SUMMARY OF THE TNI QUALITY SYSTEMS EXPERT COMMITTEE MEETING

MARCH 10, 2014

The Committee met by teleconference on Monday, March 10, 2014, at 1:00 pm EST. Chair Paul Junio led the meeting.

1 – Roll call

Katie Adams, USEPA Region 10 (Other)	Absent
Patty Carvajal, San Antonio River Auth. (Lab)	Present
Gil Dichter, IDEXX Labs. (Other)	Present
Stephanie Drier, MN DOH (AB)	Absent
Paul Junio, Northern Lake Service (Lab)	Present
Silky Labie, Env. Lab Consulting & Technology (Other)	Absent
Dorothy Love, Eurofins Lancaster lab. (Lab)	Present
Dale Piechocki, Underwriter's Lab. (Lab)	Present
Matt Sowards, ACZ Laboratories (Lab)	Present
Shannon Swantek, Oregon DEQ (AB)	Present
Michelle Wade, Wade Consulting (Other)	Present
Janice Willey, NAVSEA Programs Office (Other)	Present
Ken Jackson, Program Administrator	Present

Associate Committee Members present: Carl Kircher; Eric Denman; Randy Querry; Bill Ray; Elizabeth Turner

2 – Previous Minutes

Draft minutes from the following meetings had been circulated to the Committee Members: January 14, 2013 (Denver meeting); August 8, 2013 (San Antonio meeting); January 27, 2014 (Louisville meeting), and February 10, 2014 (previous conference call). Dale asked for the words ".. to the reporting stage" to be deleted from the fourth sentence under SIR 246 in the February 10 minutes. Also the spelling of Carl Kircher's name was corrected in the list of Associate Committee Members. With these changes in place it was moved by Gil and seconded by Michelle to approve all 4 sets of minutes. All were in favor.

3 – Standard Interpretation Requests (SIR)

Two SIRs were considered.

SIR 191. This had been discussed during the previous call, when the Committee Members had considered their response to be satisfactory. Paul now asked for a vote and all were in favor.

SIR 246. Paul had circulated a revised response following the discussion of this SIR during the previous conference call. Shannon had some reservations, saying if several samples are submitted

from a well, they may be different samples besides being in different containers. It was suggested perhaps it should be added to the response that a laboratory still has to be able to track individual containers through the laboratory. It was agreed this remains controversial and might still bounce back to the committee. The standard should be revised in the future. A vote showed all in favor of submitting this response except Janice who was opposed.

4 – Small Laboratory Handbook.

The Committee continued from where it had left off at the end of the last call.

Section 4.13 (Control of Records). It was agreed, in "Key Points", it must be checked which are "should" and which are standard requirements ("shall/must"). In the Discussion section, it should be stated that records must be retained <u>for a minimum</u> of 5 years. In the paragraph stating records must be prepared in permanent ink, it needs to be clarified that this does not apply to electronic records. It was confirmed that the statement "Archived records must have an access log" is a standard requirement and therefore correct.

Section 4.14 (Internal Audits).

In the first sentence "should" needs changing to "shall". Carl suggested adding if you don't want your auditor to find it, you should find it in your internal audit. There was discussion on whether every method has to be audited, or just every technology. Other options would be rotating the methods year to year or randomly selecting the methods to be audited year to year. It was said laboratories need to be able to determine where to put their effort; e.g., more effort on the methods they use the most. Carl added if you keep correcting the same problems it should be seen as an opportunity for preventive action. Randy said if a full audit spreads over multiple years, the laboratory needs to keep records to show it has covered everything.

Section 4.15 (**Management Reviews**). It was suggested the laboratory should look at its internal audits to ensure the system is fixed. Carl wanted this section to make it clear what a management review is compared with an internal audit, because this is often a source of confusion in small laboratories. The standard has 11 "must" items that need to be included (the handbook only has 9 of them listed). In a lot of small laboratories, management people might not be laboratory people, so the committee needed to be cautious about this section. Also, a lot in the standard might not apply to small laboratories. It was cautioned, however, that any laboratory can benefit from a management review, so small laboratories should still meet this requirement.

Section 4.16 (Data Integrity Investigations). Paul agreed with the first paragraph after Key Points, but questioned if this was part of Data Integrity.

At this point, the discussion was curtailed, and Paul announced the committee would pick up from Section 5 during the next call.

Adjournment

The meeting was adjourned at 2:30 pm EST.