Summary of the
Laboratory Accreditation Systems Committee Meeting
January 7, 2009

1. Roll call: Attendance is recorded in Attachment A.

   The meeting of the TNI Laboratory Accreditation Systems Committee (LASC) was called to order by June Flowers, Chair, on January 7, 2009 at 1 PM EDT. The meeting was adjourned at 2:45 PM.

2. Minutes

   The Draft minutes from the December 12, 2008 meeting were distributed for review.

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

   Ilona will submit to Webmaster for posting.

3. Review of new TNI Standard

   - Ilona compiled all the expert committee questions and responses and distributed a table to the group prior to the meeting. The table included the PT responses voted on by the group via e-mail (see Attachment B), the additional responses from the AB Expert Committee and the additional final responses received from the PT Expert Committee.

     Responses to PT-2, PT-4, PT-7, PT-10 and PT-12 were reviewed and approved without any objections.

     Responses to PT-3 and PT-24 will be discussed and finalized in Miami.

     Responses to AB-2, AB-4 and AB-5 were developed and approved without any objections.

     The summary table was updated to reflect the discussion (Attachment C).

4. LASC Presentation at TNI meeting in Miami

   The presentation will include a history of the review process, review of the SOP used by the committee for its review and recommendations, presentation of the recommendation and examples of action items that need to be completed prior to implementation of the standard. June and Ilona will work on this.

5. LASC Recommendation to the NELAP Board

   A Draft cover letter and summary tables were reviewed by the committee. Committee members asked if the LASC will see the finished products from the expert committees prior to finalization. This is not currently written into the process. It was decided that the

cover letter would include an offer to assist the NELAP Board with review of the items requested in the summary tables.

The goal will be to present the recommendation to the NELAP Board in Miami. In Miami, LASC will discuss the two remaining items (PT-3, PT-24), finalize the recommendation and then print the recommendation during the lunch break for presentation to the NELAP Board during their afternoon meeting.

6. Standard Review SOP

JoAnn will work with the Policy Committee to ensure that a final version is posted on the website.

7. Next Meeting

The LASC will meet in Miami on Wednesday, January 14th at 9am. On Monday at 9am, June will present a summary of standards review process to the Forum attendees. On Tuesday afternoon, June will report the progress of the NELAC 2003 Standards Interpretation Inquiries.

Action Items are included in Attachment D and Attachment E 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 - present	Absolute Standards, Inc., PT	T: 203-281-2917 E: lanceboynton@mac.com
Carol Barrick - present	FCC Environmental	T: 813-361-6911 E: cabarrick@msn.com
Brooke Connor – present	USGS	T: 303-236-1877 E: bfconnor@usgs.gov
Lewis Denny - absent	Florida DOH, AB	T: 904-791-1587 E: lew_denny@doh.state.fl.us
George Detsis - present	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 - absent	Pinellas County Utilities, Municipal Lab	T: 727-5822302 E: tgrimes@co.pinellas.fl.us
Dan Hickman - absent	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 - present	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 - absent	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

Summary Table – LASC Approval of DRAFT Comments/Insights to PT Responses
Preparation of NELAP Board Recommendation

1-7-08-v0

	June Flowers	Brooke Connor	Jack McKenzie	Dan Dickinson	Roger Kenton	Dan Hickman	JoAnn Boyd	Judy Morgan	Lew Denny	Ann Marie Allen	Lance Boynton	Carol Barrick	George Detsis	Terri Grimes	Marvelyn Humphrey	Dale Piechocki	
1.	A	A See 1.1	A	A	A	A	A	A	A	A	A	A		A	A	A See 1.2	1.1: Just like any good corrective action, the words in the response, like "they intend to include freq. req" and the clause "needs to be removed" are not concrete. I would prefer they state "the frq. Req. will be included by xx/xx/xxxx (date) and the clause will be removed by xx/xx/xxxx. Then we should state that we recommend that the CSDB view these as editorial. (OK - thanks for the clarification. It looks great!) 1.2: I think we should group items 1, 4, 7 and 10 together because they all address non-accredited PT provider vs. recognized PT provider.
2.	WAITING FOR INFORMATION FROM PT EXPERT COMMITTEE																Comment from Dale: As a lab we report results to our Minimum Reporting Level (MRL) for single and multi-point calibrations not necessarily to the lowest calibration standard. There are cases where our MRL is above the lowest calibration standard. For consistency across all labs reporting to the PTRL is the way to go. A compromise could be to simply report the labs MRL.

	June Flowers	Brooke Connor	Jack McKenzie	Dan Dickinson	Roger Kenton	Dan Hickman	JoAnn Boyd	Judy Morgan	Lew Denny	Ann Marie Allen	Lance Boynton	Carol Barrick	George Detsis	Terri Grimes	Marvelyn Humphrey	Dale Piechocki	
3.	A	A See 3.1	D See 3.2	A	A	A	A	A	A	A	A	A		A	A	A	3.1: -their response and our final comment are wishy-washy too. For concrete resolution, we need to state that LASC will recommend to the TNI Board that an appeals process must be established before this standard is adopted – or whatever it is we plan to do. (OK - thanks for the clarification. It looks great!) 3.2: State AB's were required to have appeals processes. Most states, like Kansas, do have appeals processes. In Kansas it is in law, and referred to as the "Administrative Procedures Act". There is no way the "Attorney General" of Kansas will allow us to adopt regulations that a self regulating and the Administrative Hearing Officers will not accept someone or organization usurping their authority.
4.	A	**A**	A	A	A	A	A	A	A	A	A	A		A	A	A	
5.	A	**A**	A	A	A	A	A	A	A	A	A	A		A	A	A	
6.	A	A See 6.1	A	A	A	A	A	A	A	A	A	A		A	A	A	6.1: I don't see that they agreed on any wording-change in their response. I do see that we are suggesting a wording change in our final response. Did we have a side-bar discussion that indicated they were going to change the wording? (OK - thanks for the clarification. It looks great!)

	June Flowers	Brooke Connor	Jack McKenzie	Dan Dickinson	Roger Kenton	Dan Hickman	JoAnn Boyd	Judy Morgan	Lew Denny	Ann Marie Allen	Lance Boynton	Carol Barrick	George Detsis	Terri Grimes	Marvelyn Humphrey	Dale Piechocki	
7.	WAITING FOR INFORMATION FROM PT EXPERT COMMITTEE																
8.	A	A	A	A	A	A	A	A	A	A	A	A		A	A	A	
9.	A	A	A	A	A	A	A	A	A	A	A	A		A	A	A	
10.	WAITING FOR INFORMATION FROM PT EXPERT COMMITTEE																
11.	A	A	A	A	A	A	A	A	A	A	A	A		A	A	A	
12.	WAITING FOR INFORMATION FROM PT EXPERT COMMITTEE																
~~13.~~	ALREADY AGREED TO ON PREVIOUS CALL.																
~~14.~~																	
~~15.~~																	
16.	A	A	A	A	A	A	A	A	A	A	A	A		A	A	A See 2	
17.	A	A	A	A	A	A	A	A	A	A	A	A		A	A	A	
18.	A	A	A	A	A	A	A	A	A	A	A	A		A	A	A	
19.	A	A	A	A	A	A	A	A	A	A	A	A		A	A	A	
~~20.~~	A	A	~~A~~	A	A	A	A See 20.1	A	A	A	A	A		A	A	A	20.1: I see appropriate as being the type of audit.
21.	A	A	A	A	A	A	A	A	A	A	A	A		A	A	A	
~~22.~~	A	A	~~A~~	A	A	A	~~A~~	A	A	A	A	A		A	A	A	
23.	A	A	A	A	A	A	A	A	A	A	A	A		A	A	A	
24.		A					A See 24.1		A	A							24.1: I think this is confusing for new labs

Attachment C

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

Master Table: 1-8-09-v0

	Std Ref.	Still need to address PT-3 and PT-24 in Miami before this is final. 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			

	Std Ref.	**Still need to address PT-3 and PT-24 in Miami before this is final.** **Comment/Question**	Recommendation				
			Adoption	Editorial	Policy / SOP / Guidance Document Needed	Tentative Interim Amendment	Rejection (Revision Needed)
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	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 version of the standard. OK in ISO version.		X			

	Std Ref.	Still need to address PT-3 and PT-24 in Miami before this is final. Comment/Question	Recommendation				
			Adoption	Editorial	Policy / SOP / Guidance Document Needed	Tentative Interim Amendment	Rejection (Revision Needed)
		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. LASC Final Thoughts/Comments:		X			

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		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. Furthermore, there are issues with how this language is implemented by ABs which makes additional effort by QS futile.~~	X				

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		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: Agree. Guidance document to be formed.			X		

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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			

	Std Ref.	Still need to address PT-3 and PT-24 in Miami before this is final. Comment/Question	Recommendation				
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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					
1.	V1M1: 4.1.2 V2M2: 5.2.2	This is inconsistent with V2. Use of non-accredited PT provider vs. recognized PT provider may cause confusion. See V2M2: 5.2.2. Items #4, #7 and #10 also address non-accredited PT providers. *Response: V1M1: 4.1.2 provides the laboratory requirements for initial accreditation and this section is not associated with V2M2:5.2.2, which provides the requirements that the AB must ensure are met for continued accreditation. The clause in V2M2:5.2.2 pertains to situations where an FoPT may not be available 2X per year, such as for Whole Effluent Toxicity. However, there are no FoPTs that are not currently available 2X per year and as PT requirements for new technologies such as WET are added to the PT program, the PT Committee intends to include the PT frequency requirements for unique technologies in appendices to the standard that will supersede the main text of the standard. The clause in V2M2:5.2.2 is not applicable and needs to be removed from the module.* LASC Final Thoughts/Comments: Agree with response. CSDB should review to confirm this is an editorial change.		X			
2.	V1M1: 5.2	PT sample reporting requirements may be difficult to implement. Issues with: - less than reporting, - tracking lowest calibrations. - reporting PT results to the lowest calibration standard for multi-point calibrations or the LOQ for single point calibrations (conflicts with V1:M4 1.7.1.1. (f).)					

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		Inconsistent with V3 sections: 6.3.5 / 7.1.11/ 7.3.5/ 8.4.2/ 10.3.1.1. Response: The PT Committee will review the language in each module for consistency to be sure the language is as intended. If necessary, the Proficiency Testing (PT) committee will propose editorial changes or a tentative interim amendment if there are conflicts in the language between sections. The change from Proficiency Testing Reporting Limit (PTRL) to Limit of Quantitation (LOQ) reporting and questions/concerns regarding implementation were discussed publicly during the consensus standard development process. Several Accrediting Bodies, Proficiency Testing Providers, and laboratories participated in the consensus standard development process that led to this change. Many involved in the consensus process believe the change to be consistent with the goals of the PT program and technically appropriate to ensure PT samples are handled and reported in the same manner as environmental samples. The committee will prepare a guidance document to assist with implementation of the change as this change will result in a process different from what is currently being done under the NELAC 2003 standard. The committee does not agree that this change cannot be implemented. *1-5-09 – E-mail from PT Committee: We finished our review of the standard. The committee will propose TIA for V2 in regards to #4, 7, 10 and 12 to make the language consistent with V1. The committee will propose a TIA for V3 for #2. The language in sections 10.3 needs to be revised to make the change implementable. No changes are*					

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			Adoption	Editorial	Policy / SOP / Guidance Document Needed	Tentative Interim Amendment	Rejection (Revision Needed)
		needed to any other modules for the LOQ reporting to be implemented. *The language for the TIAs will be proposed to the CSDB shortly after the Miami meeting.* *The committee is also working on a guidance document for implementation of the change from PTRL to LOQ reporting and we plan to have this complete by the Miami meeting for discussion at the assessor forum and our committee session.* LASC Final Thoughts/Comments: Agree with final response – TIA and guidance document to be prepared.					
3.	V1M1, 7.2	Reference to "appeals process" needs to be clarified with a reference to the document for that process. Does this process exist or does a document need to be created? *Response: The committee worked under the assumption that TNI would establish an appeals process for laboratories. The committee believes laboratories need a process independent of the AB to appeal decisions made by the AB when those decisions are believed to be in conflict with the TNI standard.* LASC Final Thoughts/Comments: Section 7.2 states that "the laboratory shall use the appeals process established by TNI". This process needs to be established.			X		
4.	V2M2: 4.1.4	Section 4.1.4 (non-PTPA-accredited PTs) is not consistent with Section 5.1.2 and 5.2.1 c). It is also not consistent with Volume 1, Section 4.1.2.		X		X	

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	5.1.2 5.2.1 c) 7.3 d) V1M1: 4.1.2	*Response: This clause as well as the clause in section 5.2.1 c) needs to be revised to be consistent with V2M2: 4.1.4 and V1M1: 4.1.2.* Need input from the PT Committee to understand what the intended purpose is. Section 4.1.4 discusses approved use of non-PTPA accredited PTs, but other sections require the use of PTPA accredited PTs. *Response: The requirement is as follows: Laboratories must purchase PT samples from PTPA approved PTPs for each FoPT. If there is an FoPT for which there are no PTPA approved PTPs, a lab may obtain the PT sample from any PTP and the AB must accept the choice of PTP of the laboratory. However, if PT sample is available from any PTPA approved PTP and the lab purchases the PT sample from a non-PTPA approved PTP-then the laboratory is not in compliance with the standard and the AB may change the lab's performance score to not acceptable. The committee will review all relevant sections and propose a tentative interim amendment as necessary.* *1-5-08 – E-mail from PT Committee: We finished our review of the standard. The committee will propose TIA for V2 in regards to #4, 7, 10 and 12 to make the language consistent with V1. The committee will propose a TIA for V3 for #2. The language in sections 10.3 needs to be revised to make the change implementable. No changes are needed to any other modules for the LOQ reporting to be implemented.* *The language for the TIAs will be proposed to the CSDB shortly after the Miami meeting.*					

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		The committee is also working on a guidance document for implementation of the change from PTRL to LOQ reporting and we plan to have this complete by the Miami meeting for discussion at the assessor forum and our committee session. LASC Final Thoughts/Comments: Agree with first part of response. CSDB should review to confirm this is an editorial change. Agree with final response – TIA to be prepared.					
5.	V2M2, 5.1.4	"There shall have been…" Doesn't sound right. "There shall be…" might be better. *Response: The committee agrees with the LASC recommendation.* LASC Final Thoughts/Comments: Agree with response. CSDB should review to confirm this is an editorial change.		X			
6.	V2M2: 5.2.1 a) 5.2.1 b)	Issue is use of the term "successful" between a) and b). Is the intention that a) should imply to "participate in" instead of "successfully analyze". Reconsider use of terminology to make implementation clear. As it reads, it appears there is a requirement that you must pass 2 PTs within 12 months instead of 18 months or 2 out of 3 over an 18 month period. Response: *The 18 month time-frame is for initial accreditation. For continued accreditation, laboratories must analyze 2 PT samples per year and maintain a successful performance history of 2 out of 3. This time-frame in the TNI Standard is*		X			

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		consistent with language in the 2003 NELAC standard (See NELAC 2003 Sections 2.4.1 and 2.7.2), thus implementation of the requirement should not be of concern. The statement "per year" refers to a 12 month-time frame and could be applicable to calendar or fiscal year as determined by the AB. LASC Final Thoughts/Comments: Recommend editorial change if CSDB confirms this is an editorial change. Wording in Section 5.2.1 a) should read: The laboratories "participate in at least 2 TNI compliant PT samples per year …"					
7.	V2M2, 7.3, 7.3.d	"The Primary AB shall consider the analytical result for a FoPT not acceptable when: … d) the lab submits results for a FoPT from a PTP that is not accredited by the PTPA…" V1M1, 4.1.2., 4.2.1 allows labs to use non-accredited PTPs for FoPTs not available from accredited PTPs. Response: *See #4.* *1-5-08 – E-mail from PT Committee: We finished our review of the standard. The committee will propose TIA for V2 in regards to #4, 7, 10 and 12 to make the language consistent with V1. The committee will propose a TIA for V3 for #2. The language in sections 10.3 needs to be revised to make the change implementable. No changes are needed to any other modules for the LOQ reporting to be implemented.*				X	

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		The language for the TIAs will be proposed to the CSDB shortly after the Miami meeting. *The committee is also working on a guidance document for implementation of the change from PTRL to LOQ reporting and we plan to have this complete by the Miami meeting for discussion at the assessor forum and our committee session.* LASC Final Thoughts/Comments: Agree with final response – TIA to be prepared.					
8.	V2M2: 7.3 a)	Issue on intent. PT Expert Committee Chair has stated that the intent of this section is that "limits" should be changed to "criteria" in the statement "the result reported by the laboratory for a sample is not within the established acceptance limits for that FoPT". *Response: The clause in V2M2: 7.3 a) must be changed to read: "when the result reported by the laboratory is scored not acceptable by the PT Provider".* LASC Final Thoughts/Comments: Agree with response. CSDB should review to confirm this is an editorial change.		X			
9.	V2M2: 7.3 c)	Clarification is needed to help with implementation. What is an example of a "non-specific match between the analytical result for the FoPT and any criterion that …"? *Response: The PT Committee agrees that clarification is required to ensure consistent application of the clause by all ABs. The Committee will either prepare a guidance document or propose a tentative interim amendment to the standard.*			X	X	

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		LASC Final Thoughts/Comments: Agree with response.					
10.	V2M2: 7.3 d) V1M1: 4.1.2 4.2.1 c)	There is a conflict between these sections dealing with unaccredited PT providers. How would an AB implement this? This is a change from the 2003 Standard. *Response: See #4. The clause in V2M2: 7.3 d) needs to be revised to be consistent with V1M1. A lab may use any PTP approved by the TNI PTPA. If there is not a TNI PTPA approved PTP for a FoPT the laboratory may use any PTP it chooses and the AB must accept the laboratories choice.* *1-5-08 – E-mail from PT Committee: We finished our review of the standard. The committee will propose TIA for V2 in regards to #4, 7, 10 and 12 to make the language consistent with V1. The committee will propose a TIA for V3 for #2. The language in sections 10.3 needs to be revised to make the change implementable. No changes are needed to any other modules for the LOQ reporting to be implemented.* *The language for the TIAs will be proposed to the CSDB shortly after the Miami meeting.* *The committee is also working on a guidance document for implementation of the change from PTRL to LOQ reporting and we plan to have this complete by the Miami meeting for discussion at the assessor forum and our committee session.* LASC Final Thoughts/Comments:				X	

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		Agree with final response – TIA to be prepared.					
11.	V1M1: 6	This section does not indicate that V2M2: 8.2 b) must be followed: "The lab shall notify the PT provider that the PT is for corrective action …" V3: 8.4.2 also discusses this process. *Response: The clause in V1M1:6 a) should be revised to specify that the lab shall notify the PTP that the PT will be used for corrective action so it must meet the requirements for supplemental PT, if this requirement remains in the standard. See Committee response to #17.* LASC Final Thoughts/Comments: Editorial change is needed. Text in V2:M2 and V3 needs to be added to V1:M1 to ensure lab is knowledgeable about requirements for corrective action PTs. Most labs will only be reading Volume 1.		X			
12.	V2M2: 10.1	Re-look at this section after Issue #4 in V2M2: 5.1.1 is addressed. May no longer be a conflict regarding suspending a lab for PT failures. This section does not include Non-accredited PTPs PTs. *Response: See #4.* *1-5-08 – E-mail from PT Committee: We finished our review of the standard. The committee will propose TIA for V2 in regards to #4, 7, 10 and 12 to make the language consistent with V1. The committee will propose a TIA for V3 for #2. The language in*				X	

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		sections 10.3 needs to be revised to make the change implementable. No changes are needed to any other modules for the LOQ reporting to be implemented. *The language for the TIAs will be proposed to the CSDB shortly after the Miami meeting.* *The committee is also working on a guidance document for implementation of the change from PTRL to LOQ reporting and we plan to have this complete by the Miami meeting for discussion at the assessor forum and our committee session.* LASC Final Thoughts/Comments: Agree with final response – TIA to be prepared.					
~~13.~~	~~V3: 3~~	~~Include homogeneity and stability and reference Appendix A.~~ ~~Response: It is not necessary to include the definitions for homogeneity and stability in this section since their uses are consistent with the definitions specified in relevant ISO documents. Note that Section 3.0 of V3 reads *"For the purpose of this Standard, the relevant terms conform with ISO/IEC 17011:2004(E), Clause 3 and ISO/IEC 17025:2005(E), Clause 3. Additional relevant terms are defined below"*. Only those terms not defined in ISO or not consistent with ISO are included in this section.~~ LASC Final Thoughts/Comments: Agree with response.	X				

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~~14.~~	~~V3: 4.6~~	~~4.6 states that PTPA has an appeals process. V4 section 6.4 is "complaints" – should an appeals process be described?~~ ~~Response: V4 specifies that the PTPA must have a procedure for an appeals process in Section 5.3.1 (f). The appeals process procedure is at the discretion of each PTPA.~~ LASC Final Thoughts/Comments: Agree with response.	X				
~~15.~~	~~V3: 6.1(c) 10.1.3~~	~~What about new analytes/methods/ technologies for which no historical data are available? How does this work with Experimental PTs? Add Experimental PTs as an example?~~ ~~Response: Clause (c) in Section 6.1 and Section 10.1.3 are not applicable if no historical data are available.~~ LASC Final Thoughts/Comments: Agree with response.	X				
16.	V3: 6.3.5 / 7.1.11/ 7.3.5/ 8.4.2/ 10.3/	All of these sections reference the PTRL. The PTRL has been removed and replaced with language in V1:M1 section 5.2. Need PT committee to explain this as it relates to V1:M1. *Response: The committee will propose a grammatical change or a tentative interim amendment to ensure V3 is consistent with V1 and implementable with the change*				X	

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	10.3.1.1	*from PTRL to LOQ reporting.* LASC Final Thoughts/Comments: Agree with response. A TIA will be needed.					
17.	V3: 8.4.2	8.4.2 does not have a special exception noted for PCBs, so if a corrective action PT is requested by a lab for a specific Arochlor, then the PT must contain it. Standard does not address mixed qualitative/quantitative PTs such as PCBs. *Response: The exception for PCBs is no longer applicable. Additionally, the committee strongly believes that laboratories should not be required to specify which analytes a corrective action PT sample includes. To demonstrate proficiency, the laboratory must be able to accurately quantify and identify target analytes when present and not report false positives. The committee believes the inclusion of the clause in 8.4.2 and 8.4.3 by which the laboratory must specify the analyte to be spiked into a corrective action PT should be removed.* LASC Final Thoughts/Comments: Agree with response. A TIA should be prepared to address this issue.				X	
18.	V3: 10.2.5	10.2.5 b) has an ASTM E178 reference. Should this be in Section 2 References? Response: An editorial change to include a reference to ASTME178 in Section V3, Section 2.0 should be made.		X			

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		LASC Final Thoughts/Comments: Agree with response. CSDB should review to confirm this is an editorial change.					
19.	V3: 10.3	This section, with respect to "<", is not consistent with V1:M2 Section 5.2 *Response: The committee will propose a grammatical change or a tentative interim amendment to ensure V3 is consistent with V1.* LASC Final Thoughts/Comments: Agree with response. A TIA will be needed.				X	
~~20.~~	~~V 4: 4.2.3~~	~~It appears that initial and renewal have been combined into one sentence. This sentence is confusing when discussing initial. How can an initial be biennial?~~ ~~*Response: The committee believes the requirement is understood and that a change to the standard at this time is not necessary.*~~ LASC Final Thoughts/Comments: LASC agrees with response. The standard reads: "Conduct appropriate biennial on-site assessments of any organization seeking to be a PTPA." The word "appropriate" could imply that initial assessments are conducted under a time frame other than biennial. LASC recommends that this wording be addressed in the next standard update.	X				
21.	V4: 4.3.2-b	Should the assigned value be included in the PT summary information? Would assigned value be considered "any other information"?		X			

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		Response: The assigned value should be included in the list of items to include in the PT Summary information. The Committee will propose a grammatical or a tentative interim amendment as needed. LASC Final Thoughts/Comments: Agree with response. CSDB should review to confirm this is an editorial change.					
~~22.~~	~~V4: 6.3.8~~	~~Are the terms "suspended" and "withdrawn" as they apply to PT providers defined somewhere?~~ ~~*Response: No. The committee believes the terms are self-explanatory and used consistently with ILAC, thus definitions do not need to be included in the module.*~~ LASC Final Thoughts/Comments: Agree with response.	X				
23.	V 4: 6.5.2	Is the term "revoke" as it applies to PT providers defined somewhere *Response: No. The committee believes the term "revoke" needs to be replaced with the word "withdraw". See #22.* LASC Final Thoughts/Comments: Agree with response. CSDB should review to confirm this is an editorial change.		X			

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24.	V1M1: 4.2.2 V2M2: 5.2.3 V3: 6.1(c) 10.1.3	Experimental PT participation is an issue that has not been implemented by all ABs consistently. The labs must do them, but there are no consequences. Experimental PTs are inconsistent with normal PT operations. There is a different set of rules that are not well defined. ***Response**: Experimental PT are listed on FoPT tables published by the PT Board and the FoPT tables list the required PT for which laboratories must participate for accreditation. So long as experimental PTs are listed on FoPT tables, there must be a requirement in the standard that explains the terms of participation to ensure that all ABs implement the PT program consistently. If the PT Board eliminates experimental PT, the committee will remove the language for experimental PT from the standard.* LASC Final Thoughts/Comments: **Save for Miami to discuss as a committee.**					
		AB EXPERT COMMITTEE					
~~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				

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2	V2:M1 – 4.3.5, 5.7.3b, 6.3.2	Seems to be for ABs that have more than one person on the staff but this is not always the case. - Potential implementation issue because in some states the assessor and governing AB is the same person. There is no out. With labs there is language that allows for QA Officers to be part of lab management in smaller labs. - Do smaller states need another person? ½ time person? Can you have one person and define different roles that this person has? Similar to QA Officer for small labs. - Look at 4.3.1. Make sure that quality system accounts for this. Define safeguards for objectivity. Define how something like 4.3.5 is handled in a one person state accreditation program. Response: 4.3.5 and 5.7.3b: The AB committee will add a TIA for 4.3.5 and 5.7.3b. (IT (1-6-08):This TIA has been submitted.) The ABC proposes to add the following to the end of each sentence “unless the responsible government authority allows otherwise.” 6.3.2: It is the ABC’s view that the tri annual inspection of the AB satisfies this requirement. LASC Final Thoughts/Comments: Agree with response – preparation of TIA.				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	X				

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		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. 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					
4	V2:M1 – 7.7.3	Need a guidance document or perhaps an additional "Note" in the standard to refer to specific policies and SOPs that put specific timelines on the renewal process. The ABC has reviewed this section. The current language provides the NELAP board			X		

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		with flexibility to establish though policy appropriate timelines as they see fit. LASC Final Thoughts/Comments: Agree with response. NELAP Board should establish appropriate policy to include timelines.					
5	V2:M1 – 7.7.1	"Surveillance on-site assessments" needs to be defined. There is a limited definition in V2M3 but this too needs to be explained in guidance. The ABC has reviewed this section. The current language provides the NELAP board with flexibility to establish through policy appropriate scope of surveillance on site assessment as they see fit. LASC Final Thoughts/Comments: Agree with response. NELAP Board should establish appropriate policy or guidance document.			X		

Attachment D

ACTION ITEMS
TNI
LABORATORY ACCREDITATION SYSTEMS COMMITTEE

	ACTION	WHO	ANTICIPATED COMPLETION DATE	COMPLETION DATE	COMMENTS
37	Prepare Presentation for Monday opening meeting in Miami.	JUNE, ILONA	1/9/09	1/9/09	
38	Ensure Standards Review SOP is finalized and posted on website.	JOANN	1/31/09		

ATTACHMENT E

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			