Outcome of SIR Subcommittee Discussions -- March 25 and April 8, 2014

Judy will discuss SIRs 180 and 200 with the AC at its April 21, 2014 meeting. Other SIRs will be handled as decided.

Return from AC – SIR 180

SIR 180 – since the AC's discussion of this on February 24, the LAS EC SIR subcommittee had suggested that addressing this and the other related SIRs through a FAQ might be acceptable, since finding a suitable interpretation seems terribly problematic. Council members were adamant that the issue is a valid SIR and needs a clear interpretation. Even though this is ISO language, they expressed the sentiment that if the language cannot be interpreted, it should be removed from the TNI Standard. A suitable interpretation would go beyond answering the question asked (what is meant by the requirement to use the latest valid edition of a standard…, where "standard" refers to what we call "method") and clarify what "not appropriate" to use it means, or in other words, what circumstances make it acceptable NOT to use the "latest valid edition of a standard" and how these terms relate to the method sources (Standard Methods/SM and SW 846, for instance) and how "latest valid edition" is defined with regards to federal and state regulations adopting (or not) the variations in method edition (SM) or method update numbers (SW 846.)

Discussed 3/25/14. Judy did more research into what the terms mean in ISO world, came up with the following:

Clarifying the use of "Standard" and "Method"
2009 TNI Standard and ISO 17025
4.4 Review of requests, tenders and contracts
4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that: *a) the requirements, including the **methods** to be used, are adequately defined, documented and understood (see 5.4.2);* *b) the laboratory has the capability and resources to meet the requirements;* *c) the **appropriate test** and/or **calibration method** is selected and is capable of meeting the customers'* *requirements (see 5.4.2).*
5.4.2 Selection of Methods (*ISO/IEC 17025:2005(E), Clause 5.4.2)*

The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. ***Methods published in*** *international, regional or* ***national standards*** *shall preferably be used. The laboratory shall ensure that it uses* ***the latest valid edition*** *of a* ***standard*** *unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.*

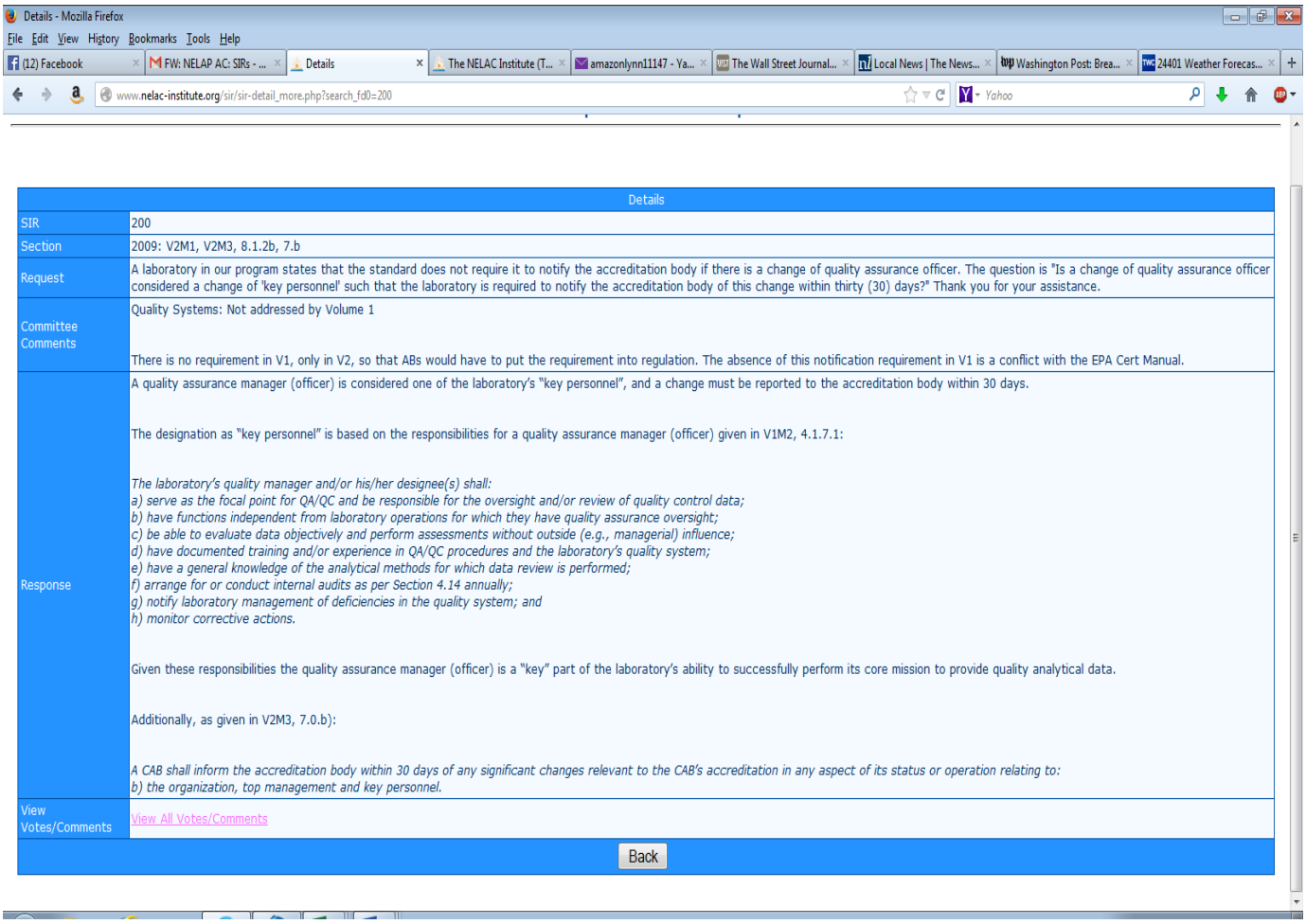
JM Comment: Where the term "standard" is used it is referring to the source of the method, not the method itself.

When the customer does not specify the ***method to be used****, the laboratory shall select appropriate methods that have* ***been published either in international, regional or national standards,*** *or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment.* ***Laboratory-developed methods or methods adopted*** *by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer shall be informed as to the method chosen. The laboratory shall confirm that it can properly operate* ***standard methods*** *before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.*

JM Comment: This is addressing the method. The first sentence of the second paragraph differentiates the term "method" and "standard", where "standard" is the source document that lists the approved methods. Where they refer to "standard method", they are referring to the methods published in international, regional or national standards, as stated above in the first paragraph under 5.4.2.

In lieu of specification by the customer, the lab must choose from International, Regional or National standards. For labs, that would be International (self explanatory), Regional (State/local/EPA Region), or National (Federal, CFR, Federal Register). Further direction is given for reputable technical organizations, scientific texts/journals and manufacturers.

SIR 200 -- aborted AC vote at the 2-week notice stage.



Details	
SIR	200
Section	2009: V2M1, V2M3, 8.1.2b, 7.b
Request	A laboratory in our program states that the standard does not require it to notify the accreditation body if there is a change of quality assurance officer. The question is "Is a change of quality assurance officer considered a change of 'key personnel' such that the laboratory is required to notify the accreditation body of this change within thirty (30) days?" Thank you for your assistance.
Committee Comments	Quality Systems: Not addressed by Volume 1 There is no requirement in V1, only in V2, so that ABs would have to put the requirement into regulation. The absence of this notification requirement in V1 is a conflict with the EPA Cert Manual.
Response	A quality assurance manager (officer) is considered one of the laboratory's "key personnel", and a change must be reported to the accreditation body within 30 days. The designation as "key personnel" is based on the responsibilities for a quality assurance manager (officer) given in V1M2, 4.1.7.1: *The laboratory's quality manager and/or his/her designee(s) shall:* *a) serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data;* *b) have functions independent from laboratory operations for which they have quality assurance oversight;* *c) be able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence;* *d) have documented training and/or experience in QA/QC procedures and the laboratory's quality system;* *e) have a general knowledge of the analytical methods for which data review is performed;* *f) arrange for or conduct internal audits as per Section 4.14 annually;* *g) notify laboratory management of deficiencies in the quality system; and* *h) monitor corrective actions.* Given these responsibilities the quality assurance manager (officer) is a "key" part of the laboratory's ability to successfully perform its core mission to provide quality analytical data. Additionally, as given in V2M3, 7.0.b): *A CAB shall inform the accreditation body within 30 days of any significant changes relevant to the CAB's accreditation in any aspect of its status or operation relating to:* *b) the organization, top management and key personnel.*
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This needs a 2-stage fix. First, an interpretation that a change in Quality Manager is a notifiable event, since that individual is clearly equivalent and interchangeable with the Technical Director and therefore "key personnel" so that all applicable requirements for TD apply to QM also. Second, the standard needs to be revised, and Quality Systems Expert Committee should be asked to address the "note" in the ISO language in doing so.

Returns from Micro

SIR #133

Question: Appendix D.3.8(b)(6)(i) to NELAC Chapter 5

The laboratory has free standing incubators that are not used every day for testing and turns them turned off and on with use. There would be times when the laboratory does not have temperatures documented twice per day with at least 4 hours apart for days of use. The incubators take about 30 minutes to 1 hour to reach the correct temperature. If the laboratory records the temperature when the samples are put in the incubator and when the samples are taken out, would this meet the standard? The laboratory would continue to record the normal morning and afternoon temperatures along with the times the samples were place in and taken out of the incubator.

New Response for SIR 133:

The Microbiology Expert Committee reviewed Standard Interpretation Request 133 and is of the opinion that this inquiry is not appropriate to be handled through the SIR process. The cited section of the standard is clear, in that it clearly states that the temperature of the incubator or water bath must be recorded twice a day.

Return to Submitter, not a SIR.

SIR 98 plus SIR 132 (same answer for both)

98
2003: 1.7.3.5c
The lab conducts SM9020a testing on potable water only. We purchase single use sterile water from IDEXX who also manufactures the Colilert media. It is their recommendation to use sterile water in blanks and dilutions. This is the only use our lab has for sterile water as everything else is prepackaged ready to use. The sterile water comes in sealed 100ml aliquots with reagent water criteria certification from IDEXX. The water is purchased in lots and the lot is verified upon receipt for pH, conductance and sterility. It is stored in a refrigerator at 4C. The lab is small and only conducts 20 tests per month. Is the in house QA and manufacture certification of the sterile water sufficient for the use of the water as a lot per TNI standards - or should it be conform to predisposed buffer water standards?
Check with Silky – conflicts with 132. Sent e-mail to Silky on 12/19/10 – Do you want to change this response? Refer to #132? Change response to #132?
(Quality System Expert Committee/NELAP Accreditation Council, DATE) If the purchased single use water is only used for preparing blanks and dilutions, this section does not apply, since those uses are not characterized as reagents. If the water is used for the preparation of reagents, then the requirements of verification stated in 1.7.3.5 c) apply.

SIR 132

2003: Appendix D.3.6c If the lab purchases prepared sterile deionized water in 99 mL bottles to make dilutions for the IDEXX products, is the lab required to test for pH and conductivity on a different 99 mL bottle from the same lot every time the labs needs to make a dilution? What is the correct frequency? The sterile deionized water is not used for media or reagent preparation.

New Response for 98 and 132:

Under the current standard, the requirement is to check the purchased water once per lot and, in addition, once per month when using a bottle that lasts longer than one month. If the water is to be used for preparation of media, reagents or as a diluent, which will put it in contact with microorganisms, then the requirements of verification as stated in 1.7.3.5 9 (c) are needed along with the verification of sterility.

Send to AC Voting site after asking Micro EC to clarify the citation in the response and to cite both standards.

Returns from PT Expert Cmte

SIR #168 – post for AC vote

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V2M2
Section (eg. C.4.1.7.4)	6.3
Describe the problem:	Looking for a clarification. Section 6.3 says: The Primary AB shall allow the laboratory to analyze the same PT sample using different technologies and/or multiple test methods for any FoPT. If a laboratory reports more than one test method per technology per FoPT, an unacceptable score for either test method shall result in an unacceptable score for both test methods for that FoPT. Question: If a lab uses 2 different extraction procedures for the same analytical method (e.g. Semi-Volatile GCMS in NPW matrix using Liquid/liquid Extraction sometimes and Solid Phase extraction at other times with many of the same analytes). Would it be acceptable to run a PT sample for each technology/extraction combination as long as they stick with the "fail one/fail both" concept that is in the referenced section? It get a little muddy since the TNI standard does not really recognize preparation methods and only looks at the technology but in reality it is like 2 different test methods. Clarification would be welcome. Thank you
Comments	
Response	The interpretation of the standard is that if PTs are analyzed using multiple preparation methods while being analyzed by a single analytical technology per an FoPT; if one PT fails, all of the groups under that technology fail, regardless of the preparation method. The PT assessment is made by analytical technology per FoPT.

SIR #176 – post for AC vote

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V2M2
Section (eg. C.4.1.7.4)	
Describe the problem:	A laboratory in our program has requested accreditation to measure analytes in biological tissue. The question is "If biological tissues are not listed as a matrix for the current NELAC Fields of Proficiency Testing, are proficiency tests of solid and chemical materials acceptable to demonstrate proficiency for testing biological testing?" Thank you for your assistance.
Comments	The question is more of an accreditation question for the PTPEC or Accreditation Council then for the PTEC.
Response	Biological tissues are not a matrix in the TNI FoPT tables, as such there would be no proficiency testing requirements for this matrix. However, since this matrix is outside the scope of the TNI program, it would be up to the discretion of the accrediting body to determine the appropriate proficiency testing standard design.

Returns from Quality Systems

TNI SIR #184 -- post for AC vote

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M1
Section (eg. C.4.1.7.4)	4.2.1
Describe the problem:	NELAC 2003 2.7.2 says, "For continuing accreditation, completion dates of successive proficiency rounds for a given field of proficiency testing shall be approximately six months apart. Failure to meet the semiannual schedule is regarded as a failed study." TNI V1M1 4.2.1 says, "The analysis dates of successive PT samples for the same accreditation FOPT shall be at least five months apart and no longer than seven months apart unless the PT sample is being used for corrective action to establish successful history …" There is no language to describe what happens after 7 months have passed. The sentence is missing from TNI that was in NELAC that directed or allowed the addition of a "failed study" when the semiannual requirement was not met. Is it the intent of the standard for ABs to continue treating a failure to meet the semiannual schedule as a failed study? This is a significant enforcement issue since a potential alternative seems to be in V2M2, 10.3: "The Primary AB shall revoke the accreditation of a laboratory for a FoPT when:(a) the laboratory does not participate in the PT program as required by this Standard." This penalty is too severe and problematic for what could be just a missed deadline.
Comments	The statement is included in V2M2 Section 7.3 part b. “7.3 The accrediting body shall consider the analytical result not acceptable when: b) The laboratory does not report results for an accredited FOPT within the time frames specified in this standard.”

Response	If a laboratory fails to report a single proficiency testing result it is evaluated as “not acceptable” per V2M2 7.3 part b. If the laboratory fails to report results for 2 out of 3 proficiency testing study time frames, then the laboratory’s accreditation shall be suspended per V2M2 10.1 for failing to participate in the timeframes specified in the standard.

TNI SIR #185 – revise to eliminate “obvious” in 1st paragraph, then in 2nd paragraph, rephrase to read that “PTs used for corrective action are viewed the same as those for continuing accreditation. For consistency….” THEN post for vote.

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M1 6.1b, V1M2 8.2c
Section (eg. C.4.1.7.4)	
Describe the problem:	There is a discrepancy between these two sections. V1M1 6.1 b) says 15 days between analysis dates for successive PTs for corrective action. V2M2 8.2 c) still uses the closing date of the previous study
Comments	**The inconsistency has been addressed in the current version of the modified working draft standards for both V1M1 and V2M2.**
Response	**There was an obvious oversight in the V2M2 section 8.2(c) requirements. Section V2M2 5.1.4 refers to time between analysis dates for Initial Accreditation and Section V2M2 5.2.1 refers to time between analysis dates for Continuing Accreditation.** **Both of these are consistent with the requirements in V1M1. Additionally, there is no reason why the requirement should be any different for PTs used for corrective action and for the sake of consistency within the PT program, the language that is in V1M1 6.1b is the TNI 2009 requirement and should be utilized by the ABs as the requirement for V2M2 section 8.2(c).**

SIR 191 – post for vote as written

Standard	2003 NELAC Standard
Volume and Module (eg. V1M2)	2003 & 2009 Standard
Section (eg. C.4.1.7.4)	2003 Std Chapter 5, section 5.5.5.2.2.1 d
Describe the problem:	I could not find this same paragraph in the new 2009 standard documents posted on the TNI site. My question pertains to the interpretation of this statement in the 2003 NELAC standard and how it applies to the 2009 TNI standard. We have been informed that Environmental lab auditors are now requiring labs to use a second vendor for their second source calibration standards even when use of a second manufactured lot from the same vendor is allowed by both the 2003 NELAC and 2009 TNI standards. We have even heard that second source from a second manufacturer raw material prepared by the same vendor is being noted as non-compliant in some instances. What is the interpretation of what this standard requires of labs where it applies to non-DoD programs with regard to the following options: 1. Same vendor/supplier - two independently prepared lots from the same raw material. 2. Same vendor/supplier - two independently prepared lots from different manufacturer raw materials when available. 3. Two different vendor/suppliers for each of the primary and secondary lot standards. Thank you
Comments	1.7.1.1.d - all initial instrument calibrations shall be verified with a standard obtained from a second manufacturer or from a different lot. Traceability shall be to a national standard, when commercially available;
Response	The purpose is to verify that the standards used for calibration have been properly prepared. The verification standard must be prepared independently from the calibration standard(s). The best option is standards from two different vendors; alternatively, standards from the same vendor but different lot numbers. While the original source (manufacturer) of the neat standard is important, the standard stresses **independent preparation.**

SIR #246, transmitted October 5, 2013

Post for vote as written. Ask QS to make it clear if they revise the wording while revising the TNI standard.

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	5.8.5.a
Describe the problem:	Question: Do labs have to uniquely identify sample containers when received at the lab? The 2009 standard states: "The laboratory shall have a documented system for uniquely identifying samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates." The 2003 standard stated the same but also added: "The laboratory shall assign a unique identification (ID) code to each sample container received in the laboratory. The use of container shape, size or other physical characteristic, such as amber glass, or purple top, is not an acceptable means of identifying the sample." Since the 2009 standard dropped the wording above in the third paragraph, some are interpreting this to mean the labs do not need to uniquely identify sample containers anymore. However, since the 2009 standard does still include sample containers in the last sentence of the second paragraph, above, some are interpreting that sample containers must be uniquely identified. I have heard this may be addressed in the upcoming standard, but I don't know that absolutely.
Comments:	
Response:	The language in the Standard does not require individual identification of each sample container beyond the laboratory sample ID.