TNI Stationary Source Audit Sample Expert Committee Teleconference
July 20, 2009

Participants:

Committee members:
Maria Friedman
Stan Tong
Gregg O'Neal
Mike Schapira
Michael Klein
Richard Swartz
Jack Herbert
Jim Serne
Ray Merrill
Jane Wilson, program administrator

Associate members:
Mike Miller
Frank Jarke

1) Double-check of spreadsheet/documents to be referenced in this teleconference

Maria emailed documents for today's call on July 17th. The Voting Draft Standards remain the same as posted on the TNI website for voting.

2) Review and approval of minutes from teleconference on July 13, 2009

Richard motioned to accept the minutes as written and was seconded by Gregg. All were in favor of the motion.

3) Chair Update

Maria provided an update about the email she sent regarding VDS comments related to the EPA proposed rulemaking and consistency with the draft SSAS standards. She requested committee members to vote on her proposal via email by close of business July 21, 2009.

Maria confirmed the guidance document for participants can be developed after the TNI standards are completed. It can be developed during the program implementation period. Central database development also needs to be completed.

Maria asked if anyone wanted to develop a set of comments to be submitted as public comment for the EPA proposed rulemaking. It may be influential for potential users to get together and develop comments about any serious concerns. EPA should consider the comments of directly affected parties. Stan noted that comments are due by August 5th. The group discussed whether they should comment as individuals or develop collective committee comments. A SSAS subgroup will

develop a list of comments, but others can comment individually as they wish. Jack will lead the team – also Mike Miller, Maria Friedman, Mike Schapira, and Gregg O'Neal. Shawn Kassner will be asked to participate as well. Other members can forward comments to Jack for inclusion.

4) Resume review of internal comments to VDS; start with Line 38, Section 7.2 of the Provider tab

Line 38, Section 7.2

The comments relate to requested clarification of the terms "packaging event" and "manufacturing lot". Ray noted that these terms are very critical to providers and should be understood between the provider and regulators. "Manufacturing lot" in the context of the current program is a set of samples in a relatively small concentration range. Homogeneity testing is relatively cheap since it can be verified by testing a relatively small number of samples. In the proposed program, the homogeneity testing could be much more expensive unless some flexibility is provided, e.g., selecting samples randomly for homogeneity testing rather than verifying every sample.

Ray suggested a potential definition for "manufacturing lot" – a group of audit samples manufactured at one time in one particular location for one specific method.

"Packaging event" is more of a preparation for shipment from previous discussion – the selection of audit samples and the associated shipping preparation.

Annex A in the Provider standard covers details of the homogeneity testing program in terms of how many samples have to be tested, etc.

Ray motioned to add the proposed definitions to the Provider document and Stan seconded. All were in favor of the motion.

Line 39, Section 7.2.1

It was noted that during the discussion of this comment that the use of the term "packaging event" is not in the proper context. Ray motioned to strike "within a packaging event" and adding the underlined text as suggested in the comment to 7.2.1. The motion also is intended to strike the new definition of "packaging event" since the term will no longer appear in the standard. All were in favor of the motion.

Line 40, Section 7.2.3

The comment is a suggestion to allow other entities besides the Laboratories to receive the audit samples, such as ship to “facility or its designated representative”. It was noted that the section is about homogeneity testing, and references to the details of shipping are not relevant. Mike S. moved to delete the last phrase ‘to participant laboratories” and end the sentence after “shipment” and Richard seconded. All were in favor of the motion.

Line 44, Section 10.1

The comment suggested that the recommended period of review of audit sample data should be defined. The frequency of data review may depend on many factors – test method, acceptance criteria, failure rates, etc. Stan suggested providing a rationale for the variability of data review to the commenter. Gregg suggested defining criteria for when data review would be triggered. It was noted that Dan Tholen had suggested leaving this open ended during the previous comment period.

Gregg motioned to leave the language as is and leave it as a Provider Accreditor decision based on the variables involved and Richard seconded. Richard also suggested looking back at Dan Tholen’s WDS comments. All were in favor of the motion.

Line 45, line 10.2
Line 46, Line 10.2.1
Line 47, Line 10.3.1
Line 48, Line 10.3.2

These four comments are being considered together. The comments suggest clarifying these sections by deleting 10.2/10.2.1 and amending 10.3.1/10.3.2. Maria noted that the TNI PT Board has passed a first version of the SSAS table and TNI still needs to make decision about ongoing approval of changes. Jack motioned to accept the comments and Stan seconded. All were in favor of the motion.

SSAS will have meetings by teleconference July 27 and August 3 prior to the San Antonio meeting. Maria asked that the committee consider those VDS comments in white first in preparation for the next meeting. She also reminded the committee to vote on her email motion regarding the comments related to the EPA proposed rule.