

**Laboratory Quality Systems Expert Committee Meeting
Environmental Measurement Symposium, Washington, DC
August 12, 2010**

Committee members in attendance:

Silky Labie - Chair
Randy Querry
Dorothy Love
Robin Cook
Michelle Wade
Eugene Klesta
Gil Dichter
Pat Conlon
Laurie Carhart – via teleconference

Silky Labie called the session to order. She announced that Tamara Demorest has changed her affiliation due to a change in her employment. Kathy Adams from EPA Region 10 is expected to join the committee.

Silky noted that the main purpose of this session is to receive public comment on the Working Draft Standards (WDS) for the Quality Systems modules. The proposed revisions are to clarify, not change, the intent of the current TNI standard. There is also an existing TIA for Module 6 Radiochemistry that needs to be incorporated into the standard. The clarifications are the result of many requests for interpretation that have been received on the standard. The committee feels it is premature to change requirements since the TNI 2009 version has not yet been fully implemented. There was also the need to clean up old ISO language in the technical modules.

The proposed revisions to each module were reviewed. In V1M2, definitions are proposed for “analyte”, “parameter”, and “reference method”. For reference method, this definition is currently buried in the technical modules and is being brought into the glossary section of V1M2. The committee is also considering the addition of “physical property”, “data integrity”, and “source water” as other possible clarifications. For consistency, the committee removed the “full-time” requirement for the acting technical director, since it is not a requirement for a permanent technical director (see 4.1.7.2).

The clarifications proposed to the standard include validation requirements in section 5.4 of V1M2 and section 1.4 and 1.5 of the technical modules. The committee has clarified the technical modules to contain the discipline-specific requirements for validations. The technical modules contained outdated ISO language and did not include all the requirements of current ISO 17025, so the committee has added back in ISO 5.4.4 and 5.4.5 to V1M2 and added references to these sections in the technical modules. Silky emphasized that at this time the committee is considering only changes that clarify, and not revise, the standard. Other suggestions will be taken under advisement for future revision.

V1M3 Asbestos

Sections 1.4 and 1.5 were cleaned up per the change to V1M2. It was noted that the V1M2 reference needs to be adjusted from section 1.5.1 to section 1.5.

V1M4 Chemistry

Section 1.4 was clarified per the change in V1M2. The committee also corrected section references in 1.5.1. The terms “parameter” and “compound” are changing to “analyte” per the new definition.

V1M5 Microbiology

Section 1.4 and 1.5 were revised per previous discussion along with other specific changes regarding validation. Section 1.6.2.2 was changed to “buffered water” instead of “phosphate or...peptone solution”. It was asked whether this defines a “clean quality system matrix” – the committee needs to consider this further. It was suggested the term “diluent” could be used instead of “matrix”. Also, the term “organism” will be used instead of “compound”. There is a clarification to section 1.7.3.1 under sterility checks.

V1M6 Radiochemistry

Similar changes to sections 1.4 and 1.5 section were incorporated as well as other discipline specific changes regarding validation. This section also includes the incorporation of the published TIA.

V1M7 Toxicity

Similar changes were proposed for 1.4 and 1.5 changes but no additional validation requirements. It was suggested for clarity that the committee add a statement that there are no additional validation requirements.

LOD/LOQ Conundrum

Silky noted that clarification is needed for which analytes LOD and LOQ must be performed. For example, is pH and temperature included? Would adding definition of “physical property” to the standard help clarify? This could be defined as “Measurement of a physical characteristic or trait of a sample as opposed to a measurement of an analyte concentration in a sample”. For LOD, it would then be possible exclude all physical properties measurement tests, tests whose results are derived from physical properties, and tests that cannot be reasonably spiked (or for which spiking solutions are not commercially available), and/or tests for which a calibration curve is not required unless the method requires a determination of LOD.

The participants discussed whether there are other ways of getting to the same place. Perhaps the standard could require performance of LOD only if the lab is reporting to the LOD? It will be difficult to create a “list” for which LOD is not needed and it can’t be kept complete. One state has required LOD studies for pH. Another approach might be to add some illustrative examples.

In discussing LOQ, the committee could exclude all tests that measure physical characteristics unless reporting to a specific level is required by the method or a regulation (e.g. residues). The standard could state that the lab may determine the LOQ based on a study using spiked samples or QC samples and/or estimate and note that the LOQ is based on the test conditions and instrument restrictions (e.g. sample volume, accuracy of balance, or method QC requirements).

Silky summarized that the committee needs to further discuss this issue and look to simplify it. The participants discussed what the NELAC 2003 standard requires and how the TNI 2009 standard is being interpreted to require. Use of the word “estimate” in the suggested language might need to be reconsidered. Others may try to expand on what is implied by using that term. Maybe at least a short list or a guidance document would be a solution for the short term. At the very least the reference to quality control samples should be taken out.

Parking lot issues:

- Microbiology module requires conductivity to 1 micro –ohm. Can that be revisited?
- Source water – term is used twice in same paragraph with different meanings.