Quality Systems Expert Committee Meeting
Forum on Laboratory Accreditation
Newport Beach, CA
January 15, 2008

Committee members in attendance:
Bob DiRienzo (Chair)
Silky Labie
Paul Junio
Wilson Hershey
Aaren Alger
Laurie Carhart
Randy Querry

B. DiRienzo welcomed the session attendees and reviewed the ground rules. The primary objective of the session is presentation of the TNI Final Standards for Quality Systems (QS). He emphasized the Standards are final, and the Committee can take suggestions for the next revision only.

B. DiRienzo reviewed how the Committee got to this point. It has been working on the Standard since the Dallas January 2004 Forum. The Draft Interim Standard was voted on by the TNI membership prior to the summer 2007 meeting. The QS Committee also had a face-to-face meeting in Lancaster, PA in October 2007. The Committee reviewed and resolved 401 comments during the last member voting period. The QS Committee reconfirmed their previous votes in November 2007 and he reviewed the voting results for each module. Committee voting was completed on December 5, 2007.

The next step in the process is for the QS modules to be reviewed by the Consensus Standards Development Program's Uniformity of Standards Committee for consistency and editorial changes. No additional substantive content changes can be made. Once the final version is available, the Consensus Standards Development Program will forward the modules to the NELAP Board and Laboratory Accreditation System Program for review and adoption.

It was noted the response to comments document is posted on the TNI website and an appeals process is open to anyone not satisfied with the disposition of their comment (See TNI standards development policies).

Volume 1, Module 2 General Requirements

The Committee reviewed comments to this module and discussed the rationale on how some key comments were handled. Some comments were difficult to handle because the incorrect section of the standard was cited by the commenter when entering into the comment system. Any comments regarding ISO text (in italics) could not be incorporated since this text cannot be changed by TNI.

Several comments were received regarding where notes and TNI language were inserted that related to sections of ISO 17025 that are used in the module. These comments were deferred for the next revision cycle. A comment regarding batch preparation was also deferred to the next cycle. The technical manager qualification requirements were another area of debate – there was stiff resistance to allowing years of experience to substitute for credit hours.

An editorial change needed to delete a drafting note at the end of the "Audit" definition was noted.

Several comments were received regarding expiration date requirements in section The Committee amended the requirements such that a lab doesn't have to make up an expiration date if one is not provided by a vendor.

An editorial change is needed in 5.9.3c to clarify reference to lab's SOPs.

Comments from attendees:

It was suggested that the "frequency of management reviews" language should be "at least" annually rather than just annually.

It was suggested that legal chain of custody requirements should be beefed up in future versions of the standard. Commercial labs are often lax in this area.

Volume 1, Module 4 – Chemistry

Some general editorial comments to the scope section incorporated of this module and many editorial comments were incorporated into sections 1.4 and 1.5. Section 1.6.2 for Demonstration of Capability (DOC) has a similar format in all of the technical modules, with analysis-specific modifications. Initial DOC requirements were differentiated from ongoing DOC requirements.

It was noted that section 1.7.5 a) ii.) can be broken into two sections (second sentence can be 1.7.5.a) iii.).

Comments from attendees:

Some analytical methods say "should" about performing Limits of Detection (LODs) – does this standard require LOD if method states "should"? The committee stated that was not the intent.

1.7.4.2.a) i.) and ii.)– The intent is the data may be reported as long as they are reported with appropriate data qualifying codes.

To meet the requirement of 1.7.5.a iii), the time the sample goes in the fridge must be recorded.

In section 1.7.1.1 j), one of the points for establishing the instrument calibration can be zero, depending on method.

The intent of 1.7.3.5 a) is to keep documentation all the time, regardless of reagent grade.

Volume 1, Module 5 – Microbiology

Several comments were received on 1.7.3.7 b) regarding using of the term "calibration", which has been changed to "verification" with respect to autoclaves and volumetric equipment.

It was noted that 1.6.1 needs to allow for off-site archives of documentation. Same allowance is needed for the Chemistry module.

Comments from Attendees: None

Volume 1, Module 7 – Toxicity Testing

An editorial correction to 1.6.3 to correct the text reference to 1.6.2.2 to 1.6.2 was noted.

A comment to section 1.7.1.6 x) was held for the next revision cycle – the Committee needs a toxicity expert to clarify the terminology "geochemical tolerance range".

Volume 1, Module 6 – Radiochemical Testing

This module included the same types of changes to 1.6 DOC. Addition of MQA and MDA requirements were rejected.

Volume 1, Module 3 – Asbestos Testing – Comments were not reviewed.