

**SUMMARY OF THE  
TNI CONSENSUS STANDARDS DEVELOPMENT  
EXECUTIVE COMMITTEE MEETING  
APRIL 23, 2013**

The Executive Committee held a conference call on Tuesday April 23, 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	Present
Justin Brown, Field Activities	Present
Richard Burrows, Environmental Measurement Methods	Present
Robin Cook, Microbiology	Present
Maria Friedman, Stationary Source Audit Sample	Absent
Paul Junio, Quality Systems	Present
Mitzi Miller, Proficiency Testing	Absent
Bob Shannon, Radiochemistry	Absent
Bob Wyeth, Chairman, At Large Member	Present
Ken Jackson, Program Administrator	Present

Agenda Item 2 – Review and approval of January 17, 2013 meeting minutes

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

Agenda Item 3 – New at-large member; volunteer from NSF

Bob Wyeth announced that Jane Wilson has resigned as an at-large member. Jessica Evans, director of the standards group at NSF International, has volunteered to take Jane's place. Bob emphasized that, in his opinion, Jessica would be an ideal replacement, having considerable experience with ISO standards and ANSI. He asked the Committee if the position should be opened up for consideration of other possible at-large members. The consensus from the Committee Members was to invite Jessica to join, and Bob said he would do so.

Agenda Item 4 – Charter updates; inclusion of terms/new members

a. Microbiology Charter approval

Bob asked all Expert Committee Chairs to send their updated charters to him. Ken reminded the Committee that the updated Microbiology Charter especially needed to be approved so that

committee's information could be put on the website. Robin believed the latest version she had sent in was still current, but would send in another copy immediately.

#### Agenda Item 5 – Chemistry Committee representation

Ken informed the Executive Committee that, during the TNI Board April conference call, an AB representative had alleged the Chemistry Expert Committee did not have adequate representation, because the one AB member apparently no longer worked directly for the state accreditation body. However, it was agreed that the member, being an employee of that state, should maintain his designation of "Accreditation Body". It was also pointed out that the person continued to present the AB perspective to the committee. An analogy drawn was a senior official of an accredited laboratory would still be designated "Laboratory" even if he/she did not have duties directly linked to the laboratory. Therefore, the Executive Committee ruled that the Chemistry Expert Committee remains balanced with one AB. Richard said the Chemistry Expert Committee had now received applications from more AB representatives, and the committee would consider adding another 1-2 ABs after it completed its current work on the EPA MDL document, but prior to considering voters' comments on the calibration VDS. Bob Wyeth said he would e-mail Sharon Mertens, the TNI Chair, to inform her of this action.

#### Agenda Item 6 – Expert Committee reports

**Field Activities.** Justin reported the committee has worked through all comments on its VDS, ruling them persuasive or non-persuasive. Care had been taken to make sure the ISO and non-ISO versions of the standard were consistent. It is planned to publish the modified VDS soon on the website. The draft response-to-comments document, prior to publication, will be sent to Ken for him to review the formatting.

**Proficiency Testing.** In the absence of a committee representative, Ken provided an update. The committee has completed its Modified WDS of V1M1 and V2M2, subject to a final check. Currently, V3 is under discussion as a WDS.

**Quality Systems.** Paul reported the committee will examine the Small Laboratory Handbook and Quality Manual template for consistency with the revised QS standard and prior to the San Antonio meeting will make recommendations to LAS. The committee is considering 2 possible TIAs. The first concerns time of analysis, because Giardia has a longer 96 h holding time, which is inconsistent with 72 h in the standard. The second TIA concerns adding a requirement for ABs to confirm that laboratory technical director applicants have degrees from accredited institutions or from foreign universities/colleges that are deemed at least equivalent to US accredited institutions. On discussion, however, there was general agreement that ABs have a responsibility for doing this already and the standard should not require further modification

through a TIA. The QS committee has also discussed substitution of experience for a technical director's college degree, but it was cautioned that this proposal had met strong opposition in the past when it was raised.

**Accreditation Body.** Jeff said the 3rd-party assessor proposal has received TNI Board approval on the first 2 items of the work plan, and the committee is now working on the other 2. He reported that the ABs are “pushing back” on the electronic application. They are asking for listings of FOAs to be included. Currently that would be too much work for the IT people, but they are working on whether it can be done. The committee is also conducting a technical review of the checklist used for AB reapplication. Karl Kircher has been appointed vice-chair of the committee.

**Stationary Source Audit Sample.** No report.

**Chemistry.** Richard said the committee continues to make progress on improvements to Appendix B of the 40CFR Part 136 MDL procedure. This work should be complete within 2 months.

**Microbiology.** Robin said the committee is helping the Quality Systems committee with the small laboratory handbook. The method code list is being pared down. She reported a spirited discussion on technical director qualifications. Giardia needs to be addressed and the committee is considering preparing a guidance document for Giardia laboratories.

**Radiochemistry.** No report.

Agenda Item 7 – Review of draft changes to SOP 2-100

Prior to the call, Bob Wyeth had circulated the attached document, which included changes made as a result of the discussion during the January Denver meeting. The following further changes were considered as the committee worked through the document.

**5.2.1.** In the first sentence “Prepare or Revise a Module” was changed to “Prepare or Revise a Module or Volume”, because some volumes (e.g., V3 and V4 of the Environmental Sector) do not include modules. In reference to the second sentence it was discussed whether to limit seeking input to selected stakeholder groups, and it was decided this needs to be expanded at least to include laboratories.

**5.2.2.** In the first sentence “modules of” was deleted as superfluous.

**5.2.4.** In the last sentence, “module” was changed to “WDS”.

**5.2.5.** In the last sentence, “and notification” becomes “with notification”.

**5.2.7.** It was suggested, since parts of this section repeat language in an earlier section, it might be better to just refer back to that earlier section. Others, however, felt it would better to deliberately spell each section out in full to minimize misunderstanding of the process.

**5.2.9.** In the first sentence, “debate” was changed to “discussion”.

**5.3.1.** It was agreed to delete “new”.

**5.3.2.** In the first sentence “modules of the” was deleted.

**5.3.3.** In the second sentence “negative votes should be accompanied” was changed to “shall be accompanied”.

**5.3.4.** In the first sentence, the superfluous wording “for ballots’ was deleted.

**5.3.6.** Two instances of “ballot items” were changed to “ballots”. It was suggested to change “Ballot items returned as negative without comment shall be recorded as negative without comment.” to “Ballots returned as negative without comment will not be counted.”

**5.3.7.** In the sentence “No written comment shall be dismissed because it does not provide alternative language or a specific remedy to the negative vote”, “negative” was deleted.

**5.3.9.** The meaning of the word “objection” in the first sentence was questioned. Paul volunteered to search for its use elsewhere.

**5.4.2.** It had been questioned earlier by Jane Wilson if singling out certain interest groups brought the consensus process into question. It was agreed all stakeholder groups must be included.

**5.4.3.** In the last sentence, “modules” was changed to “modules and volumes”. In the second sentence, “primary” was deleted, because this is the only function of the Standards Review Council.

**5.5.3.** The statement “for processing during the next revision cycle” was questioned; i.e., what happens if it gets dropped? It was suggested to change the wording to “appropriate disposition”.

The committee having completed its review of the document, Bob Wyeth said he and Ken would re-draft it for review by the committee.

#### Adjournment

There was insufficient time to address the remaining items on the agenda and the meeting was adjourned at 2:55 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  
April 23, 2012; 1:00 PM EDT  
1-626-677-3000; code 822174#  
AGENDA

1. Roll Call
2. Review and approval of January minutes
3. New at-large member; volunteer from NSF
4. Charter updates; inclusion of terms/new members
  - a. Microbiology Charter approval
5. Chemistry committee representation
6. 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
7. Review of draft changes to SOP 2-100
8. Guidance Document for Development and Maintenance of Standards regarding structure, formatting and Style.
  - a. Establish a working group ; not yet convened
9. 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**

**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, which invites stakeholders to provide input (see Section 3.2). The Expert Committees also actively seeks input from those stakeholder groups who may subsequently adopt 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 with a request for their stated interest in further participation within 30 days of said e-mail notification.

5.2.2 The Expert Committees develops 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 gathered and maintained during the development process:

- all submitted comment 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 website at least thirty (30) days prior to its public presentation and discussion.

5.2.4 The WDS is discussed publicly or by 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 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. In the event of extensive comment, the expert committee may request additional time from the Consensus Standards Development Executive Committee and notification of the Board of Directors.

5.2.6 The WDS after addressing extensive comments, if received, following its presentation, may be redrafted by the Expert Committee and 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 at least thirty (30) days prior to its public discussion whether by Webinar or any other form of accessible public communication.

5.2.8 During the MWDS presentation, 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. 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, an Expert Committee may again modify the MWDS from consideration of the comments received during the public debate and those received within the thirty(30) day timeframe following the presentation. 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 comments are minor in nature and/or noncontroversial, the Committee Members will then vote to accept the new 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 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). Ballot items returned as negative without comment shall be recorded as negative without comment. Ballot 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 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 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 [LU1] 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 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 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.