Summary of the
Laboratory Accreditation Systems Committee Meeting
December 12, 2008

1. Roll call: Attendance is recorded in Attachment A. Ken Jackson, Chair – Consensus Standard Development Board (CSDB) was also present.

   The meeting of the TNI Laboratory Accreditation Systems Committee (LASC) was called to order by June Flowers, Chair, on December 12, 2008 at 11 AM EDT. The meeting was adjourned at 1:15 PM.

2. Discussion of Tentative Interim Amendment - Draft Revision to SOP 2-100

   Ken Jackson reviewed the TIA process and reported that a draft revision has been forwarded to the Policy Committee for possible implementation and use after the Miami meeting of the TNI Board. He also explained that any editorial change to the standard would be reviewed by and approved by the CSDB before proceeding with a change to the standard. Ken reiterated the need to move the TNI standards on, and that any request to change a standard (other than using a TIA) would require another 2 year approval period. He also commended the LASC for their efforts and suggested that our review be performed prior to standard voting next time around.

3. Minutes

   The Draft minutes from the November 14, 2008 meeting were distributed for review.

   Motion: Accept Minutes from 11/14/08.
   Motion: Lew Second: JoAnn
   Approved by Committee

   Ilona will submit to Webmaster for posting.

4. Review of new TNI Standard

   Ilona distributed a table compiled of all the expert committee questions and responses (see Attachment B). The committee proceeded through each item, and posted a comment and recommendation. The Quality Systems, On-Site and part of the AB sections were completed.

   Brooke will review V1: Modules 3-7 for any ISO text that was actually printed and not simply referenced that any sections found will be added to the summary table for the Quality Systems. *(Added to Table 12/16/08.)*

   June and Ilona will meet to propose LASC language for the PT and any new AB responses that are received. These proposed responses will be distributed to committee members to vote on. If anyone disagrees with a response, the response will be further discussed via e-mail until an agreement can be reached … or the response will be discussed with the group at the next meeting.

A DRAFT NELAP Board Recommendation will be prepared and distributed to the committee by 1/6/09. A tentative meeting is scheduled for 1/7/09 to vote on the recommendation. There will be a few recommendations that can not be finalized until LASC meets in Miami (need more info from Expert Committees or LASC members want to discuss an item as a group) and these will be added to the recommendation while in Miami.

4. Next Meeting

The LASC will meet Wednesday, January 7th (time to be determined) via conference call and will meet in Miami on Wednesday, January 14th at 9am. On Monday at 9am there will be a summary of our table presented to the Forum attendees. On Tuesday, June will report at the Assessors Forum the progress of the NELAC 2003 Standards Interpretation Inquiries.

Action Items are included in Attachment C and Attachment D includes a listing of reminders.

Attachment A
PARTICIPANTS
TNI LABORATORY ACCREDITATION COMMITTEE

Member	Affiliation	Contact Information
Ann Marie Allen - present	Massachusetts, Non-nelap AB	T: 978-682-5237 x333 E: ann.marie.allen@state.ma.us
Jo Ann Boyd – present	Southwest Research Institute, Lab	T: 210-522-2169 E: jboyd@swri.org
Lance Boynton - absent	Absolute Standards, Inc., PT	T: 203-281-2917 E: lanceboynton@mac.com
Carol Barrick - absent	FCC Environmental	T: 813-361-6911 E: cabarrick@msn.com
Brooke Connor – present	USGS	T: 303-236-1877 E: bfconnor@usgs.gov
Lewis Denny - present	Florida DOH, AB	T: 904-791-1587 E: lew_denny@doh.state.fl.us
George Detsis - absent	Department of Energy, Government	T: 301-903-1488 E: george.detsis@eh.doe.gov
Dan Dickinson - present	New York DOH, AB	T: (518) 485-5570 E: dmd15@health.state.ny.us
June Flowers – Chairperson Present	Flowers Chemical Laboratories, Inc., Lab	T: (407) 339-5984 x212 E: june@flowerslabs.com
Terri Grimes - present	Pinellas County Utilities, Municipal Lab	T: 727-5822302 E: tgrimes@co.pinellas.fl.us
Dan Hickman - present	Oregon DEQ, AB	T: 503-693-5777 E: hickman.dan@deq.state.or.us
Marvelyn Humphrey – absent	USEPA Region 6, EPA	T: 281-983-2140 E: humphrey.marvelyn@epa.gov
Roger Kenton - absent	Eastman Chemical Company,	T: 903-237-6882 E: rogerk@eastman.com
Judy Morgan - present	Environmental Science Corporation, Lab	T: 615-773-9657 E: jmorgan@envsci.com
Jack McKenzie - present	Kansas DHE, AB	T: 785-296-1639 E: jmckenzi@kdhe.state.ks.us
Dale Piechocki- present	Underwriters Laboratories, Inc., Lab	T: (574-472-5523 E: dale.r.piechocki@us.ul.com
Ilona Taunton – present	TNI Program Administrator	T: 828-894-3019/828-712-9242 E: tauntoni@msn.com
Jerry Parr – absent	TNI Executive Director	T: 817-598-1624 E: jerry.parr@nelac-institute.org

Attachment B

DRAFT DRAFT Summary Table – Expert Committee Responses to Questions/Comments DRAFT DRAFT
Preparation of NELAP Board Recommendation

Meeting Master Table: 12-12-08-v0

	Std Ref.	Comment/Question	Recommendation: Adoption	Editorial	Policy / SOP / Guidance Document Needed	Tentative Interim Amendment	Rejection (Revision Needed)
		QUALITY SYSTEMS EXPERT COMMITTEE					
1	V1: M2-M7	Confusing use of "mandated method", "reference method" and "standard method." Sometimes used interchangeably. Four places in particular are confusing: V1:M2 – 5.9.3 c V1:M4 – 1.7.1.1 j V1:M4 – 1.7.3.3.3 V1:M6 – 1.7.1.a VII QS agrees that these terms appear to be interchangeable, and could be less confusing. It is our intent to use "mandated method" as a method that is required by the client or by regulation. "Reference method" and "standard method" are interchangeable, and are methods that are published by an organization that is fit to do so. There are 23 instances of mandated in Volume 1; 6 instances of reference; and 50 instances of standard. An attached file presents how we would editorially change these if we are allowed to make such changes at this stage. Essentially, the use of standard method would change to reference method (except in 3 occurrences in ISO language which cannot be changed). LASC Final Thoughts/Comments: Agree with response. CSDB should review to confirm these are editorial changes.		X			

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2	V1:M3 – 1.5	This first paragraph is ISO language. It needs to be removed. This is an issue with each of the Modules. Such a change seems to fall outside of an editorial change because it requires a change in the meaning of the Modules. There doesn't appear to be anything we can do at this point. LASC Final Thoughts/Comments: Language needs to be removed and ISO reference needs to be inserted into the non-ISO version of the standard. OK in ISO version. Other sections were also reviewed – see 2a below.		X			
2a	V1: M3-7	*(Added 12-16-08 after Brooks review.)* LASC Final Thoughts/Comments: V1 M3 through V1 M7 **all** have the same ISO language in sections 1.4 and 1.5. Some include a different word or two, and some are outlined differently, but all would be considered ISO language. ISO references need to be inserted into the non-ISO version of the standard. OK in ISO version.		X			
12	V1M7: 1.5	This is ISO language. Remove. (Besides – it's a Definition anyway) See Issue #2. LASC Final Thoughts/Comments: Language needs to be removed and ISO reference needs to be inserted into the non-ISO		X			

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		version of the standard. OK in ISO version. Modules 3-7 should be reviewed for other similar instances.					
3	V1:M3 -1.5	Confusing between Validation and Verification. Validation used in modules, but Verification is in the "Terms & Definitions". Both seem to be defined the same. Clarify the difference between Validation and Verification. It is the intent of QS for validation to mean the process that approves a method for use by the laboratory. Verification is the process of approving a calibration or batch of data. Given the problem with Items 2 and 12, this is likely to be resolved when they are resolved. LASC Final Thoughts/Comments: Add standard ISO definition for Validation to Terms and Definitions in V1:M2. Definition will need to be referenced in the non-ISO language version of the standard.		X			
4	V1M4 & V1M6, 1.5.3.a	Evaluation of Precision & Bias. "…or alternate procedure documented in the quality manual…" This requirement is not consistent with the other modules. The other modules have language like, "document in lab's quality systems, document other approaches are adequate", etc. The quality manual is not specified in the other modules. Should the word "documented" really be referenced" or should "quality manual" be replaced with quality systems? QS agrees that stating that this must be in the quality manual was not intended. We would editorially remove "in the quality manual" from Sec. 1.5.3 a of both V1M4 and V1M6.		X			

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		LASC Final Thoughts/Comments: Agree with response. CSDB should review to confirm these are editorial changes.					
5	V1M3: 1.6	The following is unclear. "In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, personnel or method, the DOC shall be acceptable". Literally, this says that a DOC must pass QC. Should it mean something else? Wording should be consistent through modules – see V1M4 1.6.1 – 3rd paragraph. Suggest adding "as an initial DOC" to this 3rd paragraph for clarification and then use similar wording in M3 and M5. Examine remaining modules for consistency. QS agrees that there could be better clarity by making an editorial change. We believe that stating '…the ongoing DOC shall be acceptable as an initial DOC." clarifies our intent. This change is required in the third paragraph of Sec. 1.6.1 in V1M3, V1M4, V1M5, V1M6, and V1M7. LASC Final Thoughts/Comments: Agree with response. CSDB should review to confirm these are editorial changes.		X			
~~6~~	~~V1M4: 1.4~~	~~The 2nd paragraph is really confusing. Would QS consider providing a guidance document?~~ ~~QS feels that a guidance document would only confuse this issue further. The committee believes the language can't be made clearer without changing the intent of the section.~~	X				

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		~~Furthermore, there are issues with how this language is implemented by ABs which makes additional effort by QS futile.~~ LASC Final Thoughts/Comments: Agree with response.					
7	V1M4: 1.6.1 last para	Search for "demonstration" and "DOC" in the document and make sure it is clear what is being discussed – initial, on-going, or both. QS agrees that this would be an editorial change, and has a table attached listing such changes. Note that the word "demonstrations" is used in three places (once each in Modules 4, 5, and 6), and is intended to mean ongoing and initial. LASC Final Thoughts/Comments: Agree with response. CSDB should review to confirm these are editorial changes.		X			
8	V1M4: 1.6.3	No where does it say that on-going DOC is annual. The only place it does is (c). Should say something along the lines of: "each analyst shall annually demonstrate". QS feels that this is covered. Section 1.6.2 states that an initial DOC must be performed if an analysis hasn't been performed within a 12 month period. If there has been no ongoing DOC, there must be an initial DOC every 12 months. A guidance document will be needed to clarify what is intended here. LASC Final Thoughts/Comments:			X		

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		Agree. Guidance document to be formed.					
9	V1M4: 1.7.1.1	"… and be appropriate for a given regulation or decision". This is EPA-speak. In other portions of the standard we use "for the intended use". This is better because not all agencies or laboratories are doing EPA work. QS agrees that this would be an editorial change. LASC Final Thoughts/Comments: Agree with response. CSDB should review to confirm these are editorial changes.		X			
10	V1M4, 1.7.1.1.h.i	Missing word? "Prior to the analysis of samples, the zero point and single point calibration shall be analyzed…" Is the word "standard" missing here (after calibration)? Just above this sentence it says, "…employing a standardization with a zero point and a single point calibration standard:" QS agrees that this would be an editorial change. LASC Final Thoughts/Comments: Agree with response. CSDB should review to confirm these are editorial changes.		X			

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11	V1M4: 1.7.4.2.a	3rd paragraph. "A LCS that is determined…" should be "**An** LCS…." There are 4 instances of "A LCS" (they are in V1M4 1.7.4.2 a – twice in the 3rd paragraph; and V1M6 1.7.3.2 c twice). QS agrees that each of these should be editorially changed to 'An LCS'. LASC Final Thoughts/Comments: Agree with response. CSDB should review to confirm these are editorial changes.		X			
~~13~~	~~V1M7 1.7.1.2.a~~	~~Standard Reference Toxicants is not in the QS Glossary. Standard Reference Material is in the glossary, so would it be appropriate to add this too?~~ ~~QS feels that this term is understood in the Toxicity field. Under the normal comment period, we would have rejected this comment since there was no proposed definition provided. QS does not support this proposed change.~~ LASC Final Thoughts/Comments: Agree with response.	X				
		ON-SITE EXPERT COMMITTEE					
1	V2:M3 6.12.4 6.12.2	Issue with 30 day requirement. ABs have expressed concerns that 30 days is not enough. Add language that if 30 day time frame can not be met, this must be communicated to the agency or lab to determine a new due date? Would this need to be put in a			X		

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		guidance document? **Response**: 1) Guidance is not enforceable; this would need to be an amendment to the standard. 2) The committee thinks that a procedure for informing the respective parties of lateness is not the solution to the issue raised and informing parties can be handled through a variety of professional avenues. 3) The committee is willing to extend the time in section 6.12.2 to 45 calendar days provided LASC can give specific examples of why 30 days is not sufficient. 4) The committee does not agree that 30 days is not enough time for a CAB to prepare a response to the report of findings and will not extend the time frame of section 6.12.4. a) Since only a *plan* of corrective action is required of the CAB, not *implementation,* 30 days should be sufficient. b) During the closing conference of the assessment the CAB receives a good idea of what issues need to be corrected and can be working on a plan of corrective action during the 30-45 days that the AB is working on the official report. LASC Final Thoughts/Comments: Accept with the condition of a guidance document to encourage ABs to communicate delays and determine a new due date. This comment should be forwarded to the expert committee and considered during the next standard update.					

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PROFICIENCY TESTING EXPERT COMMITTEE **(LASC language will be proposed via e-mail and voted on.)**							
AB EXPERT COMMITTEE **(LASC language will be proposed via e-mail for #2, 4 and 5. #1 and #3 were discussed and responded to at meeting.)**							
~~1~~	~~V2:M1 – 2.0~~	~~Acronyms used need to be spelled out. Could be part of a guidance document?~~ ~~The AB committee will add definitions for the listed acronyms as an editorial change.~~ LASC Final Thoughts/Comments: LASC feels comment can be removed. It is a referenced document that mentions these acronyms.	X				
3	V2:M1 - 7.6.2	"Accreditation Body shall appoint" – many state ABs don't have this authority. Does something need to be added to the "Note" to clarify that the state needs an appeals process that the ABs can refer to? Perhaps add back some Ch 6 language that states this can not precede any state laws defining an Appeals Process. Add this to the end of the "Note"? Something like 7.9.4.2 language needs to be applicable to this section? Would it be an editorial addition to refer to 7.9.4.2? Additional Information regarding possible language as discussed during the 10/24/08 LASC conference call is included in Note 1 below.	X				

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		The following is a portion of the NOTE to section 7.6.2: “An independent person, or group of persons, may consist of another group within the accreditation body organization whose responsibility is to handle investigations and appeals.” The language here accommodates state ABs and allows for the AB to follow the prevailing laws and regulations governing appeals. The AB Committee’s intent was that “accreditation body organization” could be broadly interpreted to mean state government. This allows for any appeals procedures established by the state and adopted by the AB, as required by Section 7.6.1. LASC Final Thoughts/Comments: Agree					

Attachment C

ACTION ITEMS
TNI
LABORATORY ACCREDITATION SYSTEMS COMMITTEE

	ACTION	WHO	ANTICIPATED COMPLETION DATE	COMPLETION DATE	COMMENTS
34	Compile PT responses and propose LASC response.	JUNE, ILONA	12/16/08	12/16/08	
35	Forward LASC proposed responses to LASC members to vote on. Agree, Disagree.	ILONA COMMITTEE MEMBERS	12/16/08 12/19/08	12/16/08	
36	Prepare DRAFT NELAP Board Recommendation and forward to Committee for review and vote.	JUNE / ILONA COMMITTEE MEMBERS	1/6/09 1/7/09		

ATTACHMENT D

BACK BURNER/REMINDERS
TNI
LABORATORY ACCREDITATION SYSTEMS COMMITTEE

		LASC MEETING REFERENCE	COMMENTS
1	Lemuel Walker (EPA OW) requested that EPA have access to Standard Interpretation Requests and responses.	8-22-08	
2			