

**Summary of the  
Laboratory Accreditation Systems Committee Meeting  
September 18, 2008**

1. Roll call: Attendance is recorded in Attachment A. Kirstin McCracken (Chair – PT Expert Committee) was also present.

The meeting of the TNI Laboratory Accreditation Systems Committee (LASC) was called to order by June Flowers, Chair, on September 18, 2008 at 11 AM EDT. The meeting was adjourned at 12:30 PM.

2. Minutes

Review of minutes was delayed to the September 26, 2008 meeting so that the meeting could focus on review of the PT Standard with the Chair of the PT Expert Committee.

3. Review of new TNI Standard

- Earlier in the week, the LASC forwarded the DRAFT Comment/Question – PT Standard Table to Kirstin for her review prior to the meeting. She responded by inserting her comments and a color coding system to help her committee determine how to address the comments:

**Yellow:** Issue that I do not think should be listed in the table as they are concerns that were publicly addressed during voting, or they are inconsistencies in definitions that were already corrected, or I don't understand the comment.

**Green:** Issues that are probably grammatical but need further committee review or guidance documents.

**Red:** Issues that need further committee review and may also require an amendment.

**Pink:** Clear cut editorial change.

- Kirstin and the LASC reviewed all the yellow items and determined that most of these comments and questions had been addressed and could be deleted from the chart. A few comments:
  - o Experimental PTs were added because they exist and there needs to be something in the standard.
  - o Dan Hickman provided some clarification wording that would help with the issue in V 4: 4.2.3. This issue was changed from yellow to pink. Wording: Conduct an initial on-site assessment of any organization seeking to become a PTPA and appropriate biennial on-site assessments for any organization renewing status as a PTPA.
  - o V3, Section 8.4.2: This issue was changed from yellow to red after a discussion of the issue and noting that questions regarding this come up frequently.

- V4, Section 4.3.2-b: This issue was changed from a yellow to a green (possibly pink). Kirstin would like to look at this with her committee before deciding whether to delete it or make an editorial change. The thought was that the information was contained within “any other information ...”.
- A few of the green items were reviewed by Kirstin:
  - There were four comments regarding the PTPA. She would like to take these back to her committee and examine text and grammar clarification. She felt the AB standard is inconsistent and might need some grammatical/editorial work.
  - The appeals process was mentioned in a generic sense. TNI needs to establish an appeals process; this would not be a task for the PT Expert Committee. They did receive some comments during the voting period on this item. It was mentioned that in some ways the Standards Interpretation Request process may work as the appeals process. This needs to be further examined by LASC and considered when the committee makes its recommendations.
- Ilona was asked to update the changes to the Table discussed today and include it in the minutes and forward it to the PT Expert Committee Chair. (See Attachment B.)
- Next steps include:
  - Receive written response from the PT Expert Committee regarding the LASC Comments/Questions Table.
  - Decide whether comments/questions are no longer an issue or whether they are still an issue and can be recommended with one of the procedures described in the Standards Review SOP.
  - Make recommendation to NELAP Board.
- Quality Systems review will be next. A blank Question/Comment table was distributed to committee members on 9/5/08 to capture comments regarding V1M2. Comments are due to Ilona on 9/25/08 for inclusion into a master table that the committee will use to perform its review.

#### 4. Next Meeting

The LASC will meet via conference call on Friday, 9-26-08 at 11am EST. The main topic for the call will be review of the Quality Systems standard.

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

**Attachment A**  
**PARTICIPANTS**

**TNI LABORATORY ACCREDITATION COMMITTEE**

<b>Member</b>	<b>Affiliation</b>	<b>Contact Information</b>
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Jack McKenzie - absent	Kansas DHE, AB	T: 785-296-1639 E: <a href="mailto:imckenzi@kdhe.state.ks.us">imckenzi@kdhe.state.ks.us</a>
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## Attachment B: Comments and Questions from LASC on new TNI Standards – PT

Master Table: 9-18-08-v0 w/ comments from PT Expert Chair and 9/18/08 LASC Meeting

	Std Ref.	Comment/Question	LASC Review Category				
			Clarification Needed	Implementation Issue	Editorial	Inconsistent / Conflict	Error or Omission
		<p>Kirstin's Initial Review:</p> <p><b>Green:</b> Issues that are probably grammatical but need further committee review or guidance documents.</p> <p><b>Red:</b> Issues that need further committee review and may also require an amendment.</p> <p><b>Pink:</b> Clear cut editorial change.</p>					
1.	V1M1: 4.1.2	<p>This is inconsistent with V2. Use of non-accredited PT provider vs. recognized PT provider may cause confusion. See V2M2: 5.2.2.</p> <p><b>Response:</b></p> <p><i>V1M1 is correct. All sections of V2M2 should be revised to be consistent with V1M1.</i></p>			X	X	
2.	V1M1: 5.2	<p>PT sample reporting requirements may be difficult to implement. Issues with:</p> <ul style="list-style-type: none"> <li>- less than reporting,</li> <li>- tracking lowest calibrations.</li> <li>- 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).)</li> </ul> <p>Inconsistent with V3 sections: 6.3.5 / 7.1.11/ 7.3.5/ 8.4.2/ 10.3.1.1.</p> <p><b>Response:</b></p> <p><i>Guidance Document Needed-otherwise changes were discussed publicly. Comments were received and considered. See Response to Comments Document for explanation.</i></p>	X	X		X	

	Std Ref.	Comment/Question	LASC Review Category				
			Clarification Needed	Implementation Issue	Editorial	Inconsistent / Conflict	Error or Omission
3.	V1M1, 7.2	<p>Kirstin's Initial Review:</p> <p><b>Green:</b> Issues that are probably grammatical but need further committee review or guidance documents.</p> <p><b>Red:</b> Issues that need further committee review and may also require an amendment.</p> <p><b>Pink:</b> Clear cut editorial change.</p>	X				
4.	V2M2: 4.14 5.12 5.2.1 c) 7.3 d)  V1M1: 4.1.2	<p>Section 4.1.4 is not consistent with section 5.12 and 5.2.1 c). It is also not consistent with Volume 1, Section 4.1.2.</p> <p>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.</p> <p><b>Response:</b></p> <p><i>See Comment #2. The requirement is as follows: labs must purchase PT samples from approved PTPs for each FoPT. If there is an FoPT for which no approved PTPs can provide a sample, a lab may obtain the sample from any PTP and the ABs must accept the choice of PTP used by the lab-but if an approved PTP is available for any FoPT and the lab uses a non-approved PTP-then they are not in compliance with the standard and the AB may change the lab's performance score to not acceptable.</i></p>	X				

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<b>5.</b>	V2M2, 5.1.4	<p>“There shall have been...” Doesn't sound right. “There shall be...” might be better.</p> <p><i>Response:</i> <i>Agreed.</i></p>			X		
<b>6.</b>	V2M2: 5.2.1 a) 5.2.1 b)	<p>Issue in use of the term “successful” between a) and b). Is the intention that a) should state “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.</p> <p><i>Response:</i> <i>The 18 month time-frame is for initial accreditation. For continued accreditation, 2 PT per year with a history of 2 out of 3 is required. The committee will review the proposed change.</i></p>	X	X			
<b>7.</b>	V2M2, 7.3, 7.3.d	<p>“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...”</p> <p>V1M1, 4.1.2., 4.2.1 allows labs to use non-accredited PTPs for FoPTs not available from accredited PTPs.</p> <p><i>Response:</i> <i>See #1 and #4.</i></p>				X	

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<b>8.</b>	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".  <b>Response:</b>  <i>Actually, the language should read performance score. The committee will review and propose a change.</i>	X				
<b>9.</b>	V2M2: 7.3 c)	Is clarification needed to help with implementation? Guidance document?? An example of a non-specific match?? Include notes?  <b>Response:</b>  <i>A non-specific match would be if a lab reported one method but was accredited for a different method, different technology... examples may be appropriate.</i>	X				
<b>10.</b>	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.  <b>Response:</b>  <i>See #1, 4, 7.</i>				X	

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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:  <i>Committee review needed.</i>					X
12.	V2M2: 10.1	Re-look at this section after Issue #3 in V2M2: 5.1.1 is addressed. May no longer be a conflict.  Response:  <i>See #1, 4, 7 &amp; 10.</i>				X	
13.	V3: 3	Include homogeneity and stability and reference Appendix A.  Response:  <i>Editorial.</i>			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:  <i>If V4 does not include a requirement for the PTPA to have an appeals process; the requirement should be added unless the complaint process includes appeals. Committee review needed.</i>	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:  <i>Committee review needed. No adverse comments were raised during voting period. Guidance document?</i>	X				
16.	V3: 6.3.5 / 7.1.11/ 7.3.5/ 8.4.2/ 10.3/ 10.3.1.1	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:M!  Response:  <i>The PTRL for V3 language is not related to V1M1 but applies to PTPs. Guidance document is needed.</i>		X		X	

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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:  <i>There is no requirement in any of the other modules that a corrective action PT for PCB include a specific Arochlor. (9-18-08: Assessors are doing different things and various questions often come up surrounding this issue. Committee will look at this.)</i>	X				
18.	V3: 10.2.5	10.2.5 b) has an ASTM E178 reference. Should this be in Section 2 References?  Response:  <i>Editorial</i>			X		
19.	V3: 10.3	This section, with respect to "<", is not consistent with V1:M2 Section 5.2  Response:  <i>This language may need to be revised. Committee review needed.</i>	X	X		X	

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			Clarification Needed	Implementation Issue	Editorial	Inconsistent / Conflict	Error or Omission
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?  Note: Clarifying language was suggested during the 9/18/08 meeting: Conduct an initial on-site assessment of any organization seeking to become a PTPA and appropriate biennial on-site assessments for any organization renewing status as a PTPA.  Response:			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"?  Response:  <i>If assigned value is needed, it would be included in any other information. (9-18-08: Review with committee to see if this should be specifically added.)</i>	X				
22.	V4: 6.3.8	Are the terms "suspended" and "withdrawn" as they apply to PT providers defined somewhere?  Response:  <i>If not, they should be. Committee review needed.</i>	X				

	Std Ref.	<b>Comment/Question</b>  Kirstin's Initial Review: <b>Green:</b> Issues that are probably grammatical but need further committee review or guidance documents.  <b>Red:</b> Issues that need further committee review and may also require an amendment.  <b>Pink:</b> Clear cut editorial change.	LASC Review Category				
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23.	V 4: 6.5.2	Is the term "revoke" as it applies to PT providers defined somewhere  <b>Response:</b>  <i>If not, it should be. Committee review needed.</i>	X				

**Attachment C**

**ACTION ITEMS**

**TNI**

**LABORATORY ACCREDITATION SYSTEMS COMMITTEE**

	<b>ACTION</b>	<b>WHO</b>	<b>ANTICIPATED COMPLETION DATE</b>	<b>COMPLETION DATE</b>	<b>COMMENTS</b>
9	Update any needed changes to the DRAFT SOP: 5-102: Review of Accreditation Standards for Suitability.	JOANN	9/29/08		Subcommittee has been formed to review this SOP and recommend any final changes – see Action Item #16.  Recommended changes reviewed and approved by LASC.
20	Review Quality Systems – V1:M2 (pg 1-39). Prepare comments on table distributed 9/5/08 and send to Ilona by 9/25/08.	ALL	9/25/08		
21	Prepare master summary of V1:M2 comments for 9/26 meeting.	ILONA	9/25/08		
22	Send finalized Standards Review SOP to the Policy Committee – Alfredo.	JOANN	9/16/08		
23	Send Final PT Comment/Questions Table to Chair of PT Expert Committee	ILONA	9/26/08	9/25/08	
24	Confirm 9/26/08 meeting time with Paul Junio, future Chair of Quality Systems Committee.	ILONA	9/18/08	9/18/08	

