Quality System Expert Committee (QS)
Meeting Summary

January 29-30, 2019

1. Roll Call:

Paul Junio, Chair, called the meeting to order at 8am Central on January 29, 2019 and January 30, 2019 in Milwaukee, WI and by Webex. Attendance is recorded in Attachment A – there were 10 members present on January 29th and 8 members present on January 30th.

2. **January 29, 2019 (Tuesday)**

Paul reviewed the work the committee did to organize the 2016 Standard into the ISO/IEC 17025:2017 format. He reviewed each section on screen and invited people to make comments.

- It was asked what the difference is between an Example or a Note? Chris commented that they are both not assessable.

- Marlene Moore – Looking at Section 4.1.8. She thinks some of the information the Committee put in Section 4 belongs in Section 6.

- Additions to Technical and Quality Manager language should be made – shall appoint, however named, (s) – duties can be performed.

- Steve Arms – Asked if there is a system for track changes that helps someone know where the language came from? Paul will see if he can somehow add this.

- Michael Michaud – Section 5.7 g) He noted that this should be everyone in the lab – not just the Quality Manager.

- Chris noted that the intent of the 2017 version was to spread some of these responsibilities and that is why they removed the name Quality Manager in the new version.

- Marlene Moore noted that management should designate a person to do these things instead of using the term Quality Manager. Paul noted that he thought at the NOLA meeting the agreement was that the Committee should keep the concept of Quality Manager and Technical Manager.

- Steve Arms – Are we trying to preserve only TNI language from the TNI 2016 Standard or also language from 2005? If we are trying to preserve 2005, why? Don't we want to write a Standard that is better than the current Standard. Paul noted the

Committee started by moving TNI language and then they will look at the 2005 ISO Standard and see if something still needs to be added that is missing in 2017. Steve continued that maybe there is a reason it was removed from the 2017 and this should be seriously considered.

- Aaren Alger – She thinks they should continue to use the ISO Standard as a base, but noted TNI is not ISO. The majority of the labs she accredits would not be able to pursue ISO if it weren't for the TNI language. It is important to write a Standard for our community. If we just leave ISO, why do we exist? Need to look at value for everything added. Just because it was removed from ISO … we shouldn't automatically cut it.

- Michelle – Introduce new topics now and still keep what people are familiar with.

- Stacie Crandall – Don't muddy the waters. Say what you mean to make it clear. There is no problem stating you have to have a Quality Manager with these requirements. Think about who the audience is. You cannot hand someone an ambiguous standard. The main users of the Standard are not here this week.

- Ray Frederici – The new ISO language is impartial. You can get rid of the Quality Manager term. We are keeping some of the old stuff, but not clicking with the new 2017 Standard.

- Sheri Heldstab – Need to define "absent". People stay connected to their labs when they are not there – with technology you are not "absent". Chris commented that it should say absent for a specific time period.

- Aaren Alger – What is the function of the Technical Manager? What is supervision? Keeping in touch with LIMS may not be enough. Seeing emails may not be enough. PA has labs define what absent is and then they evaluate it. They have people that want someone to have oversight at multiple locations. PA want to see them and sometimes they approve them and sometimes they don't. Maybe ABs need some training on this. She would not use the term "unable to work". Paul is trying to use language that prevents people from constantly having to check in with the AB. PA is 21 days. Kristin (Utah) is only 15 days.

- Jessica noted that she works with labs that she only visits once a month.

- Stacie Crandall – the goal is make sure the lab functions as it should when the Technical Manager is absent. Is work functioning normally? She feels the current language is overly proscriptive. The goal is to ensure the business proceeds as normal – not to check itself.

- Kathi – Unable to provide adequate supervision or oversite? Stacie Crandall – it should read that the lab has to show there is still adequate supervision – back-ups? It is currently overly proscriptive. Earl commented we want a system that works.

- Michelle – Want to take the burden off the AB, but it is their role to decide if the lab is meeting the requirements.

- Chris thinks it is covered already and it should be taken out. 6.2 ensures adequate personnel. ISO took out requirement for deputies, but if we leave this in … shouldn't this cover it.

Marlene Moore – She thinks this is too proscriptive. Someone out 16 days … is it a finding? She thinks it is in the current standard because EPA wanted something in the Standard that if a QA Manager or Technical Director cannot do their jobs, there needs to be a replacement appointed. She thinks this is covered in other language too. They need a system for handling this type of problem.

The deputy needs to meet the same requirement of QA Manager or Technical Director.

Dorothy Love – She agrees with Stacie and Marlene. You have to have a process or a plan in writing. If the plan is that they are on Skype or some other means of communication and it works, it should be OK. If they are in the hospital or they left the company, you have to notify and name someone else. How is the work going to be covered? Don't give specific number of absent days.

Section 6.2.2

Technical Manager requirements will be discussed tomorrow. We will not get into this today.

Section 6.2.5

- Christ suggested under d) that something be added to address the comments above.

- Move Section 6.2.4 quality manual requirement to QA Manager duties. Move to 5.7. Or perhaps because there are other requirements to keep documentation current – maybe this is redundant?

- Aaren Alger – Just wanted to point out that adding (h) for a requirement that is already there may be a waste of resources. PA uses a system for RESERVE.

- Marlene Moore – The management has to ensure the quality manual and all documentation is current. Remove requirement that it has to be done by a specific individual. (Document Control at 8.3).

Section 6.3.4

- Does periodically need to be defined? General agreement this should not be made more proscriptive.

Section 6.5.2

- Paul commented if we are purchasing supplies from someone who is ISO accredited, shouldn't we be able lean on that ISO accreditation and some requirements are not needed?

- Scott Siders – Raised some concerns that Section 6.5.2 may cause confusion for labs and they may need help to understand it. Paul asked Scott to submit some ideas for clarification.

- Ray Frederici – Track firmware version of PCs? How many people are able to do this? What does this have to do with all of this? If the equipment is running properly – why do you need this? It is firmware and is not changing. Michelle noted that there may be opportunities for some firmware to be updated. There are differences in abilities of different firmware. She does not think this should be removed. Aaren Alger put thumbs up.

Jessica – Need to be sure firmware is not part of a recall. She thinks it needs to be kept.

Section 6.5.4

- e)i) – Need to check correct reference.

- Marlene Moore - Put support equipment under equipment – not under metrological section.

- Sheri Heldstab – Fridge thermometers, IR gun thermometer (3 pts) – quarterly checks. How close do these have to read? Apply correction factors. DW certification manual has recommendation of 1 degree. Thermometer needs to be calibrated to a NIST.

BREAK

Paul turned on Track Changes so it is now clear on screen what is TNI language.

Section 6.6.1

- Marlene Moore - Section 7.1.3 is talking about the specification. This involves decision rules. It is extremely important for RCRA, not important for DW and not as important for NPW. Steve Arms – They put a flag on a result when there was a violation on an MCL – so he does think it applies to DW.

- Marlene Moore – If a lab makes a statement that your water is safe to drink – then they have to do this. The MCL and significant figures comes in later in the Standard

under technical competency. This is about pass and fail. You have to have an agreement with your client what is pass and fail and this is where this section comes in.

- Cathy Westerman – The glossary needs to become part of the Standard so they can get to definitions. They need to be in the Standard so they are enforceable. Paul asked if you can regulate to a Definition. Cathy does.

- Stacie Crandall– We talked about maybe there is not a need for a QA Manual …. Do you want to add this specificity for SOPs? Isn't this an issue for small labs? Does TSD really need pollution prevention? Paul invited Stacie to submit some language. She asked the attendees if they agree … there was quite a bit of agreement. It was pointed out that this is "where applicable" should be considered. Stacie still thinks this is an issue because a new lab sees this all as a requirement.

- Paul questions if Safety needs to be in the SOP? Scott Siders said there is a reason.

- Jessica – TNI has templates for SOPs – perhaps point people there instead of having it in the Standard. Ilona noted these templates are available for sale and are in the Small Laboratory Handbook.

- Stacie Crandall– Commented she had to re-do 100 SOPs. How do you decide what is applicable?

- Scott Siders – We have an opportunity to move to a new Standard and think about what we want to keep and don't. Now is the time to be thinking about these things.

- Paul noted that the committee has to have a consensus on what is removed or changed in the new Standard. That is part of the reason for today … getting input from attendees to help them make these decisions.

- Marlene Moore – This was put in the Standard because this is how EPA methods were written. This has been changed. We should specify what should be in an SOP instead of giving people headers. Need to make it clear administrative and technical SOP needs are different.

- Jessica – Lists are intimidating to new labs, but she also thinks it is intimidating not to have a list. Stacie Crandall agreed.

- Sheri Heldstab – Should this be moved to the section where SOPs are discussed – 5.5.c)?

- Marlene Moore – It hould go under document control. Leave technical SOPs where it is and move administrative under document control.
- Kirstin Daigle – It is not a requirement for an SOP format – people are just misinterpreting the Standard. Should state in the Standard that this is not a format. A

lot of the SOPs are written for the assessors, but they should be written for the analysts.

- Ilona emphasized that language being looked at today is the first time the committee is looking at this – no decisions have been made. This is the time for input.

- Kirstin suggested reorganizing the sections in this section. 7.2.1.2. - Make it clear this section is only for test methods and e) should be moved up. The first sentence needs some work to make it clear what it says. The assessment experience is not collaborative and assessors do come in with strong ideas on how it should be done. It needs to be clear. Reorganize this section. Address administrative SOPs in a different section. EPA G6 and the TNI template are examples to help develop administrative SOPs.

- Alfredo Sotomayor – This is a mash of old and new. Is there a goal of what this update is to accomplish? Is it to simplify the Standard? We are debating the merits of what to add or delete. You need an overlying goal for how/why you make your decisions.

- Scott Siders – He assumes that the Committee sets its goals and objectives. Is it auditable or assessable? Remove redundancy? If the Committee establishes goals up front … it drives them. Language needs to be enforceable.

- Jessica – The Committee doesn't write the Standard alone – it is written with lots of input. Jessica wants clarity in the standard.

- Michelle – now that the language has been moved – the committee will work on moving language and setting goals. This was is just the place to start.

- Marlene Moore – Section 7.2.1.3 - We can't always use the latest version of a method. It still needs to say that regulatory requirements trump.

- May need to pull more TNI language over into the DRAFT. Section 1 and 2 are not pulled over.

- Kristin – Also based on Project DQO's. There are conflicts sometimes between projects.

- Marlene Moore – Can a lab say sampling is or is not a part of our accreditation?

- Ilona noted there is a Task Force that may be providing input on this section too. Field Activities Task Force.

- Aaren Alger – They don't accredit for sampling, but they have the authority to make labs follow regulatory requirements. They can still lose accreditation on a test if they have problems with the sampling. They have to have DOCs for Sampling

(Note: Get a copy of PA's guidance document about Sampling – guidance if lab does or does not do the sampling.)

- Paul commented that maybe there could be guidance from the NELAP AC on how they would like this section addressed. Section 7.3.2.

- Sections under 5.7.4 could be deleted because it is covered in the language above.

- Sheri Heldstab: Where it says irrelevant – can you define this? If the lab didn't do the sampling … does that make it irrelevant? Paul commented that the lab would still need to state something – perhaps point to the organization that submitted the sample? Kirstin would define it in her quality system.

- Bob Wyeth – Why does this section on sampling requirements have to be here? He suggested moving it.

- Silky Labie: Asked why this can't be exempted for lab accreditation? Just exempt the whole section.

- Marlene Moore: This is a tough one. This can be done by labs or FSMOs. If you get into ISO/IEC 17011 you only assess what the AB recognizes. She commented that PA example may be an issue under 17011?

- Kevin Holbrooks invited people to the Field Activities Committee (FAC) meeting at 1pm where FAC will be continuing their work of placing the Field Standard into the ISO/IEC 17025:2017 format.

The review ended at Section 7.4.

The meeting was adjourned at 11:58pm Central.

3. **January 30, 2019 (Wednesday)**

Technical Manager Qualifications

Paul shared a document that summarizes some of the discussion and ideas received and discussed by the Committee regarding Technical Manager qualifications. Nothing has been finalized and the purpose of the meeting is to get feedback from more people. This document is included below and has the following key for text colors:

Black – Current 2016 TNI Standard language
Red – Ideas suggested for addition to the standard or discussion topics for today
Blue – Notes/comments during this meeting

6.2.2.1 Technical Manager Qualifications

The applicable requirements for technical managers are given below.

a) Any technical manager of an accredited environmental laboratory engaged in chemical analysis shall be a person:
with a bachelor's degree in the chemical, environmental, biological sciences, physical sciences or engineering Could this be opened to a broader number of degrees.

[EDIT – what about this list - in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public health engineering, natural or physical science; or this list [- in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering; or this list - in chemistry or a biological science; if the bachelor's degree is in a field other than chemistry or a biology science, the individual should have college-level credit hours sufficient to qualify for a minor in chemistry or biology]; and [edit – need a well-defined job description to the function of the position – probably falls on the laboratory; edit – accredited degrees as opposed to non-accredited degrees needs to be addressed; foreign or other degrees need vetting of some sort – translation service exists (example language - *TRANSCRIPT REQUIREMENTS - Candidates MUST submit a copy of their official college or university transcript(s) indicating completion of the educational requirement at the time of application. Transcripts MUST indicate conference of the appropriate degree. Candidates with a degree from foreign colleges or universities must submit proof of degree as certified by a professional evaluation service.*

Association of International Credential Evaluators, Inc.

http://aice-eval.org

Two providers:

North American Educational Group

International Educational Credentials
450B Paradise Road U#254
Swampscott, MA, 01907
info@NAEG.org
Tel: 1-888-539-2804
http://www.naeg.org

Scholaro

https://www.scholaro.com/reports/Transcript-Evaluation

i.)]

ii. with at least twenty-four (24) college semester credit hours (or at least thirty-six (36) college quarter credit hours) in chemistry; and

Paul - Is 20 hours OK?
Elisa Snyder – her college was a minor in Chemistry – 23 hours – so she was missing one credit. There is no consistency in credit hours between colleges.
Stacie Crandall – What is the goal? She feels like the Committee is dipping into her job descriptions. Paul noted that ABs do not want it to say that it is up to the lab. Stacie thinks it should talk about competency. Some analysts come up through certification programs – not college. There is a disconnect between what we are doing and what is happening in this industry. Does the lab have leadership to meet the Standard? Paul noted that there is an exemption for licensing. Stacie asked if the education requirement is a barrier for states to come on board. She said it also impedes her ability to do business. Stacie would like to get away from box checking. Why is someone with 30 years experience not as good as someone with a college education?
Kirstin Daigle – Experience is as important as education and it should be considered. This is a designation – not a job description. It needs to change. It is too proscriptive.
Michelle – reminded everyone that everyone has to agree to this. The ABs need to be on board with any changes.
Scott Siders – This Committee, stakeholders and ABs have the opportunity to correct a mistake. They currently have to turn away qualified candidates. Scott is concerned that his comments are not reflected in what is on screen. There is time to do this. The ABs are missing the mark if they don't do something.
Silky Labie – All the Technical Directors that were grandfathered in at the beginning are now retiring and labs are struggling to meet these requirements. Silky has been in a wastewater lab with a high school graduate lab director/technical director that had a system that was impeccable. It was a small lab – 1 person – open 3 days a week. She's been in other labs with Technical Manager/lab directors that are good analysts, but quality systems were awful. In another lab she found a Technical Manager that failed the chemistry classes, but had credits – she ran a great program. If the lab meets the Standard – does it matter what degree the person has?
Katie Kohoutek – If she took a class in a department outside of chemistry – could it still be counted as hours? A degree or a certain number of years of increasing responsibilities should be considered. Instead of all the "AND" … how about some "'OR".
Judy Morgan – She read out of the DW Certification manual. Do we know what the minimum acceptance is from the ABs. Maybe this would help drive this process. Need a base line of where to start. Paul noted that the minimum assessor requirements are going up and the minimum technical manager requirements are going down. Paul – just leaving it to the labs is not going to fly.

Eric Davis – Who are we writing the Standard for? He feels the ABs are strong arming the labs. The ABs are not compromising anymore. It is frustrating. What is the minimum? Again we are asking the ABs. We need to ask the labs what they need. He understands the ABs need to assess it. The SOPs and job descriptions should be written for the lab and not the assessor. Requirements should be written to make the lab better. It has been frustrating working on the Chemistry Standard because everything they sent to the NELAP AC was rejected. Finally asked what do you want?
Michelle – Kansas's regulations had things in it that stopped her from making changes when she was an AB. ABs are often bound by what they can and cannot change in their states. Making changes is a difficult task. They can't adopt anything that goes against the regulations in their state.
Sheri Heldstab – She has a small lab – less than 10 people. This should be scrapped. She liked what Judy read. She has fired analysts that met the requirements. She hired someone with a biology degree with a minor in chemistry … and they were awesome. Does my college degree from 35 years mean anything? Is this pertinent? Technology has changed so much. Technology is changing fast.
Deb Waller (AB) – If it is relaxed too much – NJ would not stay in the program. She likes the idea of increasing responsibility over time.
Judy Morgan – Looking at the qualifications the degrees look scientific. Why do we need to specify a certain number of hours in Chemistry? Why not just leave it to the degree? Why focus on certain subject matter? 24 hours of science courses.
Jessica – What about statistics? She would like to see it go to having the ABs approve the courses. She cautions again that we need to put something together that is auditable for ABs and works for the labs.
Scott Siders – You have had lots of comments – this Committee needs to go back and start from scratch. This is the topic that is resonating with lab management because it is affecting how they can do their business.
Earl – Asked if ABs can work on this outside of the box.
Chris – When they train assessors and labs – they say the Standard is for the labs. It is about demonstrating competence … not demonstrating degrees. It makes his job harder as an assessor. Outside of TNI, the lab determines the requirements and the assessor sees if it works.
Sheri Heldstab – She thinks it should just say degree.
Chris – The lab should set education requirements.
Bob Shannon – He is not qualified to be a technical manager. These requirements should be effective. Judy's language is effective. It opens the door for an assessor to review the effectiveness. What matters is whether the lab is running well. Bob has taught more chemistry than what he has taken at the university.
Michelle – ABs have the mutual recognition policy. If we make the requirement too subjective, this might affect reciprocity. You can't take away the state's rights – so another state could disagree.
Eric Davis – There is already lots of subjectivity in the Standard. He would like to see more give and take. There needs to be some trust.
Jessica – There is a misconception that the ABs don't want a change here. Labs want it gone and there are ABs that want it as it is … but there has to be some give.

Robin Cook – The standard is written for the labs so we know the expectations. We need to find the middle ground. Taking away too much removes uniformity. Need to keep in mind that if this change is made … it would take a lot of training to keep uniformity.
Kirstin Daigle – One state used to be very effective in NELAP and their regulation required 24 hours. The NJ tiered blue book is a great option. The QS Committee should look at it as an option.
Ray Frederici – There were no ABs back when this was written. There were ABs that said they wouldn't become ABs if this didn't get written as it was.
Michelle – reminded the Committee that they had discussed a course possibility.

iii. and at least two (2) years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

b) Any technical manager of an accredited environmental laboratory limited to inorganic chemical analysis, other than metals analysis, shall be a person:
i. 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; and
ii. with a minimum of sixteen (16) college semester credit hours (or at least twenty-four (24) college quarter credit hours) in chemistry; and
iii. and have at least two (2) years of experience performing such analysis.

c) Any technical manager of an accredited environmental laboratory engaged in microbiological or biological analysis shall be a person:
i. with a bachelor's degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering; and
ii. with a minimum of sixteen (16) college semester credit hours (or at least twenty-four (24) college quarter credit hours) in general microbiology and/or biology; and
iii. at least two (2) years of experience in the environmental analysis of representative analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

A person with an associate's degree in an appropriate field of the sciences or applied sciences, with a minimum of four (4) college semester credit hours in general microbiology may be the technical manager(s) of a laboratory engaged in microbiological analysis limited to fecal coliform, total coliform, E. coli, and standard plate count. Two (2) years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree. In addition, each person shall have one (1) year of experience in microbiological analyses. [ed – less complex tests? What should be the limitations here? New requirements/analyses don't get addressed]

d) Any technical manager of an accredited environmental laboratory engaged in radiological analysis shall be a person:
   i. with a bachelor's degree in chemistry, environmental, biological sciences, physical sciences or engineering; and
   ii. with twenty-four (24) college semester credit hours (or at least thirty-six (36) college quarter credit hours) of chemistry; and
   iii. with two (2) or more years of experience in the radiological analysis of environmental samples. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year experience.

e) The technical manager(s) of an accredited environmental laboratory engaged in microscopic examination of asbestos and/or airborne fibers shall meet the following requirements:
   i. For procedures requiring the use of a transmission electron microscope, a bachelor's degree; and
      a. successful completion of courses in the use of the instrument;
      b. and one (1) year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.
   ii. For procedures requiring the use of a polarized light microscope;
      a. an associate's degree or two (2) years of college study; and
      b. successful completion of formal coursework in polarized light microscopy; and
      c. one (1) year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.
   iii. For procedures requiring the use of a phase contrast microscope, as in the determination of airborne fibers:
      a. an associate's degree or two (2) years of college study; and
      b. documentation of successful completion of formal coursework in phase contrast microscopy; and
      c. one (1) year of experience, under supervision, in the use of the instrument.

f) Any technical manager of an accredited environmental laboratory engaged in the examination of radon in air shall have:
   i. at least an associate's degree or two (2) years of college; and
   ii. one (1) year of experience in radiation measurements; and
   iii. at least one (1) year of experience in the measurement of radon and/or radon progeny.

The Committee also started drafting language for discussion in Section 6.2.2.2. He reviewed this modified section and asked for feedback. The new language is not highlighted.

6.2.2.2 Technical Manager Qualification Exceptions

a) A person who has passed a course offered by an organization such as WEF, AWWA (whether local or national) or TNI for managing or operating a laboratory appropriate to the nature and size of such facility shall be deemed to meet the educational requirements as the technical manager. A technical manager shall have two (2) year testing experience devoted exclusively to the testing of environmental samples specified in the scope of the facility's regulatory permit. Such accreditation for a water treatment facility and/or a sewage treatment facility shall be limited to the scope of that facility's regulatory permit. [edit – address lab scope and size as well, not just for treatment facilities]

Paul asked – what if there were courses? The courses don't necessarily exist and would need to be developed. It could be an exemption?

Scott Siders – The importance is the quality system. What is being suggested is the same as someone having to go out and take some chemistry classes.
Michelle – How is this different than assessors having to take courses to be able to do assessments? This is an opportunity that a lab person could take without having to go back to school. If something like this exists – wouldn't it be helpful?
Scott Siders – He used to be an AB assessor. TNI did what they could to make sure assessors are competent through their Standards.
Kirstin Daigle – She thinks assessor qualifications are different than technical manager. What would the course include? Would it need to be standardized? Raises more questions. Are the AB requirements because of what is in the Standard?
Deb Waller (AB) – They wanted a pathway for someone to show that they are qualified. They wrote – we have the right to waive anything in the rule if the person meets the requirements. The primary AB should review the personnel. It is their job to protect their state. They also need to take secondary into consideration. Add this simple sentence.
Michelle – this was thrown out – leave it up the ABs. No one seemed to like it.
Andy Valkenberg – DW manual requires Quality Manager to have a degree. He knows someone with 18 years experience – but no technical experience. He has a team that supports him. If you don't meet these requirements – you need a letter from the primary AB that they accept the qualifications of the Quality Manager. Look at demonstrating competency.
Judy Morgan – There are people that would have to take this course that could teach the class. Her degree is in Chemistry, but it doesn't help her manage a lab. She again emphasized that she wants to look at what the minimum is.
Stacie Crandall – Have we asked what the ABs want? Paraphrase – they don't want to have to decide on a case by case basis who meets the requirements. She would like to talk about a systematic approach. Isn't the technical manager's competence shown by having a lab that meets the requirements of the Standard? She doesn't have their transcripts in the lab … they are maintained by HR. See what the ABs want and work towards a systematic approach. Remove the band-aids.
Sheri Helstab – What is the purpose of chemistry hours? What is the purpose of using 17025 in this standard? Aren't we looking at more outcome based?

Paul noted that the general consensus in the room is to throw it all out and go to ISO/IEC 17025:2017 and add to that as needed. We don't have a deadline. He is not sure this will be accomplished in 3 years. There is paranoia about risk. It is new and we are trying to get used to it. Robin asked if the committees should keep working on this? Paul said yes. Maybe they will come up with the better solution.

Jessica noted that we should talk to all the states – not just NELAP.

Paul went back to the Standard and read the intro to Section 6 and 6.2.3 and 6.2.4, 6.2.5, 6.2.6. Start with just the ISO/IEC language.

Scott Siders – sent in comments to the Committee. This is the part of the Standard that captures it. This is a volatile issue that is impacting labs. This may be something that we need to expedite through TNI.
Kristin – lets start here and work through this.

The committee will go to Section 6.2 and talk to ABs about minimum requirements.

Katie – for starting point – great to start with ISO. Instead of taking a poll – make a list of all the state requirements. Look at what is required.
Andy Valkenberg – DW manual and EPA regions should be considered. CWA too.

Ilona suggested putting together a list of specific questions before people start sending in information.

Michael Michaud - There are some programs that have courses that help people meet requirements. He suggested looking at Texas.

b) Notwithstanding any other provision of this Section, a full-time employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational requirements as the technical manager. A technical manager shall have two (2) year testing experience devoted exclusively to the testing of environmental samples specified in the scope of the facility's regulatory permit. Such accreditation for a water treatment facility and/or a sewage treatment facility shall be limited to the scope of that facility's regulatory permit.

c) A full-time employee of an industrial waste treatment facility with a minimum of two (2) years of experience under supervision in testing of environmental samples taken within such facility for the scope of that facility's regulatory permit shall be deemed to meet the requirements for serving as the technical manager of an accredited laboratory. Such accreditation for an industrial waste treatment facility shall be limited to the scope of that facility's regulatory permit.

d) Persons who do not meet the education credential requirements but possess the requisite experience of Section 6.2.2.1 shall qualify as technical manager(s) subject to the following conditions.

i) The person shall be a technical manager of the laboratory on the date the laboratory applies for accreditation and/or becomes subject to accreditation under this Standard, and shall have been a technical manager in that laboratory continuously for the previous twelve (12) months or more.

ii) The person will be approved as a technical manager for only those fields of accreditation for which he/she has been technical manager in that laboratory for the previous twelve (12) months or more.

iii) A person who is admitted as a technical manager under these conditions, and leaves the laboratory, will be eligible for hire as a technical manager for the same fields of accreditation in another accredited laboratory.

iv) [edit – leave open to the AB to approve a person by overriding these requirements]

BREAK

Standard Interpretation Requests (SIRs)

The topic for the second half of the meeting was SIRs. Paul pulled up the SIR table the committee looked at when it reviewed the SIRs for possible relevance to writing a new standard. The committee looked at each item to determine whether an SIR should just be left in place or whether the Standard could be changed in such away to address the SIR. A summary of comments can be found in Attachment D.

Discussion:

SIR 79 – This one is more of a compliance issue – not clarification.
Kirstin Daigle – If the TNI logo is on the report … it is an issue. It is not required if TNI requirements are not needed. She does think this does cause confusion for clients.
Bob Wyeth – Need to be careful with wording. It is a problem to say you are not TNI accredited for a parameter – the client might think you are not accredited at all.
Judy Morgan – What is the intent of it? What is the purpose?
Paul is not sure that this is a requirement. The attendees think this does not to be fleshed out more.
Silky Labie – If the TNI logo is on the report – they do need to follow the requirement.
Paul commented that perhaps this is one that needs implementation guidance.
Robin Cook – It only becomes an issue if you are not certified for something.
Jessica – They use different reports depending on what the lab is certified for. There needs to be some clarification because people are confused.
Valerie Slaven – They put it on there. It is easier to include it. Easier for data user too.

Bob Shannon – Isn't there a requirement that the method used is clear.

302 – Address 302 in the Standard when you address Technical Director.

180 – Address
Judy Morgan – We use it as a specification Standard. ISO uses it for anything that drives how you do something – it can me a method.
Kirstin Daigle – It presumes the client always needs the latest version. It may not be what is required.
Scott Siders – There is a big out in the language.

21 – Not being addressed. Method issue.

66 – Needs a note or reference to Module 6 in the Standard. Is there an issue for WET too? Sheri Heldstab will send more exceptions.

Bob Shannon – in Radiochemistry – uncertainty is a requirement. It would make sense to make a note about Radiochemistry requirements.
Silky Labie - You can just reference to the method.
Bob Shannon – in Radiochemistry – the requirements are not necessarily just method driven.
Sheri Heldstab – will send comment – more exceptions
Andy Valkenberg – The lab has to have a procedure how they do it. Wouldn't this all be addressed already?

270 – Done

274 –
Judy Morgan – They have a response from NIST that only glass can be Class A. The plastic "Class A" only says it conforms too. It is not Class A.
Kathi Gumper – she noted that there is plastic that can go above 180 degrees.
Jessica – It will say – marked as Class A.
Bob Shannon – asked if a footnote needs to be added?
Bob Wyeth – It says glassware.
Eric Davis – Definition is buried somewhere in ASTM.

304 – SIR is still valid. No clarification will be made.

Judy – Gas tight syringes do fail. They need to be verified.

206 – no need to address

290 – Judy thought it didn't get posted. Need to work on this.

77- SIR still valid – Clear in the Standard – no more work being done.

124 – SIR still valid – Clear in the Standard – no more work being done.

192 – SIR still valid – Clear in the Standard – no more work being done
You have to deal with finding if you can't access it.

198 – SIR still valid – Clear in Standard

251 – SIR still valid – Clear in Standard

43 – SIR still valid – Clear in Standard

38 - SIR still valid – Clear in Standard

246 – Will look at again. Need to see final language approved.

81 – SIR still valid – Clear in Standard

105 – Canceled.

The meeting was adjourned at 12pm Central.

(Addition: Jerry has requested that each Expert Committee use the same format to summarize the status on each SIR. The table was distributed to each Expert Committee and is due before the summer meeting. The Quality Systems Committee will take the table in Attachment D and summarize the information in the new table and provide any new information needed.)

4. Action Items

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

5. New Business

   None.

6. Next Meeting and Close

   The next meeting will be on Monday, February 11th at 1pm Eastern. 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 January 29th meeting at 11:58am Central and the January 30th meeting at 12pm Central.

Attachment A

Participants
Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Paul Junio (Chair) **Present – 29 and 30**	Northern Lake Service	2019	Laboratory	paulj@nlslab.com
Jessica Jensen (Vice Chair) **Present – 29 and 30**	Meridian Analytical Labs	2021	Laboratory	jessica.j@meridiantesting.com
Kristin Brown **Present – 29 and 30**	Utah DOH	2021	Accrediting Body	kristinbrown@utah.gov
Lizbeth Garcia **Absent**	Oregon Dept. of Environmental Quality	2019*	Accrediting Body	LIZBETH.GARCIA@dhsoha.state.or.us
Kathi Gumpper **Present – 29 and 30**	ChemVal Consulting	2021*	Other	kgumpper@chemval.com
Chris Gunning **Present – 29 and 30**	A2LA	2021	Accrediting Body	cgunning@a2la.org
Earl Hansen **Absent – 29 and 30**	Retired	2021*	Laboratory	papaearl41@hotmail.com
Jenna Majchrzak **Absent**	NJ DEP	2021*	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Jacob Oaxaca **Absent**	California State Water Board	2019*	Accrediting Body	Jacob.Oaxaca@Waterboards.ca.gov
Shari Pfalmer **Present - 29**	ESC Lab Sciences	2021	Laboratory	spfalmer@esclabsciences.com
Dale Piechocki **Present - 29 and 30**	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 – 29 and 30**	Wade Consulting	2021*	Other	michelle@michellefromks.com
Alyssa Wingard **Present - 29**	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	
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	Complete
59	Review Milwaukee minutes and add to Parking Lot list as appropriate.	Paul/Jessica	4/8/19	
60				
61				

Attachment C

Backburner / Reminders – QS Executive Committee

	Item	Meeting Reference	Comments
1	Review charter in November 2018	Ongoing	Ongoing

Attachment D - SIR Summary Table (minus date and Standard references)

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
158	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	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

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
13	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	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

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
70	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	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	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,	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

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
230	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	see 308			see 308
64	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	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	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	This section was edited in 2009 but the SIR is still valid.	This relates to SIR 323 which was rejected as an SIR. There needs to be clarification that the Standard DOES NOT apply where it has not been requested or where it isn't the regulation of the land. As it relates to this	question of clarity, not enforcement, so a NOTE isn't exactly an issue

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
154	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	This response was not what QS submitted - it was the response to a different SIR. The submitted response was: Comment - 4.2.8.4 r) The quality manual shall contain or reference: policy addressing the use of unique electronic signatures, where applicable 4.13.3 Additional Requirements f) All information necessary for the historical reconstruction of data shall be maintained by the laboratory. viii) analyst's or operator's initials/signature or electronic identification; See V1:M2 4.2.8.4(r) Response: Electronic signatures are acceptable (see references above). Note: a signature must be unique to the individual. Some states may have regulatory requirements pertaining to the use of electronic signatures. The laboratory should ensure that state requirements are met.	

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
101	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.	17025-2017 8.3.1 has a note to address this. QS should identify the note as a required list and add these items (instrument manuals and equipment manuals) as among the required items.	
18	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	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	No change in language in 2009 ar	address - 17025 addresses the outcome of, not the timeframe between, assessments	risk
115	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	This language is unchanged in the 2009 and 2016 standards. The SIR is still valid.	address	

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
82	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	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	archive
79	LAB'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?	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 - try to clarify the requirement / expectation	depends on the accreditation claims made by the report - statement of 'TNI accreditation not required for this analyte/project/something'
16	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-	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	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.	maintain the language from 5.10.11 b) in its new location (possibly within 7.8.3.1)	

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
93	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.	How would a NOTE be received indicating that reporting requirements to this level are not addressed by the Standard, but should be verified with the end user? Talk to the AC for advice. Capture the scope of accreditation	if requested or required, the revision number however specified

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
296	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. And on the same topic, the 2009 standard for (c) below for limited microbiological analytes also no longer contains the wording "environmental" and just states "microbiological analyses", so may this also be interpreted as any	The terms "such analysis" indicates that the technical manager shall have experience in the fields of accreditation for which the laboratory is seeking accreditation. The experience required is of environmental analysis in the first question, and environmental microbiological analysis in the second. In both cases, the Standard requires that the analyses performed which would qualify as experience are those that would be performed by the laboratory at which a person would be the technical manager.		come back to this one	

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
212	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 : What is the difference between "..experience in the environmental analysis of..." , as stated in paragraph a and "...experience performing such analysis", as stated in paragraph b. Question #2 : relating to the interpretation of "representative organic and inorganic analytes".... to what degree does methodology/technology coming in to play. Can the word "representative" be better defined? We do not find anywhere in the document that requires	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 methods. A Technical Director must have experience in the typical methods/technologies used by the laboratory.	This language is unchanged in the 2016 standard. The SIR is still valid.	This strikes me as a complaint about Technical Manager requirements more than an SIR.	address
302	Please clarify 16 hours of microbiology and biology Is it 16 hours combined total of microbiology and biology?	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.	Bulleting each of the requirements into separate points would clarify each of these as requirments	

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
180	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	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	This language is unchanged in the 2016 standard. The SIR is still valid.	Has this been addressed in an FAQ or through Technical Advice? If so, that language should be added for clarity (2003 maybe?) There are 2 different SIRs relating to 5.4.2	

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
21	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	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*	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.	This should not be an SIR, but a method interpretation	agreed

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
66	Please explain what types of procedures for estimating uncertanity 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	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.	17025-2017 7.6 addresses uncertainty in greater depth than the previous Standard. I don't feel that the Committee intends to reply with a how-to document.	note that radiological requirements are well defined and are addressed in Module 6, and may also be addressed by WET methods
270	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	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.	We should add language addressing single use items as needing to be checked once per lot. EDIT SINCE NEW ORLEANS - we already did this	done

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
274	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.	done	

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
304	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. We're hesitant about using DI water to perform the quarterly checks on these syringes because they're used for preparing gas standards and we're unsure if moisture in the syringe would affect standard preparation. We're also unaware of how we could complete the quarterly checks using air. Our syringe vendor only offers a verification certificate for newly purchased syringes. For these reasons, it may be impractical to complete quarterly checks. As I understand it, glass microliter syringes do not require quarterly checks because they deliver such	If the syringe in question is neither Class A nor a glass microliter syringe, then it must be checked for accuracy on a quarterly basis. The laboratory must have documentation on file of this quarterly check.	This language is unchanged in the 2016 standard. The SIR is still valid.	there seems an obvious difference between a microliter and non-microliter syringe	

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
206	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	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.	This has been addressed in a modification to the Standard and needs no further discussion or changes	

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290	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?	Awaiting AC Approval, but response was - TNI EL-V1M2 Section 5.5.13.1 b states "All support equipment shall be calibrated or verified at least annually, using a recognized National Metrology Institute, such as NIST, traceable references when available, bracketing the range of use. The results of such calibration or verification shall be within the specifications required of the application for which this equipment is used or: i) the equipment shall be removed from service until repaired; or ii) the laboratory shall maintain records of established correction factors to correct all measurements." The TNI Standard does not prescribe control limits which must be met in order for a piece of equipment, whether analytical or support, to be determined to be acceptable. TNI EL-V1M2 Section 5.5.7 states "Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of	This language is unchanged in the 2016 standard. The SIR is still valid.	This problem appears to be a technical issue and not a request for interpretation of the Standard.	

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232	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	Yes graduated cylinders, glass to-deliver pipets, and other garden-variety glassware, which are not Class A, must be checked quarterly		'garden variety glassware' is not equivalent to volumetric despensing device, which is where the requirement lies.	work to be done on suppo
39	Are electronic records sufficient for instrument maintenance? If not, can the electronic records be printed and indexed periodically	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	Although this section was slightly revised in the 2005 version of ISO 17025, the SIR is still valid.	electronic requirements - it may be addressed	

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73	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.	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	This languagae is unchanged in the 2009 and 2016 standards. The SIR is still valid.	support equipment needing clarification	
77	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	Althought this language was revised in the 2005 version of ISO 17025, the SIR is still valid.	done	
124	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	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	This language is unchanged in the 2009 and 2016 standards. The SIR is still valid.		done
192	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	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	This language is unchanged in the 2016 standard. The SIR is still valid.	done	
198	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	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	This language is unchanged in the 2016 standard. The SIR is still valid.	done	

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251	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	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.	verify that this doesn't conflict with micro autoclave cycle	

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43	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.	archive	

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38	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	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.	done.	

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246	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	about to be posted for AC voting (10/15/18)			

#	Actual Request	Final Response	Comment	Paul Comments	Outcome
81	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	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	The response discusses the differences between 2003 and 2009 (and 2016) and is still valid.	done	
105	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?	Cancelled January 2018 - direct to lab's AB			