

**SUMMARY OF THE
TNI CONSENSUS STANDARDS DEVELOPMENT
EXECUTIVE COMMITTEE MEETING
APRIL 12, 2012**

The Executive Committee held a conference call on Thursday April 12, 2012, at 1:00 pm EST. Chair Bob Wyeth led the meeting.

Agenda item 1 – Roll call

Attendance:

Joe Aiello, Accreditation Body	present
JoAnn Boyd, At Large Member	absent
Justin Brown, Field Activities	present
Richard Burrows, Environmental Measurement Methods	present
Maria Friedman, Stationary Source Audit Sample	absent
Paul Junio, Quality Systems	present
Mitzi Miller, Proficiency Testing	present
Jane Wilson, At Large Member	present
Bob Wyeth, Chairman, At Large Member	present
Ken Jackson, Program Administrator	present

Agenda Item 2 – Review and approval of March 8 meeting minutes

It was moved by Mitzi and seconded by Joe to approve the March 8 minutes as presented. All were in favor.

Agenda Item 3 – Revised Charters

Bob reported that the revised charter was approved, two-thirds of the Committee Members having voted in favor.

Agenda Item 4 – Clarification on Notes. (Verification by AB Committee chair regarding ISO compliance).

A document from Joe Aiello (attachment 1), listing the notes in Volume 2 Module 1 of the standard, was again briefly discussed. It appears the notes are all used correctly; i.e., clarifying the standard clauses and not themselves containing standards requirements. Bob asked Committee Members to again look at Joe’s document for further discussion during the next meeting.

Agenda Item 5 – Expert Committee reports

- Proficiency Testing

Mitzi reported the committee is working on two Standards Interpretation Requests (SIR). The first concerns the time schedule for completing remedial PTs to get back into compliance after failures. The second SIR is an AB question on PCBs in oil and PCBs in solid materials. Since both have FoPT table listings, it was asked if a lab accredited for both must do both PTs. The WET TIA nears completion. Work on the V3 WDS has started, and the Committee is considering whether to use analysis dates or study dates for setting the time between PTs. It also needs to be made clearer when remedial PTs are required. A target date of early July has been set for the WDS.

- Field Activities

Justin reported the WDS should be ready by early July. They have just about completed V1 and are now focusing on V2. The PT task group has submitted its recommendations and the Committee is now developing language. A second task group on scope of accreditation is considering where mobile labs fit into the standard.

- Quality Systems

Paul reported the Committee is continuing to work through the comments received on the VDS. Their goal is to have reached a tentative decision on each comment prior to the Washington DC meeting, and then present all comments for public discussion prior to making a final decision. A commenter voted negative, but provided a question rather than a comment. Paul asked if it is permissible for him to go back to the commenter and answer the question, then asking the commenter if that will change the vote. This is permissible practice as long as it is done openly.

- Accreditation Body

Joe said the Committee is focusing on issues presented by the AB Task Force. The draft generic application was provided to the ABs, who have returned comments. Since ABs have many differing requirements for information provided on the application, the Committee is considering including all those requirements and then applying a filter so each AB receives only the information it needs. Fields of accreditation are also being worked on and a prototype document should be ready by the Washington DC meeting. They are re-thinking whether it would be of value to collect assessor information and whether TNI should be credentialing them. Mitzi commented if an assessor is being used by 4-5 NELAP states it is unfair if other states do not then accept them as already qualified.

- Stationary Source Audit Sample

No report.

- Environmental Measurement Methods

Richard reported the Committee continues to make good progress on writing calibration language into the laboratory chemistry module (V1M4). However, it still needs to be decided how this will be implemented. This led into the next agenda item

Agenda Item 6 – EMMEC/QS Implementation Work Group

Bob described a conference call, held the previous day, between Bob Wyeth (chair), Paul Junio, Silky Labie, Richard Burrows, Jerry Parr, and Ken Jackson.

At the previous day's meeting, Richard explained that the EMMEC is already incorporating its calibration material into Module 4 (QS chemistry), and his committee believes that is where it belongs to avoid fragmenting the QS material throughout the standard. The draft module 4 will be ready by the August meeting. Jerry raised concerns about which committee will then be responsible; i.e., if QS will delegate to EMMEC? Paul said that could work, and then QS will merge the final product into its QS standard. Bob then raised concerns that this will involve a much more lengthy standards development process, since QS would essentially have to start over again with a WDS and then a VDS.

Ken had reiterated Jerry's earlier suggestion that EMMEC should be given responsibility for Module 4, since most (all?) of the chemistry standards material EMMEC will develop will go into Module 4. Jerry agreed, and suggested also having separate subcommittees under QS for microbiology and radiochemistry (there might not be enough people for separate asbestos and toxicity subcommittees). Silky had said that might be awkward, since there would be the EMMEC expert committee doing chemistry and then subcommittees for microbiology and radiochemistry. Jerry responded they could all be expert committees, but then he is concerned about the extra infrastructure of supporting more expert committees and finding times for them at the public meetings etc. Ken had raised the question of consistency between all the ensuing QS modules, and Bob had suggested that could become the responsibility of the CSD Executive Committee.

The problem of QS getting comments on such as LOQ and LOD was discussed, and how they would handle them since EMMEC will be working on those issues. It was said they could be tabled, and then passed on to EMMEC.

After this introduction by Bob, the following discussion ensued.

Paul said he would be quiet amenable to QS being broken into several committees, and perhaps EMMEC could become the Chemistry Committee. Jane and Ken both stressed there must be clear delineation of responsibility, i.e., two committees cannot share responsibility for a module. Ken said QS has now become so large it may be too big a task for a single committee, even with subcommittees. Joe cautioned that it might be difficult to find enough volunteers to serve on several extra committees. After further discussion, the following structure was proposed:

Expert Committee	Responsibilities
Quality Systems	V1M2 (QS General requirements), with subcommittees for asbestos (V1M3) and toxicity (V1M7)
Chemistry	V1M4 (QS Chemistry). This committee would be the current EMMEC
Microbiology	V1M5 (QS Microbiology)
Radiochemistry	V1M6 (QS Radiochemistry)

Bob asked Committee Members to consider this proposal and to be prepared to vote during the next conference call

Agenda Item 7 – Uniformity of Standards Workgroup

After it had been agreed during the previous month’s meeting that the CSD Executive Committee would assume this task, discussion followed on the way to do this. Ken suggested following a similar plan to the last time (the 2009 TNI standard), but emphasized that it will now be a much easier task, with only the PT standard being considered at this time. For the PT standard, it was suggested the Expert Committee Chairs could compare the new standard with their own modules for uniformity and consistency. The CSD Executive Committee members-at-large could look at the PT modules for any internal conflicts or inconsistencies. Bob will prepare a draft document and will circulate it before the next conference call.

Agenda Item 8 – Guidance Document for Development and Maintenance of Standards regarding structure, formatting and Style.

Jane has prepared a second very detailed draft, and she agreed with Bob that it is now ready for circulation to the Committee for comments. Bob will circulate this document before the next conference call.

Agenda Item 9 – Old Business

Two-thirds of the Committee Members approved SOP 2-101. Bob has sent both SOP 2-100 and SOP 2-101 on to the Policy Committee.

Adjournment

The meeting was adjourned at 2:30 PM EDT.

LIST OF ACTION ITEMS TO BE COMPLETED

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:
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	4/3/12 (call scheduled for 4/11/12)
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

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:
7	4/12/12	Review Joe Aiello's notes document	All Committee Members	5/9/12
8	4/12/12	A draft procedure for uniformity of standards review will be prepared and circulated	Bob	5/9/12
9	4/12/12	The draft Guidance Document for Development and Maintenance of Standards will be circulated to Committee Members	Bob	5/9/12

Consensus Standard Development Executive Committee
Conference Call
April 12, 2012; 1:00 PM EDT
1-218-936- 4700; code 822174#
AGENDA

1. Roll Call
2. Review and approval of March 8, 2012 meeting minutes
3. Revised Charters
 - a. Revised Charted for CSDExC to be submitted
4. Clarification on Notes
 - a. Verification by AB Committee chairs regarding ISO compliance
5. Expert Committee Reports
 - a. Field Activities
 - b. Proficiency Testing
 - c. Quality Systems
 - d. Accreditation Body
 - e. Stationary Source Audit Sample
 - f. Environmental Monitoring Methods
6. EMMEC/QS Implementation Work Group
7. Uniformity of Standards work group
 - a. PT WDS
8. Guidance Document for Development and Maintenance of Standards regarding structure, formatting and Style.
 - a. Work group draft under review
9. Old Business
 - a. SOP 2-101 Revision; submitted to Policy Committee
 - b. SOP 2-100 Revision; submitted to Policy Committee

Attachment 1

ISO clauses in italics & TNI clauses in normal font.

VOLUME 2 MODULE 1

7.5.2 *The accreditation body shall, without undue delay, make the decision on whether to grant or extend accreditation on the basis of an evaluation of all information received (see 7.8.6) and any other relevant information.*

NOTE: An accreditation body, in recognizing the accreditation granted by another accreditation body, which has a law or decision resulting from a legal action, the legal effect of which precludes the accreditation body from granting any accreditation to a particular CAB, would not be required to accept the accreditation of this CAB.

VOLUME 2 MODULE 3

6.3.3 *The accreditation body shall inform the CAB of the names of the members of the assessment team and the organization they belong to, sufficiently in advance to allow the CAB to object to the appointment of any particular assessor or expert. The accreditation body shall have a policy for dealing with such objections.*

NOTE: Accreditation bodies may conduct unannounced assessments. The requirement to notify the CAB in advance of the names of the members of the assessment team does not apply to unannounced assessments. An unannounced assessment should not be used by an accreditation body to appoint a known objectionable assessment team. The policy established for dealing with objections from a CAB to the appointment of an assessor or expert to the assessment team should specify the type of objections under which an accreditation body may consider assigning a different assessor or expert. When assembling a team for an unannounced assessment, accreditation bodies should consider previous objections to an assessor made by a CAB. A CAB retains the right to raise an objection to an assessor or expert at the time of the unannounced assessment but should not raise objections to avoid or delay an unannounced assessment.

6.3.5 *The accreditation body shall establish procedures for sampling (if applicable) where the scope of the CAB covers a variety of specific conformity assessment services. The procedures shall ensure that the assessment team witness a representative number of examples to ensure proper evaluation of the competence of the CAB.*

NOTE: Accreditation bodies should establish procedures for selecting systems, methods and analytical activities that will be observed during an on-site assessment based on the accreditation scope and complexity of the CAB to be assessed. Assessors should strike a balance between thoroughness and practicality while determining the extent to which CABs meet this Standard. The examination of the systems, processes and procedures of

the CAB should give a general sense of its past and present capabilities to perform work of known and documented quality.

- 6.3.6 *For initial assessments, in addition to visiting the main or head office, visits shall be made to all other premises of the CAB from which one or more key activities are performed and which are covered by the scope of accreditation.*

NOTE 2: Each fixed-base branch or subsidiary of a CAB with multiple locations is customarily accredited separately by accreditation bodies and requires separate initial assessments. Mobile facilities of fixed-base CABs or mobile facilities not directed by or attached to a fixed-base CAB may be required to maintain distinct accreditations by different accreditation bodies and may require separate initial assessments.

- 6.3.7 *For surveillance and reassessment, where the CAB works from various premises, the accreditation body shall establish procedures for sampling to ensure proper assessment. All premises from which one or more key activities are performed should be assessed within a defined timeframe.*

NOTE: Each fixed-base branch or subsidiary of a CAB with multiple locations is customarily accredited separately by accreditation bodies and separate surveillance and reassessments. Mobile facilities of fixed-base CABs or mobile facilities not directed by or attached to a fixed-base CAB may be required to maintain distinct accreditations by different accreditation bodies and may require separate surveillance and reassessments.

- 6.3.8 *The accreditation body shall agree, together with the CAB and the assigned assessment team, to the date and schedule for the assessment. However, it remains the responsibility of the accreditation body to pursue a date that is in accordance with the surveillance and reassessment plan.*

NOTE: Accreditation bodies may conduct unannounced assessments. The requirement to notify the CAB in advance of the names of the members of the assessment team does not apply to unannounced assessments. An unannounced assessment should not be used by an accreditation body to appoint a known objectionable assessment team. The policy established for dealing with objections from a CAB to the appointment of an assessor or expert to the assessment team should specify the type of objections under which an accreditation body may consider assigning a different assessor or expert. When assembling a team for an unannounced assessment, accreditation bodies should consider previous objections to an assessor made by a CAB. A CAB retains the right to raise an objection to an assessor or expert at the time of the unannounced assessment but should not raise objections to avoid or delay an unannounced assessment.

- 6.4.2 *The accreditation body may decide not to proceed with an on-site assessment based on the nonconformities found during document and record review. In such cases, the nonconformities shall be reported in writing to the CAB.*

NOTE: The assessment team assigned to the CAB usually makes a recommendation to the accreditation body to not proceed with an initial on-site assessment when it encounters significant nonconformities during document and record review. Accreditation bodies should inform CABs of a cancellation of an initial on-site assessment for those conditions as soon as feasible. For other types of assessments, nonconformities found while reviewing documents and records before an on-site assessment would not result in cancellation of an on-site assessment.

- 6.7 Accreditation bodies shall assign an adequate number of assessors to complete an assessment within a reasonable period.

NOTE: The length of an assessment is determined by the scope of accreditation of a CAB, the number of assessors in an assessment team, the size of a CAB, the number of findings encountered during the assessment, and the cooperativeness of the CAB staff.

- 6.8 The assessment team shall commence the on-site assessment with an opening meeting at which the purpose of the assessment and accreditation criteria are clearly defined, and the assessment schedule as well as the scope for the assessment are confirmed.

NOTE: Additional items that may be covered or addressed during an opening meeting include: identification of records and operating procedures to be examined and the responsible CAB individuals that will provide the assessment team with the necessary documentation, procedures to be followed when a CAB claims information to be confidential business information (CBI), and safety procedures that the CAB may think necessary for the protection of the assessment team.

- 6.9.2 *The assessment team shall witness the performance of a representative number of staff of the CAB to provide assurance of the competence of the CAB across the scope of accreditation.*

NOTE: Assessment team members have the authority to conduct interviews with any or all CAB staff.

- 6.10.1 The assessment team shall analyse all relevant information and evidence gathered during the document and record review and the on-site assessment. The analysis shall be sufficient to allow the team to determine the extent of competence and conformity of the CAB with the requirements for accreditation. The team's observations on areas for possible improvement may also be presented to the CAB. However, consultancy shall not be provided.

NOTE: It is customary and permissible for assessors to provide instruction or guidance on the meaning of accreditation and method requirement during the on-site assessment process. Offering such instruction and advice does not constitute consultancy. Assessors should not prescribe specific tasks on how to develop or implement management systems or operational procedures to comply with accreditation or method requirements to avoid engaging in consultancy.

6.11.1 The accreditation body's reporting procedures shall ensure that the following requirements are fulfilled.

b) The assessment team shall provide only preliminary determinations of potential findings and shall inform the CAB that final determinations concerning the number, nature and extent of assessment findings shall be made by the accreditation body after reviewing reported findings.

NOTE: The assessment team may only provide a preliminary written or oral report at the closing meeting because all final determinations of findings are subject to the approval of the accreditation body.

6.12.4 The CAB shall provide to the accreditation body a plan of corrective action to address findings in the assessment report within thirty calendar days from its receipt.

NOTE: Customarily, a CAB that does not address all findings satisfactorily within two responses is scheduled for a follow-up evaluation or is subject to administrative procedures that deny accreditation to the CAB or that reduce its scope of accreditation.

6.12.5 Only accreditation bodies are allowed to release assessment reports initially. An assessment report shall not be released to the public by an accreditation body until the report has been provided to the CAB, and until the findings of the assessment and the associated corrective actions have been finalized.

NOTE: The on-site assessment process concludes when a CAB addresses all findings in the on-site assessment report to the satisfaction of the accreditation body.

6.12.6 The accreditation body shall ensure that the responses of the CAB to resolve nonconformities are reviewed to see if the actions appear to be sufficient and effective. If the CAB responses are found not to be sufficient, further information shall be requested. Additionally, evidence of effective implementation of actions taken may be requested, or a follow-up assessment may be carried out to verify effective implementation of corrective actions.

NOTE: The accreditation body may consult with the assessment team while reviewing CAB responses to nonconformities and before arriving at decisions on the accreditation status of a CAB.