SUMMARY OF THE
TNI CHEMISTRY EXPERT COMMITTEE MEETING

FEBRUARY 10, 2017

The Committee held a conference call on Friday, February 10, 2017, at 2:00 pm EST. Chair Valerie Slaven led the meeting.

1 – Roll call

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

Associate Committee Members present: Paul Bergeron; Lynn Boysen; Richard Burrows; Yoon Cha; Arthur Denny; Myron Gunsalus; Carl Kircher; Chuck Lytle; Anand Mudambi; Chuck Nessler; Michele Potter; Erin Ryder.

2 – Previous Minutes

It was moved by Shawn and seconded by Colin to approve the minutes from the meeting in Houston on January 24, 2017. All were in favor.

3 – Changes to Module 4

Editorial changes to the 2016 Volume 1 Module 4 and substantive changes that would require development of a new standard were discussed.

Reference to 40 CFR Part 136

Valerie outlined the problem that the standard referred to the new MDL process in 40 CFR Part 136, but its publication by EPA was now on hold. It was unknown if and when this would be published. Several editorial options were considered: the document was already on the EPA website, and that could be referenced, but there was no guarantee EPA would keep it there; it could be reproduced as an appendix to Module 4; it could be published on the TNI website and the standard could refer to that; it could be removed completely; or it could be added to the standard as a requirement. Eric favored adding it as an appendix, but Shawn questioned if this would be an editorial change. Richard said it would be editorial if it was made clear it was not mandatory. Shawn cautioned this might not be permissible, because the PT Expert Committee had been told to remove guidance from the standard. Valerie said she would send

an e-mail to Bob Wyeth for his opinion. Lynn Bradley reminded the committee there was an existing agreement to provide a guidance document to the Module, so it could go in there. Shawn agreed, saying that guidance document could then be referenced in the note in the Module. Lynn Boysen favored keeping it as a document separate from the standard, because it would then be available for anyone and not just those who bought the standard.

It was considered whether the committee should make changes to the MDL procedure to match the changes in the unpublished 40 CFR Part 136; e.g., the 2016 Module 4 requires MDLs to be run in the appropriate sample preservative, but EPA has removed it in the new 40 CFR Part 136. Such changes would not be editorial and would have to be part of the new standard. Myron Gunsalus said it would be easier for the Kansas accreditation program to remain consistent with the current MUR for enforcement purposes. Michele Potter said the New Jersey program would follow the existing MUR until the new one was published. Valerie added that laboratories would prefer not having to run the MDL procedure in the sample preservative. Richard said taking the requirement out would be consistent with the current MUR and what the new one would also be consistent, so the committee was already in consensus. It was moved by Shawn and seconded by Eric to remove the requirement. All were in favor.

Requirement for the LOQ to be at leat 3 times the MDL

Valerie said feedback from the Houston meeting and a comment from Scott Hoatson made it clear the difficulty in getting a low enough LOQ for some analytes was not restricted to drinking water methods. Valerie had proposed the language. "If regulatory limits would hinder the ability to set the LOQ at least 3x the DL and qualified data is strictly prohibited by the agency or program the laboratory shall have and shall follow a written procedure that defines LOQ acceptability under these circumstances." Richard pointed out the current (2009) standard just says the LOQ must be greater than the Detection Limit. He said there is a scale between good data quality and practicality, and the current TNI standard is way on the side of practicality, making little accommodation to data quality. Conversely, the "3x rule"is way on the side of good data quality but has some problems regarding practicality. He then suggested reducing the requirement to having the LOQ at least 2x the MDL. Richard's laboratory had found not an insignificant number of analytes where the "3x rule" would cause them to raise the reporting limit, and a "2x rule" would not have nearly so much of an impact. The AB representatives were asked for their opinions. Myron Gonsalus said laboratories have to verify the LOQ, so if it is above the MDL that should be sufficient. Richard added that the new standard has more rigorous LOQ verification requirements, so it could be argued that would be sufficient. Lynn Boysen agreed that should suffice. Carl Kircher said the LOQ must be above the DL and the LOQ should be at or above the lowest point of the calibration curve, and the LOQ or DL should be reflective of whatever number goes on test reports where non-detects show up. Rich agreed all that is in the standard. Deb raised concerns there could then be pressure on a laboratory to have every analyte with an LOQ that is as close to the DL as possible. Richard countered by stating the new standard would require laboratories to set their LOQ at a level at which they could reliably analyze the sample. They must do it every quarter on every instrument, collect data spiked at that level, and demonstrate what their precision and accuracy are. There is also the additional requirement of measuring Relative Error in the calibration, so there will be additional controls that we don't have now. Richard suggested asking the Accreditation Bodies if it would be sufficient that the LOQ just must be greater than the DL, or if they would prefer the LOQ being at least 2x the DL. Valerie asked, if anyone had appropriate language, they should send it to her in time for the ABs to review it before their next meeting.

Mean recovery of the initial LOQ

Valerie said it was the committee's intent that the initial LOQ have recoveries calculated based on the mean, but this was not stated explicitly. She asked if this should go forward as a change in the 2017 standard. Section 1.5.2.2 d) states "The laboratory shall establish acceptance criteria for accuracy for the LOQ verification spikes.", but it was meant to say "The laboratory shall establish acceptance criteria for **mean recovery** for the initial LOQ verification spikes." Also, in Section 1.5.2.2.1 c) ii, it was meant to say the **mean** recovery for each analyte in the set of initial LOQ spikes is within the laboratory established accuracy acceptance criteria. Valerie stressed this was just about adding "mean" so the laboratory would take the mean of all 8 spikes and compare those against the laboratory established limits. Shawn asked if the laboratory could use (say) 10 spikes and "cherry pick" out of them. Richard assured him the intent was the laboraotory had to use all the spikes it ran. Shawn agreed using the mean would be the way to go, and he asked if any of the ABs on the call would have a problem with that. No one disagreed, but it was suggested adding that it should be the mean recovery **of each analyte** for the initial LOQ verification spikes. That addition would just be an editorial change. It was moved Shawn and seconded by Deb to add "mean" where appropriate and to clarify it is for each analyte All were in favor.

Accuracy of the ongoing LOQ

Scott Hoatson had suggested changing "zero" to "detection limit" in the first paragraph of Section 1.5.2.2.2 a), and Richard proposed modified language for the second paragraph. Val then suggested the following language:

"Results of each LOQ verification sample analysis shall be evaluated at the time of the testing and shall meet the qualitative identification criteria in the method and laboratory Standard Operating Procedure (SOP). The quantitated result shall be greater than the DL and meet the laboratory established accuracy criteria.

If a continuing LOQ verification test does not meet this requirement, the laboratory shall take corrective action. Corrective actions shall include (i) correcting method or instrument performance and repeating the verification test, (ii) evaluating the laboratory established control limits to ensure they reflect current performance or (iii) raising the spiking level (and the quantitation limit if the spiking level is above it) and repeating the initial verification study. Any samples analyzed in a batch associated with a failing LOQ verification shall be reanalyzed or reported with qualifiers."

Valerie was concerned a laboraotory could just change its limits if it does not work, but it does add an initial layer of protection if the "3x rule" is taken out. Carl Kircher, Myron Gonsalus, and Michele Potter were all agreeable the language would be acceptable to their accreditation programs It was moved by Shawn and seconded by Deb to accept this proposed language. All were in favor.

4 – Next Steps

Valerie said she would circulate the agreed changes to the committee, and then send it to LASEC and the AC for their opinions.

5 – Adjournment

The meeting was adjourned at 3:30 pm EST.