TNI Stationary Source Audit Sample Expert Committee Teleconference
September 21, 2009

Participants:

Committee members -
Maria Friedman, Chair
Richard Swartz, Vice Chair
Michael Schapira
Gregg O'Neal
Jack Herbert
Stan Tong
Jane Wilson, program administrator

Associate members -
Shawn Kassner
Mike Miller

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

Maria confirmed the SSAS standards dated 9-14-09 are the reference documents for today's call, as well as the other documents provided in her email of 9-18-09 (received by some on 9-19-09).

2) Review and approval of minutes from teleconference on September 14, 2009

Maria noted she will add a note to the 9-14-09 minutes indicating that the minutes from 8-31-09 were reviewed and approved via email.

Richard moved to accept the 9-14-09 minutes with Maria's addition, and Mike Schapira seconded. Motion carried.

3) Address comments re. SSAS Standards review in emails from Richard, Stan, and Jack

Richard's email comments:

Provider document, V1M1

1.2a) – Typo – has been corrected by Maria.

3.15 – Maria suggested not changing the definition for consistency across the SSAS documents so that they have the same definition. Richard considered his suggestion to be editorial, so it's ok as is.

5.1.3 – Providers will participate in TNI SSAS program, and do not have their own SSAS programs. The consensus was to leave the wording as is.

5.3.2 – All agreed to replace “achieve” with “obtain” for consistency.

7.2.1 – For clarity, the committee decided to keep reference to whole section rather than saying “this section”.

7.3.2 – The group discussed what is meant by “Where appropriate…” It is vague, but it could be according to manufacturing needs or the provider oversight body. It may depend on the audit sample design. Shawn noted that providers would typically retain at least one sample of each concentration in a manufacturing lot. Gregg noted that in some cases we need to allow for an audit sample to go out and then be returned. The group agreed to the following wording “If appropriate according to the sample design, providers shall retain samples from each audit sample manufacturing lot …”.

8.1 – The group decided to strike the reference to email, since the request could be transmitted some other way and email is not cited elsewhere as the sole means of transmittal.

8.2 b) – Item 3 in the attestation statement list. The group discussed that the attestation is not for the provider, but is relayed by the provider to the recipient of the audit sample. It was noted that the attestation is currently written in the wrong person – it needs to be changed to first person, such as “I am attesting…” rather than “You are attesting…”. The provider just receives the attestation statement, and doesn’t get the laboratory result.

Richard’s comment to revise the statement to read “The stationary source test laboratory results…" is related to consistency with changes made to section 4.4.2 of the Participant module. Jack asked about method 25 which is collected in the field. Who reports the sample volume information to determine the concentration? Is this a level of detail that can be addressed by the standard? The group discussed various options, including addressing the issue in the guidance document. The Provider instructions should include guidance on what constitutes the lab results, and will include the reporting units, etc. The committee recommended the inclusion of Richard’s proposal.

8.3 d) – Typo – corrected by Maria.

Maria asked for a collective vote on all changes above related to Richard’s comments on V1M1. Jack moved to accept the decisions as proposed/Stan seconded. All were in favor so the motion carried.

Provider accreditor document, V1M2

3.12 (same as previous 3.15) – No change needed.

6.4.3 b) – Maria's recommendation is to leave this section as is. The 45 day allotment is for Providers to resolve complaints, whereas the 90 days that Richard is questioning is for Provider Accreditors to oversee overdue complaints.

Gregg motioned to accept Maria's recommendation as discussed/Richard seconded. Motion carried.

Participants document, V1M3

4.1.5 – The item was proposed for deletion for consistency with action taken on on section 4.2.5. Jack's email explanation supports deletion too. The committee discussed whether acceptance/rejection by the regulatory agency is outside the scope of the standard. Other options could be to convert this to a note explaining that the acceptance/rejection is up to the regulatory agency or moving it to the guidance document. The discussion continued on the intent and is this something worth keeping in the standard.

Richard moved to accept the proposal to delete/Gregg seconded. The motion carried to delete.

<u>Stan's email comments</u>

Provider document, V1M1

6.4.2 Stan proposed to delete the reference to isotope activities. Jack confirmed some methods for isotopes are referenced, so Stan withdraws this comment.

Discussion concluded at this point due to time limitations. Maria will begin an email discussion to see what can be resolved on Stan and Jack's comments via email. She reminded the group of the need to not add new comments, just to review the documents for editorial consistency and other corrections.

The committee still has a deadline to completion work before the upcoming holidays. Next meeting will be Monday September 28th, 2:00 pm EDT.

4) Discuss SSAS Central Database field "Container"

This item was not discussed due to time constraints.