendations for starting ranges.

Limit of Quantitation has always been based on the lowest Standard in your calibration. Not something that has been digested or extracted. Section 1.5.2.2)

The Committee should explain in the response-to-comments why the lowest standard is not used.

40 CFR Part 136 Appendix B states "a minimum of two spiked samples and two method blank samples prepared and analyzed on different calendar dates is required for each instrument". The Draft Standard only requires only one spike and routine blank be analyzed on each instrument. (Section 1.5.2.1.1)

40 CFR Part 136 Appendix B states "during any quarter in which samples are being analyzed, prepare and analyze a minimum of two spiked samples on each instrument, in separate batches...". The Draft Standard only requires a minimum of one verification spike and one blank analyzed on each instrument. (section 1.5.2.1.2)

Val pointed out that 2 samples would have to be run anyway if there is just one instrument. EPA requirements supercede TNI.

The use of the term "spike blank" is inconsistent with "low level spike" used in 1.5.2.1.1, though they appear to refer to the same activity. Is it possible to use one or the other? (Section 1.5.2.2.1 a)

The Committee will use “low level spike”.

"and document a technically valid reason for the corrective action" - It does make sense that an ongoing LOQ failure suggests the need for corrective action, however documenting corrective actions (assuming this means a full blown CAPA investigation) may pose an added burden on the laboratory without much added value especially where there are poor performing analytes involved. (Section 1.5.2.2.2)

Val pointed out it was not intended to be a full corrective action. Francoise suggested explaining this in the guidance document. The meaning of “corrective action” is not clear throughout the standard and should go in the parking lot for the next revision. However, the glossary definition is correct.

"Any samples analyzed in a batch associated with a failing LOQ verification shall be reanalyzed or reported with qualifiers." This only encourages the laboratory to do all verifications separate from samples which is quite inefficient. If all method required QC are passing, there is no added value in invalidating samples run with failing LOQ verification unless a LOQ check is required QC. (section 1.5.2.2.2)

Val said, if you run an LOQ verification, and you know the batch is not valid at the LOQ, you have a responsibility to let data users know.

This section references the DL determination and that the determination must incorporate the "entire analytical process". Does the "analytical process" include sample preparation? This section should be reworded similar to 1.5.2.2.b. which includes sample preservation, processing and analysis. (Section 1.5.2.1.1 b)

Val suggested, since it should be encouraged to include sample preparation, this should be left as-is. It will probably be addressed as a Standards Interpretation Request (SIR) in the future. Nicole suggested replacing “entire analytical process” with “method”.

Removal of the word "sample" makes the sentence unclear. Recommend changing "at least one spiked" to, "at least one low level spike". Section also does not clarify what is a "low level" concentration. (Section 1.5.2.1.1 c)

This will be fixed editorially to be consistent.

If the determined DL is greater than the LOQ value, the laboratory should evaluate the DL and LOQ data and redetermine the DL or the LOQ value, not just raise the LOQ value. (Section 1.5.2.1.3)

Both options are given

The laboratory established accuracy acceptance criteria should be based on in-house limits, not just an arbitrary limit, i.e.-50%. But TNI should set a minimum criteria considering the laboratory is reporting data at this concentration. (Section 1.5.2.2.1. c ii)

The Committee had previously discussed this at length and decided it would not be possible.

If the LOQ is less than the DL, the laboratory should evaluate the DL and LOQ data and redetermine the DL or the LOQ value, not just raise the LOQ value. (Section 1.5.2.2.1 c iii)

This was discussed at length and would be an unnecessary burden.

It is stated that the LOQ must be at or above the lowest corresponding calibration standard concentration. This should state "at or below the lowest corresponding calibration standard, not above. (Section 1.5.2.2.c)

The Committee disagreed with the comment.

Is there a definition of 'low level' spike? This seems to be used and has not been part of the terminology previously.

Francoise said there is a recommendation in the guidance document, but it will vary from laboratory to laboratory.

4 – Next Steps

There was discussion on how to designate the comments. Many were valid and would result in changes. However, “Persuasive” means a substantive change to the standard is needed. The Committee believed all the changes would be for clarification and hence would be editorial. As such they would be “Non-Persuasive”, and this would need to be explained in the response-to-comments document.

SOP 2-100 requires the comment to be discussed publicly, and Ken suggested doing this during the next conference call. He would post a notice on the TNI website that the conference call would be a public discussion of comments.

Meanwhile, Val would contact each commenter to explain the Committee’s preliminary recommendations and ask if any of them would thus withdraw their comments. Prior to the next conference call, Val would send out a draft of the revised comments.

5 – Adjournment

There being no further business, the meeting was adjourned at 3:00 pm EDT. The next call would be on November 1, 2017.