

## Quality System Expert Committee (QS) Meeting Summary

May 13, 2019

### 1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 1pm Eastern by teleconference on May 13, 2019. Attendance is recorded in Attachment A – there were 8 members present. Associate Members present: Rachel Van Exel, Carl Kircher, Janette Hernandez, Chaney Arend, Cindy Gaddis, Eric Davis, Eric Denman, Carol Barrick, Joe Manzella, Linda O'Donnell, Patricia Carvajal, Paul Junio, Roberto Cabrera, Roe Cruz, Silky Labie and Terry Romanko (guest).

The March minutes were distributed by email and reviewed. A motion was made by Kathy to approve the March 11, 2019 minutes as written. The motion was seconded by Jenna and unanimously approved.

There was no meeting in April 2019.

### 2. SIR Review

Jerry has asked that all the Expert Committees use the same table to summarize the status of the SIRs. Paul left off at SIR #246 in March and that is where the Committee started today.

Ilona reminded the committee that columns C,D and E should also be reviewed and updated if needed. These columns give the reference in the 2003, 2009 and 2016 Standards. Jerry Parr commented to Paul by email that he thinks Column L is the rationale/discussion and Column K shows the SIR is still active and relevant.

Paul provided notes in the SIR table that can be found in Attachment D. Paul will review the table and compare it to the table prepared by the PT Expert Committee to make sure the same format was followed and then send it to Jessica and Ilona for review and finalization by July.

### 3. Technical Manager

Jessica shared a version of language for Technical Manager (provided by the Radiochemistry Expert Committee) that she been modified to fit Quality Systems – Module 2. There was general support for the new language.

- 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 biological science; 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.*
  - 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.*

Jessica wanted to be sure all were good with the hours. It was agreed it is a reasonable number.

Jessica asked if this covers anyone that might not be covered currently. Linda asked about Microbiology – specifically Cryptosporidium and Giardia. Jessica noted that the Microbiology Expert Committee will be submitting their own recommendation for Technical Manager to QS. This should be reviewed at that time.

Amber asked about 1 year of experience equaling 4 hours. How is this impacted by the part of the Standard that says a master's degree counts as 1 year – this seems unequal.

Terry Romanko noted that Radiochemistry is expecting 16 hours of Radiochemistry classes, but not all schools offer them. Turning experience into semester hours helps solve this issue.

Jessica asked if there were any alternate solutions and none were offered. Amber noted that she would like to discuss this with her supervisor before commenting.

Terry emphasized that laboratory experience is important. Book work/knowledge is important too, but experience would still need to be included. Terry also noted that they removed the specific degree and it is important that there is increasing experience.

Michelle – Why is this committee working on this when the other expert committees are doing this? Chemistry is not writing their own.

Cindy noted 5.2.6.1 language is different. Jessica used the term biological to include more. She thought environmental would fit into this. She was trying to be more inclusive and use a generic word. A better word could be used. The suggestion was to keep it as it is in the 2016 Standard - with the longer list. Jessica's concern is that people will think these are the only things possible – she was trying to be more generic.

Terry noted we could add “such as, but not limited to, ...”.

Jessica asked the committee to carefully review the language and provide additional comment by email. She would like to finish this discussion during the June meeting.

#### 4. Update to Standard

Jessica and Ilona reviewed next steps in updating the Standard. The Committee will begin looking at the Standard again in June and then plan to prepare an outline of changes by August, with a goal of doing a Public meeting for comment in Fall. The outline will be an overview of the changes the Committee expects to make to the Standard.

#### 5. Action Items

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

#### 6. New Business

There is an early conference registration deadline of June 10, 2019.

#### 7. Next Meeting and Close

The next meeting will be on Monday, June 10, 2019 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 2:27pm Eastern. (Shari- motion Jenna – second, Unanimous approval).

Attachment A

**Participants**  
**Quality Systems Expert Committee (QS)**

Member	Organization	Expiration	Representation	Email
Jessica Jensen (Chair) <b>Present</b>	Meridian Analytical Labs	2021	Laboratory	jessica.j@meridiantesting.com
Kristin Brown <b>Absent</b>	Utah DOH	2021	Accrediting Body	kristinbrown@utah.gov
Lizbeth Garcia <b>Absent</b>	Oregon Dept. of Environmental Quality	2019*	Accrediting Body	LIZBETH.GARCIA@dhsosha.state.or.us
Kathi Gumpfer (Vice-Chair) <b>Present</b>	ChemVal Consulting	2021*	Other	kgumpfer@chemval.com
Chris Gunning <b>Present</b>	A2LA	2021	Accrediting Body	cgunning@a2la.org
Earl Hansen <b>Absent</b>	Retired	2021*	Laboratory	papaearl41@hotmail.com
Jenna Majchrzak <b>Present</b>	NJ DEP	2021*	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Shari Pfalmer <b>Present</b>	ESC Lab Sciences	2021	Laboratory	spfalmer@esclabsciences.com
Dale Piechocki <b>Absent</b>	Eurofins Eaton Analytical	2020	Laboratory	DalePiechocki@eurofinsUS.com
William Ray <b>Absent</b>	William Ray Consulting	2020*	Other	Bill_Ray@williamrayllc.com
Amber Ross <b>Present</b>	PA DEP/Bureau of Laboratories	2022*	AB	ambross@pa.gov
Pepa Sassin <b>Absent</b>	US-EPA Region III	2022*	Other	Sassin.Pepa@epa.gov
Matt Sowards <b>Present</b>	ACZ Laboratories, Inc.	2020	Laboratory	MattS@acz.com
Michelle Wade <b>Present</b>	Wade Consulting	2021*	Other	michelle@michellefromks.com
Alyssa Wingard <b>Absent</b>	NAVSEA LQAO	2021*	Other	alyssa.wingard@navy.mil
Ilona Taunton (Program Administrator) <b>Present</b>	The NELAC Institute	n/a	(828)712-9242	<a href="mailto:ilona.taunton@nelac-institute.org">ilona.taunton@nelac-institute.org</a>

## 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 Director Questions to Committee to get comments and ideas for other questions.	Jessica	3/11/19	
61				



Attachment D: SIR Status Table with reference, question and response columns removed.

#	Comment	Applicable to 2003	Applicable to 2009	Applicable to 2016	Addressed/Clarified in 2016 Standard
13	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. 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 identifiable with the specific task). I don't feel that this requires addressing in our revision. The SIR is still valid.	Y	Y	Y	Not addressed in Standard. Committee feels this is clear
16	This 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 and can be removed from the web when 2003 Standard is no longer in use.	Y	N	N	Obsolete
18	No change in language in 2009 and 2016. 17025-2017 addresses the outcome of, not the timeframe between, assessments. SIR should be posted on web for future questions, but requires no clarification.	Y	Y	Y	Not addressed in Standard. Committee feels this is clear
21	The 2009 standard moved this language into Module 4, but 2016 corrected this and moved it back into Module 2. This should not be an SIR, but a method interpretation. SIR should be posted on web for future questions, but requires no clarification	Y	Y	Y	Shouldn't have been an SIR
22	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 SIR, a laboratory can't be expected to have a procedure for a process that it doesn't perform. This seems to be a question of clarity, so the use of a NOTE isn't exactly an issue.	Y	Y	Y	A Note or FAQ could clarify this, as it is not exactly a Standard issue

#	Comment	Applicable to 2003	Applicable to 2009	Applicable to 2016	Addressed/Clarified in 2016 Standard
38	This language was moved into the technical modules in 2009 and 2016. SIR should be posted on web for future questions, but requires no clarification. The SIR is still valid.	Y	Y	Y	Not addressed in Standard. Committee feels this is clear
39	Although this section was slightly revised in the 2005 version of ISO 17025, the SIR is still valid. It may be further addressed in 17025-2017. SIR should be posted on web for future questions, but requires no clarification	Y	Y	Y	Not addressed in Standard. Committee feels this is clear
43	This sentence is not in the 2009 or 2016 standards. The policy still exists, but not the requirement to make it available to the client. The SIR is obsolete and can be removed from web when 2003 Standard is no longer in use	Y	N	N	Obsolete
64	The 2009 and 2016 standards contain the identical language. The SIR is still valid. Adding timeliness requirements may only further confuse the issue and cause unintended consequences. The Committee feels no further action need be taken.	Y	Y	Y	Not addressed in Standard. Committee feels this is clear
66	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. " 17025-2017 7.6 addresses uncertainty in greater depth than the previous Standard. The Committee doesn't intend 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	Y	Y	Y	Not addressed in Standard. Committee feels this is clear



#	Comment	Applicable to 2003	Applicable to 2009	Applicable to 2016	Addressed/Clarified in 2016 Standard
	The SIR still has relevance, and should be posted on web for future questions, but requires no clarification				
70	<p>This language is unchanged in the 2009 and 2016 standards. 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.)</p> <p>The SIR is still valid. SIR should be posted on web for future questions, but requires no clarification.</p>	Y	Y	Y	Not addressed in Standard. Committee feels this is clear
73	<p>This language is unchanged in the 2009 and 2016 standards.</p> <p>The SIR is still valid. SIR should be posted on web for future questions, but requires no clarification</p>	Y	Y	Y	Not addressed in Standard. Committee feels this is clear
77	<p>Although this language was revised in the 2005 version of ISO 17025, the SIR is still valid. SIR should be posted on web for future questions, but requires no clarification</p>	Y	Y	Y	Not addressed in Standard. Committee feels this is clear

#	Comment	Applicable to 2003	Applicable to 2009	Applicable to 2016	Addressed/Clarified in 2016 Standard
79	<p>The 2009 and 2016 standards retain the requirement. The SIR is still valid. Clarification may be needed in the next update. It depends on the accreditation claims made by the report - a statement of 'TNI accreditation not be required for this analyte/project/something' may absolve the lab of any requirement. Claims of TNI accreditation must be made accurately and completely (to the analyte/technology/matrix).</p>	Y	Y	Y	An FAQ may help this, similar to SIR 22
81	<p>The response discusses the differences between 2003 and 2009 (and 2016) and is still valid. SIR should be posted on web for future questions, but requires no clarification</p>	Y	Y	Y	Not addressed in Standard. Committee feels this is clear
82	<p>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." This is obsolete and can be removed from web when 2009 Standard is no longer in use.</p>	Y	Y	N	Obsolete
93	<p>This language is unchanged in the 2009 and 2016 standards. The SIR is still valid. Another SIR relates to this question. Clarification - if requested or required, the revision number however specified. 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</p>	Y	Y	Y	A Note or FAQ could clarify this, as it is not exactly a Standard issue

#	Comment	Applicable to 2003	Applicable to 2009	Applicable to 2016	Addressed/Clarified in 2016 Standard
101	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.	Y	Y	Y	ISO Note should be made a requirement
115	This language is unchanged in the 2009 and 2016 standards. The SIR is still valid. SIR should be posted on web for future questions, but requires no clarification.	Y	Y	Y	Not addressed in Standard. Committee feels this is clear
124	This language is unchanged in the 2009 and 2016 standards. The SIR is still valid. SIR should be posted on web for future questions, but requires no clarification	Y	Y	Y	Not addressed in Standard. Committee feels this is clear
125	SIR should be posted on web for future questions, but requires no clarification	Y	Y	Y	Not addressed in Standard. Committee feels this is clear
144	SIR should be posted on web for future questions, but requires no clarification	Y	Y	Y	Not addressed in Standard. Committee feels this is clear

#	Comment	Applicable to 2003	Applicable to 2009	Applicable to 2016	Addressed/Clarified in 2016 Standard
154	SIR should be posted on web for future questions, but requires no clarification. 17025-2017 does not address electronic signature, so this TNI language will need to be retained.	Y	Y	Y	Retain previous TNI language
158	The Committee disagrees 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. The Committee feels that this doesn't require addressing in the next revision, and that this can be removed from the web.	N	N	N	Shouldn't have been an SIR
180	This language is unchanged in the 2016 standard. The SIR is still valid. Clarification needed in next update, or an FAQ could be written on this subject. An FAQ is probably the better option.	N	Y	Y	A Note or FAQ could clarify this, as it is not exactly a Standard issue
192	This language is unchanged in the 2016 standard. The SIR is still valid. SIR should be posted on web for future questions, but requires no clarification. Keep in mind that you have to deal with a finding if the on-demand system fails.	N	Y	Y	Not addressed in Standard. Committee feels this is clear
198	This language is unchanged in the 2016 standard. The SIR is still valid. SIR should be posted on web for future questions, but requires no clarification.	N	Y	Y	Not addressed in Standard. Committee feels this is clear
206	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 and can be removed from web when 2009 Standard is no longer in use.	Y	Y	N	This was revised in 2016. Obsolete
212	This language is unchanged in the 2016 standard. The SIR is still valid. Clarification needed in next update. This strikes the Committee as a complaint about Technical Manager requirements more than an SIR. Those requirements are under review for the next revision.	N	Y	Y	Technical Manager will be revised

#	Comment	Applicable to 2003	Applicable to 2009	Applicable to 2016	Addressed/Clarified in 2016 Standard
232	'Garden variety glassware" is not equivalent to volumetric dispensing device, which is where the requirement lies. The SIR is still valid. SIR should be posted on web for future questions, but requires no clarification.	N	Y	Y	Not addressed in Standard. Committee feels this is clear
246	Requires clarification in next update. As this is still being voted on, the Committee will defer to see any final comments from the AC. Consider adding the response to the SIR - or starting over with that language (and don't try to band-aid again).	N	Y	Y	Clarify the requirements in revision
251	This language is unchanged in the 2016 standard. The SIR is still valid. SIR should be posted on web for future questions, but requires no clarification.	N	Y	Y	Not addressed in Standard. Committee feels this is clear
270	This language is unchanged in the 2016 standard. The SIR is still valid. SIR should be posted on web for future questions, but requires no clarification.	N	Y	Y	Not addressed in Standard. Committee feels this is clear
274	This language is unchanged in the 2016 standard. The SIR is still valid. SIR should be posted on web for future questions, but requires no clarification. This may require an FAQ or some clarifying NOTE regarding plasticware is NOT glassware, and that by definition plasticware can't be Class A. Paul to contact Judy about FAQ	N	Y	Y	A Note or FAQ could clarify this, as it is not exactly a Standard issue
290	This language is unchanged in the 2016 standard. The SIR is still valid. SIR should be posted on web for future questions, but requires no clarification. This appears to be a technical issue and not an interpretation issue. This has been submitted for an FAQ.	N	Y	Y	A Note or FAQ could clarify this, as it is not exactly a Standard issue
296	This language is unchanged in the 2016 standard. The SIR is still valid. SIR should be posted on web for future questions. Technical Manager requirements are on the list of items for review for the next update.	N	Y	Y	Technical Manager will be revised

#	Comment	Applicable to 2003	Applicable to 2009	Applicable to 2016	Addressed/Clarified in 2016 Standard
302	<p>This language is unchanged in the 2016 standard.</p> <p>The SIR is still valid. SIR should be posted on web for future questions. Bulleting the list of requirements may make this clearer in the next revision.</p>	N	Y	Y	Technical Manager will be revised
304	<p>This language is unchanged in the 2016 standard.</p> <p>The SIR is still valid. SIR should be posted on web for future questions, but requires no clarification. There seems to be an obvious difference between microliter syringes and non-microliter syringes.</p>	N	Y	Y	Not addressed in Standard. Committee feels this is clear
308	<p>This language is unchanged in the 2016 standard.</p> <p>The SIR is still valid. SIR should be posted on web for future questions, but requires no clarification.</p>	N	Y	Y	Not addressed in Standard. Committee feels this is clear
321	<p>This language is unchanged in the 2016 standard.</p> <p>The SIR is still valid. SIR should be posted on web for future questions. Bulleting the list of requirements may make this clearer in the next revision.</p>	N	Y	Y	Technical Manager will be revised