

**SUMMARY OF THE  
TNI CONSENSUS STANDARDS DEVELOPMENT  
EXECUTIVE COMMITTEE MEETING  
JUNE 13, 2013**

The Executive Committee held a conference call on Thursday, June 13, 2013, at 1:00 pm EST. Chair Bob Wyeth led the meeting.

Agenda item 1 – Roll call

Attendance:

Jeff Flowers, Accreditation Body	Present
JoAnn Boyd, At Large Member	Absent
Justin Brown, Field Activities	Present
Richard Burrows, Environmental Measurement Methods	Absent
Robin Cook, Microbiology	Present
Jessica Evans, At Large Member	Present
Maria Friedman, Stationary Source Audit Sample	Present
Paul Junio, Quality Systems	Absent
Mitzi Miller, Proficiency Testing	Present
Bob Shannon, Radiochemistry	Absent
Bob Wyeth, Chairman, At Large Member	Present
Ken Jackson, Program Administrator	Present

Bob Wyeth introduced Jessica Evans, the new At Large Committee Member and welcomed her to the committee.

Agenda Item 2 – Review and approval of April 23, 2013 meeting minutes

It was moved by Jeff and seconded by Robin to adopt the minutes as presented. All were in favor.

Agenda Item 3 – Charter updates; inclusion of terms/new members

Bob announced that the previously submitted charter for the Microbiology Expert Committee had been approved by e-mail. He reminded all Committee Chairs to submit their revised charters.

Agenda Item 4 – Expert Committee reports

**Field Activities.** Justin reported the Voting Draft Standard (VDS) had been modified as a result of persuasive comments received during the voting process. It was posted on the TNI website on June 5 for 15 days, in accordance with SOP 2-100, during which any Committee member may change his or her vote. The vote will then be re-tallied and, in order to pass, requires an affirmative vote of at least two-thirds of the combined affirmative and negative votes cast by

Committee Members. The results of the vote on the modified VDS will then be published. If the modified VDS passes, it becomes the Interim Standard (IS). Justin had notified the NEFAP Executive Committee they should expect to receive the IS in July for comment.

**Proficiency Testing.** Mitzi said the Committee had almost completed its QA on the PT modules in Volumes 1 and 2. She and Ken said the PT Provider Volume 3 was slowed down because the committee had to decide on 3 options. The first would be similar to the current V3 which does not directly incorporate any parts of the ISO standard or guidance document. A difficulty would be to include similar requirements to ISO 17043 and Guide 34 without infringing on ISO copyright. The second option would include all of ISO 17043 and Guide 34 with additional TNI requirements as extra clauses. This would be analogous to the Quality Systems General Requirements in V1, but more complicated with two ISO documents plus additional requirements. The third option would require all PT Providers to be separately accredited to ISO 17043 and Guide 34 (as they are now). Then V3 would incorporate only the additional TNI requirements, and would be a much shorter document. She said all outstanding Standards Interpretation Requests had been dealt with.

**Quality Systems.** Paul had reported by e-mail that the committee was working on the Small Laboratory Handbook and Quality Manual review. They planned to add some new members due to a retirement and a resignation.

**Accreditation Body.** Jeff said Brenda Bettencourt had been added as a new Committee Member, and they were still looking for someone in the “Other” interest category. The checklist for the NELAP technical review was being examined, especially to check that items were appropriately designated for the audit teams.

**Stationary Source Audit Sample.** Maria said progress was being made on the central database of user ids and codes for testing laboratories and facilities. There were already 2 audit sample providers and the program would become official on June 16. The alternate Method 25 would be submitted to EPA for approval.

**Chemistry.** Bob said Richard had reported the revised MDL draft was almost complete, and the committee would review the comments received from voters on the Calibration VDS. Several Committee Member nominees had been invited to participate as Associate Committee Members pending the committee’s deliberation on their nominations.

**Microbiology.** Robin said the committee was continuing to work with the Quality Systems committee on the small laboratory handbook, having taken over the microbiology section. She said ambiguities in the existing standard are hampering the handbook, and those aspects of the standard will be addressed in due course. They are collecting information on parasitology and hoped to recruit a Giardia/Cryptosporidium expert in due course.

**Radiochemistry.** No report.

Agenda Item 5 – Review of draft changes to SOP 2-100

Bob asked the Committee to consider the composition of the Standards Review Council, which would be inserted in Section 1.3 (Definitions). He recommended the Consensus Standards Development Executive Committee should perform this function, since the Expert Committee chairs would be ideally placed to compare a new standard with their own modules/volumes for consistency etc. After some discussion there was general agreement on this. However, it was decided to retain flexibility by not specifying the group's composition in the SOP.

Bob had circulated the attached revised draft of Sections 5.2 through 5.5 of SOP 2-100, and the committee worked through it section by section. The following are those sections on which there were comments or suggestions.

**5.2.1.** Ken had deleted reference to specific groups who would be canvassed for comments on the standard, and had changed the wording to include all stakeholder groups who might be affected. Jessica agreed with this approach that would remove any suggestion of allowing any entity to have an undue influence on the standard development. There was general agreement on this change.

**5.3.6.** Jeff pointed out an inconsistency in the sentence *“Ballots returned as negative without comment will not be counted”*. This should not include Committee Members whose votes must be tallied. Therefore, it was agreed to change the sentence to read *“Ballots returned from Associate Committee Members and Affiliates as negative without comment will not be counted.”*

**5.4.2.** As in 5.2.1, reference to specific groups was removed.

**5.4.3.** It was agreed to remove the last sentence and transfer it to the Definitions section (as 1.3.9).

The Tentative Interim Amendment (TIA) Section (5.5, to be re-numbered 5.6) was also considered. The final paragraph stated: *“A Tentative Interim Amendment may remain in effect for a maximum of two (2) years from the date of its adoption. Within this time period, the section or subsection of the standard that incorporates the Tentative Interim Amendment will be re-introduced as a Voting Draft Standard which will proceed through the normal standards development and voting process.”* Ken pointed out the new standards development process will include more steps, and it may be impossible to process a TIA through the entire process in 2 years as required in the section. However, given the nature of a TIA, which is expected to be non-controversial, he suggested it need only be processed through the Voting Draft Standard part of the procedure. It was agreed to modify the above paragraph to read *“.....the Tentative Interim Amendment will be re-introduced as a Voting Draft Standard which will proceed through steps 5.3.1 through 5.3.9 before being accepted as a TNI standard.”*

It was moved by Justin and seconded by Maria to accept the draft changes to SOP 2-100 with the additional changes discussed during this conference call. All were in favor and the motion passed.

Adjournment

There was insufficient time to address the remaining items on the agenda and the meeting was adjourned at 3:00 pm EDT.

**LIST OF ACTION ITEMS TO BE COMPLETED**

<b>Item No.</b>	<b>Date Proposed</b>	<b>Action</b>	<b>Assigned to:</b>	<b>To be Completed by:</b>
1	2/1/12	The Uniformity of Standards Committee should be re-constituted	Committee	Not yet determined
2	2/1/12	The Executive Committee should prepare a summary of the CSDP plans for laboratory accreditation standard updates with projected time-frames, and submit this to the NELAP Accreditation Council.	Committee	Not yet determined
3	3/8/12	Bob will forward the new roster for the AB Committee to Ken for posting on the website.	Bob	4/3/12
4	3/8/12	Joe Aiello's, list of notes in Volume 2 Module 1 of the standard will be studied by committee members.	All Committee Members	4/12/12
5	3/8/12	Jerry Parr, Paul Junio, Richard Burrows and Ken Jackson will be invited to a conference call re: the EMMEC/QS implementation Work Group	Bob	completed
6	3/8/12	The revised SOP 2-100 and 2-101 will be sent to committee members for an e-mail ballot.	Bob	3/22/12 Final approved SOPs sent to Policy Committee on 4/9/12

<b>Item No.</b>	<b>Date Proposed</b>	<b>Action</b>	<b>Assigned to:</b>	<b>To be Completed by:</b>
7	4/12/12	Review Joe Aiello's notes document	All Committee Members	Ongoing
8	4/12/12	A draft procedure for uniformity of standards review will be prepared and circulated	Bob	Ongoing
9	4/12/12	The draft Guidance Document for Development and Maintenance of Standards will be circulated to Committee Members	Bob	Ongoing
10	5/10/12	It will be recommended which of the notes should remain and which should eventually become standards.	Jane, Mitzi, Ken	Not yet determined
11	5/10/12	A short e-mail will be drafted to the Expert Committee Chairs regarding how notes are to be used, and to clarify the use of any ISO notes.	Mitzi	Not yet determined
12	5/10/12	A draft recommendation to the TNI BoD will be prepared on the proposed formation of additional Expert Committees.	Bob and Ken	Completed

<b>Item No.</b>	<b>Date Proposed</b>	<b>Action</b>	<b>Assigned to:</b>	<b>To be Completed by:</b>
13	5/10/12	A short draft to precede an SOP on the Uniformity of Standards process will be prepared.	Bob	Not yet determined
14	7/12/12	The memo on formation of new committees will be completed and sent to the Board of Directors	Ken, Bob	Completed
15	7/12/12	The report from the Standards Corrective Action Committee will be obtained and sent to CSD-EC members	Ken	8/1/12
16	9/13/12	Ken will discuss with Jerry the development of a tracking system for standards development, and will look for information on the way ASTM does it.	Ken	Not yet determined
17	10/18/12	Bob will forward Kirstin's and Lynn's thoughts from the LASC on the Standards Corrective Action Committee to Ken.	Bob	Not yet determined

Consensus Standard Development Executive Committee  
Conference Call  
June 13, 2013; 1:00 PM EDT  
1-626-677-3000; code 822174#  
AGENDA

1. Roll Call
2. Review and approval of April, 2013 minutes
3. Charter updates; inclusion of terms/new members
4. Expert Committee Reports
  - a. Field Activities
  - b. Proficiency Testing
  - c. Quality Systems
  - d. Accreditation Body
  - e. Stationary Source Audit Sample
  - f. Chemistry
  - g. Microbiology
  - h. Radiochemistry
5. Review of draft changes to SOP 2-100
6. Guidance Document for Development and Maintenance of Standards regarding structure, formatting and Style.
7. Webinars for information exchange
8. Old Business

## Revision of SOP 2-100 as recommended by CA Task Force

Further revisions by KJ – 12/10/12

Committee comments from Denver meeting

Further revisions by KJ – 5/11/13

### 5.2 Working Draft Standard

5.2.1 Before starting preparation of the Working Draft Standard (WDS), Expert Committees publish a notice of Intent to Prepare or Revise a Module or Volume, which invites stakeholders to provide input (see Section 3.2). The Expert Committees also actively seek input from those stakeholder groups who may subsequently adopt, use, or be accredited to the standard (~~e.g., the NELAP Accreditation Council; the Laboratory Accreditation System Executive Committee; and other accreditation bodies~~). Notification will be made by e-mail to the respective Chairs or stakeholder representatives on the intent to prepare or revise the Module-module or volume with a request for their stated interest in further participation within 30 days of said e-mail notification.

5.2.2 The Expert Committees develop ~~module(s) of~~ a WDS. The Committee Chair may delegate the standard-writing process to the Committee Members or to any task group formed from the Committee Members, Affiliates and Associate Committee Members. All Committee Members, Affiliates and Associate Committee Members are afforded the opportunity to contribute to the standard-development process. All stakeholder input is gathered and considered in the standards-writing process. If the WDS will be an update of an existing TNI standard, the following records are to be gathered and maintained during the development process:

- all submitted Standards eComment Forms from all stages of the most recent previous standards development activity, complete with the Expert Committee's written deliberations and disposition of those comments;
- all Response to Comments documents from voting on the most recent previous standards development activity;
- all comments previously placed on hold that remain on hold;
- all pertinent Standard Interpretation Request resolutions
- all Tentative Interim Amendments (see Section 5.5).

5.2.3 An official vote of the Committee Members, with at least two-thirds of the members voting affirmative, is required for release of the WDS by an Expert Committee for publication. The WDS is published on the TNI website at least thirty (30) days prior to its public presentation and discussion.

5.2.4 The WDS is discussed publicly or by Webinar-webinar or any other form of accessible public communication. At this time, any TNI member or any member of the public may propose changes for consideration by an Expert Committee, and should submit those comments in writing to the committee on the Standards Comment Form, available on the TNI website, within thirty (30) days following the public meeting. The Expert Committee may choose to limit discussion and consideration of submitted comments to those sections or specific clauses of the ~~module-WDS~~ that have been presented for proposed modification.

5.2.5 An Expert Committee may, within ninety days, modify the WDS based on comments received during the public discussion and those received within the thirty (30) day timeframe following the public presentation and discussion. In the event of extensive comment, the expert committee may request additional time from the Consensus Standards Development Executive Committee and with notification of the Board of Directors.

5.2.6 ~~If extensive comments are received and addressed, an Expert Committee may re-draft the WDS, after addressing extensive comments, if received, following its presentation, may be redrafted by the Expert Committee and which~~ will again proceed through the review process presented above.

5.2.7 The WDS as modified to address the comments received during this review process will be referred to as the Modified Working Draft Standard (MWDS). An official vote of the Committee Members, with at least two-thirds of the members voting affirmative, is required for release of the MWDS by an Expert Committee for publication. The MWDS is published on the TNI website at least thirty (30) days prior to its public discussion whether by Webinar-webinar or any other form of accessible public communication.

5.2.8 During the MWDS ~~presentation~~public discussion, any TNI member or any member of the public may propose changes for consideration by an Expert Committee, and should submit those comments in writing to the committee on the TNI Standards Comment Form within ~~thirty(30)~~ days following the public ~~presentation~~discussion. The Expert Committee may choose to limit discussion and consideration of submitted comments to those sections or specific clauses of the WDS that have been presented for further proposed modification in the MWDS.

5.2.9 Following the close of the above comment period following the public ~~presentation~~discussion, an Expert Committee may again modify the MWDS from consideration of the comments received during the public ~~debate~~discussion and those received within the ~~thirty(30)~~ day timeframe following the ~~presentation~~discussion. If changes are numerous and/or significant to TNI stakeholders, the Expert Committee may again modify the document and present a revised MWDS following the process outlined above.

5.2.10. If the Committee Members consider the comments are minor in nature and/or noncontroversial, ~~the Committee Members~~they will then vote to accept the ~~new~~revised MWDS. A two-thirds affirmative vote of the Committee Members is required for passage. If a two-thirds affirmative vote is not realized the new MWDS would repeat those steps in section 5.2.

### 5.3 Voting Draft Standard

5.3.1 The ~~new~~MWDS then becomes the TNI-Voting Draft Standard (VDS) after acceptance by the Expert Committee members.

5.3.2 All Committee Members, Affiliates and Associate Committee Members may vote on their committee's ~~modules of the~~VDS. Each Committee Member, Affiliate and Associate Committee Member has one vote. All voting is conducted by electronic ballot

5.3.3 Prior to voting, the VDS is published, together with an electronic ballot form. TNI shall indicate conspicuously on the ballot that negative votes ~~should~~shall be accompanied by written comments related to the proposal, preferably accompanied by proposed alternate language, and that negative votes unaccompanied by such written comments will be recorded

as “negative without comments” and without further notice to the voter. Such ballots, however, will not be counted as either negative or positive. TNI is not required to solicit any comments from the “negative without comment” voter.

5.3.4 Fifteen (15) days after publication of the VDS, the voting period ~~for ballots~~ shall begin. The voting period shall last for thirty (30) days. Early voting will be permitted; i.e., all votes cast from the date of publication of the electronic ballot form up to forty-five (45) days after the date of its publication will be accepted. Each Committee Member, Affiliate and Associate Committee Member will vote on one of the following positions:

- Affirmative
- Affirmative with comment
- Negative with comment
- Abstain

5.3.5 A negative vote may be withdrawn at any time by written electronic submission to TNI. The voter shall instruct TNI if the withdrawn negative is to be changed to an affirmative vote or to an abstention.

5.3.6 In order for the VDS to pass, an affirmative vote of at least two-thirds of the Committee Members is required, and all written comments accompanying votes cast by Committee Members, Affiliates and Associate Committee Members must be considered and brought to resolution as described below (Sections 5.3.7, 5.3.8 and 5.3.9). Ballots ~~items~~ returned as negative without comment ~~shall be recorded as negative without comment~~ will not be counted. Ballots ~~items~~ returned unmarked shall be considered as unreturned ballots.

5.3.7 All written comments accompanying negative or affirmative votes cast by Committee Members, Affiliates and Associate Committee Members shall be recorded and considered publicly. Following its discussion, each written comment shall be ruled persuasive or non-persuasive by a simple two-thirds vote of the Committee Members. The Expert Committee’s deliberation and disposition of the comments shall then be compiled in a Response to Comments document. No written comment shall be dismissed because it does not provide alternative language or a specific remedy to the ~~negative~~ vote. The committee may, subject to the restrictions in 5.3.8, prioritize the comments and may place any comments on hold until the next revision cycle of the standard, if the comments are too numerous to be dealt with in the time-frame available until the TNI Standard is published. Any comment placed on hold must be addressed during the next revision cycle of the standard and must be recorded and considered as a comment at that time.

5.3.8 An Expert Committee may prioritize the comments received and may place a comment on hold until the next revision cycle of the standard if all of the following conditions are met:

- the comment would introduce a concept that had not been subject to public review by being included in a related proposal as published in the VDS;
- the comment would change the text proposed by the Expert Committee to the point that the Expert Committee would have to restudy the text of the VDS;

- the comment would propose something that could not be handled properly within the time frame for processing the changes.

In making the determination whether to place a comment on hold, the Expert Committee may consider relevant factors, including but not limited to: the extent to which the comment proposes a change that is new and/or substantial; the complexity of the issues raised; and whether sufficient debate and public review have taken place. The negative commenter must be informed, in writing, of the reasons the comment has been placed on hold.

5.3.9 A persuasive negative vote or an objection<sup>[kj1]</sup> received from a member of the public will require the Expert Committee to consider whether modification of the VDS is appropriate. The committee may modify the standard, if such modification will lead to removal of the cause for the negative vote. The modified standard must then be made available through publication on the TNI website, together with a Response to Comments document summarizing all persuasive and non-persuasive votes and their resolution, and any objections received from the public and their resolution, for all Committee Members, Affiliates, Associate Committee Members and the public to review. Within fifteen (15) days of this publication, any Committee Member may change his or her vote (from 5.3.6), providing written electronic notice to TNI. The vote is then re-tallied and, in order to pass, requires an affirmative vote of at least two-thirds of the Committee Members. Within fifteen (15) days the tally from the vote on the VDS is published as: number of affirmative votes; number of persuasive negative votes; number of non-persuasive negative votes; number of negative votes without comment; and number of abstentions.

## 5.4 Interim Standard

5.4.1 If the VDS passes, it becomes the Interim Standard (IS). If the VDS fails, it is returned to the Expert Committee for processing during the next revision cycle. All individuals who provided negative votes or who submitted public review comments that were ruled non-persuasive shall be so notified and shall be informed of their right to appeal. Any appeals registered with TNI must be considered in accordance with Section 6 of this Policy.

5.4.2 The IS shall be presented for further comments to those stakeholder groups who may subsequently adopt, use, or be accredited to the standard ~~(e.g., the NELAP Accreditation Council; the Laboratory Accreditation System Executive Committee; and other accreditation bodies)~~. These groups shall be allowed 30 days to discuss the IS with the Expert Committee and to submit any further comments. As a result of this input the Expert Committees may further modify the IS.

5.4.3 The IS shall be submitted to the Standards Review Council for review and approval. The Standards Review Council <sup>[LU2]</sup> may recommend further changes, which will be incorporated prior to the Council's approval. The primary function of the Standard Review council is to insure consistency in format with Guidelines for Standards Development, editorial and/or grammatical corrections, clarity of content and overall consistency with other modules and volumes of the Standard.

5.4.4 If the IS has been modified, the Committee Members vote to accept the modifications. A two-thirds favorable majority vote of the Committee Members is required for passage.

5.4.5 The IS undergoes the voting process described in Section 5.3.1 through 5.3.9 above.

## 5.5 TNI Standard

5.5.1 If the IS passes, it becomes the TNI Standard. If any standard module or volume fails, it is returned to the Expert Committee for processing during the next revision cycle. All individuals who provided votes or who submitted public review comments that were ruled non-persuasive will be so notified and will be informed of their right to appeal. Any appeals registered with TNI must be considered in accordance with Section 6 of this Policy.

5.5.2 The TNI Standard is made available to all interested parties, including standards-adoption organizations.

5.5.3 If any appeal is upheld by the appeals panel, the affected module or section of the TNI Standard is withdrawn by the Expert Committee that developed that module or section for ~~processing during the next revision cycle~~ appropriate disposition.