

**DRAFT SUMMARY OF THE
TNI QUALITY SYSTEMS EXPERT COMMITTEE MEETING
JANUARY 31, 2012**

The Committee met during the Forum on Laboratory Accreditation, Sarasota FL, on Tuesday January 31, 2012, at 1:30 pm EST. Chair Silky Labie led the meeting.

Committee members were present in person or by teleconference:

Silky Labie	present
Katie Adams	present
Brian Boling	
Laurie Carhart	
Robin Cook	present
Tamara DeMorest	
Gil Dichter	present
Stephanie Drier	present
Eugene Klesta	present
Dorothy Love	present
Robert Martino	
Fred McLean	
Michelle Potter	present
Randall Querry	present
Kristina Spadafora	present
Michelle Wade	present

Introduction

Silky explained that the Voting Draft Standard (VDS) under consideration is to clarify language and fix problems such as ISO language that appeared in the technical modules. It is not to introduce any new standard. Also, the 2009 TIA in the radiochemistry module needs to be formalized. The VDS is currently being voted on, and the purpose of this meeting is to consider those comments submitted by TNI members who had cast their votes by noon the previous day. Voters' comments received during the remainder of the voting period will be considered during the Washington DC meeting in August. Any comments that would change the standard are being tabled until the next revision. Two handouts were provided, titled "Summary of Changes to V1 M2-M7"; and "Comments on Voting Draft Standard (1-30-2012). These are appended as Attachment 1. The negative comments would be addressed first, and then positive comments if time permitted.

Silky went briefly through the Summary of Changes, and stressed that the VDS posted on the website is not the complete standard, only those clauses that the Committee has proposed to change. The voting rules require 2/3 of Committee Members to be present, and then a simple

majority for an item to pass. Since 11 Members were physically present or on the phone, these requirements were met.

Consideration of Comments with Negative Votes

V1M2

5.8.5 a) (page 1). Silky first responded to this comment by stating that if a sample had 5 different containers you could not say the correct sample is used if all are not labeled. However, it was commented by Bob DiRienzo that you don't report specific containers, so it doesn't mean anything to samples collected in the field. Larry Penfold said a client can specify what is in individual containers that may be spiked in the field. Kirstin Daigle suggested getting rid of "uniquely", since you don't need to differentiate between 2 or 3 identical bottles that are all labeled the same. If several bottles have different preservatives these are listed on the bottle, so the preservative type becomes part of the unique i.d. The COC tells the laboratory which containers are which. Bob DiRienzo said if you need to clarify the intent, it should not be in the standard and the ISO clause should be sufficient. Silky said if the wording is left as it is, then it must be made sure the assessors understand it. Robin said the whole clause needs to be addressed if it persuasive.

It was moved and seconded that the comment is persuasive. The motion passed with 8 Members in favor and 3 opposed.

5.4.4; 5.4.5.3; 5.4.5.4 (page 1). Clauses 5.4.4 and 5.4.5.3 are there because they are ISO language that was moved from the technical modules where it had been incorrectly placed. Bob DiRienzo suggested making sure there is now a cross-reference to the technical module, and it was pointed out that is already there. Clause 5.4.5.4 is already a TNI clause and it has just been revised for clarity.

It was moved and seconded that the comment on clauses 5.4.4, 5.4.5.3, and 5.4.5.4 is non-persuasive. The motion passed unanimously.

5.4.5.2 (page 1). This is an ISO clause that must be in the standard.

It was moved and seconded that the comment is non-persuasive. The motion passed unanimously.

Last comment on page 1 (Three concerns....). Clause 5.4.6 was not changed so the comment is not applicable. Clauses 5.6.1 and 5.6.2 are excluded because they are for a calibration laboratory only. However, Randy remarked that it says in Clause 1.2 that the standard follows

ISO 17025 verbatim, but it does not if these clauses are omitted. Strictly the clauses should be included with the statement that they are not applicable to environmental testing.

It was moved and seconded that parts 1 and 3 of the comment are persuasive and part 2 is not applicable. The motion passed unanimously.

V1M3

1.6.2.1 c) (page 5). The definition of analyte includes parameters.

It was moved and seconded that the comment is non-persuasive. The motion passed unanimously.

V1M4

1.5.2.1 c) (page 5). Silky said sensitivity fluctuates, so you need to say what is a drastic change in sensitivity. Can you say in your quality manual what is a “major change in sensitivity”? Paul Junio said you can, but it is difficult to do so. Gene commented that the responder is confused in his second sentence. Paul Junio suggested referring to the last sentence of 1.5.2.1.

It was moved and seconded that the comment is persuasive. The motion passed unanimously.

1.5.2.1 e) (page 6). It was moved and seconded to table this comment, because it would introduce a new requirement. The motion passed unanimously.

1.5.2.2 b) (page 6). It was moved and seconded to table this comment, because it would introduce a new requirement. The motion passed with 10 Members in favor and 1 opposed.

1.5.2.2 c) (page 6). It was moved and seconded to table this comment, because it would introduce a new requirement. The motion passed unanimously.

1.6.1 c) (12 identical comments; page 6 through 8). It was moved and seconded that this comment is non-persuasive, since the new language does not change any requirement. The motion passed unanimously.

V1M5

1.6.1 c) (12 identical comments; page 10 through 13).

It was moved and seconded that this comment is non-persuasive, since the new language does not change any requirement. The motion passed unanimously.

Multi-section comment (top of p.12).

1.5. This should be different, because (b) shows it is a different path; i.e., reference methods need only a less rigorous validation.

It was moved and seconded that the comment is non-persuasive. The motion passed unanimously.

1.6.2.2 and 1.6.3.2. No, the subsections were not changed (they were just not presented).

It was moved and seconded that both comments are non-persuasive. The motion passed unanimously.

1.7.3. The subsections were left out and not changed.

It was moved and seconded that the comment is non-persuasive. The motion passed unanimously.

“Suggestion: on page 11...”. Robin commented that the Committee needs to read the whole section to make sure all these comments are there because the Committee left out parts that did not change. Silky will ask Jerry to put a note on the website that only the changed sections are listed. **“Ready-to-use media..”.** If the media has expired in one case, it was asked why you can re-test in one case and not the other. The answer is if the manufacturer says it is good longer than the prescribed method, then it is OK.

It was moved and seconded that the whole comment is non-persuasive, but there needs to be a check on the numbering. The motion passed unanimously.

V1M6

1.6.1 3rd paragraph (12 identical comments; page 17 through 20).

It was moved and seconded that this comment is non-persuasive, since the new language does not change any requirement. The motion passed unanimously.

V1M7

1.6.1 c). (12 identical comments; page 20 through 22).

It was moved and seconded that this comment is non-persuasive, since the new language does not change any requirement. The motion passed unanimously.

Consideration of Comments with Positive Votes

V1M2

3.1 (page 2, 1st comment A). It was moved and seconded that this comment is persuasive, and the first suggested definition should be used. The motion passed unanimously.

3.1 (page 2, 1st comment B and C). These are editorial changes that the Committee accepts.

3.1 (page 2, 2nd comment). This is an editorial change that the Committee accepts.

3.1 (page 2, 3rd comment). It was agreed that “documentation” is better, but “record” may be better still.

It was moved and seconded that the comment is persuasive. The motion passed unanimously.

3.1 (page 2, 4th comment). Although the voter provided a comment, no recommendation was provided.

It was moved and seconded that the comment is non-persuasive. The motion passed unanimously.

3.1 (page 2, 5th comment). The commenter has not provided alternative language, and the Committee cannot see how it could be made clearer.

It was moved and seconded that the comment is non-persuasive. The motion passed unanimously.

3.1 (page 2, 5th comment; ref. to 4.2.8.1 item 3). This is an editorial change that the Committee accepts. The Committee also decided to make an additional editorial change by striking “data integrity”, which was a typographical error; i.e., you can only monitor data and not data integrity.

4.1.7.1 (page 2). Items (a) – (g) were intentionally omitted. It is agreed Section 5.2 is an incomplete sentence.

It was moved and seconded that the comment on Section 5.2 is persuasive. The motion passed unanimously.

5.8.5 a) (page 2). This was already ruled persuasive based on an earlier comment.

5.8.5 a) (page 3). The first part is editorial. The second part was already ruled persuasive based on an earlier comment. The Committee decided to look at this entire section again.

5.4.4 (page 3). This is an ISO note, but it could be made a requirement, so the vote is valid.

It was moved and seconded that this comment should be tabled until next time, because it would be a substantive change to the standard. The motion passed unanimously. It was further suggested the Committee should, in the future, look at all notes to decide if they should become standards.

5.6.1 (page 3). The Committee will re-instate ISO 17025 language for 5.6.1 and 5.6.2. The comment on 5.6.2.1.1 was already ruled persuasive based on an earlier comment. Comment E (top of page 5) is editorial and already addressed.

V1M3

1.5 (page 5). This is editorial.

1.6.1 a) (page 5). This is editorial. (It was already changed in other modules, but missed in this one).

V1M4

1.4 (page 8). Adding EPA is an editorial change that will be made.

It was moved and seconded that the comment on section 1.5.1 is non-persuasive, since by default it refers to the present module. The motion passed unanimously.

In reference to 1.5.2.1, the acronyms and "x" will be changed editorially as suggested. In reference to 1.5.2.2, the committee agrees and will insert "however" editorially.

1.4 (second comment on page 8). Adding EPA is an editorial change that will be made.

It was moved and seconded that the comment on section 1.5.1 is non-persuasive, since by default it refers to the present module. The motion passed unanimously.

1.5.1 c) (page 8). It was the intent to put this in all the technical modules. This will be remedied editorially.

Time did not permit consideration of remaining comments.

Other business

Silky reported that 5 Committee members are rotating off, and the Committee has voted on replacements. She thanked the outgoing members for their outstanding work and expressed hope that they will all continue as active Associate Committee Members.

Adjournment

The meeting adjourned at 5:00 pm EST