SUMMARY OF THE
TNI QUALITY SYSTEMS EXPERT COMMITTEE MEETING

FEBRUARY 10, 2014

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

1 – Roll call

Katie Adams, USEPA Region 10 (Other)	Present
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)	Absent
Dale Piechocki, Underwriter's Lab. (Lab)	Present
Matt Sowards, ACZ Laboratories (Lab)	Present
Shannon Swantek, Oregon DEQ (AB)	Absent
Michelle Wade, Wade Consulting (Other)	Present
Janice Willey, NAVSEA Programs Office (Other)	Absent
Ken Jackson, Program Administrator	Present

Associate Committee members present: Carl Kircher; Eric Denman; 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); and January 27, 2014 (Louisville meeting). Paul asked the Committee members to vote on these minutes by e-mail within the week.

3 – Standard Interpretation Requests (SIR)

Two SIRs were considered.

SIR 191. This concerned second source standards. The allowance for preparing the same lot in the laboratory by two different people had been removed. It was remarked this would be an "easy out" for a laboratory. It was pointed out in radiochemistry even different vendors may have materials from the same source, and this had also been seen in chemistry. However, this was acceptable if the laboratory had acted in good faith. Dale remarked that a supplier had sent two shipments with the same lot number but different expiration dates. There was a problem with radium-228 being unavailable, and in such case it was questioned if the laboratory should qualify the data in its report. It was agreed that question goes beyond the SIR and the response was satisfactory.

SIR 246. The question was whether laboratories must uniquely identify sample containers when received at the laboratory. Carl Kircher said the 2009 standard does not require each container to have a separate identification, but the laboratory needs to have a way of knowing what it is (e.g., to make sure a nitric acid stabilized sample does not go to the microbiology section). Matt added that, as the standard is written, the laboratory does not need a unique id going right through to reporting, but it does need a way of internally identifying the containers. Dale said his laboratory labels 3 vials "A", "B" and "C" and keeps track all the way through the laboratory. It was questioned if the 2003 language should go back in the standard, but after a protracted discussion, Paul suggested going with Matt's point and working on a FAQ for this. He said he would write one up and circulate it for e-mail vote.

4 – Small Laboratory Handbook

The Committee continued from where it had left off in Louisville. Paul reminded the participants that it must be made clear where it needs to say "should" or "shall", and there must be no requirements that are not in the standard.

Section 4.9 (Control of Non-Conforming Testing Work). It was stated that responsibility and authority need to be defined in this section. Committee members did not agree with the statement on page 29 beginning with "The highest incidence of non-conformance…". It was said an SOP should say what to do if there is a QC failure. It was agreed the whole paragraph needs to be re-written.

Section 4.10 (Improvement). The Committee felt this was satisfactory.

Section 4.11 (Corrective Action). It was emphasized this section should address fixing the system and not just the symptom. The third bullet needed modifying, because TNI only requires root cause for systemic issues (and being a requirement, the word is "shall"). Towards the bottom of page 31, it is stated *"If non-conforming data is reported with qualification, documentation must include who made the determination and why it was made. This is commonly included in the narrative"*. The committee did not agree with the last statement, since it is included in the analytical report, but not necessarily the narrative. Silky pointed out this fails to address section 4.11.6 in the standard.

Section 4.12 (Preventive Action). Paul commented the first paragraph reads like corrective action, and asked what should be added for preventive maintenance. Carl suggested the laboratory needs to be as effective anticipating problems as fixing problems. It was added that corrective action could turn out to be a preventive action moving forward. On Carl's suggestion Paul said he would include examples of preventive actions.

Adjournment

The meeting was adjourned at 2:30 pm EST.