

**Quality Systems Expert Committee Meeting  
Cambridge, MA  
August 20, 2007**

**Committee Members Present:**

Bob DiRienzo (Chair)  
Aaren Alger  
Silky Labie  
Laurie Carhart  
Wilson Hershey  
Paul Junio  
Fred McLean  
Randy Querry  
Robin Cook

**Not Present:**

Karen Varnado  
Michelle Potter

Committee members gave self-introductions and B. DiRienzo reviewed the ground-rules for administration of the meeting. He noted the Expert Committee will schedule a face-to-face meeting to review and resolve comments in late October. The date and arrangements will be posted in TNI's website. Due to the limited time to discuss comments during this session, the Expert Committee will review selected significant comments according to several categories that they have identified. Typo and formatting comments will not be discussed as they are editorial in nature.

The Quality Systems modules are currently in the Draft Interim Standard status. The six volumes cover the following:

Volume 1, Module 2, Quality Systems, General Requirements  
Volume 1, Module 3, Asbestos Testing  
Volume 1, Module 4, Chemistry Testing  
Volume 1, Module 5, Microbiological Testing  
Volume 1, Module 6, Radiochemical Testing  
Volume 1, Module 7, Toxicity testing

**Review of Selected Comments**

Comment #27, Module 2, 1.2

Several comments were received concerning the wording of this section. P. Junio provided background – the intent is to establish the applicability of the standard as it relates to the project requirements rather than data quality objectives.

Comment #126, Module 2, 5.6.4.2.b)

Requiring expiration dates for certain compounds doesn't make sense, such as salt. Some alternatives are to establish a default expiration date, or let each lab document their own policy for maximum flexibility. As written the standard does not differentiate between open and unopened containers as well.

Comment #4, Module 2, 5.8.7.2.b) ii)

Review consistency in using the term “flagged” versus “qualified”.

Comment #318, Module 2, 5.8

Clarify requirements for a durable label – does that include indelible ink such as a Sharpie?

Comment #396, Module 5, 1.7.3.5 c) v)

Comment to clarify requirements for reagent water.

Comment #295, Module 4, 1.6

Demonstration of Capability (DOC) requirements comments included the need for review of repetitive language under 1.6.2. Some requirements are only applicable to ongoing DOC, not the initial DOC.

#518, Module 2 (and several others in the same vein)

Comments regarding the availability of the TNI standards with the ISO language included – without the ISO language it is difficult to use the TNI language alone. Ken Jackson confirmed that the TNI standards will be available with the ISO language as a combined document.

Other comments on ISO usage included where the additional TNI language has been inserted (at end of ISO sections rather than inserted within the ISO numbering). Other committees have done it differently. Need to make it easy for the reader and locate the TNI text where it makes the most sense and results in the lab-friendly document. Another alternative would be to put a pointer in place within the ISO numbering to the TNI additional requirements at the end of the section.

#300, Module 5, 1.7

Question on whether matrix spikes are used in microbiological testing.

#222, Module 2, 3

Comments were received on the selection of the definitions used in the module. The process in selecting the terms was described – existing terms were used where possible, sources were listed in general, but not the specific source for each definition. A process is needed to make selections when two sources conflict in the definition.

#341, Module 2, 3.1

Comment noted that 20 is an arbitrary size for batch preparation if technology is available to prep more than 20 samples using the same personnel, reagents, and process.

#413, Module 2, 1.2

Already reviewed under comment #27.

#505, Module 2, 1.1

Comment that the standard needs to identify that activities irrelevant to the testing performed at a lab are not required.

#440, Module 2, 5.2.6.1

Comments to the Technical Manager qualifications – should more consideration be given to experience to substitute for some educational credit hours for flexibility? One approach may be to define targeted competency demonstrations like are used in other fields. While experience alone can't be relied upon, more flexibility is desirable as some labs have problems identifying qualified candidates. Experience should also be matched with responsibilities and expected level of performance.

#585, Module 2, 4.1.7.3

Comment regarding the allowance for up to 65 days of leave for key staff – suggest shortening period to 30 days. The accrediting body should be notified of leaves of longer duration. It was also questioned whether this should be covered in lab SOPs.

#156, Module 5, 1.7.3.5.a) 2)

Citation to Standard Methods is irrelevant if lab is not accredited to those methods.

#463 and #509, 1.7.3.7 b) ii)

Comments on autoclave maintenance as an annual pressure check – suggestion to make this a leak check instead.

#235, Module 4, 1.7.3.3.2.a)

Comment regarding field duplicate versus matrix duplicate – remove the language that defines matrix duplicate and also review matrix spike/matrix spike duplicate.

#253, Module 4, 1.7.1.1

Comment regarding minimum number of calibration points needed – currently it must be specified by lab if not defined in the analytical method.

#608, Module 3, General comment

Comment to revisit the “shoulds” in the text to confirm they are to be permissive requirements. Asbestos testing is something of an artform, and flexibility in the language is needed.

#294, Module 4, 1.5

Comments regarding confusion between limit of detection (LOD) and limit of quantitation (LOQ). The session chaired by Richard Burrows may help sort this out. The lab does LOQ if it does not do LOD.

Comment to review consistency in terms used in 1.5.2.2e – “performed” versus “determined” versus “verified”, etc.

B. DiRienzo closed the session with an overview of how the committee will move forward with the comment resolution process. The responses to comments will be posted in advance of the January 2008 Forum.