TNI Winter Conference
Quality Systems Committee Meeting
January 14, 2013
Paul Junio, Chair

Meeting convened @ 1:30p with the following attendees present.

Paul Junio, Northern Lake
Gene Klesta, Underwriters Laboratory
Stephanie Drier, Minnesota DOH
Gil Dichter, IDEXX
Dorothy Love, Lancaster Labs
Michelle Wade, Kansas DHE
Silkie Labie, Elcat
Katie Adams, Manchester lab., WA (by phone)
Michelle Potter, NJDEP (by phone)
Scott Siders, ILEPA (by phone

Changes to the standard were based on input provided by commenters and standard interpretation requests (SIRS) decisions. The changes in Volume 1, Modules 2-7 were reviewed and discussed with questions answered by the committee. A copy of the modules with changes in track changes mode and comments from the committee will be provided by the committee chair. Many of the changes were editorial in nature.

The following specific and general changes were discussed:

Module 2 – Quality Systems General Requirements: General: references were updated, additions and deletions were made to terms and definitions. ISO 17025 language was included without deletion, and notes explain the intent to disregard when not applicable.

Section 4. New personnel requirements were added.

Section 5.

5.4.4 Tech module language was added to the standard, and edited to be applicable rather than not applicable.

5.4.6 ISO language was edited through a note to reflect that it does not apply.

5.6.1 This is not applicable.

5.8.5 Confusion was noted regarding interpretation of sample numbering requirement, but the need to identify each container was even in the 2003 NELAC standard. Scott Siders remarked that laboratories already seem to understand every container needs to be separately identified, so he saw no need to change the language. June Flowers said laboratories don't want to have to state

the container used in their test reports, and believe it should be sufficient for that information to be in the laboratory records. Scott Siders suggested checking if there is any SIR dealing with this issue; ie., if it has already been clarified, get it from the SIR to put into the standard The Committee decided not to change the language at this time, and requested input on proposed language.

5.8.7.3 Modifications were made for clarity.

5.10 It was noted that calibration certificates do not apply for environmental testing.

Module 3: Asbestos Testing: General – changes that were discussed are documented in track changes mode. Most changes are editorial in nature, and references have been updated.

Module 4: Chemical Testing: General – changes that were discussed are documented in track changes mode . Most changes are editorial in nature, and references have been updated.

Some definitions were edited and discussed. Clarifying statements for highlighted passages were included. The Committee clarified demonstration of capability (DOC) requirements, adding specifications for continuing DOCs.

Module 5: Microbiological Testing: General – changes that were discussed are documented in track changes mode.

Definitions and references were updated. Clarifying detail was added to validation and validation documentation specifications. DOC requirements were tweaked to be specific for microbiological testing. Clarifying language was added to sterility checks. An autoclave note was incorporated as a requirement into specifications.

Module 6: Radiochemical Testing: General – changes that were discussed are documented in track changes mode.

Validation requirements were redefined. Definitions were updated. Clarifying specifications were added for minimum detectable activity (MDA). Initial and ongoing DOC requirements were specified. New background specifications were added. Several notes were upgraded and incorporated into the standard.

It was questioned whether DOE employs these requirements for radiochemical testing.

Module 7: Toxicity Testing: General – changes that were discussed are documented in track changes mode.

Method validation specification was clarified. Initial and ongoing DOC requirements were clarified/specified. The definitions of standard method vs. reference method were specified.