

**Summary of the
Laboratory Accreditation Systems Committee Meeting
July 10, 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 July 10, 2009 at 11 AM EDT. The meeting was adjourned at 12:00 PM.

2. Minutes

The Draft minutes from the June 12, 2009 meeting were not yet distributed. June is working on the May and June minutes and will distribute them for review at the next meeting.

3. Standards

According to the CSDB (7/9/10), the schedule to get the final standards to the NELAP Board is 7/20/09. A final vote is planned by August.

Discussion of TIA #1. Concern was expressed that Neptune may not be able to adjust the PT database to accommodate Section 10.3 of Volume 3. The database allows for only one format. It was stated that A2LA would be dealing with this issue, and that several AB's would have to change regulations to address this new way of interpreting PT results. There is concern that this issue addresses a small number of industrial laboratories for AB's to monitor PTRL's.

There was some discussion on the guidance documents that are being worked on. LASC has not been requested to produce any policies or guidance documents at this time.

See Attachment B for LASC's comments. Attachment C contains details regarding TIAs that were incorporated into the TNI Standard.

5. Next Meeting

The LASC may meet in San Antonio prior to the Thursday, August 13, 2009, NELAP presentation meeting. If so, this will be an informal lunch meeting.

The meeting was adjourned.

Attachment A**PARTICIPANTS****TNI LABORATORY ACCREDITATION COMMITTEE**

Member	Affiliation	Contact Information
Ann Marie Allen - absent	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: iboyn@swri.org
Lance Boynton - present	Absolute Standards, Inc., PT	T: 203-281-2917 E: lanceboynnton@mac.com
Carol Barrick - absent	FCC Environmental	T: 813-361-6911 E: cabarrick@msn.com
Brooke Connor – absent	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 - 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 - 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 - absent	Environmental Science Corporation, Lab	T: 615-773-9657 E: jmorgn@envsci.com
Dale Piechocki- absent	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

**Review of Summary of Action Items/Conditions
(NELAP Board Recommendation – Attachment B**

UPDATE: PROPOSED EDITORIAL CHANGES

	Reference	Reference to LASC Review	Editorial Change	Status of Change
1	V1:M2-M7	QS - 1	Correct inconsistent terms (“mandated method”, “reference method” and “standard method”).	Complete “Test” method definition has been stricken and “reference method” replaces the previous “standard method”. Added text: (When ISO refers to a standard method, that term is equivalent to reference method.) Appears in section 1.4 for V1:M3-M6 as applicable.
2	V1:M3-M7	QS – 2, 2a, 12	ISO language needs to be removed from the non-ISO version of the standard. A reference to this language needs to be added. -	Complete Quality Systems (QS) decided to leave language in. It is language NELAC was using before ISO. It appeared that it would be difficult to make the change smoothly. Jerry said it would be OK to look at this next standard update period. LASC agrees with QS.
3	V1:M2	QS-3	Add the ISO definition for “Validation” to Terms and Definitions.	Complete QS felt paragraph where validation is mentioned clarified the term sufficiently. Not a significant enough issue to make a change now. LASC agrees with QS.

	Reference	Reference to LASC Review	Editorial Change	Status of Change
4	V1:M4 & V1:M6, 1.5.3.a	QS-4	Remove "... in the quality manual." Error.	Complete It has been changed in the other modules as well.
5	V1:M3 – M7 1.6 (third para)	QS-5	State "...the ongoing DOC shall be acceptable as an initial DOC." Change clarifies intent.	Complete Change made.
6	V1:M4 1.6.1 (last para) V1:M5 – M6	QS-7	Correct inconsistent terms ("demonstration" and "DOC".)	Complete Clarified the use of the terms "demonstration" and "DOC". Clarified by adding "initial" or "on-going."
7	V1:M4 1.7.1.1	QS-9	Correct inconsistent use ("... and be appropriate for a given regulation or decision" vs. "... for the intended use.")	Complete Changed to "intended use".
8	V1:M4 1.7.1.1.h.i	QS-10	Add missing word – "standard."	Complete Added.
9	V1:M4 1.7.4.2.a V1:M6 1.7.3.2.c	QS-11	Correct use of "An" to "A."	Complete Changed to "An" LCS.
10	V2:M2 5.2.2	PT-1	Wording is not applicable and needs to be removed.	Complete PT committee explanation suggests that WET PT

	Reference	Reference to LASC Review	Editorial Change	Status of Change
				may not be available 2X per year....perhaps the reference to WET can be added? We recommend that this be done in the next standard update, but this is not a show stopper now.
11	V2:M2 4.1.4 5.1.2 5.2.1 c) 7.3 d) - V1:M1 4.1.2	PT-4 -	Correct inconsistent language between sections.	THIS HAS BEEN CONSIDERED AS A TIA (TIA#3) AND SHOULD BE REMOVED FROM THIS TABLE.
12	V2:M2 5.1.4	PT-5	Correct grammar.	Complete It has been corrected.
13	V2:M2 5.2.1 a)	PT-6	Wording should read: The laboratories “participate in at least 2 TNI compliant PT samples per year ...”	Complete The word “successfully” has been removed.
14	V2:M2 7.3 a)	PT-8	The clause must be changed to read: “when the result reported by the laboratory is scored not acceptable by the PT Provider”. -	THIS IS BEING ADDRESSED THROUGH TIA #6 AND SHOULD BE REMOVED FROM THIS TABLE.
15	V1:M1 6	PT-11	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.	ADDRESSED BY TIA #5. THIS SHOULD BE REMOVED FROM THIS TABLE.
16	V3 2	PT-18	Add missing reference.	Complete

	Reference	Reference to LASC Review	Editorial Change	Status of Change
				The reference to ASTM E178 Standard Practice for Dealing With Outlying Observations has been added.
17	V4 4.3.2-b	PT-21	Include "assigned value" in listing.	Complete Change made and re-numbered accordingly.
18	V 4 6.5.2	PT-23	Correct term. Should be "withdraw", not "revoke."	Complete Change made.

UPDATE: PROPOSED POLICY/SOP/GUIDANCE DOCUMENTS

	Reference	Reference to LASC Review	Proposal	Responsible	Estimated Completion Date
1	V1:M4 1.6.3	QS-8	Original: Guidance document needed to clarify need for on-going DOGs. Update: Work with the Technical Assistance Committee (TAC) in the development of examples for the QAM Template.	Quality System TAC	Jan 2010
2	V2:M3 6.12.2 6.12.4	On-Site - 1	Original: Guidance document needed to encourage ABs to communicate delays and new due dates. Final: Delete recommendation. Though increased communication would be helpful, it would be awkward to prepare a guidance document for this recommendation. This should be considered during the next standard update.		
3	V2:M2 7.3 c)	PT-9	Original: Guidance document needs to be prepared to provide clarification to help with implementation. PT-9: 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 ..."? <i>Response: The PT Committee agrees</i>		

			<p><i>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.</i></p> <p><u>LASC Final Thoughts/Comments:</u> Agree with response.</p> <p><u>NELAP Response:</u> no objections</p> <p>Final: Delete recommendation. Upon review of the updated standard, this does not appear necessary.</p>		
4	V1:M1 V2:M1 V3	PT-2	<p>Original: Prepare guidance document for implementation of the change from PTRL to LOQ reporting.</p> <p>Final: Prepare PowerPoint to present change from PTRL to LOQ reporting. This presentation will be placed on the TNI website to provide guidance to implement this change.</p> <p><i>(E-mailed Kirstin to confirm they are OK with this change or to find out what they propose.)</i></p>	PT Expert Committee	March 2010
5	V2:M1 7.7.3	AB-4	Policy needed to establish timelines.	NELAP Board	DRAFT by December 2009
6	V2:M1 7.7.1	AB-5	Policy or guidance document needs to be established to define "Surveillance on-site assessments".	NELAP Board	DRAFT by December 2009

UPDATE: PROPOSED TENTATIVE INTERIM AMENDMENTS
(See Attachment 1 for copies of the TIAs that were incorporated into the TNI Standard.)

	Reference		Recommendation	TIA Status
1	V3 10.3	PT-2	This section, with respect to “<”, is not consistent with V1:M1 Section 5.2	PT-TIA #1 Issue has been addressed. Note: The TIA did make improvements to the language. The process is much more understandable, but concern has been expressed by some LASC members that this process, explained more clearly, may have some issues. Is the NELAP Board willing to accept a less than value as an affirmative test when the value is within the testing range? This new wording may put PT providers in a position where a result may be acceptable to a TNI state, but not in another state. Do we want multiple scoring criteria for different states?
2	V1:M1 7.2	PT-3	A TIA is needed. The PT Expert Committee needs to reconsider “appeals process” language and rewrite this paragraph to be consistent with their intent.	PT-TIA #2 Clause was removed.
3	V2	PT-4, 7, 10, 12	The PT committee will propose TIA for V2 to make the language consistent with V1 (non-PTPA accredited PTs.)	PT-TIA #3 , Sections 5.1.2, 5.2.1, 7.3 PT-TIA #4 , Section 4.2.1 PT-TIA #5 , Section 6.1 Issue resolved.
4	V3 6.3.5 / 7.1.11/ 7.3.5/ 8.4.2/ 10.3/	PT- 16	PT sample reporting requirements may be difficult to implement. Issues with: - less than reporting, - tracking lowest calibrations. - reporting PT results to the lowest calibration	PT-TIA #1 Changes in section 10.3 as TIA. It appears PTRL still exists in Volume 3 for PT providers, but nor labs. This appears acceptable.

	10.3.1.1		<p>standard for multi-point calibrations or the LOQ for single point calibrations (conflicts with V1:M4 1.7.1.1. (f).)</p> <p>Inconsistent with V3 sections: 6.3.5 / 7.1.11/ 7.3.5/ 8.4.2/ 10.3.1.1. (PTRL language)</p>	<p><i>Note from PT Expert Committee: Yes, PTRL is only for PTP – not applicable to labs so there does not need to be any mention of PTRL in V1.</i></p> <p>Note: The TIA did make improvements to the language. The process is much more understandable, but concern has been expressed by some LASC members. The expert committee did what they could to deal with the issues identified, but there may still be implementation issues with the LOQ concept. The lab may have to prove their LOQ to the AB if questioned and they can receive an acceptable score using a less than value.</p>
5	V3 8.4.2	PT-17	<p>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.</p>	<p><i>Note from PT Expert Committee: A TIA is not in progress – the committee did not agree with the LASC regarding the PCB exception. We intentionally removed the PCB exception and have no intent to add it back. The clauses cited here may be removed in the next revision but we did not believe this change needs to be made now or is of emergency nature.</i></p> <p>LASC agrees a TIA is not needed at this time.</p>
6	V3 10.3	PT-19	<p>The PT committee will propose a grammatical change or a tentative interim amendment to ensure V3 is consistent with V1.</p>	<p>PT-TIA #1</p> <p>Issue resolved.</p>
7	V2:M1 4.3.5 5.7.3 b	AB-2	<p>The AB committee has proposed 2 tentative interim amendments to address this issue.</p>	<p>Dan Hickman said that NELAP Board agreed that this concern is no longer a concern and recommends that this recommendation be eliminated. The NELAP Board had a conversation with Marlene Moore and agreed that a wording change is not needed, because the ISO</p>

				<p>language does not conflict with current AB practices.</p> <p>LASC is in agreement with the NELAP Board for the reasons stated above.</p> <p>No TIA needed.</p>
8	V2M2 7.3	New	Scoring of PT results.	<p>PT-TIA #6</p> <p>This came from NELAP Board discussions.</p> <p>This TIA is important for states that are both an AB and a PT provider. There are instances where a result is acceptable for a PT, but the state does not accept the method ... so it is reported as unacceptable.</p> <p>Agree that issue has been addressed.</p>
9	V1M6 1.7.1 c) and V1M6 1.7.1 c) iii	New	Provides clarification. This change was not related to the original NELAP Board Recommendation, but was included here to provide information to the NELAP Board.	<p>QS-TIA #1</p> <p>LASC agrees with the change.</p>

Attachment C – Details Regarding TIAs That Were Incorporated Into The TNI Standard

PT TIAs

The PT Committee presents the following Tentative Interim Amendments (TIA) to the CSDB for consideration in response to the LASC recommendations as documented in the LASC Report to the NELAP Board.

LASC Proposed TIA #1:

- a. the section(s) of the standard that should be amended;

V3 10.3, V3 10.3.1, V3 10.3.2, V3 10.3.3, V3 10.3.4, V3 10.3.5, V3 10.3.6

- b. the rationale for the Tentative Interim Amendment:

The TIA will correct an implementation problem that was discovered during LASC review.

- c. the factor(s) that would determine whether the amendment qualifies as a Tentative Interim Amendment:

These sections contain an error or omission that was overlooked during regular standard development, the language in these sections conflicts with other language in related PT modules and the proposed amendment will correct a circumstance that will result in an adverse impact to laboratories if the amendment is not made.

- d. the proposed change to the standard, including suggested wording is as follows:

10.3 Evaluation of Individual Participant Results

10.3.1 If the assigned value is greater than “0” the numerical value reported shall be evaluated “Acceptable” if it is within the established acceptance limits and evaluated “Not Acceptable” if the numerical value reported is outside the established acceptance limits or the numerical value is reported with a less than (<) sign and the numerical value is less than the lower acceptance limit.

Examples are as follows:

If the Assigned Value is “10.0”, the lower acceptance limit is “5.00” and the upper acceptance limit is “15.0”.

- a) Any reported numeric value between 5.00 and 15.0 shall be evaluated “Acceptable”
- b) Any reported numeric value greater than 15.0 shall be evaluated “Not Acceptable”.
- c) Any reported numeric value less than 5.00 shall be evaluated “Not Acceptable”.
- d) Any numeric value reported with a less than sign (<) shall be evaluated “Acceptable” if the reported numeric value associated with the less than sign is equal to or greater than the lower acceptance limit. In this example, a reported value of ‘< 5.00’ shall be evaluated as “Acceptable” because 5.00 is equal to the lower acceptance limit.
- e) Any numeric value reported with a less than sign (<) shall be evaluated “Not Acceptable” if the reported numeric values associated with the less than sign is less than the lower acceptance limit. In this example, a reported value of ‘< 4.99’ shall be evaluated as “Not Acceptable” because 4.99 is less than the lower acceptance limit.

10.3.2 If the Assigned Value is set to the PTRL with a less than sign (<) or set to “0”, any numeric value reported with a less than sign (<), a reported value of “0” or a reported numeric value less than the PTRL shall be scored “Acceptable”.

For example, if the assigned value is set to “< 2.50” and 2.50 is the PTRL associated with a less than sign (<):

- a) Any reported numeric value reported with a less than (<) sign shall be evaluated “Acceptable”.
- b) A reported value of zero “0” shall be evaluated “Acceptable”.
- c) A reported numeric value between “0” and 2.50 shall be evaluated “Acceptable”.
- d) A reported numeric value greater than 2.50 shall be evaluated “Not Acceptable”.

10.3.3 A reported value shall be evaluated as “No Evaluation” if it cannot be evaluated (e.g. alpha characters for a quantitative test).

10.3.4 Analytes include in a PT Sample but not reported by the laboratory shall be evaluated as “Not Reported”.

10.3.5 If the PT Provider invalidates an analyte in a PT study, all evaluations for data reported for that analyte shall be “No Evaluation” and a discussion of the situation leading to the invalidation shall be included in the final report to participant labs and ABs.

Proposed Tentative Interim Amendment (TIA) for PT Modules, TNI Standard 2008

Submitted By: Kirstin McCracken, PT Committee Chair

March 26, 2009

The PT Committee presents the following Tentative Interim Amendments (TIA) to the CSDB for consideration in response to the LASC recommendations as documented in the LASC Report to the NELAP Board.

TIA #2 (LASC Proposed):

- e. the section(s) of the standard that should be amended;

V1M1 7.2

- f. the rationale for the Tentative Interim Amendment:

Some members of the NELAC Board will not accept the standard if the term “appeals” is used in the PT module. Additionally, this section refers to a TNI process that does not yet exist. The TNI Executive Director has notified the committee that a process for complaint resolution between laboratories and ABs is under development with the Policy Committee and a procedure will be in place before the implementation date of the Standard. The Policy will establish the complaint resolution process for all aspects of accreditation including PT, hence this “requirement” does not need to be included in the standard.

- g. the factor(s) that would determine whether the amendment qualifies as a Tentative Interim Amendment:

The proposed amendment will correct a circumstance that will result in an adverse impact to NELAC ABs if the amendment is not made.

- h. the proposed change to the standard, including suggested wording is as follows:

Remove the clause in its entirety.

TIA #3 (LASC Proposed):

- a. the section(s) of the standard that should be amended;

V2M2 5.1.2 , V2M2 5.2.1 c), V2M2 7.3 d)

- b. the rationale for the Tentative Interim Amendment:

The TIA will correct an implementation problem that was discovered during LASC review.

- c. the factor(s) that would determine whether the amendment qualifies as a Tentative Interim Amendment:

The language in these sections conflicts with other language in related PT modules.

- d. the proposed change to the standard, including suggested wording is as follows:

Section 5.1.2: The Primary AB shall require that the PT samples for initial accreditation be obtained from any PTPA-accredited PT provider as part of a TNI-compliant PT study, unless there are not any PTPA-accredited PTP for the FoPT in which case the PT sample may be purchased from any PTP and the AB shall accept the results from the PTP selected by the laboratory.

Section 5.2.1 c): The laboratories obtain PT samples from any PTPA accredited PTP unless there are not any PTPA-accredited PTP for the FoPT in which case the PT sample may be purchased from any PTP and the AB shall accept the results from the PTP selected by the laboratory.

Section 7.3 d): the laboratory submits analytical results for a FoPT from a PT provider that is not accredited by the PTPA unless there are not any PTPA-accredited PTP for the FoPT in which case the PT sample may be purchased from any PTP and the AB shall accept the results from the PTP selected by the laboratory.

The PT Committee presents the following Tentative Interim Amendments (TIA) to the CSDB for consideration in response to the LASC recommendations for editorial changes as documented in the LASC Report to the NELAP Board. After review of the LASC recommendations the Committee concludes that these changes could not be considered “editorial” thus TIA are proposed. The “LASC Editorial” reference corresponds to the item numbers listed in Attachment 1 of the LASC Report to the NELAP Board.

TIA #4 (Committee Proposed) - LASC Editorial #10

- a. the section(s) of the standard that should be amended;

V1M1 4.2.1

- b. the rationale for the Tentative Interim Amendment:

The TIA will correct a potential implementation problem that was discovered during LASC review. The LASC originally proposed an editorial change to remove the clause in V2M2 5.2.2 because it was not included in V1M1. After committee deliberation, the group decided that the clause was not included in V1M1 due to an oversight during standards development. Although the clause is part of the 2003 NELAC Standard, it was not included in the TNI standard and because it adds a requirement to the standard, this change cannot be considered editorial and must be corrected with a TIA.

- c. the factor(s) that would determine whether the amendment qualifies as a Tentative Interim Amendment:

The section contains an error or omission that was overlooked during regular standard development.

- d. the proposed change to the standard, including suggested wording is as follows:

To maintain accreditation the laboratory shall:

- a) analyze at least two TNI-compliant PT samples per calendar year for each accreditation FoPT for which the laboratory is accredited unless TNI-compliant PT samples are not available from any PTPA approved PT provider at least twice per year, in which case the laboratory shall analyze the PT samples in the minimum time frame in which the PT samples are available. The analysis dates of successive PT samples for the same accreditation FoPT shall be at least five (5) months apart and no longer than seven (7) months apart unless the PT sample is being used for corrective action to reestablish successful history in order to maintain continued accreditation, or is being used to reinstate accreditation after suspension, in which case the analysis dates of successive PT samples for the same accreditation FoPT shall be at least fifteen (15) days apart.

TIA #5 (Committee Proposed) - LASC Editorial #15

- a. the section(s) of the standard that should be amended;

V1M1 6.1

- b. the rationale for the Tentative Interim Amendment:

The TIA will correct a potential implementation problem that was discovered during LASC review. The LASC originally proposed an editorial change to add a clause to V1M1. After committee deliberation, the group decided that the clause was not included in V1M1 due to an oversight during standards development. Although the clause is part of the 2003 NELAC Standard, it was not included in the TNI standard and because it adds a requirement to the standard, this change cannot be considered editorial and must be corrected with a TIA.

- c. the factor(s) that would determine whether the amendment qualifies as a Tentative Interim Amendment:

The section contains an error or omission that was overlooked during regular standard development.

- d. the proposed change to the standard, including suggested wording is as follows:

.... The following requirements shall apply to the PT sample used to re-establish successful history:

a) The PT sample shall be obtained from any PTPA accredited PTP unless there are not any PTPA-accredited PTP for the FoPT in which case the PT sample may be purchased from any PTP. The laboratory shall notify the PTP that the PT sample will be used for corrective action purposes so the PTP may ensure that the PT sample supplied meets the requirements for supplemental PT as defined in Volume 3 of this standard.

Proposed Tentative Interim Amendment (TIA) for PT Modules, TNI Standard 2008
Submitted By: Kirstin McCracken, PT Committee Chair
May 12, 2009

The PT Committee presents the following Tentative Interim Amendments (TIA) to the CSDB for consideration in response to the LASC recommendations as documented in the LASC Report to the NELAP Board.

TIA #6 (LASC Proposed):

- i. the section(s) of the standard that should be amended;

V2M2, Section 7.3, Clause a)

Please note that this TIA applies only to clause a). No other clauses in this section are to be revised.

- j. the rationale for the Tentative Interim Amendment:

The TIA will correct a potential implementation problem that was discovered during LASC review. The LASC originally proposed an editorial change to replace words "acceptance limits" from clause a) with alternate language to support the change from PTRL to LOQ reporting. After committee deliberation other conflicts with the language in this section were found but could not be resolved by the committee membership. To resolve the situation, the Chair forwarded the concern to TNI Executive Director who subsequently forwarded the concern to the NELAC Board for their consideration and recommendation. The language in the proposed TIA is the product of the recommendation of the NELAC Board.

- k. the factor(s) that would determine whether the amendment qualifies as a Tentative Interim Amendment:

The proposed amendment will correct a circumstance that will result in an adverse impact to laboratories and some ABs if the amendment is not made.

- l. the proposed change to the standard, including suggested wording is as follows:

7.3 The primary AB shall consider the analytical result for a FoPT not acceptable when:

- a) the result reported by the laboratory does not meet the criteria for “acceptable” as specified in V3, Section 10.3 and associated subsections of this Standard. If the criteria in V3, Section 10.3 are met, and the result for the FoPT was scored “not acceptable” by the PTP, the AB shall overturn the performance evaluation and score the analytical result “acceptable”.

Quality System TIAs

Proposed Tentative Interim Amendment (TIA) for QS Module 6, TNI Standard 2008

Submitted By: Paul Junio, Quality Systems Committee Chair

June 11, 2009

The Quality Systems Committee presents the following Tentative Interim Amendment (TIA) to the CSDB for consideration in response to a Request for Standards Interpretation.

TIA #1:

- m. the section(s) of the standard that should be amended;

V1M6 1.7.1 c) and V1M6 1.7.1 c) iii

- n. the rationale for the Tentative Interim Amendment:

Following a Request for Standard Interpretation of the 2003 NELAC Standard, a review of the relevant TNI Standard indicated a laboratory requirement that will create a severe burden on laboratories and their ability to produce results.

- o. the factor(s) that would determine whether the amendment qualifies as a Tentative Interim Amendment:

The proposed amendment will correct a circumstance that will result in an adverse impact to NELAC laboratories if the amendment is not made.

- p. the proposed change to the standard, including suggested wording is as follows:

- c) Background Measurement

Background measurements shall be made on a regular basis and monitored using control charts or tolerance charts to ensure that a laboratory maintains its capability to meet required measurement quality objectives. *This background measurement is not the short term check for contamination that is addressed in 1.7.1 d).* These values ~~may~~ must be subtracted from the total measured activity in the determination of the sample activity.

- i) For gamma-ray spectroscopy systems, background measurements shall be performed on at least a monthly basis.
 - ii) For alpha-particle spectroscopy systems, background measurements shall be performed on at least a monthly basis.
 - iii) For gas-proportional counters background measurements shall be performed ~~each day of use~~ on at least a weekly basis.
 - iv) For scintillation counters, background measurements shall be performed each day of use.

Revised based on feedback from comment received