SUMMARY OF THE
TNI LABORATORY QUALITY SYSTEMS EXPERT COMMITTEE MEETING

AUGUST 8, 2013

The Committee met on Thursday, August 8, 2013, at 1:30 pm CDT at the Environmental Measurement Symposium, San Antonio, TX. Chair Paul Junio led the meeting.

1 – Roll call and Introductions

Katie Adams (Other)	Absent
Gil Dichter (Other)	Absent
Stephanie Drier (AB)	Present
Paul Junio, Chair (Lab)	Present
Silky Labie (Other)	Present
Dorothy Love (Lab)	Present
Michele Potter (AB)	Absent
Scott Siders (AB)	Absent
Michelle Wade (AB)	Present
Janice Willey (Other)	Present

Paul welcomed the attendees, and the Committee members introduced themselves.

Paul made a PowerPoint presentation, describing the agenda, background on the QS committee, and listed the Committee Members. He said the Committee was looking to recruit new members, including an AB since Scott Siders was resigning to join the Chemistry Committee.

2 – Quality Manual Template

The Committee was reviewing this template to assure its consistency with the 2009 standard. Committee Members had been assigned to review specific items, and the initial intent was for the Committee to work through those items during this meeting.

The first item identified was in **Section 3.1 Scope of Testing**, which stated "*The laboratory's scope of analytical testing services includes those listed in…"*. Silky had commented there is nothing in the standard that specifies what is listed here but the scope of testing is a good thing. It was added that laboratories are putting it elsewhere (not in the Quality manual (QM)), with a link or reference. This needs clarity. It should require the full scope and then note any items that are not part of the TNI scope. Robin Cook suggested the laboratory should identify what is and what is not accredited, since a client may want to see that information. It was suggested to note in guidance there is a lot of flexibility in what to include and not include. A grey box may be needed to specify what is required and what is discretionary. It was added that not all laboratories are aware that everything in the template may not be required.

At this point the discussion digressed to a more general consideration of the template and its purpose. The scope of the organization should be in the QM, as well as the scope of testing. Paul suggested having text that will refer the reader to the applicable section of the standard that will then tell the laboratory if an item has to be in the QM or if it can be referenced. Janice suggested, instead of going through the template item-by-item, work on its format to show what is and what is not a requirement. Silky added that the template says "a subcontracted laboratory is defined as…", and this is wrong because there is no such definition in the standard. There followed a lengthy discussion on how to design the template so that people cannot get away with simply plugging in the required information without necessarily understanding why it is required. It was agreed the template needs to force people to read and understand the standard before they are able to fill in the blanks.

Paul summarized this discussion, saying the Committee needs to get rid of (or at least identify) the non-requirements, and then try to link what is in the template to where it comes from in the standard.

3 – Small Laboratory Handbook

Committee members had been assigned to review specific items in the handbook, and the committee worked through several of those items during this meeting. A spreadsheet was presented, listing the Committee Member's comments on each item.

117 General. The committee agreed the writing style of this document uses many "shoulds" when in reality, the statement needs to be "must". The handbook has to be consistent with the standard.

The Preface was also examined, and it was suggested some of this might also go in the QM Template.

It was noted that the **Definitions** section needs to be examined to assure they all match the TNI definitions.

118 General. The references to TNI will be reviewed to ensure that it states correctly if it is a TNI Standard requirement. It was agreed the reference to TNI in general may cause confusion between the organization and the Standard it produces through the consensus standards development process (e.g. handbook section 1.7).

119 General. It will be ensured all acronyms are spelled out in the paragraph or in the glossary for user reference (e.g. LCS).

120 General. Stephanie said the key points are helpful, but perhaps they should be formatted to ensure they are at the end of each section and not inserted between the general paragraphs. The committee agreed.

121 General. The committee agreed the NELAP SIRs are helpful, but they should include the SIR reference number or the date of response.

V1M1 Proficiency Testing

122 Section 4.1. The committee agreed with Paul that this needs correcting to state "with the analysis date of the most recent PT sample having been **no more than 6** months prior to the application date for accreditation".

123 Section 4.2. The committee agreed with Paul that this needs correcting to state that the laboratory must participate in **at least** two (2) studies per year.

124 Section 4.2. The last paragraph is extraneous, having been already explained in a preceding section.

125 Section 4.1. This was a repeat of the comment on line 122.

126 Section 4.2. The committee agreed with Dorothy that "…potable water and non-potable water are made…" is not covered in the standard.

127 Section 5.1. It says "Laboratories may submit data by technology for multiple methods…", but the standard includes an exception to this for drinking water. It was agreed this needs to be clarified.

128 Section 6. Dorothy pointed out that two of the bullets are not described in the standard; i.e., "The laboratory shall complete all investigative and corrective action reports with 30 days of receipt of the PT study results" and "Copies of the corrective action report should be provided to the accrediting authority". Also a global search is needed to correct every instance of "accrediting authority" to "accreditation body".

129 Section 6. The reference to Module 2 needs to clarify it refers to Volume 1.

V1M2 Quality Systems General requirements

131 Section 4.1. In the key points, every "should" needs changing to "shall".

133 Section 4.2. It is not in the standard that "The Quality Policy must be issued under the authority of the chief executive." The correct term is "top management".

134 Section 4.2. The definition of "Procedure" is not the TNI definition

135 Section 4.2. There's a muddying of the waters between a procedure, and a standard operating procedure.

136 Section 4.2. In the statement "We do not perform legal CoC and will refuse any samples requiring legal CoC, although this is not mandatory", the last phrase (".. although this is not manadatory) needs removing.

137 Section 4.2. In the statement "A copy of a published test method is generally NOT a substitute for a laboratory procedure for that test", "generally" should be removed.

138 Section 4.2. The following sentences in the handbook imply, incorrectly, that a corrective action form is required. "The mechanism for recordkeeping is up to the laboratory but the corrective action form is usually a good place to record the description of the departure and the approvals. The rest of the CA form can be ignored."

139 Section 4.3. In the key points, every "should" needs changing to "shall".

140 Section 4.3. It is stated "Electronic distribution is common for large laboratories with an established intranet.", but "large" should be removed.

141 Section 4.3. The first two sentences of the paragraph beginning "Small laboratories usually control distribution by simple hand distribution…" should be changed to "**L**aboratories **may** control distribution by simple hand distribution to employees or **to** a single centrally located manual. If multiple copies are available, each copy must be uniquely identified."

142 Section 4.3. The statement "This is usually done in the Quality Manual or the Document Control SOP" implies a required document. It should be changed to ".. a Document Control SOP".

143 Section 4.3. In the statement ".. and when hand changes have to be incorporated into revised documents.", "when" needs changing to "how soon".

144 Section 4.3. The statement "Analysts should not be allowed to develop Quality Systems forms for their own use." should be qualified by adding **"unless there is a defined approval process in which the form undergoes appropriate laboratory review**."

145 and 146 Section 4.5. In the bullet "The subcontracting laboratory is responsible to the customer for the subcontractor's work", it should be "The contracted laboratory is responsible…"

147 Section 4.5. Under "Discussion a.", it should be "NELAP-accreditation" and "matrix/method/analyte combination" not "subject analyte".

148 Section 4.6. In the first sentence, "delivered by 3rd parties" needs removing, since supplies may not only be purchased from third parties.

149 Section 4.6. In the first bullet, where specified, supplies and services must meet specifications of method, etc. The term "adequate quality" does not describe the requirements.

150 Section 4.6. The committee agreed, in the Discussion, the laboratory must have both a policy **and a procedure** for selecting and purchasing supplies (4.6.1).

151 Section 4.6. The committee agreed, in the Discussion, the policy not only refers to reagents (as stated), but all supplies **and** services.

152 Section 4.6. Section 4.6.3 of the standard is not discussed.

153 Section 4.6. The bullet "The PO is approved by the Lab Manager…" is too restrictive. The laboratory just needs a process for purchasing, and it may be someone else who approves the PO.

154 Section 4.9. The first Key Point bullet seems to imply that a procedure only relates to results. The standard is more global in that it encompasses any process that does not conform. This could be a procedure that does not directly involve the results but affects the overall quality.

155 Section 4.9. In the first paragraph, the corrective action process must be used. It is not only an "evaluation".

The second bullet "Corrective actions should be taken immediately" needs re-wording. It was suggested to change it to "corrections should be taken" or "the corrective action process should begin immediately"

156 Section 4.11. It was agreed that the third Key Point bullet is modified by the TNI requirement that only systemic problems require root cause analysis.

157 Section 4.11. The committee agreed, in the last paragraph - it is more than a "good idea" to track corrective actions. It is a requirement to monitor any corrective action for effectiveness and for continued use.

158 Section 4.11. It was agreed the process fails to address 4.11.6 in its discussions on procedures.

4 – Feedback/Closing

Paul summarized the committee's next steps after completion of the present tasks. Standard Interpretations will need to be included in the next version of the standard. This includes a Standard Interpretation on second source standards that has been under consideration for some time, and needs to be finalized. A definition of DQO is required in Module 2.

Paul asked the participants to let the committee know of anything else that should be in the standard and/or the small laboratory handbook.

4 – Adjournment

The meeting was adjourned at 5:00 pm CDT.