

**Quality System Expert Committee (QS)  
Meeting Summary**

**Jacksonville, FL  
August 5 and 8, 2019**

1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 1:30pm Eastern in Jacksonville, FL on August 5, 2019. Attendance was: Earl, Kristin, Michelle, Kathi, Matt, Jessica, Dale, Alyssa, and Sharri (9 members).

Jessica, Chair, called the meeting to order at 9am Eastern in Jacksonville, FL on August 8, 2019. A phone line was provided during this meeting. Attendance was: Shari, Jessica, Kristin, and Michelle Phone: Matt, Jenna (6 members).

The slide presentation for the Monday and Thursday meetings can be found in Attachment A.

2. Monday – August 5, 2019

TECHNICAL MANAGER DISCUSSION:

Jessica presented the different Technical Manager requirements submitted by the various modules for consideration. She displayed them on the overhead.

Radiochemistry:

The in lieu is there for the people without the bachelors degree.

Paul pointed out that it is not an OR ... it is each one of these requirements.

Bullet point 2 - Wording – chemistry and physics – maybe should be and/or. This came up a few times. Could also consider: total credit hours in the combined chemistry and physics disciplines.

Shawn Kassner – How can an English major be qualified? Maybe it should be degrees and then you don't need all the hours? Comment: Too many universities have different majors.

Chemistry:

QS still needs to talk about what the number of hours that can be substituted should be. They will also be discussing the in lieu. Should be all relevant ABs? Not just primary.

Mei Beth – Environmental analysis may be too broad. It is everything that is not covered somewhere else? Needs to be more specific?

Kristin Daigle – The Standard makes it clear that it can be more than one person. She just wants to be sure this is not lost.

It was noted that these requirements don't address competency at all. Robin Cook commented that they needed to come up with something that could be looked at and the old language did not address competency either.

Aaren does not think this is a good idea.

Jessica asked for hands to show how many are able to find Technical Manager's that meet today's requirements. This is an issue for many labs.

Aaren is not opposed to something new, but she wants consistency. Education is the easiest way to do this?

If you are going to bring education requirement down, it should be replaced with manufacturer training.

Aaren would be more supportive if the last bullet was gone? Still need clear information on the substitution of education. This needs to be clear.

Scott Siders thinks Radiochemistry's hours are ridiculous. Too high. Scott thinks the Committee needs to look at what the Quality and Technical Managers actually do. Need to look at how well they fulfill their roles. Education doesn't represent whether they will do a good job.

Jessica noted that all labs are unique. It can't be one size fits all.

Kirstin Daigle thinks the number of hours for Radiochemistry would be difficult to find. People with those qualifications would be going into pharmaceuticals.

Could there be competency assessments for people filling these roles. Treat them like assessors.

Earl – we have to start somewhere. There have to be some basic qualifications. Then pertinent experience needs to count for something.

Bob Dizenzo – He is spending time with the ISO/IEC language and they put this on the lab. The lab has to demonstrate the competency.

Nicole – why do we have to define criteria like this? What about management training? We need to move more towards competency?

Others agreed they would like to see more flexibility for the labs to decide who is competent.

You lose the consistency if let the lab handle it.

Silky Labie: This is an improvement over what is there now, but she also thinks there needs to be a link to competency.

Chuck Nesslin – Educational standards should be maintained at a level that captures 90% of that bell curve.

Trinity –

She is from a municipality. They have a captive lab. The operators aren't required to have degrees.

Sheri Heldstab – They have an analyst that is an expert without a degree. The exception statement is needed. What happens with emerging technologies? Need to make sure you don't paint yourself into a corner.

Ken Lancaster – These are qualifications – not competence. You have to do the work and show you are competent. Texas feels the last bullet opens up too many requests.

Aaren – this creates a situation where the state has to defend their decision. They don't want to do this. Explain what experience can be used – give more info.

Chad Stoicy – ALS – He thinks the experience section is where the competency may come in. The Quality manager has specific items that they do and no qualifications are noted. Why can't this be done with Technical Manager. Are they doing what they are supposed to do? Michelle noted that the states do have to legally defend what they have to do.

Can't answer whether Module 2 Section 5.2.6.2 is staying in place because we haven't talked about it yet. Jessica thinks the exceptions should be there.

Scott really thinks competency should be the key item in writing these requirements. Put the absolute minimum of requirements. Minimum hours.

Amanda – General Laboratories – from Radiochemistry. She has a degree in Chemistry. She learned more at the bench top. 16 hours is realistic. Exchange for the hours is realistic.

Mitzi – there were no radiochemistry classes in her day. She thinks you need to allow for more experience. Labs won't meet this.

Trinity – She wants to know why there is an in lieu (last bullet)? She sees this as an opportunity to come to some agreement that works for both. She would like to see people come up with solutions.

Kirstin – Re-hashing January? She thinks this is nothing new. She would like to hear how the assessors are currently auditing the technical manager role. This lets more people in, but it is still not the direction she would like to see this go.

Microbiology:

Jessica reviewed the Microbiology requirements.

Aaren – Also an advocate of if you are doing something more difficult, shows you can probably do something simpler.

Environmental analysis should be microbiological experience.

Scott Siders wanted to emphasize that the minimum number of hours is needed and then look for competency.

Jessica – Need to figure out how competency can be a yes or no.

BREAK

Microbiology – Continued:

Microbiology course language is not consistent between ii and v. To include 4 credit hours ... No lab required and yes it can be an online course.

Kasey – degree could be anything – but courses are the requirements.

Robin – if you are a person who wants to change your career path, you can take classes and not need to get a second degree.

Maria – City of West Palm Beach – make sure it is clear it is microbiology experience and not environmental.

Jessica asked what happens if a lab does it all? Robin Cook thinks that the lab has to meet all the requirements. Sheri Heldstab said in many labs each department has their own technical manager.

STANDARD INTERPRETATION REQUESTS - DISCUSSION

These are SIRs that the Committee thinks need to be addressed:

22/79 – If TNI logo is on a report ... it must meet TNI requirements.

93/180 – It can't be clearly defined. This is something AB related.

101 – ISO/IEC 17025:2017 addresses this and thus it will be added.

246 – unique identification of sample containers.

She presented each SIR (see Attachment A).

#### OPEN DISCUSSION:

The Committee is also meeting on Thursday to continue work on the new Standard.

DOC – QS is not aware that there is something that needs to be done with DOCs.

There was a question of how long you need to keep iDOCs. This will be looked at when it gets worked on in the Standard.

The goal is to have some sort of a DRAFT of the new Standard by the Long Beach meeting. This could take longer if more time is needed.

Alyssa: QSM 5.3 – Bridge Standard. Puts them in compliance with 2017. All labs are expected to be in compliance with QSM 5.3 by the end of 2020. QSM 6.0 is expected to be in place by the end of 2020 or 2021.

Jessica presented her contact information.

### 3. Thursday, August 8, 2019

#### TECHNICAL MANAGER

Jessica shared WET Expert Committee language for Technical Manager. They do not have any experience substitution language.

Asbestos is also working on language.

#### NEW STANDARD

Jessica reviewed the work the Committee has previously done to merge the 2016 TNI Standard language into the new ISO/IEC 17025: 2017. Only the TNI language was transferred in – not the ISO/IEC 17025:2005 language. She reviewed the work done to Section 7 during the last meeting.

Jessica noted that the Committee may want to add something to the Standard about the lab having a legitimate copy of the TNI Standard. It should be a copy of the Standard being assessed to. Could be added to the section where a lab is required to have a copy of the method. Section 8.3.1? Could be Section 8.3.1.1.

Kristin noted that in Utah, everyone after January 31, 2020 will be assessed to the 2016 Standard.

Have Microbiology take a look at the language in Section 5.2.6.1 c) iii) – give to Microbiology because NELAP AC would like to see this added.

5.2.6.1 b) is an exception for Chemistry that still needs to be considered.

5.2.6.1 e) should go back to Radiochemistry for consideration.

Maybe these could be called limited scope requirements?

Christina Hilton – Why would you separate the exceptions from their sections? Would prefer that the information be kept together.

Iлона commented that we really need to be sure that all the language has been transferred from the TNI 2016 Standard. Based on discussions today, it looks like there have been some changes as language was transferred. The ISO/IEC 17025:2005 language still needs to be looked at too.

6.2.5 – procedure for managing absences. How long do you need to be out before you notify AB? If you are connected electronically, are you absent, etc ....

John South – Illinois AB – Asked if labs are going to be allowed to define what needs to be in the SOP and in what order. Still need the required information. Just want to change format of what is written so people don't think they have to put it in the same order. Don't put it in an outline form.

Nick Lawson – A2LA: Do you want to move 4.2.8.5 (ISO/IEC 17025:2017 – Section 7.2.1.2) – should it be moved to 8.2 or 8.3? Yes.

**BREAK**

Subsampling should be addressed in the Standard.

Jessica added notes to the DRAFT Standard as they reviewed Section 7.

Section 7.4.2 - discussed issue on labeling containers and SIR 246.

The laboratory will define a system that identifies what a unique container is. – Jessica added this to the document.

You have to be able to trace the data and need a way to tie it back to the records. Need traceability. Does it necessarily need to be a label? Lab has to prove their system works.

John South (IL-AB) agrees you don't need a label, but they need a system for traceability they can prove.

Nicole Cairns: Need a system to make sure samples don't get mixed up. The sharpie number on the container will be washed off.

Scott Siders: The current language lends assessors to stating they need unique identifiers on tubes.

Iлона commented that this might be something to expand on in the Small Lab Handbook where you can give implementation guidance. Maybe start keeping a running list of what we want to track for the Handbook.

Michelle reminded people that the Committee would gladly take recommended language to address this.

A2LA: TNI 5.8.7.2 – seems like it repeats the language in ISO/IEC 7.4.3. Jessica put a strike through it. Nicole noted that a) is what you decide to do with it. Maybe you don't need to strike the language. Scott Siders agreed that language should not be stricken at this time. The first sentence was corrected – striking removed.

John South – Keep language. There is also an issue that there is nothing about retaining it.

A2LA: Retention of the records is in Section 8.4.

Samples that are rejected still need to be logged in and formally rejected. This was crossed out in 5.8.7.2 a) – Is this duplicated? Does it need to be kept?

7.5.1 – is the language in TNI 4.13.3 duplicated?

Some assessors are using 4.13.3 to its extreme. They want to see what pH strip was used, Lot of Sulfuric Acid you used, etc ...

A2LA – Nick Slawson; 7.5.1 – If possible – the TNI language is more definite.

Jennifer Claypool – FL DOH: She has used this section when she can't trace extraction records. It is a little repetitive but it goes into more details and is a better citation.

#### 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 by teleconference on 9/9/19 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.

Jessica adjourned the meeting at 4:15pm Eastern on Monday, August 5, 2019.

Jessica adjourned the meeting at 11:57am Eastern on Thursday, August 8, 2019.



Attachment A:






## Quality Systems - Module 2 Revision Technical Manager and SIR

Summer TNI Meeting  
Jacksonville, FL  
08/05/19




## Quality Systems

Labs (5) – Jessica Jensen (Chair), Earl Hansen, Shari Pfalmer, Dale Piechocki, Matt Sowards  
ABs (5) – Kristin Brown, Lizbeth Garcia, Chris Gunning, Jenna Majchrzak, Amber Ross  
Others (5) – Kathi Gumpper (Vice Chair), Bill Ray, Pepa Sassin, Michelle Wade, Alyssa Wingard




Feels a little humid today




## Quality Systems - Module 2 Revision

Technical Manager



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Technical Manager




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Technical Manager

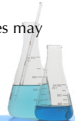

- Radiochemistry (Voted/approved by the RadChem Committee during the July Meeting)
- Chemistry
- Microbiology
- Wet
- Asbestos







## Quality Systems - Module 2 Revision Radiochemistry

- Any technical manager of an accredited environmental laboratory engaged in radiological analysis shall be a person:
  - with a bachelor's degree; and
  - with thirty-two (32) college semester credit hours of chemistry and physics; and
  - with sixteen (16) college semester credit hours of radiochemistry; and
  - 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.



## Quality Systems - Module 2 Revision Radiochemistry Cont.

- 1 year experience working in an environmental radioanalytical laboratory may be substituted for 4 credit hours. Multiple years of substitution may be utilized, but each year substituted must be related to the learning of and proficiency in a different analytical method/technique or instrumentation type. This will help ensure an increasing level of knowledge in radiochemistry analyses (preparation and/or instrumentation) during that time period. No more than 24 hours total may be substituted – at least 24 hours must be from actual college courses.
- In lieu of any of the above, the laboratory may petition each body for which accreditation is sought, presenting the candidate's qualifications in a consistent format to each.



## Quality Systems - Module 2 Revision Chemistry

- a) Any technical manager of an accredited environmental laboratory engaged in environmental analysis shall be a person:
  - i. with a bachelor's degree; and
  - ii. with twenty-eight (28) college semester credit hours of chemistry and/or natural sciences; and
  - iii. with two (2) or more years of experience in the environmental analysis of environmental samples.
  - iv. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year experience.

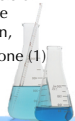

## Quality Systems - Module 2 Revision Chemistry Cont.

- v. 1 year experience working in an environmental laboratory may be substituted for 4 credit hours. Multiple years of substitution should show increasing level of knowledge in environmental analyses (preparation and/or instrumentation).
- vi. In lieu of any of the above, the laboratory can petition the primary accrediting body, presenting the candidate's qualifications.


## Quality Systems - Module 2 Revision Microbiology

- Any technical manager of an accredited environmental laboratory engaged in microbiological/biological analysis shall be a person:
  - i. with a bachelor's degree; and
  - ii. with sixteen (16) college semester credit hours of biological science to include at least one course in general microbiology; and
  - iii. with two (2) or more years of experience in the analysis of microbiological environmental samples representative of the analyses for which the lab seeks and maintains accreditation,
  - iv. A master's or doctoral degree may be substituted for one (1) year experience.

## Quality Systems - Module 2 Revision Microbiology Cont.



- v. 1 year experience working in an environmental laboratory may be substituted for 4 credit hours.
  - a. Multiple years of substitution shall show increasing level of knowledge in environmental analyses (preparation, instrumentation and/or technology).
  - b. The 4 credit hour general microbiology course cannot be substituted with experience
- vi. In lieu of any of the above, the laboratory may petition all applicable accrediting bodies, presenting the candidate's qualifications to document competency.





## Quality Systems - Module 2 Revision



Standard Interpretation Requests



## Quality Systems - Module 2 Revision


6 SIRs will be addressed in the next Revision

- 22 – procedures that don't apply
- 79 – handling of non-TNI work
- 93 – revision number of methods on reports
- 101 – instrument software (note clarification)
- 180 – which version of a method is acceptable
- 246 – unique identification of sample containers



## Quality Systems - Module 2 Revision

SIR Chart



## Questions?

Jessica Jensen  
Chair – Quality Systems Committee  
Meridian Analytical Labs  
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316-618-8787



## Attachment B

### Action Items – QS Expert Committee

	<b>Action Item</b>	<b>Who</b>	<b>Expected Completion</b>	<b>Actual Completion</b>
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	
59	Review Milwaukee minutes and add to Parking Lot list as appropriate.	Paul/Jessica	4/8/19	
60	Send Technical Manager Questions to Committee to get comments and ideas for other questions.	Jessica	3/11/19	
61	Send SIR 350 Response to Lynn.	Jessica	7/31/19	
62	Update SIR Summary to match procedure used by the PT Expert Committee.	Jessica/Paul Junio	8/5/19	
63	Consider starting a list of items to add to the small laboratory handbook.	All	TBD	

	<b>Action Item</b>	<b>Who</b>	<b>Expected Completion</b>	<b>Actual Completion</b>
64	Review language in DRAFT Combined Standard to make sure all TNI language was transferred.	TBD	TBD	
65	Add ISO/IEC 17025:2017 language from the 2016 TNI Standard into the DRAFT Combined Standard.	TBD	TBD	

