### SUMMARY OF THE TNI CHEMISTRY EXPERT COMMITTEE MEETING

### JULY 10, 2015

The Committee held a conference call on Friday, July 10, 2015, at 2:00 pm EST. Chair Richard Burrows led the meeting.

#### 1 – Roll call

Present
Present
Absent
Present
Present
Present
Absent
Present
Absent
Present
Absent
Present

Associate Committee Members present: Dan Dickinson; Chuck Lytle

### 2 – Previous Minutes

It was moved by John and seconded by Francoise to approve the minutes of May 8, 2015, with the change that Francoise was present. All were in favor.

#### 3 - Consideration of Comments on the Detection/QuantitationVDS

Voting was complete and the committee started a preliminary discussion of comments received. The open discussion of comments would be at the upcoming Chicago meeting. Ken expressed concern over the low voter turn-out. Only 33 TNI members had voted, with just 3 voting affirmative with comment and 4 voting negative with comment. Just 6 members who were Accreditation Bodies had voted; e.g., it was surprising the Pennsylvania AB did not vote after Aaren Alger had submitted a lot of comments at the Working Draft Standard stage.

Dan Dickinson had made several comments and these were discussed first.

**General**. Dan explained his comment to combine on-going verification of MDL and LOQ. He thought the spiked sample from the initial level in the MDL verification was not necessary to verify the ongoing MDL. However, if the committee wanted to combine the verification of the MDL and the verification of the LOQ into one event, it could do so by specifying a combined verification with criteria. Richard pointed out that MDL spikes can be those used for the LOQ, and perhaps that needed to be

made clearer, with more guidance in the on-going MDL section. Dan said something should also be in the on-going MDL section to tell you what the action should be if the blank came back above the MDL, and in the LOQ section the action required if that spike sample came back as a non-detect or a detect but below the MDL.

**1.5.2.1.1** Dan had made several comments

1.) The third sentence, "One option is to follow EPA's MDL procedure specified at 40 CFR Part 136 Appendix B." should be converted to a note. The committee agreed.

2.) He suggested re-wording the last sentence before a)-g), "*The determination, at a minimum, shall incorporate language addressing the following requirements:*" to read "*The Laboratory SOP for determining the MDL, at a minimum, shall incorporate language addressing the following requirements:*" The committee agreed.

3.) Dan suggested changing "must" to "shall" in items a) through e). The committee agreed.

4.) He suggested item g) should be moved into the ongoing verification of the MDL section 1.5.2.1.2 as the second paragraph, because it addresses method alterations after an MDL has been established and whether or not the alteration merits another verification of the MDL. The committee agreed.

5) In Item g) he thought the phrase "reasonably expected" would be difficult to explain and apply consistently among assessors. A better term would be "method alteration", which is already a strong phrase reserved for significant change in the analytical system. When a method is altered, the MDL should be verified as a rule. He wanted to distinguish changes such as altering the instrument gain to adjust sensitivity, which would not involve "method alteration". Richard suggested this might be discussed at the Chicago meeting to solicit input from the audience, and it was questioned whether a definition was needed.

**1.5.2.2.1** In the note under item a) Dan suggested adding advice to also perform method blanks, to comport with the EPA MDL procedure and 1.5.2.1.1.e. Richard was hesitant, not wanting to give the impression that blanks for MDL have to be associated with spikes used for MDL or LOQ. They could be on-going method blanks. However, the committee would consider adding guidance to the LOD verification on spike level, and what action is required if the blanks exceed the MDL.

**1.5.2.2.** This comment generated a protracted discussion. Dan said the first sentence reads very much like the LOD verification, and he did not think the LOQ verification should be the same thing as the LOD verification. Instead, the LOQ verification sample should be spiked at the LOQ level (3x MDL). Richard responded the committee had discussed this at length. In most cases the LOQ verification would be spiked at the LOQ level but in those cases where it is necessary to elevate the LOQ because the MDL was too high, then the LOQ spiking level is allowed to be below the LOQ. The main reason the committee did that was to make it easier for poor-performing analytes in multi-analyte methods.

Dan added, in 1.5.2.2.2 a, the only requirement on verifying the LOQ is that it is above zero and it meets the method qualitative identification criteria. He suggested, because of the required 3x factor from the MDL, the committee was viewing the LOQ determination to be similar to Currie's L<sub>D</sub>, which protects against false negatives. So the criterion to be above zero is not appropriate because above zero includes

levels less than the MDL (the false negative zone). Dan said the real test is whether the LOQ level is still above the MDL, so he suggested testing the LOQ value at 3xMDL and have the criterion that it must have a result above the MDL. That would guard against setting the LOQ too low. Richard replied that, ideally, it would be good to have all LOQ verification samples return results above the MDL, but for multi-analyte methods the existence of analytes with low recovery would make this problematical.

**1.5.2.2.3** Dan had suggested an editorial change that the committee would fix.

Two commenters had suggested the requirement for the LOQ to be 3x the MDL could be too high. While the specific comments were not discussed, the committee considered this issue. Richard said this had been questioned in the past by others, and he reviewed the reasons the arbitrary 3x multiplier was adopted. He agreed there should be some discussion, and also agreed in some cases 3x was more than required. It was suggested a caveat might be added to provide an option for a lower multiplier in specific cases. This would be a topic that could be discussed during the Chicago meeting.

# 4 – Chicago Meeting

Richard suggested 2-3 hours of audience participation to get feedback on some of the issues. It was recognized participants should have the opportunity to discuss any of the voters' comments. Then the committee might work on proposed language and offer this for audience discussion.

## 5 – Committee Vice-Chair

Richard announced that Valerie would be vice-chair, having volunteered for the position.

# 6 – Adjourment

The meeting was adjourned at 3:30 pm EDT