Quality System Expert Committee (QS)
Meeting Summary

August 9, 2018

1. Roll Call:

Paul Junio, Chair, called the meeting to order at 9am Central on August 9, 2018 in a face-to-face meeting in New Orleans. Attendance is recorded in Attachment A – there were 9 members present.

2. Review of Special Meeting Regarding ISO/IEC 17025:2017

Paul reviewed the slides presented at the Special TNI Session on ISO/IEC 17025:2017. (Attachment D)

The question of Volume 2 language being added to Module 2 was raised. The Committee can easily use old Ch 6 language. Ken thought the Committee may be able to paraphrase the ISO/IEC 17011 language. Jerry will be checking on this. *(Addition: Jerry would like to see what the paraphrased language would look like before checking on this.)*

Summary Notes –
- How do we address unresolved SIRs?
- Are there AC policies that need to be addressed?
- Need language for ISO 17011. Paraphrased?
- Don't need to use exact terms for Technical Manager and Quality Manager. Paul would prefer to keep them as is. Need to make sure responsibilities are taken care of. Need some sort of requirements for Technical Manager.
- Quality Manual. Clients are used to seeing it. Not clear.
- Sampling. Require NEFAP? Not clear what to do with sampling.
- When? Ilona commented that NELAP AC does not want to adopt another Standard for another 5 years. NEFAP is targeting 2019 for a new Standard.

Comments:
Michelle – Would prefer a one big step approach. Labs would come up speed just like they have had to in the past.

Jessica – A two step approach would be hard. Where do you draw the line on the steps?

Chad – ALS – Would prefer one big step. The rest of the world will be doing it by 2020. Why are we different? Make the jump.

Chris Gunning – You can't decide now whether to do a two step approach. Need answers to all the questions asked yesterday.

Bob DiLorenzo – How do we teach labs to start looking at the risk if we keep a lot of the current requirements. TNI is taking the "risk" factor away from them.

Sheri Heldstab – This is like the new MDL requirements. It was done in one step. Do a few year lead into it and do training.

3. Standard Interpretation Request (SIR)

SIR 329

Paul usually tries to attempt a response to all SIRs that are received by the committee. He reviewed the question and then provided his suggested response (Attachment E).

Chris Gunning attempted a response included in Attachment E. Michelle had commented this is a gripe session directed toward the AB. Seems like more of an argument against an assessor.

Initial Comments:

Bob Di Renzo – Support equipment needs to be tracked, but you have to look at impact. It is not important to give a hot block number, but it is important to have a tracked thermometer.

Michelle – If a thermometer is really being used, you wouldn't need to track the hot block. The alternative is if the hot blocks are monitored with a thermometer periodically, you would need a hot block number.

Chad, ALS – He got a deficiency because each hot block location needs to be checked.

City of San Diego – Asked about pipettes. Paul - Class A glassware is exempt from some of the requirements.

Mike Shepherd – He wrote the finding that resulted in the SIR being looked at. He agrees with Chris (Attachment E) and he provided that rational back to the lab.

Kathleen Roche – They ran into a dessicator deficiency. Do they have to track the dessicator? It is not critical. Need to look at the definition of support equipment and make sure it is clear.

Tyler Sullens – Without traceability of pipettes, how can you confirm they have all been verified?

Michelle asked what the actual deficiency was? Mike Shepherd thinks it was a mechanical pipette. There were also some sterility items in microbiology.

Eric Davis, City of Austin – They don't necessarily identify which fridge number samples are in because if there is a problem, they inventory the samples in the fridge then. Chris Gunning commented that you are always going to need traceability. Not just when it goes bad. Eric commented this is a situation where "risk" should be considered.

You can't use risk to "risk" away a requirement.

Sheri Heldstab – provided an example of how much needs to be documented in a simple metals digestion. Track balances, weights, thermometers, pipettes, etc …

Bob DiRenzo – What about 2 minute shakeouts? Will people have to document 2 minutes in the future?

Response:

Yes. All support equipment, whether calibrated or verified is required to be traceable to individual results. This applies to any support equipment that is calibrated or verified.

Discussion:

There was general agreement on the committee for this response.

A number of people felt that more information is needed in this response. Can some of Chris' language be paraphrased?

The Committee needs to update the definition for support equipment.

Robin Cook – We are over thinking the calibration verses verification concern that was being raised.

Jessica – if something is not verified, it is taken out of use. Why track something that is not going to be in use? Eric Davis commented that this works, but what do you do when it fails? How do you go back through data if you have a failure? She is talking about disposal pipets – so the lot is checked.

Rose, Municipality Lab – The devices are calibrated by the manufacturer.

Scott Siders – Wanted the committee to confirm that all support equipment must be calibrated or verified. The committee agreed.

Robin Cook – Bench sheet has a date. Lot numbers are included. If a pipette is used, it will be listed. Thermometer in incubator is noted, etc …

Mike Shepperd – There was no link to the device being used. They don't care where it is recorded, but there has to be a record to make it traceable.

Vote:
A motion was made by Jessica to accept the following response:
Yes, all support equipment, whether calibrated or verified is required to be traceable to individual results. This applies to any support equipment that is calibrated or verified.
The motion was seconded by Michelle and unanimously approved. The motion passed. Paul will send the final response to Lynn Bradley for LASEC review. *(Addition: See August 13, 2018 meeting notes for further discussion on this topic and a request to withdraw the response to Lynn Bradley and LASEC.)*

4. SIR Review for Standard Update

Paul continued to review the SIR Summary Table started during the July meeting.

SIR 93 –
The method should match what is on the lab's certificate.

Jennifer, FL DEP – It can make a difference because the calculations can sometimes be different. She thinks the Standard needs to be clear on what is needed. Paul noted that he doesn't want to force it on someone if it is not being required of them.

City of Fort Worth - Requirement is to use most current method, but permits may still require older method. Chris Gunning noted that if you need an older version of a method … it needs to be added to your accreditation Scope.

Mike Shepherd – Not all states list specific method versions on the Scopes. Florida is changing what they are doing – they want the specificity. This is an AB issue … not a QS issue.

Patty Snyder – There are even situations where the lab SOP doesn't have the version reference.

Robin Cook – A state can require more. If in contract review a specific method version is stated, it should be reported.

Nilda – Some PT Providers require the specificity when reporting PT results.

Alyssa – Think of it as an end user. If you are reviewing the report, you need to know exactly which method was used.

Probably won't be able to state in the Standard that specific method has to be referenced because this is different across states. This can't be solved today. This will be further considered.

Silky suggested adding something like: If requested or required, the revision number however specified.

296 – This SIR was just finalized. Final response is on the website.

212 – Response was completed. Technical Manager requirements are being worked on and should take care of this.

302 – This will be taken care of when the Technical Manager requirements are re-done. Micro will be providing input on how the requirement should be re-written.

180 – Need to figure out if this has been addressed before. If language has not changed, this needs to be clarified in the new Standard. Others in the room think the language is clear.

21 – Nothing needs to be addressed.

66 – Nothing needs to be addressed.

270 – Single use needs to be added. This needs work in the new Standard. *[edit – this was addressed in the 2016 Standard. Paul had pulled an old version of the Standard by mistake.]*

274 – Change from glassware to labware? This will be further discussed.

Mike Shepherd – The Standard is currently being applied to mean that digestion tubes need to be looked at every 3 months. This shouldn't be done because it is not a dispensing device.

Patty – Don't single use items fall under consumables? This will be looked at by the Committee.

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 will be planned by email. Paul will decide whether to have the regularly scheduled call next 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 11:55pm Central.

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 **Absent**	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 **Present**	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	
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	Complete
55	Send a picture of a Class A non-glassware item.	Kathi	7/9/18	Complete
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	

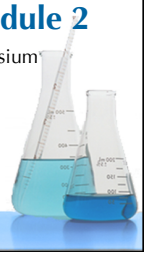
Attachment C

Backburner / Reminders – QS Executive Committee

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

Quality Systems - Module 2 Revision
ISO 17025:2017 / TNI Module 2

Environmental Measurement Symposium
New Orleans, LA
08/08/18



Quality Systems - Module 2 Revision

Module 2 Revision

- Previous SIRs
- Parking Lot Document
- ISO/IEC 17025-2017

Quality Systems - Module 2 Revision

Previous SIRs

- How does QS Committee deal with the SIRs where agreement hasn't been reached yet?
- Have ABs developed Policies that QS Committee needs to address in Module 2?

Quality Systems - Module 2 Revision

Parking Lot Document

- Volume 2 Module 1 (General Requirements for Accreditation Bodies Accrediting Environmental Laboratories) contains responsibilities of the lab and of the AB (17011 language)
- These items AREN'T listed in any Module that a laboratory is expected to have
- Some of this is NELAC Chapter 6
- We have to develop workable language

Quality Systems - Module 2 Revision

What about?

- Technical Manager
- Quality Manager
- Quality Manual
- Sampling

Quality Systems - Module 2 Revision

What about – Technical Manager?

- Technical Manager isn't listed/discussed/required by ISO 17025:2017
- There are requirements to have adequately staffed and knowledgeable management
- Multiple requirements that DON'T all need to be done by one person

Quality Systems - Module 2 Revision

What about – Technical Manager?

- Special session in Albuquerque regarding Technical Manager
- We captured 3 pages of notes on likes, dislikes, requirements
- Can we align with CA ELAP requirements?

Quality Systems - Module 2 Revision

What about – Quality Manager?

- Quality Manager isn't listed/discussed/required by ISO 17025:2017
- There are requirements to have adequately staffed and knowledgeable management
- Multiple requirements that DON'T all need to be done by one person

Quality Systems - Module 2 Revision

What about – Quality Manual?

- There is no stated requirement for a Quality Manual
- The words aren't used in 17025:2017
- You have to have all (probably) of those things that previously were required to be in the Manual

Quality Systems - Module 2 Revision

What about – Sampling?

- Clearly required procedures if the laboratory does sampling
- Many labs don't do sampling
- We have a Standard that addresses sampling
- Let's not re-invent the wheel

Summary of Special Session

Q - How do we address unresolved SIRs?

A – Reach out to the AC. They might be resolved. If not, we'll push for an answer.

Q - Are there AC Policies that we need to address?

A – None yet approved.

Q - We need language for 17011 requirements of labs.

A – We have a start, and MIGHT be able to legally paraphrase.

Summary of Special Session

Q - Do we want the term Technical Manager?

A – Not exactly, and we might have a path to revising the requirements. Doesn't hurt to keep it, though.

Q - Do we want the term Quality Manager?

A – Definitely need the requirements. Probably easier to keep than to discard.

Q - Do we want the term Quality Manual?

A – It might be that we can just have a list of those things that the lab needs, and they don't HAVE to be in a Quality Manual, but they CAN be.

Summary of Special Session

Q - Do we REQUIRE NEFAP or just direct interested parties to NEFAP?

A – This is less clear. It appears to be a state-regulatory issue more than anything.

Q - When does this need to be done?

A – Varied timeframes based on what we do. (1) A partial approach; or (2) a complete update

Quality Systems - Module 2 Revision

Previous SIRs

- Review all SIRs
- Assure that they are properly addressed in this revision
- Working session today

Quality Systems - Module 2 Revision

Volume 2 Requirements of the Lab

The laboratory shall

- Agree to be assessed in conjunction with an initial application.
- Agree to be assessed every two years while accredited.
- Agree to be assessed at a time mutually agreed upon with the Accreditation Body
- Allow an assessor on-site for an unannounced assessment, if such an assessment is attempted by the Accreditation Body

Quality Systems - Module 2 Revision

Volume 2 Requirements of the Lab

(cont.)

The laboratory shall

- Agree to display, use, or represent the logo of TNI and/or the Accreditation Body as required or allowed by TNI and/ or the Accreditation Body
- Make accurate statements regarding the laboratory's Fields of Accreditation and Accreditation status
- Agree to discontinue use of the logo of TNI and/or the Accreditation Body upon suspension, revocation or withdrawal of the laboratory's accreditation

Quality Systems - Module 2 Revision

Volume 2 Requirements of the Lab

(cont.)

- A suspended lab shall not continue to perform analyses for the affected scope of accreditation.
- A suspended lab shall not have to reapply for accreditation if the cause/causes for suspension are corrected within six months or before the end of the period of accreditation, whichever is longer.
- If the lab fails to correct the causes of suspension within six months after the effective date of the suspension or by the end of the period of accreditation (whichever is longer), the the lab is required to reapply for accreditation.

Questions?

Paul Junio
Chair – Quality Systems Committee
Northern Lake Service
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715-219-2662

Quality Systems Calls
2nd Monday of the month at 1PM Eastern

Attachment E:

SIR 329

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	4.13.2.1 & 4.13.3.a
Describe the problem: Please see the attached file.	
Upload a File	2016-TNI-Support-Equipment-SIR_18-Jul-2018.docx
Comments:	[editor] the attached file is reproduced below without any identifying marks. The question asked has been **bolded.** At the end of the question below is information that led us to this response.
Response:	Yes, all support equipment, whether calibrated or verified is required to be traceable to individual results. This applies to any support equipment that is calibrated or verified.

18 July 2018

TNI Program Administrator

The NELAC Institute

We seek a Standard Interpretation Request (SIR) for the 2016 TNI Standard, EL-V1M2-Rev.2.1, Sections 4.13.2.1 and 4.13.3.a.

Both 4.13.2.1 and 4.13.3.a are general standards that do not prescribe specific items be traced to analytical measurements. The TNI standard makes a clear distinction between laboratory instrumentation used to generate analytical data and support equipment such as balances, ovens, volumetric dispensing devices (pipettes) and temperature monitoring devices. Section 5.5.13.1 of the standard requires that support equipment be properly maintained and calibrated, but does not require the tracking of individual pieces of equipment. Previous discussions with our accreditation body had indicated that, while traceability to measuring equipment is required, support equipment should be documented as being calibrated and maintained but not necessarily linked to individual test results.

We have been a NELAC accredited lab since 2001 and have witnessed a steady and increasing application of traceability requirements being applied by some assessors over the years. We believe that traceability requirements for support equipment are being extended beyond the intent of the standard and can potentially be extended to the point of absurdity while contributing little to data quality. Traceability requirements for support equipment are often a burden for labs while offering little value and no improvement in data quality. Even more concerning is that these additional requirements to maintain traceability for support equipment ultimately divert attention from matters that have greater data quality implications.

One argument that has been advanced by some assessors is that the tracking of individual pieces of support equipment should enable one to calculate the amount of uncertainty contributed by that device (balance, pipette) to the final uncertainty in the concentration of analyte in the sample. While this argument is theoretically valid, such a calculation (the consideration of a specific pipette in the calculation of a specific result) is virtually never conducted in practice. In fact, in the many years of operation of our laboratory, traceability of support equipment to individual measurements has never been an issue, and we are unaware of any other environmental laboratories where it has been an issue either (other than in audits). The measures of accuracy and precision reported by labs are generally made at the level of the analytical instrument. The sample precision reported by labs to customers encapsulates all the uncertainties of intermediate measurements (metadata) carried out by support equipment prior to analysis. It also includes the variability in sampling conducted in the field.

> We believe that as long as all support equipment is properly calibrated, and the calibration documented using established protocols, there should be no need for labs to track the identity of individual pieces of support equipment to individual results. The cumulative extra work that some TNI auditors have, or are seeking to impose, upon laboratories, when compared to any potential gain, is onerous. We feel our lab is spending time and resources to collect large amounts of data, the only purpose of which is to satisfy an audit, and is therefore a potential for an audit deficiency. There is an argument that environmental factors may have more impact on precision and accuracy than the differences between individual calibrated pipettes, for example. Should we be tracking lab temperature and humidity to individual data points? Should we be tracking the make, model, and serial number of our air-conditioning unit? A number of similar factors that may be considered to affect uncertainty in a theoretical sense could be cited, but likewise are of little practical value for establishing uncertainty.

In conclusion, the generality of sections 4.13.2.1 and 4.13.3.a allows for unrestricted interpretation of what should be documented and traceable. We would therefore appreciate your assistance in clarifying traceability requirements for support equipment. **Does TNI contend that all support equipment is required to be traced to individual results, or is there a distinction between analytical equipment, that**

is required to be traced to individual results, and support equipment, that is required to be calibrated and correctly maintained, but not necessarily traceable to individual results? If the former, then where exactly is the limitation on what is required to be traceable? It is our hope that TNI will consider a cost to benefit comparison in their deliberation on this SIR.

Thank you for your consideration of this issue.

From Chris Gunning:

Good morning all,

This question feels like déjà vu for me here as we at A2LA debated this exact clause nearly a year ago at our annual meeting of the Life Sciences Advisory Committee. This one is a hard topic to draw the line in the sand as to what equipment must be traced to an individual test per 4.13.2.1 but let me explain my reasoning as to how A2LA has answered this question.

We first must go to 5.6.1 which states that:

All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established programme and procedure for the calibration of its equipment.

This clause is stating that if it is determined that the equipment has a significant impact on the test, then we need to calibrate it.

Then we can go to 4.13.2.1 which states:

The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original.

This clause requires the lab to record factors that affect the uncertainty and allow the test to be performed as close to the original as possible. Therefore we reasoned that if clause 5.6.1 told us that we need to calibrate equipment that has a significant effect on accuracy, then this same equipment affects the uncertainty and is important enough to be recorded and traced to the test. So we decided that if the standard or our policies required a piece of equipment to be calibrated, then it would follow that this equipment was deemed to have a significant effect on accuracy of the test per 5.6.1 and would have to be able to be traced to specific tests per 4.13.2.1. This was a black and white answer that we could give our labs and assessors. If it must be calibrated, then it must be traceable to the

test. Otherwise you have this type of argument on each piece of equipment and its importance to the result.

This then will raise the question as to are we being overzealous when prescribing what equipment must be calibrated versus verified, but that is a question for another day.