Quality System Expert Committee (QS)
Meeting Summary

July 9, 2018

1. Roll Call:

Paul Junio, Chair, called the meeting to order at 1pm Eastern on July 9, 2018 by teleconference. Attendance is recorded in Attachment A – there were 9 members present. Associate Members present: Nick Haring, Eric Denman, Chaney Arend, Tyler Sullens, Cindy Gaddis, Gil Dichter, Carl Kircher, Rose Cruz, Silky Labie, and Amber Ross.

The June minutes were distributed by email and reviewed on Webex. A motion was made by Dale to accept the 6/11/18 minutes as written. The motion was seconded by Bill and unanimously approved.

2. New Orleans Meeting

Paul noted that there will be a meeting on Wednesday afternoon to discuss the impact of the new ISO/IEC 17025:2017 Standard on the TNI Standard. There will also be a discussion on possible overlap of sampling between the lab and field Standards.

Paul pulled up the Sampling section of ISO/IEC 17025:2017. There is concern that TNI may expand the Sampling section of the next version of the TNI Environmental Laboratory Standard and that this will impact the NEFAP Standard.

Paul put up the proposed agenda for the Special Wednesday meeting. The QS agenda on Thursday will be planned on Wednesday evening after the Special Session. The Thursday meeting will be a working session.

Silky commented that the panel is missing a state that has an independent sampling program, like Kentucky, NJ and Florida. Oregon has a sampling program for Cannabis under NELAP. USGS has an extremely active sampling program. Ilona noted that Jerry selected the panel from people that have registered to be in New Orleans.

Ilona noted that there are lots of ideas on how sampling should be handled going forward. She asked everyone to be thinking about this and provide comment by email. The input is needed. Also … be sure to look for Paul's slides for the New Orleans presentation to comment on.

3. ISO/IEC 17025:2017 and Revision to Module 2

The Committee continued to review the work done to place the TNI Environmental Laboratory 2016 Standard into the new ISO/IEC 17025:2017 format. The Committee started again in Section 6.

The addition to 6.2 looks fine.

The additions to 7.2.1.2 (added 4.2.8.5 from 2016)

The additions to 7.3.3 (added 5.7.4 from 2016

7.4 added 5.8.6, 5.8.9

7.4.2 added 5.8.5 and 5.8.8

7.4.3 added 5.8.7

7.5 added 4.13.3

7.7 added 5.6.4, 5.9.3

7.8.2.1 added 5.10.10

7.8.3.1 added 5.10.11

8.2.1 added 4.2.8.3 and 4.2.8.4

8.7.1 added 4.11.7

8.7.3 added 4.11.6

8.8.2 added 4.14.5

8.9.1 added 4.15.3

Paul reviewed where all the language was placed. He asked for comments. There were none. He will begin renumbering things and looking for things that are repeated (things that are already covered in ISO/IEC 17025:2017 language). Paul will save today's version so it will be clear where things came from. The new document will be renumbered and this might not be as easy as the committee moves forward.

4. SIRs

Paul started reviewing older SIRs. Ilona noted that the table being reviewed has been updated and she will provide a copy to Paul.

Ilona suggested that each expert committee have an SIR table that they keep comments in to validate whether the Standard was updated or not.

SIR 158

Ilona noted that SIR 108 and 230 were addressed through SIR 308.

SIR 154 needs to be looked at. Paul will send a copy of the proper response to Ilona so she can get the correction made.

5. Action Items

A summary of action items can be found in Attachment B.

6. New Business

None.

7. Next Meeting and Close

The next meeting is planned for August 9, 2018 at 9am Central in New Orleans. Paul will decide after Thursday's meeting whether to have the regularly scheduled call that following Monday on the 13th.

A summary of action items and backburner/reminder items can be found in Attachment B and C.

Paul adjourned the meeting at 2:27pm Eastern. (Bill - motion Lizbeth – second, unanimous approval).

Attachment A

Participants
Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Paul Junio (Chair) **Present**	Northern Lake Service	2019	Laboratory	paulj@nlslab.com
Jessica Jensen (Vice Chair) **Present**	Meridian Analytical Labs	2021	Laboratory	jessica.j@meridiantesting.com
Kristin Brown **Absent**	Utah DOH	2021	Accrediting Body	kristinbrown@utah.gov
Lizbeth Garcia **Present**	Oregon Dept. of Environmental Quality	2019*	Accrediting Body	LIZBETH.GARCIA@dhsoha.state.or.us
Kathi Gumpper **Present**	ChemVal Consulting	2021*	Other	kgumpper@chemval.com
Chris Gunning **Present**	A2LA	2021	Accrediting Body	cgunning@a2la.org
Earl Hansen **Absent**	Retired	2021*	Laboratory	papaearl41@hotmail.com
Sara Hoffman **Absent**	Kansas DHE	2019*	Accrediting Body	sara.hoffman@ks.gov
Jacob Oaxaca **Present**	California State Water Board	2019*	Accrediting Body	Jacob.Oaxaca@Waterboards.ca.gov
Shari Pfalmer **Present**	ESC Lab Sciences	2021	Laboratory	spfalmer@esclabsciences.com
Dale Piechocki **Present**	Eurofins Eaton Analytical	2020	Laboratory	DalePiechocki@eurofinsUS.com
William Ray **Absent**	William Ray Consulting	2020*	Other	Bill_Ray@williamrayllc.com
Matt Sowards **Absent**	ACZ Laboratories, Inc.	2020	Laboratory	MattS@acz.com
Michelle Wade **Present**	Wade Consulting	2021*	Other	michelle@michellefromks.com
Alyssa Wingard **Absent**	NAVSEA LQAO	2021*	Other	alyssa.wingard@navy.mil
Ilona Taunton (Program Administrator) **Present**	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B

Action Items – QS Expert Committee

	Action Item	Who	Expected Completion	Actual Completion
25	Follow-up with Bob Wyeth and Jerry Parr about experience vs. course hours for Technical Directors.	Paul	TBD	
26	Provide in writing, thoughts regarding options for Technical Director approval.	Robin	TBD	
38	Continue SIR 246 and 296 discussions.	All	TBD	
40	Get PT root cause analysis example from Scott Hoatson.	Paul	8/31/17	
45	Review Ch 1 Application section for the use of "shall" and "may". Are uses correct?	Paul, Sara	11/20/17	
51	Send example of Shari's report to NELAP AC to confirm format of listing all certifications without logo's is an acceptable process to report certifications for work being done.	Shari Paul	5/11/18	
52	Send copy of Chris and Paul's presentation to Jerry.	Paul/Ilona	5/15/18	Complete
53	Look into CWEA certification requirements.	Nick Jacob	7/9/18	
54	Send request to Robin and Micro Expert Committee to look at Technical Manager requirements and propose changes in the language back to QS.	Paul	7/9/18	
55	Send a picture of a Class A non-glassware item.	Kathi	7/9/18	
56	Reach out to Marlene Moore for additional information on Class A glassware.	Paul	7/9/18	
57	Look into status on labware SIR.	Paul	7/9/18	
58	Look into SIR 154 Response. Incorrect response may be posted.	Paul/Ilona	9/10/18	

Attachment C

Backburner / Reminders – QS Executive Committee

	Item	Meeting Reference	Comments
1	Update charter in October 2016.	n/a	Delayed. Waiting for format from Policy Committee.

#	Date Submitted	2003	2009	2016	Actual Request	Final Response	Comment	Paul Comments	Outcome
158	2/9/11		4.1.7.2 and 5.2.6.1 (a)	4.1.7.2 and 5.2.6.1 (a)	At present, our laboratory has a NELAC Lab (Lead) Technical Director who fulfils the NELAC requirements as per referenced sections above. We also have three other Technical Directors whose responsibilities are either for environmental analysis of representative organic analytes or inorganic analytes for which our lab maintains NELAC accreditation. Our laboratory is in process of management change where current NELAC Lab Technical Director will be reassigned to other duties and no longer will have responsibility over the NELAC accredited lab. The annual renewals of the NELAC accreditations with our primary and secondary Accrediting Bodies require a "Certificate of Compliance" to be signed by a Lab Key Staff, often listing a Lead Technical Director as the one who needs to sign this document. The Lead Technical Director is also listed on each NELAC certification we maintain. Although the NELAC standard allows for more than one Technical Director, do we must have a Lead Technical Manager/Director who fulfils above requirements for both	There is no requirement for a "lead technical director". The standard requires that the individual (or individuals) who are identified as technical directors meet the applicable credentials for the areas over which he/she has oversight.	This language is unchanged in the 2016 standard. The SIR is still valid.	I disagree that this is an SIR. This is an AB, possibly more than one, who has used a term on their application and certificate that TNI has not defined. The root of this question is 'who is our Lead Technical Director', and TNI doesn't ask that question. I don't feel that this requires addressing in our revision.	committee agreement that this need not be addressed in revised Module 2
13	07/22/08	5.4.12.2.2	4.13.2	4.13.2	This section of the standard talks about observation, data and calculations recorded at the time they are made. Currently our lab has a policy in place to mark the preservation checks for each sample separately. Example a specific sample has a pH of less 2 and chlorine result of zero. Would it be sufficient to document the pH and chlorine checks by a general statement for example "all samples extracted in the batch had a pH less than 2 and chlorine result of zero"?	No. 5.4.12.2.1 requires observations to be recorded at the time they are made. 5.4.12.2.5.1 requires date/time of sampling to be recorded, so as to demonstrate compliance with holding times. 5.5.8.3.1(2) states the laboratory shall implement procedures for checking chemical preservation prior to or during sample preparation or analysis. 3(b) requires the results of these checks to be recorded. 5.5.8.3.1(d) (2) (iv) requires comments resulting from inspection for sample rejection to be linked to the laboratory ID code. So, the lab could, for example, use a check box on a sample receipt form to indicate a sample's preservation was checked and the result was less than 2 and chlorine was zero as long as the observation was unequivocally linked to each sample checked. The lab could not simply preprint this statement on an analytical report or document preservation after-the-fact in an extraction log because doing so would not comply with requirements to record observations at the time they are made and link the results of preservation checks unequivocally with sample identification numbers.	The 2009 and 2016 standards are virtually identical to 2003 Notes from ISO 17025 are now included but does not change the intent of the language.The SIR is still valid.	4.13.2.1 of ISO refers to retaining original records. One can't retain an original record if only a generic statement is made. 17025-2017 covers this in 7.5.1 (Original observations, data and calculations shall be recorded at the time they are made and shall be identifable with the specific task). I don't feel that this requires addressing in our revision.	committee agreement that this need not be addressed in revised Module 2
70	6/15/09	5.4.13.1	4.14.1	4.14.1	This section deals with the annual Quality Audit. One sentence reads: "Such audits shall be carried out by trained and qualified personnel who are, whenever resources permit, independent of the activity to be audited." What is the meaning of "trained and qualified" as used in the sentence? Trained and qualified in environmental matters, auditing techniques etc?	Since "trained and qualified" is not defined, it would be up to the laboratory to state what their requirements are. It would be expected that the person performing the audit has a knowledge of the portion of laboratory operations that are being audited. NELAC 5.5.2.6 states that the lab management defines the minimal level of qualifications for all positions.	This language is unchanged in the 2009 and 2016 standards. The SIR is still valid.	17025-2017 covers this in 6.2.3 (The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.) I don't feel that this requires addressing in our revision.	committee agreement that this need not be addressed in revised Module 2

108	1/27/10	5.4.13.1	4.14.1	4.14.1	In the description of internal audits, it states "The internal audit program shall address all elements of the quality system, including the environmental testing activities." Does this mean that every method has to be audited yearly? For Labs that are running 300 or more methods this doesn't seem reasonable.	see 308			see 308
308			4.14.1	4.14.1	Per Clause 4.14.1, the internal audit program shall address all elements of the management system, including the testing and/or calibration activities. It is unclear if all test methods need to be audited annually since 4.14 never uses the word "methods" but rather "areas" or "activities". Can the test methods be grouped by technology (i.e. GC/MS, ICP/MS, ICP, Spectrophotometry, Gravimetry, Meters, Titrimetry, SFIA, etc.) or does every method have to be audited annually? If grouped by technology, can different test methods within each technology be scheduled annually? The schedule beyond one year would show that tests are rotated for internal audits over time.	No, not every method needs to be assessed annually in the laboratory's internal audits. Yes, different methods within each technology may be assessed on an annual basis.			The committee agrees that this needs to be addressed for clarity in Module 2
230	2/8/13	5.4.13.1	4.14.1	4.14.1	The standard states that "The internal audit program shall address all elements of the quality system, including the environmental testing activities." We are unclear as to what is expected in reference to "Environmental Testing Activities." For example, if we have 10 methods used for environmental testing are we required to audit each of those specific test methods yearly, or is acceptable to audit the laboratory as a whole is operating under the quality system.	see 308			see 308
64	5/8/09	5.4.2.6	4.2.8.1	4.2.8.1	This standard calls for "3) in-depth, periodic monitoring of data integrity". What is TNI's interpretation of "periodic"? ELAP suggested "Each calendar quarter the QAO audits 5 % or 5 data packages, which ever is more" in the DI plan template we provide to labs. However, the monitoring should be dependent upon the lab's scope (chemistry, microbiology, asbestos) and workload (number of samples analyzed).	There is no definition of periodic. The laboratory must clarify its intentions for complying with this requirement in the QAM or elsewhere. If the laboratory hasn't defined its requirements sufficiently, it could be cited for failure to comply with this section.	The 2009 and 2016 standards contain the identical language. The SIR is still valid.	address	The committee agrees that this needs to be addressed for clarity in Module 2
22	08/07/08	5.5.4.1.1	4.2.8.5	4.2.8.5	Are SOPs required for procedures not performed (e.g., “legal coc” 5.5.8.3.1 f) says “if required”; or subcontracting)	SOPs are not required for activities that the laboratory is not required to perform. The converse is obviously true, in that you must have an SOP if you perform, or are required to perform, these activities. The first paragraph of 5.5.4.1.1 states that SOPs must "accurately reflect all phases of current laboratory activities". Where an activity is not performed, such as legal	This section was edited in 2009 but the SIR is still valid.	address	start here
154	1/13/11		4.2.8.4.r		If a lab's QAM defined "signature" on technical records, reports and chain of custodies as the hand written signature or electronic equivalent, would this meet the signature requirement for each of these documents? As we upgrade our LIMS and QC software, we have the ability to electronically sign off on chains and lab documents but want to know if this would be acceptable.	Each individual analyst must have documentation on file that indicates that he/she is competent to independently perform the portion of the analysis for which he/she is responsible. Work cells may be used. The laboratory needs to define how the concept is used to demonstrate individual competence.	This answer does not relate to the SIR		

101	12/1/09	5.4.3.1	4.3.1	4.3.1	Is instrument software (or any other software) considered a controlled document? Are equipment manuals considered controlled documents?	Software is among the items listed in Section 5.4.3.1 as a document that must be controlled. Equipment manuals fall under the categories of "procedures, specifications" that are also listed in 5.4.3.1 as documents that form part of a laboratory's quality system 5.4.2.1 and 5.4.2.3.m also support having control over the documents, such as software and equipment manuals, that are part of a laboratory's quality system.	This language is unchanged in the 2009 and 2016 standards. The SIR is still valid.	PJ thinks this will be clear in 17025
18	08/05/08	5.4.3.2.2.b	4.3.2.2.b	4.3.2.2.b	This section requires documents to be reviewed "periodically". I have interpreted this to mean that NELAC wants the documents reviewed but requires the lab to establish the frequency. NELAC further supports this position by specifically requiring data integrity procedure to be reviewed annually (5.4.2.6). However, some assessors with whom I work take the position that since 5.4.14.1 requires labs to annually review the "suitability of procedures" and 5.4.13.1 requries labs to annually conducts audits on "all elements of the quality system" that these are inferred or indirect requirements to annually review all procedures. Since 5.4.3.2.2.b addresses the issue directly, I take the position that it prevails over any indirect or inferred interpretation of the standard.	The Quality Systems Committee sees no conflict here. The internal audits must show compliance with the laboratories policies and procedures. This is a procedural review for compliance and suitability. The periodic review of SOPs is set by the lab and does require that technical management review current procedures. This can be done with internal method audits. If the AB finds issues that would indicate that periodically has been stretched too long, then the AB could impose a finding that would require the timeframe be shortened. Also, support	No change in language in	address
115	3/15/10	5.4.5.4	4.5.4	4.5.4	What is the documentation needed as the 'record of evidence of compliance'? Our clients are asking for our NELAP certificate, PT results, insurance certificates and QA manual. But we interpret this statement to mean having the NELAP certificate on file.	The requirements outlined in 5.4.5.1 refer to a subcontracted laboratory and the tests to be performed. They are 1) the laboratory is accredited under NELAP for the tests or 2) the laboratory meets the statutory or regulatory requirements for performing the tests. In the case of the first requirement, the NELAP Certificate that identifies the accredited test would meet the requirement. If other statutory or regulatory requirements exist, the	This language is unchanged in the 2009 and 2016 standards. The SIR is still valid.	address
82	8/13/09	5.5.5.2.1 b	5.5.2.11	5.5.2.1	The standard reads: "All support equipment shall be calibrated or verified at least annually, using NIST traceable references when available, over the entire range of use". My question is, does the NIST tracablle reference, in this case a thermometer that is sent out annually to an accredited company for verification, as well as the laboratory supprt equipment which is verified against this thermometer, also need to be calibrated by that company over the range of use?	A NIST-traceable reference sent out annually to an accredited company for verification or calibration is to be verified or calibrated over its entire range of use. Laboratory support equipment verified or calibrated in the laboratory against the NIST-traceable reference is to be verified or calibrated over its entire range of use.	The 2009 standard contains identical language. This section was revised in the 2016 standard to allow a single point verification "if the temperature measuring device is used over a range of 10°C or less."	5.5.13
79	8/5/09	5.5.10	5.10.11	5.10.11	LEGEND's question for TNI concerns the documentation of the laboratory's scope of accreditation in the test report. In this situation, our laboratory is licensed for a small number of tests in the State of Minnesota, which is adopting the NELAC Standard. Our laboratory is licensed for a full scope of parameters in the State of Arizona, a non-NELAC state. In Section 5.5.10 of the 2003 NELAC Standard, is there a requirement for qualifying data that is not included in the laboratory's scope of accreditation? If there is a requirement (either directly or implied), how should the laboratory indicate the lack of NELAC licensure on the Arizona-only parameters in order to comply with the NELAC Standard? Is it sufficient to include a disclaimer on the cover page of the reports for Arizona-only work that indicates the data may only be used for compliance purposes in the State of Arizona and not in NELAC states?	Based on the standards quoted above, if the laboratory is issuing a NELAC-compliant report and the report has results that are not accredited under NELAC, you must identify those methods that do not meet the NELAC requirements (i.e., methods certified by another accrediting body). The committee cannot comment on reports that are issued for Arizona compliance purposes.	The 2009 and 2016 standards retain the requirement. The SIR is still valid	address

16	07/31/08	5.5.10.2(i)	5.10.11 (b)	5.10.11 (b)	The standard states the report should note whether the sample result was calculated on a wet weight or a dry weight basis. The narrative that accompanies every analytical report out of our laboratory states "all sample results are reported on an "as-received" basis unless otherwise noted". Why does the report have to note whether it is dry or wet weight a second time, when we have already noted "as-received"?	5.5.10.2(i) requires identifying whether data are calculated on a dry weight or wet weight basis Recording sample result as being calculated on the basis of 'as received' does not indicate wet or dry weight basis. As or more importantly, identifying results as having been calculated on an 'as received' basis would not comply with requirements in 5.5.10.1	Thi section was revised in the 2009 standard to read "Results that are reported on a basis other than as received (e. g., dry weight)." The SIR is obsolete.	carry language along
93	10/2/09	5.5.10.2	5.10.2	5.10.2	This section deals with information that shall be on the Test Report. e) identification of the test method used; and h) reference to the sampling plan and procedures used by..... Is it a requirement that the revision level of these documents be listed on the Test Report?	The laboratory should verify how the state requires reporting methods.	This language is unchanged in the 2009 and 2016 standards. The SIR is still valid.	start here
296	11/6/15		5.2.6.1	5.2.6.1	The 2009 standard, below (b), no longer contains the wording "environmental" analysis in the area of experience. Since it now states "such analysis" does this pertain to any type of laboratory experience in chemical, physical or environmental sciences (not just environmental)? b) Any technical manager of an accredited environmental laboratory limited to inorganic chemical analysis, other than metals analysis, shall be a person with at least an earned associate's degree in the chemical, physical or environmental sciences, or two (2) years of equivalent and successful college education, with a minimum of sixteen (16) college semester credit hours in chemistry. In addition, such a person shall have at least two (2) years of experience performing such analysis.	Unresolved		
212	5/29/12		5.2.6.1 a and b	5.2.6.1 a and b	With respect to the wording about experience, paragraph A, sentence number one states ".....and at least two (2) years of of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory seeks or maintains accreditation." Paragraph b sentence 2 states...., " In addtition, such a person shall have at least two (2) years of experience performing such analysis".	Question 1 - There is no difference in the meaning of the wording of the two paragraphs. Each refers to two years' experience in the analysis of samples. (not oversight/management of sample analysis). Question 2 - Representative - exemplifying a group or kind; typical: a representative selection of analytical	This language is unchanged in the 2016 standard. The SIR is still valid.	
302	5/23/16		5.2.6.1.c	5.2.6.1.c	Please clarify 16 hours of microbiology and biology Is it 16 hours combined total of microbiology and biology? Is it 16 hour of microbiology and 16 hours of biology 32 hours total?	The requirement is for a combined minimum 16 hours of microbiology and biology, not for 16 hours of each.	This language is unchanged in the 2016 standard. The SIR is still valid.	
180	8/31/11		5.4.2	5.4.2	5.4.2 includes the following statement: "The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so." In general, it seems that most certification authorities certify for the method, but not the version, allowing any version that is still valid to be run, which seems to violate/contradict this statement. Does this statement mean that all previous valid method versions are NOT to be used and that the lab MUST update to the newest version of a standard? For example, if the lab runs EPA 8270C which is still valid, must the lab update to 8270D if it can? In other words, does running 8270C (when 8270D is the latest version) become a violation of the standard?	The term "Standard", as defined by ISO, is as follows: "Standard: document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. NOTE - Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits." "Standard" refers to the source document or publication that mandates the "approved test method." For laboratories, this use of the term "standard" in V1M2 Section 5.4.2 is a reference to the most current publication(s) that define or require certain methods/actions based on program or regulatory need, such as: - International (global documents), - Regional (i.e., requirements specific to State, local, EPA Region, etc.), or - National (i.e., requirements by Federal	This language is unchanged in the 2016 standard. The SIR is still valid.	

21	08/07/08	5.5.4.4; 5.5.4.5; C3.3b)	5.4.4 and 5.4.5	5.4.4 and 5.4.5	1) EPA 245.1 vs SW846 7470: SW requires heating the standards, the EPA method doesn't. Is it acceptable to do the same for both (i.e., batch them together), and still be accredited for both methods in non-potable water? The Standard says validation is to be as extensive as necessary and C3.3b) only applies if the method was not in use prior to 7/03. If there are 20 years of at least 4 PT standards per year without a failure, the method should be sufficiently validated. This can't be left to individual state interpretation since one lab could be required to do two digestions/calibrations and other labs not, depending on where they're located. What if a lab is bidding on work in a state that allows the modification, but the home state doesn't? The real question is: Who decides if the modification is acceptable, if it has been sufficiently validated, and whether a lab can be accredited for "the method"? (especially when something is common practice) 2) Same issue with using HCL instead of H2SO4 to make the stannous chloride solution (the instrument manufacturer recommends HCl although the method says H2SO4).	Note: Laboratories should attempt to reconcile all differences in the interpretation of the NELAC 2003 standards and/or analytical methods with the applicable EPA Program, Regional office and/or NELAC accreditation body. The following response was obtained from EHSG MICE. *First off, we would like to clarify a common misnomer pertaining to SW-846 methods that is alluded to in question one. Please stress to this member that Methods 245.1 and 7470 are in fact both EPA publications. The former from the Office of Water while the latter is published by the Office of Solid Waste. Now to answer the questions, it is recognized that historically the most common practice was to digest the calibration standards in the same manner as the samples. However, with the newer instrumentation direct calibration using an aqueous standard is now possible, so the digestion steps are no longer necessary. So, in this particular case it depends more on the instrumentation and the manufacturer's calibration requirements rather than what is specified in the method. In addition, using EPA OSW's PBMS approach any calibration format is considered acceptable as long as adequate performance data are generated. If the desired sensitivity is attainable and QC data meet the project requirements, the practice of not digesting standards should be considered acceptable. The direct*	The 2009 standard moved this language into Module 4, but 2016 corrected this and moved it back into Module 2. The SIR is still valid.
66	5/18/09	5.5.4.6.1	5.4.6	5.4.6	Please explain what types of procedures for estimating uncertainty of measurements. I am not sure which area you mean.	Section 5.5.4.6 "Estimation of Uncertainty of Measurement" has created some confusion. Please note that as a laboratory it is impossible for you to calculate "Total Uncertainty" unless you are given all of the additional pieces from external sources to the lab itself. This section is intended to advise a laboratory to have a "Procedure on Uncertainty for the Laboratory Portion" in place, so that if requested by a client it could be determined. The key language within this section can be found in Section 5.5.4.6.2, " ... In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable	This section was rewritten in the 2009 (and 2016) standards to state "Quality control measurement data may be used to determine analytical uncertainty." This definition was also added: "Analytical Uncertainty: A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis. " The SIR still has relevance.

270	8/15/14		5.5.13.1	5.5.13.1	This section requires verification of volumes of volumetric dispensing devices (except Class A Glassware) if quantitative results are dependant on their accuracy. Historically, this section has been interpreted to include disposable pipettes and plastic tubes used for measuring sample volumes or final volumes after digestion. Section 5.5.13.1.d appears to require quarterly checks of these devices. Quarterly checks seem excessive when the items are one use items. Once per lot number seems more reasonable and would be similar to receiving a certificate from the manufacturer about the accuracy of a particular lot number.	A verification of one pipette or tube per lot would meet the requirements stated in Sections 4.6.2 and 5.5.2.	This language is unchanged in the 2016 standard. The SIR is still valid.
274	9/22/14		5.5.13.1	5.5.13.1	The standard states "Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall be checked for accuracy on a quarterly basis." Would class A plasticware be considered the same as Class A glassware ie - you do not need to check it on a quarterly basis? Or would Class A pastic ware be considered the same as non-class A labware? The same question for V1M5 section 1.7.3.7 iii.2 "2. equipment such as filter funnels, bottles, non-Class A glassware, and other containers with volumetric markings (including sample analysis vessels) shall be verified once per lot prior to first use. This verification may be volumetric or gravimetric." Would you need to check Class A plasticware once per lot?	Plasticware is not glassware. Any volumetric dispensing devices that are not Class A glassware or glass microliter syringes must be checked for accuracy on a quarterly basis.	This language is unchanged in the 2016 standard. The SIR is still valid.
304	10/12/16		5.5.13.1.3	5.5.13.1.3	Volume 1, Module 2, Section 5.5.13.1.e states, "Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall be checked for accuracy on a quarterly basis." Our laboratory analyzes VOCs in air, and uses gas tight syringes up to 100 mL to prepare gas standards. We are unsure of whether or not we must complete quarterly checks on these syringes.	Unresolved	
206	4/6/12		5.5.13.1.b	5.5.13.1.b	This section requires support equipment to be calibrated or verified annually with references "bracketing the range of use". The 2003 NELAC standard had comparable language requiring calibration or verification "over the entire range of use". Under the 2003 standard, an exception was permitted allowing the use of a single point calibration for narrow range use thermometers, such as those used for sample storage (>0-6C), BOD (20+/-1C) and micro incubators (35+/-0.5C and 44.5+/-0.2C), drying ovens (103C-105C), etc. However, the same exception has not been extrended to the 2009 TNI standard requirement. As a result, labs are being cited for not performing bracketing checks for these thermometers. Although the AB for the state where this issue developed allows the use of a temperature at or below and at or above the boundary of the range of use, the requirement still requires the lab to take the equipment out of normal use and re-adjust the settings multiple times. The process provides data that is probably less reliable than a single point check and requires significantly more time to perform. For example, a single point check in the range of 44.3-44.5 C for a fecal incubator would seem to be better data than a check around 40C and a second around 50C.	An exemption for narrow range use thermometers is not described in the 2003 NELAC Standard and historical data does not provide that an exemption was made on an organizational level. The use of a single point calibration/verification check for the narrow use range thermometers exemption is not described in the 2009 TNI Standard.	This section was revised in the 2016 standard to allow a single point verification "if the temperature measuring device is used over a range of 10°C or less." The SIR is obsolete.
290	7/13/15		5.5.13.1.b	5.5.13.1.b	Our laboratory is required to calibrate all thermometers annually against a NIST traceable thermometer, bracketing the range of use. If the 2 temperatures that the thermometer is calibrated produce different correction factors, which correction factor is used?	Unresolved	

232	2/26/13		5.5.13.1.e	5.5.13.1.e	How encompassing is the universe of “volumetric dispensing devices (except Class A glassware and glass microliter syringes)” needing quarterly checks for accuracy? Specifically, do graduated cylinders, glass to-deliver pipets, and other garden-variety glassware, which are not Class A, need to be checked quarterly? NELAC 5.5.5.2.1.e read, “Mechanical volumetric dispensing devices including burettes (except Class A glassware) shall be checked for accuracy on a least a quarterly use basis.” The introductory paragraph to NELAC 5.5.5.2.1.e includes “… volumetric dispensing devices (such as Eppendorf or automatic dilutor/dispensing devices).” Both of these examples are mechanical volumetric dispensing devices and supported “mechanical” in NELAC 5.5.5.2.1.e. TNI V1M2-5.5.13.1.e does not include the word “mechanical” which previously appeared in NELAC 5.5.5.2.1.e. However, the introductory paragraph to TNI V1M2-5.5.13.1 is identical to that in NELAC 5.5.5.2.1 (i.e., continues to includes two examples of mechanical volumetric dispensing devices).	Unresolved	
39	11/09/08	5.5.5.5	5.5.5	5.5.5	Are electronic records sufficient for instrument maintenance? If not, can the electronic records be printed and indexed periodically (perhaps monthly) to satisfy hard copy requirements? We can currently record all maintenance in our LIMS system.	There is nothing stated in 5.5.5.5 that states that records must be hard copy. If the records are maintained in a secure manner (presumably the LIMS contains audit trails and password protection), all of	Although this section was slightly revised in the 2005 version of ISO 17025, the SIR is still valid.
73	7/8/09	5.5.5.8	5.5.8	5.5.8	Does the requirement to indicate the status of calibration apply to devices such as a TCLP tumbler? Although we check the rotational rate monthly, there does not seem to be any adjustment on this device. Some support equipment have no "calibration" and would seem to be exempt from this regulation.	The cited section is preceded by "Whenever practicable". If a piece of support equipment does not require a calibration, it cannot require a notification of calibration status. It may, however, have an indication of the verification of its effectiveness (e.g., such as a date when the number of revolutions per minute on a	This languagae is unchanged in the 2009 and 2016 standards. The SIR is still valid.
77	8/4/09	5.5.6.3.1	5.6.3.1	5.6.3.1	I'm trying to determine if NELAC requires that the weight sets used to verify balances prior to use MUST be Class 1.	A laboratory may use any class to verify the balance if the weights are traceable to a national standard. A Class 1 (or "S") weight is normally considered a reference standard, but may be used as a working standard. If the laboratory has designated the weight as a reference standard, the weight may only be used for calibration	Althought this language was revised in the 2005 version of ISO 17025, the SIR is still valid.
124	5/24/10	5.5.6.4	5.6.4	5.6.4	For subsection a), I would like an interpretation of the requirement to obtain the manufacturer's Certificate of Analysis for reagents. Does this mean just "ready-made" reagents (e.g. the color reagent for a test) or does this also include pure chemicals (e.g. a bottle of sodium chloride crystals)?	The standard requires that Certificates of Analysis be obtained for all reagents. This does not mean that the C of A is automatically supplied. In some cases, you may need to request such information from a manufacturer. This includes both	This language is unchanged in the 2009 and 2016 standards. The SIR is still valid.
192	11/16/11		5.6.4.2	5.6.4.2	This section requires the lab to retain records of the standard or reagent manufacturer's Certificates of Analysis. One of our largest standard manufacturers recently stopped automatically sending hard copies of the C of A with the material, stating that it can be accessed electronically from their website. The manufacturer says an advatange of this, among other things, is "immidiate accessibility for audits". My question is if hard copy of the C of A onsite at the lab is stictly required, or if access to the electronic copy "on-demand" is sufficient.	The laboratory must maintain copies of the Certificates of Analysis (CoAs), whether in hard copy or electronic format, in accordance with the lab's records and document control procedures and as required by the TNI Standard. The laboratory must maintain and control all records used to document lab activities, including CoAs, and all records must be made available to the accreditation body. The laboratory must retain all records (hard copy or electronic) for a minimum of	This language is unchanged in the 2016 standard. The SIR is still valid.

198	3/5/12		5.6.4.2	5.6.4.2	My question is about documentation and traceability of consumables. Are environmental labs required to maintain records (ie Certificate of Analysis, storage, date of receipt, etc.) for such consumables as carrier gasses used for MassSpec or Spec type instrumentation?	5.6.4.2 requires documentation for "standards, reagents, reference materials, and media". Carrier gasses are not referenced within this section. However, a carrier gas is a laboratory consumable material that affects the quality of tests, and is subject to the policy and procedure	This language is unchanged in the 2016 standard. The SIR is still valid.
251	2/4/14		5.6.4.2 d)		Assuming that we have a working definition for reagents, does the word "prepared" in 5.6.4.2(d) refer only to standards or all three (standards, reference materials and reagents)? Assuming the latter, see the discussion below for the actual question). Prepared reagents are readily defined as reagents that are prepared in the lab by modifying (diluting, mixing, etc.) one or more precursor reagents or standards. However there is some ambiguity concerning the term “container”. Suppose I make 200 ml of a reagent stock, say the Ammonium Molybdate reagent used in total phosphorus analysis that is stored in a lab refrigerator. Every time we perform a TP run, a small amount of this reagent is poured into a second container, a removable, plastic reagent well that is part of our discrete analyzer’s autosampler. At the end of the day, this reagent is not completely used up, and to minimize waste, we cap the removable plastic well and store it in the refrigerator overnight. It is refilled the following day for the next day’s analysis. Since the reagent stock was prepared only once, it would be assigned a single, unique serial number. The mere act of pouring some of this reagent into a second container should not (logically) require one to generate a second serial number. To summarize the question, is only one unique serial number needed for each contiguous preparation, regardless of the number of containers in which the reagent might be stored? i.e., Is this description of unique identifiers for prepared reagents consistent with the meaning and intent of 5.6.4.2 (d)?	The use of the reagent at analysis requires that all data necessary for the historical reconstruction of the data be available (see 4.13.3 f). Somewhere with the analytical batch, reference must be made to the unique serial number of this reagent. A new serial number need not be created due to the act of pouring the reagent from one container to another. The unique serial number is created at a point in time when the reagent, standard or material is made in the lab. If no changes are made, then a new number need not be created. The act of removing the container from its specific location on the instrument requires that the container be labeled with the reagent's unique identifier in order to comply with the traceability requirement of 5.6.4.2 c.	This language is unchanged in the 2016 standard. The SIR is still valid.
43	11/24/08	5.5.8.3.2	5.8.3	5.8.3	Is the sample acceptance plan required to be communicated to clients at any particulary frequency, i.e. annually?	5.5.8.3.2 states that the "sample acceptance policy shall be made available to sample collection personnel." The introduction included in 5.5.8 states "the following are essential to ensure the validity of the laboratory's data," which would mean that the laboratory can't invoke 5.1.2, which states "When a laboratory does not undertake one or more of the activities covered by this Standard, such as sampling and the design/development of new methods, the requirements of those clauses do not apply" to avoid having such a policy. However, the Standard makes no mention of any period under which the acceptance policy must be communicated to clients.	This sentence is not in the 2009 or 2016 standards. The SIR is obsolete.

38	11/05/08	5.5.8.3.1	5.8.3 and V2: 1.7.4	V2: 1.7.4	The test method specifies thermal preservation at a temperature of 4 C. The samples are hand delivered on ice to the lab on the same day as they are taken. They are received on ice, but the samples taken at the end of the sampling route may have only been chilling 15 - 30 mintues and may not be at or below 6 C as specified by the test method. The NELAC sample receipt protocol in 5.5.8.3.1 states that such samples may not meet the temperature criteria and that in such cases, the samples shall be considered acceptable. The question has arisen as to whether under these circumstances, documentation of receipt on ice is sufficient to meet the method and preservation documentation as the protocol implies, or does the actual sample receipt temperature still have to be recorded? What is the purpose of recording a temperature that is clearly acknowledged as likely to be outside the acceptance criteria if the sample is clearly deemed acceptable as described above. Would recording such temperature data actually make the data more susceptible to challenge by a third party?	The allowance for samples exceeding temperature requirements when delivered shortly after sampling does not alleviate the requirement to record a temperature, even in the presence of ice. No, documentation of receipt on ice is not sufficient to meet method requirements, since methods require the temperature upon receipt. Methods and regulations require that the temperature upon receipt be recorded, regardless of whether that information is in compliance or out of compliance. This should not make the data more susceptible to challenge, since it is clearly allowed as an exception.	This language was moved into the technical modules in 2009 and 2016. The SIR is still valid.
246	9/30/13		5.8.5 a)		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.	Unresolved	
81	8/11/09	5.4.12.2.5	5.8.8	5.8.8	I am a project manager for Head Start child care centers in New York City. We needed samples of drinking water to be tested for lead. I was disturbed to to see ATC Associates (NELAC certified) did not have a chain of custody form. I was concerned that there was an unsigned gap in the chain of custody when samples were delivered by FedEx courier to a lab nearby. The question is: isn't a complete continous, signed Chain of Custody form required so the sample could be accounted for specifically by a signed individual - in order to be in accordance with Nelac and the EPA method?	A complete, continuous Chain of Custody form is not required for samples submitted under NELAC, unless otherwise specified by the client. Note that 5.4.12 differentiates between sample handling and tracking and legal chain of custody protocols. 5.4.12.1.5 requires that a record keeping system allow historical reconstruction of all laboratory activities. "The records shall include the identity of personnel involved in sampling, sample receipt, preparation, extraction, A	The response discusses the differences between 2003 and 2009 (and 2016) and is still valid.
105	1/14/10				General question: does the accreditation process include all steps in the process, including sample prep? Specifically, if a lab is not accredited but performs the digestion of a water sample for method 6020 analysis then sends the digested aliquot to an accredited lab for the actual analysis can the results be considered valid from an accredited lab?	Unresolved	