Quality System Expert Committee (QS)
Meeting Summary

January 11, 2021

1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 1pm Eastern by teleconference on December 14, 2020. Attendance is recorded in Attachment A – there were 14 members present. Associate Members present: Amy Schreader, Brian Lamarsh, Chris Fuller, Chris Gunning, Cindy Redmond, Denman Eric, Jeanette Hernandez, Paul Junio, Karna Holquist, Kelvin Yuen, Linda O'Donnell, Lisa Parks, Patricia Carvajal, Rachel van Exel, Renee Jernigan, Tiffany Shaw, Tom Widera, Joe Manzella and Nicole Cairns.

The December minutes were sent by email and shared on Webex. Earl made a motion to approve the December 14, 2020 minutes as written. The motion was seconded by Lizbeth. There was no further discussion, and they were unanimously approved.

New Committee Members: Nicole Cairns and Amy Schraeder have accepted membership. David Caldwell has not responded yet. Shari, Kristin and Jessica are rotating off. *(Addition: Kathi, Earl, Jenna, Michelle and Alyssa have agreed to serve a second term. There were no objections to these second terms.)*

2. Chair and Vice Chair

Kathi nominated Debbie Bond to be the new Chair of the Quality Systems Expert Committee. The nomination was seconded by Earl and unanimously approved.

Earl nominated Kathi Gumpper to stay on as vice-Chair of the Quality Systems Expert Committee. The nomination was seconded by Kristin and unanimously approved.

Ilona will set-up a meeting the first week of February with Debbie, Kathy, and Jessica.

3. Review of Public Meeting Comments

Jessica continued review of the written comments starting with those related to ISO/IEC 7.8.4.1. Changes were made as a appropriate to the Summary of Suggested Changes table (see Attachment D). The changes that have been made since the Public Webinar can be found in track changes. The Committee finished its review.

The Committee took one last look at the responses prepared to send back to the Public Meeting attendees (Attachment E). A motion was made by Earl to approve the responses.

Michelle seconded the motion and it was unanimously approved. Ilona will work on getting the responses sent to all the Public Meeting attendees.

4. Action Items

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

5. New Business

- Ilona asked Alyssa if she had an update on what DoD is doing with their QSM update related to when QS needs to be done with the TNI Standard update. Alyssa noted that Covid has thrown a wrench into things. They are now meeting every 3 weeks by telecon, so the process has been slowed down. She was told not to rush the completion. DoD/DOE QSM 5.3 2019 was published to deal with ISO 17025:2017 and they shouldn't need to rush the next update.

  DoD/DOE will roll out modules and appendices as they become available. They will follow the format of ISO/IEC 17025:2017 and incorporate 2016 TNI Standard language. They talked to Jerry about his willingness to sell this update and TNI has agreed to do this. He said it was also OK to make changes to language.

  Alyssa sees no reason to rush the TNI Standard update because it will be difficult for DoD/DOE to change the work they have already done with the 2016 Standard.

- SIR 393: Jessica will resend this to Lynn Bradley.

6. Next Meeting and Close

The next regular meeting will be on January 26, 2020 at the virtual conference. The meeting will begin at 10am Eastern.

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

Jessica adjourned the meeting at 2:08 pm Eastern (Motion – Kathi, Second – Tony Unanimous Approval).

Attachment A

Participants

Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Jessica Jensen (Chair) **Present**		2021	Laboratory	jessica.jensen@kcmo.org
Kristin Brown **Present**	Utah DOH	2021	Accrediting Body	kristinbrown@utah.gov
Michael Demarais **Present**	SVL Analytical	2023*	Lab	michael@svl.net
Tony Francis **Present**	SAW Environmental	2023*	Other	tfrancis@sawenviro.com
Lizbeth Garcia **Present**	Oregon Dept. of Environmental Quality	2022	Accrediting Body	LIZBETH.GARCIA@dhsoha.state.or.us
Kathi Gumpper (Vice-Chair) **Present**	ChemVal Consulting	2021*	Other	kgumpper@chemval.com
Nicholas Slawson **Present**	A2LA	2023*	Accrediting Body	nslawson@a2la.org
Earl Hansen **Present**	Retired	2021*	Other	papaearl41@hotmail.com
Jenna Majchrzak **Present**	NJ DEP	2021*	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Shari Pfalmer **Present**	Pace Analytical Services	2021	Laboratory	shari.pfalmer@pacelabs.com
William Ray **Absent**	William Ray Consulting	2023	Other	Bill_Ray@williamrayllc.com
Amber Ross **Present**	PA DEP/Bureau of Laboratories	2022*	AB	ambross@pa.gov
Debbie Bond **Present**		2023*	Lab	dbond@southernco.com
Michelle Wade **Present**	A2LA Workplace Training	2021*	Other	mwade@a2lawpt.org
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
63	Consider starting a list of items to add to the small laboratory handbook.	All	TBD	
65	Add ISO/IEC 17025:2017 language from the 2016 TNI Standard into the DRAFT Combined Standard.	TBD	TBD	
73	Change black text in combined Standard to italics in preparation of starting to work on updating language in the Standard.	Jessica	2/2/20	*4/15: Needs to be started.*
77	Prepare summary document of comments received during the 9/25/20 Public Webinar.	Jessica, Kathi, Paul Junio	11/9/20	
78	Send SIR 393 back to LASEC.	Jessica	11/16/20	1/11/21 – will be resent.
79	Send Public Webinar responses to attendees of the webinar.	Ilona	2/15/21	

Attachment C

Backburner / Reminders – QS Executive Committee

	Item	Meeting Reference	Comments
1	Review charter in November 2020	Ongoing	Ongoing

Attachment E:

Q&A Session for TNI Quality Systems Public Webinar - Noon EDT

Session Number: 1278751715
Date: 2020-9-25
Starting time: 11:31

- 12:06
Q: prefer include as note. Guidance documents are buried on website
Priority: N/A—

It is the committee's intentions to avoid any list in the standard. The committee plans to address all list with notes as opposed to any guidance documents. The note may just be a reminder that lists are not all inclusive or always essential requirements.

-12:09
Q: Is the ISO17025 based on 2017 or 2005?
Priority: N/A-

The 2016 TNI Standard is based on ISO 17025:2005. The revision that is beginning now will be based on ISO 17025:2017

- 12:11
Q: is TNI adding the requirement for SOP that is not in the ISO language? If so, why do we believe that written documentation is essential?
Priority: N/A-

In addition to providing a record of how the method was performed at a detailed level, not having clear instructions has been demonstrated to be a risk that the committee feels is appropriate to mitigate by requiring written instructions for methods-

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- 12:14
Q: Based on my experience, we have to have clear detailed SOPs! Or we have all kinds of problems arise.
Priority: N/A--
The Committee is in agreement with you. What the Committee hopes to do is address this list of SOP requirements and reaffirm that they are not required in the order or format provided. All of the items in the list must be addressed in one way or another, but the laboratory is free to decide how that happens.

- 12:15
Q: Within the TNI2016, is the intent of clarifying the original text to weave in the ISO17025 (2017) in addition to the existing ISO17025 (2005)?
Priority: N/A--
Module 2 will be completely re-written, using ISO 17025:2017 as its base. Language that TNI has previously added to ISO 17025:2005 has been reviewed to determine whether or not it is (1) redundant and (2) necessary to include due to providing more detail than the ISO language. The next step is determining which items in the Standard need to be changed, clarified, removed, or

otherwise addressed.

-12:15
Q: Will there be a definition of what an Adminstrative SOP. I think HR and accounting when I see administrative.
Priority: N/A-

"Administrative SOPs" are a term we are using without defining at this point. It might be better to consider SOPs as "method" and "non-method" as we determine the required elements of each. Some examples of non-method or administrative SOPs are sample handling, records storage, corrective action and reporting to list a few.

-12:22
Q: Would that subsample refer back to the original container or to the site location where sample is taken? LIMS can be set=up both ways based on interpretation.
Priority: N/A--
That is more explicit than the Standard needs to be. The requirement is that any container that contains a sample must be traceable and that it must be identifiable.

- 12:22
Q: no more -a, -b, -c, etc sampl IDs? They can all be the same number?
Priority: N/A--
That hasn't been determined. As stated in the answer to a previous question, the requirement is that any container that contains a sample must be traceable and that it must be identifiable. The current Standard does not mandate that different containers are identified as -a, -b, and -c, for example. That is just one of many ways of complying with this requirement.

- 12:26
Q: does the internal audit include technical review of the method?
Priority: N/A--
The Standard contains a Management requirement to perform internal audits, and a technical requirement to verify that the methods being performed are adequate and followed. Keep in mind that only a portion of the Standard is contained in this Q&A as we look for feedback.

-12:26
Q: Suggest not using calendar year. some labs work off of fiscal year.
Priority: N/A--
Timeframes that are requirements will likely be specified in terms of the amount of time that is allowed. The Standard won't refer to something such as calendar year or fiscal year, as that becomes more of a statement of HOW something must be done.

- 12:26
Q: Would that be applicable across the board and not only internal audit?
Priority: N/A--
Again, timeframes for requirements will be addressed wherever they are mentioned in the Standard. What is stated in one part of the Standard may not be the same as in another, but there won't be conflict among requirements.

- 12:26
Q: Will the standard retain languange that this can be done in smaller sections throughout the year instead of all at once?
Priority: N/A-
The language does not currently require the audit be performed all at once and there is no intention to add that requirement-

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- 12:27
Q: What's the current position on whether all methods must be audited annually?
Priority: N/A-
As per the SIR page on the NELAC website:

TNI Response to SIR on Module 2 Section 4.14.1: 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 response to this SIR clarifies that all methods need not be audited annually.

- 12:29
Q: every 12 months not to exceed 18 months from the last internal audit
Priority: N/A--
Where the committee feels that something could extend to 18 months without having a potentially negative impact on data, that might be the requirement. The committee intends to discuss timeframes on a case-by-case basis. What is now “annual” may be differently described based on risk and impact on data.

- 12:29
Q: Doesn't this allow for annual requirements to be completed every 18 months?
Priority: N/A--
The committee will be reviewing any timeframe stated in the Standard to make sure that there is no negative impact on data.

- 12:30
Q: on the annual review of QM would that be based on major changes or do we need to review section(s) affected and not change the approvals (ex: change in appendices)) and not have to go to another approval proces/signatures?
Priority: N/A--
The Standard has no requirement for an annual review of the QM. If the laboratory has written that into its own procedures, then it must be followed.

- 12:31
Q: Suggested language will promote 18 month schedule vs 12 month
Priority: N/A--
The committee will consider timeframes on a case-by-case basis. “Not to exceed 18 months” has received poor feedback thus far.

- 12:37

Q: How is it expected to be identifed in EDD? Most EDD formats are user defined. Some may not allow specific flags.
The Standard won't define HOW it must be done. We have always tried to steer clear of the hows

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- 12:38
Q: Is it based on data user's requirement and EDD or EDT are regulatory specified format?
Priority: N/A--
The requirement, as it is now, is that the RESULT must be clearly identified. The Standard is silent regarding how that must be done. The committee will work to assure clarity on this language.

- 12:39
Q: Should "shall" be changed to "must" for 5.10.11?
Priority: N/A-
Shall typically = must in standard wording. I don't know of exceptions to this.-

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- 12:44
Q: Does it change what it is if we call it a QA Manual or administrative SOP?
Priority: N/A-

Requirements that are made in the Standard must be met. The naming of a document or title of a person being changed doesn’t remove the requirement from existing.

- 12:44
Q: is this becuase it is being interpreted as an acutal book and not an online format?
Priority: N/A--
The committee is considering the way that ISO 17025-2017 is written. That document, which is the basis for the TNI Standard, does not mention a QA Manual. It does, however, continue to have a list of required elements that a laboratory must meet and document.

- 12:45
Q: Would the ISO language still exists as italics (2017 or 2005)? I thought ISO17025 (2005) will be phased out this Nov2020?
Priority: N/A-

Module 2 will be completely re-written, using ISO 17025:2017 as its base. Language that TNI has previously added to ISO 17025:2005 has been reviewed to determine whether or not it is (1) redundant and (2) necessary to include due to providing more detail than the ISO language. The next step is determining which items in the Standard need to be changed, clarified, removed, or otherwise addressed. ISO language will continue to be italicized so that it stands out as noneditable.

- 12:50
Q: Any guidance on what undue delay is? Could a lab define it as 2 month and that still be reasonable?
Priority: N/A--
Undue delay will be up to the laboratory to define, this is iso language and cannot be modified, this term will not be defined by the committee as it can be different on a case by case basis. However, the corrective action process needs to be begin immediately (as soon as practicable), but the actual action taken can be any appropriate timeframe as defined within the individual corrective action.

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- 12:52

Q: In general, it makes me nervous when we leave responsibilities such as this to the labs. Give them an inch and they tend to take a foot. The standards should be as clear and specifc as possible.
Priority: N/A--

The Standard is written through the collaborative process of all stakeholders. The Committee strives to write a Standard that is acceptable to all stakeholders. The Committee agrees that the Standard should be as clear as possible. However, the specificity of HOW something must be done has not been the direction that we have gone within TNI.

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- 12:56

Q: Record retention for regulatory related data have set timeframes not only 5 years
Priority: N/A--

The Standard is defining the minimum requirements for timeframes. The committee has no control over additional requirements made by data users or other regulations any additional requirement are up to the laboratory to establish how they meet their data users needs.

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12:57

Q: How about purchasing documents related to data generated?
Priority: N/A--

If those documents are needed to provide an unambiguous historical record of the data generated, then yes they would need to be maintained.

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- 12:58

Q: Why are initial demonstrations considered so important if there are ongoing demonstrations available?
Priority: N/A--

The requirements of initial demonstrations are different from ongoing demonstrations. Some of the different requirements are evaluation of precision and establishing accuracy near the LOQ. If an ongoing demonstration is always performed by repeating an initial demonstration, then there is no issue.

_____-Melanie Levesque-

-12:58

Q: Can the initial demonstration and training records be maintained electronically or must it be hardcopies?
Priority: N/A--

Either of these would be acceptable.

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- 12:58

Q: can the retaining of records be defined as keeping record of the storage transmittals?
Priority: N/A--

The records must be readily retrievable.

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- 13:00

Q: ISO 17025 states the laboratories must have a plan and schedule to conduct the internal audits. Frequency can be defined in the schedule.
Priority: N/A-

You are correct, but TNI has historically added additional requirements to the ISO language and we intend to continue this practice.-

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- 13:00
Q: Would personnel training include only regular staff and not student interns doing lab work?
Priority: N/A-

Any personnel whether permanent or temporary who perform laboratory activities within the scope of accreditation must meet all training requirements-

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- 13:01
Q: This was in chat and is for later discussion. I am unclear why we would want to extend an annual requirement to 18 mths, as I believe this would set a new "normal". I understand the need for flexibility, but to extend to 18 months seems overly generous.
Priority: N/A-
The committee will consider timeframes on a case-by-case basis. “Not to exceed 18 months” has received poor feedback thus far.

- 13:07
Q: Record retention policy needs to be standardized all across. It creates confusion if the policy is different for different records. I think 5 year record retention makes sense.
Priority: N/A--
There is only one record retention policy described in the TNI Standard. TNI can’t control requirements made by other organizations.

- 13:10
Q: I missed that. Is ok not to list qualifiers if the client requests it?
Priority: N/A-
The exceptions for reporting requirements are found in Section 5.10.10. Those exceptions could not be used to justify NOT qualifying data where required by the Standard.

- 13:11
Q: can we look at the language does it say available or does it say report shall have? This would be a huge difference.
Priority: N/A-
The exceptions for reporting requirements are found in Section 5.10.10. There are specific situations which allow for a lessened report format, but all information must still be readily available.

-13:11
Q: for the identification on the methods used, will it for what the laboratory uses or the method the clients use in the field that needs to be on the report?
Priority: N/A--
If the laboratory is reporting its data, it must report the method that it follows. If there is an arrangement between the laboratory and the client to report field data, that arrangement is between the laboratory and the client.

- 13:14
Q: Do you anticipate that a change in requiring the revision to an analytical report will also require the FOA to be specific on the revision number?
Priority: N/A-
This is outside of the purview of the committee.

- 13:17

Q: I would like to know if the technical manager qualifications under Section 5.2.6 will be revisited soon. I don't know if it was on today's agenda or not. Sorry if I am not following proper protocol - new to this webinar format.

Priority: N/A-

Those changes are under discussion. The committee has no final answer on what those requirements will be

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-13:18

Q: Need to clarify LIMS validation; it is different from lab validation.

Priority: N/A-

This is addressed as a note in 17025:2017 Section 7.11.2. It is the intention of the committee to adopt this note as part of the standard requirements.

- 13:23

Q: Will the committee being taking public suggestions at some point regarding these requirements?

Priority: N/A-

Yes, public suggestion is welcome at all public meetings, conferences and webinars.