

**SUMMARY OF THE
TNI QUALITY SYSTEMS EXPERT COMMITTEE MEETING**

JANUARY 27, 2014

The Committee met at the Forum on Laboratory Accreditation, Louisville, KY on Monday, January 27, 2014, at 1:30 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)	Present
Paul Junio, Northern Lake Service (Lab)	Present
Silky Labie, Env. Lab Consulting & Technology (Other)	Present
Dorothy Love, Eurofins Lancaster lab. (Lab)	Present
Dale Piechocki, Underwriter's Lab. (Lab)	Absent
Matt Sowards, ACZ Laboratories (Lab)	Absent
Shannon Swantek, Oregon DEQ (AB)	Present
Michelle Wade, Wade Consulting (Other)	Present
Janice Willey, NAVSEA Programs Office (Other)	Absent
Ken Jackson, Program Administrator	Present

2 – Introduction

Paul welcomed the attendees and the Committee Members introduced themselves. Paul gave a short slide presentation, explaining the main purpose of the meeting would be to continue the committee's review of the draft Small Laboratory Handbook. The review would be conducted in concert with the 2009 TNI standard.

3 – Small Laboratory Handbook

Paul said the day's plan was to review as much of the handbook as possible. A lot of "shoulds" would need to be checked to see which were standard requirements and hence needed changing to "shall".

Disclaimer.

Ken was asked to check if TNI has specific requirements for a disclaimer (subsequent to the meeting he identified Policy 1-105, and this established that TNI-specific language had mostly been included in the disclaimer). A Committee Member pointed out the disclaimer should reference the 2009 standard.

Preface.

There was a protracted discussion on Getting Started Step 4 (“Make a list of your laboratory equipment, location, and purchase dates.”). It was questioned if the TNI standard requires the location of equipment to be specified, because this seems unnecessary in a small laboratory that may have only one room. The requirement in ISO 17025 is “the current location, where appropriate”, and it was suggested the guidance document should say what that means.

In Getting Started Step 5, it was pointed out the reference to sample duplicates and spikes in SM 1020B should make it clear this is just chemistry. Control charts are mentioned in this paragraph, and it should be checked if the latest Standard Methods require them.

Introduction.

Silky suggested “minimal” in the first sentence should be changed to “essential”. In the second paragraph “performance testing” should be changed to “proficiency testing”. References to “sections” in the TNI standard should be changed to modules where appropriate. It was noted that inappropriate word use should be checked.

Definitions.

All acronyms used in the document should be defined here.

Volume 1 Module 1 Proficiency Testing.

It was suggested to include DMRQA as guidance, even though the TNI standard does not address it. In Section 4.2 Continued Accreditation Key Points, the laboratory must pass 2 out of the last 3 studies. In Section 4.2 Discussion, first paragraph, “at least 5 months and no greater than 7 months” should be changed to “less than 6 months”. It was questioned what is meant by “same water source”. It was suggested not to use “2-fold increase”. The addition of a table to show when a laboratory can schedule its PTs was suggested. In Section 5.3 Sample Records, “COC” is not needed.

Volume 1 Module2 Quality Systems General Requirements.

It was suggested, on page 16, it should be clarified what are policies and what are procedures. A link should be provided to the Standards Interpretation Request (SIR) that explains procedures do not always have to be written, though SOPs do have to be written. The use of “should” was questioned, since some policies and procedures are required to be in the quality manual. In Section 4.3 Document Control it is written that “the analyst’s training file must also contain a certification that the technical personnel have read, understand, and agree to perform the latest version of the test procedure”. It was pointed out, however, the standard only requires it to be on file, and not necessarily in the training file. Section 4.5 refers to Subcontracting of Tests and Calibrations. The word “calibrations” should be deleted, because it is a throwback to the inclusion of calibration laboratories in ISO 17025. The TNI standard specifically excludes calibration laboratories. Also in Section 4.5, it was suggested deleting the superfluous language “It should be noted that..”

General Discussion

The specific discussion of the handbook stopped just before Section 4.9 Control of Non-Conforming Work.

A general discussion followed in which Cathy Westerman emphasized people should be told to read the relevant section of the standard first. It needs to be emphasized that this document is a supplemental guidance document and not a substitute for reading the standard. An additional suggestion was to include “How do I..” and then give the answer.

Paul thought the document might have been better if a section of the standard had been written followed by the necessary guidance.

Next Steps

Paul asked committee members to send to him any useful notes they had written during the discussion, and he would then compile them. The committee would then continue working on the document.

The committee would be working on a parking lot for issues that needed to be addressed. It would also be working on SIRs and a Small laboratory Advisory Group.

Adjournment

The meeting was adjourned at 5:00 pm EST.