Quality System Expert Committee (QS)
Meeting Summary

February 12, 2018

1. Roll Call:

Paul Junio, Chair, called the meeting to order at 1pm Eastern on February 12, 2018 by teleconference. Attendance is recorded in Attachment A – there were 7 members present. Associate Members present: Tyler Sullens, Alyssa Wingard, Gil Dichter, Carl Kircher, Eric Denman, Pepa Sassin, and Kathi Gumpper,

The minutes were distributed by email (1/8 and 1/24/18) and will be reviewed by email and voted on. Paul asked that people send comments within the week about the minutes and if no substantial changes are needed, he will request an email vote.

(Addition: A motion was made by Sara Hoffman on 2/23/17 by email to approve the 1/8/18 and 1/24/18 minutes as written. The motion was seconded by Shari Pfalmer on 2/23/17 by email.

Vote:
Paul – For (Email – 2/23/17)
Jessica – For (Email – 2/23/17)
Michelle – For (Email – 2/23/17)
Dale – For (Email – 2/23/17)
Ray – For (Email – 2/23/17)
Chris – For (Email – 2/23/17)
Jacob – For (Email 2/23/17)
Matt – For (Email 2/26/17)
Lizbeth – For (Email 2/26/17)
Kristin – For (Email 2/26/17)

The minutes were approved and will be posted on the TNI website.)

Paul reminded the Associate members to please delete the Crosswalk document sent out by email that included ISO language.

2. Albuquerque Meeting

There was a Quality Systems Expert Committee (QS) meeting and an additional session discussing Technical Managers. Paul reviewed a document summarizing the discussion regarding Technical Managers – Attachment D.

Paul requested that the ABs on the call review the information and provide any insight if they feel something is incorrect or not implementable.

Paul questioned whether modern technology and the ability to review information offsite should be considered when deciding if the Technical Manager is absent. Carl noted that the Standard requires the Technical Director to be present onsite. If this is looked at for a change in the new Standard, computer crashes should be considered.

The attendees during the QS meeting were asked to put 10 sections of current Standard language into the sections of the new ISO/IEC 17025:2017 – Attachment E.

Paul pointed out that there were some concerns raised about removing terms like Quality Manual, Quality Manager, etc.

Carl suggested adding obligations that the laboratory has which are in Volume 2 Module 1 of the Standard. They are things the AB needs to ensure the labs are doing. These things also need to be added into the QS Section. Paul commented that he already has this in the Parking Lot document. A lot of it is ISO 17011 language and the committee will need to figure out how to do it.

The minutes from the New Mexico meeting are a "stream of consciousness" of what happened. He would like everyone to be sure to review the minutes closely.

3. Committee Membership

Paul distributed committee application. There are 4 applications, but only 3 spots open. He is planning to handle this by email by ranking the candidates and figuring out the final 3 candidates. After that, there will be discussion by email and voting. The vote will be done by email. Committee members can also let Paul know if a meeting is needed rather than doing this by email.

Paul is the only person rotating off the committee this year. We may need to look at membership to make sure there are people rotating off each year. Ilona will check into this.

(Addition: Paul distributed information by email to rank the candidates to determine 3 candidates for voting (2/16/18). He received information through 2/28/18 and then established the ballot to include Alyssa Wingard, Kathi Gumpper and Earl Hansen. A motion was made by Dale to approve the candidates for addition to the committee on 3/2/18. The motion was seconded by Matt.
Vote:
Paul – For (Email 3/2/18)
Bill – For (Email 3/2/18)
Lizbeth – For (Email 3/2/18)
Sara – For (Email 3/2/18)
Dale – For (Email 3/2/18)
Matt – For (Email 3/2/18)

Shari – For (Email 3/2/18)
Michelle – For (Email 3/2/18)
Chris – For (Email 3/2/18)
Jacob – For (Email 3/2/18)
Jessica – For (Email 3/2/18)

The motion passed and the new members will be added to the committee. Paul notified each candidate by email on 3/5/18.)

4. Standard Interpretation Request (SIR)

SIR #246 was sent to Lynn Bradley. She will let the committee know what happens next.

5. ISO/IEC 17025 and Revision to Module 2

Paul wants to start by looking at the current SIRs and see what changes are needed to the Standard to incorporate the SIR. The first SIR is related to Technical Directors, so he would like to save this for later.

The committee looked at the information in the SIR Summary table and the language in the 2016 Standard and filled in the QS Notes column (Attachment F) to determine how the SIR should impact the Standard update.

6. Action Items

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

7. New Business

None.

8. Next Meeting and Close

The next meeting is planned for March 12, 2018 by teleconference. Ilona will send a Webex invitation the morning of the meeting.

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

Paul adjourned the meeting at 2:24pm Eastern.

Attachment A

Participants
Quality Systems Expert Committee (QS)

Members (Exp)	Affiliation	Balance	Contact Information	
Paul Junio (2018) (Chair) **Present**	Northern Lake Service	Lab	262-547-3406	paulj@nlslab.com
Kristin Brown (2018*) **Present**	Utah DOH	AB	801-965-2530	kristinbrown@utah.gov
Chris Gunning (2018*) **Absent**	A2LA	AB	301-644-3230	cgunning@a2la.org
Sara Hoffman **Present**	Kansas Health and Environmental Laboratories	AB	785-291-3162	Sara.hoffman@ks.gov
Jessica Jensen (2018*) **Present**	Meridian Analytical Labs	Lab	316-618-8787	jessica.j@meridiantesting.com
Silky S. Labie (2018) **Absent**	Env. Lab Consulting & Technology, LLC	Other	850-656-6298	elcatllc@centurylink.net
Jacob Oaxaca (2019*) **Absent**	CA Water Board	AB	916-323-3433	Jacob.oaxaca@waterboards.ca.gov
Shari Pfalmer (2018*) **Present**	ESC Lab Sciences	Lab	615-773-9755	spfalmer@esclabsciences.com
Dale Piechocki (2020) **Present**	Eurofins Eaton Analytical	Lab	574-472-5523	DalePiechocki@eurofinsUS.com
Matt Sowards (2020) **Present**	ACZ Laboratories, Inc.	Lab	970-879-6590	matts@acz.com
Lizbeth Garcia (2019*) **Absent**	Oregon Health Authority	AB	503-693-4115	lizbeth.garcia@state.or.us
Janice Willey (2018) **Absent**	NAVSEA Programs Field Office	Other	843-794-7346	Janice.willey@navy.mil
Bill Ray (2020*) **Absent**	William Ray Consulting, LLC	Other	925-352-5205	Bill_Ray@williamrayllc.com
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	
46	The committee should continue review of the SLH and send comments before completion of the Final DRAFT.	ALL	11/20/17	
47	Send ranking information to committee members by email.	Paul	3/1/18	
48	Send new committee member vote to committee members.	Paul	3/9/18	

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.

Attachment D: Technical Manager

Below is a summary of the discussion the ABs had regarding the technical director qualifications. This is just a general summary, and probably just a starting point.

Changes-
Removes requirements for "environmental" in experience
Flexible on chemistry credit hours, but feel 20 hours would be minimum required to show that an upper level chemistry class has been taken

Keep-
Degree Requirement, but look at expanding options similar to language in proposed CA regulations (A baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or chemical engineering, natural or physical science)

Additions-
Add that degree must be from accredited university

Clarification-
In microbiology section clarify whether the 16hrs is biology and mircobiology combined for each.

and in general clean up language in section.

DISCUSSION AT OPEN FORUM

The following are the notes that I took during the open forum discussion on Technical Manager:

It's shocking that there could be no degree required to be the TM

There are degrees that don't require a significant number of Chemistry hours

New requirements/emerging technologies won't possibly have 2 years of experience possible

This is a 'how-to' not a 'what to do', which isn't what the TNI Standard has been

Experience doesn't equal knowledge of Quality Systems

Requirements shouldn't be based on experience only

You can be good at running a lab – there should be a performance based outcome involved

If the lab isn't operating well, then the finding might be that the TM isn't competent

Could there be a TNI Training Course on TM

CWEA certification includes continuing education and covers many things

Degrees earned in the past may not apply to today's knowledge and technology

Government job descriptions make this difficult

QS knowledge doesn't come with a degree

What is the goal of the TM?

Is it the supervisor is it the person in charge?

Trace training back to the originally accepted person, and then track the historical knowledge that can be passed along

'shall' makes this limiting

Different states and different requirements will make this a challenge

Lower the chemistry degree hours based on experience (maybe one year / one hour)

Use the CA ELAP language

Tough access to qualified people at times – qualified based on the current requirement

These are dictatorial requirements that aren't necessarily relevant

It's hard to capture experience in lieu of a degree

You can train someone to fill this role

Is experience in the current version of the method? That disqualifies someone out of the lab at some point as methods are updated

Delete the absence requirement, as we can work remotely these days / are we ever really absent?

People aren't one-stop shops - does anyone have all of these requirements?

Who can do each task best on staff and why?

Equivalency of experience and education is subjective

Colleges that grant degrees can also grant credit based on experience

Both education and experience are important

Theory behind testing and science is important

Experience versus hours of chemistry

Hesitant to reduce chemistry hours for experience

Technical Manager – Other – should that be left up to the lab?

Management/ownership knows what it needs at its location

There is a sewage lab exemption that commercial labs can't have – unfair

Needs to be a minimum license/education/fit for use – possibly a three-pronged approach

Totally risk based approach could be a Wild Wild West

Add a certificate of competency

Need a minimum number of hours of Chemistry and then factor in experience

Look at the EPA DW Manual and job descriptions regarding what you would want to hire

How to deal with remote crashes / loss of connectivity [relating to absence]

Differentiate from vacation / extended illness [relating to absence]

Must be reachable if needed based on training requirements in the lab

Attachement E

	ISO/IEC 17025: 2017 Section 4	ISO/IEC 17025: 2017 Section 5	ISO/IEC 17025: 2017 Section 6	ISO/IEC 17025: 2017 Section 7	ISO/IEC 17025: 2017 Section 8	Trash - Not Needed	Total
4.1.7.1		4	3		1		8
4.1.7.2		4	4				8
4.2.8.1		2		1	4		9
4.2.8.2		5			4		9
4.2.8.3					9		9
4.2.8.4		5		1	2		8
4.2.8.5				1	8		9
4.5.5			2	7			9
4.11.6				2	8		10
4.13.3				1	7		9
4.14.5					8		8
4.15.3					8		8
4.16		2		4	1		7
5.2.6.1		3	5				8
5.2.6.2		2	7			1	10
5.2.7		4	2				8
5.4.4				4	1		6
5.4.5				7			8
5.4.6				7			7
5.5.13.1		1	2	3			6
5.6.4.1		1	3	4			8
5.6.4.2		1	5	1			7
5.7.4			1	6			7
5.8.5			1	7			8
5.8.6				8			8
5.8.7.1		1		7			8
5.8.7.2				9			9
5.8.7.3				8			8
5.8.7.4				9			9
5.8.7.5				7	1		8
5.8.8		1		7			8
5.8.9				8			8
5.9.3				6	2		8
5.10.10				9			9
5.10.11				9			9

#	Date Submitted	2003	2009	2016	Actual Request	Final Response	Comment	QS Notes
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.	pass
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.	individual observations need to be recorded
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.	who is qualified? Note up to the lab
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.	Unresolved		address

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.	Unresolved		address
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.	Unresolved		address
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
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 Chain of Custody, the laboratory should not be required to have an SOP for what it doesn't do. Compliance could be demonstrated if the lab's Quality Manual states 'We do not	This section was edited in 2009 but the SIR is still valid.	address
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 procedures can be allowed to have longer periods between review, such as when changes are needed due to a change in laboratory practice	No change in language in 2009 and 2016	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 laboratory must be prepared to provide documentation to indicate that these additional requirements have been met. However, under "Service to the Client" (5.4.7), the laboratory shall cooperate with the client "to monitor 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 to report results unambiguously. The laboratory could have a statement: "All results are wet weight unless otherwise noted."	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