Radiochemistry Expert Committee (REC)
Meeting Summary

February 25, 2015

1. Roll Call and Minutes:

Bob Shannon, Chair, called the meeting to order at 1 pm EST on February 25, 2015. Attendance is recorded in Attachment A – there were 6 members present on the call. Associate Members: Arianna and Terry.

Minutes for the day long February 3, 2015 meeting are just about done and will be distributed by email this week.

Associate members need to let Bob and Ilona know they own a copy of ISO 17025 so they can be included in distributions of the draft working standard updates.

2. Review of Comments

Bob asked if people had looked at the comment summary. There were no concerns expressed. Bob moved to the bottom of the table to address the issues added to the table during the Crystal City meeting. (See Attachment D.)

Comment 42 and 43 (Section 1.7.2.2 b) ii)

Tom had a comment about quantity.

Bob made the following change:

> The quantity of the aliquot used for the method blank shall be similar to that of routine samples. If the size of samples in a Preparation Batch varies (e.g., due to differences in sample density or restrictions on the activity or mass residue that may be processed), the laboratory shall use acceptance criteria that compensate for differing aliquot sizes (e.g., z-score per MARLAP, Vol. 3, Chapter 18, Section 18.4.1).

Keith and Marty liked the language better before. They think the change is more confusing.

Terry suggested the following: If the sample aliquot used for the method blank shall be similar to that of routine samples. If the sample aliquot in a Preparation Batch varies …

There were some issues with the phone line and the committee had to hang-up and call back in.

There is parallel language that also needs to be changed in the similar section under LCS: The aliquot used for the LCS …

Comment 44

Taken care of.

Comment 45

Ilona will again look into a consistent format for references.

Comment 46:
This relates to questions that Carl and Tom brought up during the review process. Carl was concerned the Quality Systems matrix was being removed.

The first sentence in 1.7.2.2 b) i) can cause trouble. It causes a trap for the laboratories. There was general agreement that it could just be left out. Leaving it out does not omit anything essential. If left it would raise too many questions during assessments.

Larry's New Standard Issues:

1.5.1 g):

Carl raised the concern that the committee is encouraging people to use non-accredited PT Providers.

The following note will be added to the Standard under 1.5.1 g):
The use of non-TNI accredited PT providers is strictly for method validation purposes and not for laboratory accreditation.

There were no objections to this addition.

1.6.2.2.a):

Section 1.7.2.3 deals with laboratory control samples.

Should the text be changed to:
Prepare 4 test samples consistent with requirements for laboratory control samples (LCS) in Section 1.7.2.3.

Bob asked if there were any more outstanding concerns? This is our last chance before it becomes the VDS.

People want to review the Final Draft that will be submitted as the VDS before they vote.

Everyone would like to see the final standard based on the conversation today. It also needs to be reviewed by the Standards Review Committee (SRC). Bob will send out an update later today.

Bob asked people to get back to him with any final review comments by 3/6/15. He should also have SRC comments by then. If no comments still need to be addressed, Bob will set up a meeting the following week to vote. He will send out a Doodle to determine a meeting time. He will also send any comments he receives to the entire committee over the next week.

Larry and Carl are part of SRC and their comments have already been received by the committee. Larry noted that there are three other SRC reviewers finishing up their review.

3. New Business

- None.

4 Action Items

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

5. Next Meeting and Close

The next meeting will be planned by email to accommodate any final comments and to vote the standard to a VDS.

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

The meeting was adjourned 2:04 pm EST. (Motion: Marty Second: Keith Unanimously approved.)

Attachment A
Participants
Radiochemistry Expert Committee

Members	Affiliation		Contact Information	
			Phone	Email
Bob Shannon (Chair) **Present**	QRS, LLC Grand Marais, MN	Other	218-387-1100	BobShannon@boreal.org
Tom Semkow (Vice Chair) **Present – am,pm**	Wadsworth Center, NY State DOH Albany, NY	AB	518-474-6071	tms15@health.state.ny.us
Sreenivas (Vas) Komanduri **Phone Absent**	State of NJ Department of Environmental Protection Trenton, NJ	AB	609-984-0855	Sreenivas.Komanduri@dep.state.nj.us
Marty Johnson **Present**	US Army Aviation and Missile Command Nuclear Counting Redstone Arsenal, AL	Lab	865-712-0275	Mjohnson@tSC-tn.com
Dave Fauth **Phone Present**	Consultant Aiken, SC	Other	803-649-5268	dj1fauth@bellsouth.net
Carolyn Wong **Absent**	Lawrence Livermore National Laboratory Livermore, CA	Lab	925-422-0398	wong65@llnl.gov
Keith McCroan **Phone Present**	US EPA ORIA NAREL, Montgomery AL	Lab	334-270-3418	mccroan.keith@epa.gov
Nile Ludtke **Present**	Dade-Moeller and Associates Oak Ridge, TN	Other	865-481-6050	nile.luedtke@moellerinc.com
Larry Penfold **Present**	Test America Laboratories, Inc; Arvada, CO	Lab	303-736-0119	larry.penfold@testamericainc.com
Richard Sheibley **Absent**	Sheibley Consulting, LLC	Other (Former AB)	651-485-1875	RHSHEIB111@yahoo.com
Ilona Taunton (Program Administrator) **Present**	The NELAC Institute	n/a	828-712-9242	Ilona.taunton@nelac-institute.org

Attachment B

Action Items – REC

	Action Item	Who	Target Completion	Completed
58	Review and update Standard and Summary.	Bob	2/10/15	Complete
59	Make discussed changes in the Standard and send out to the committee for a final review. Comments due 3/6/15.	Bob	2/25/15	3/6/2015
60	Review final version of the standard and send comments to Bob.	All	3/6/15	3/6/2015

Attachment C – Back Burner / Reminders

	Item	Meeting Reference	Comments
1	Update charter in October 2015	n/a	
2	Issue of noting modifications to methods.	1/16/13	
4	Look at need to reference year for any standard references– which version is being referenced. Is this necessary?	5/22/13	
5	Form subcommittee of experts in MS and other atom counting techniques to see that these techniques are adequately addressed in the radiochemistry module.	9/24/14	

Attachment D: MWDS Comments and Responses – Radiochemistry Expert Committee

Document No./Title: STD-ELV1M6-Radiochemistry-MWDS-2/25/25

Note on procedure used to address comments received. Only two of the coments below (from PCI labs) were received during the review period. They will be dealt with formally (i.e., deemed persuasive or non-persuasive by vote).
The rest of the comments were receieved outside the comment period and need not be formally classified as persuasive or non-persuasive. Most of the following comments were editorial in nature, and/or non-controversial. In the interest of documenting changes, comments will be tracked and action (or non-action) noted as below. Comments that were technical or potentially controversial, however, were put to a vote, as noted below.

#	Section/ Clause No.	Comments	Comment Resolution. P = Persuasive NP = Non-Persuasive	
1	1.4	This entire section refers to three sections in Module 2. However, Section 5.4.4 does not really exist since the Quality System Expert Committee took the ISO language out in the 2009 version. The latest proposal for Module 2 was to re-insert it, but there is some snafu that the QS Committee needs to fix (which I am not clear about at all). I hope that the QS Committee is able to re-insert some real standards back into Module 2, Section 5.4.4; otherwise, your Committee may have to revise this whole section to insert language similar to the other Technical Modules.	According to Paul Junio - the ISO langauge was intially stricken from 5.4.4, but has been restored . A note has been added to the end of 5.4.4 that restores the eleven items that need to be considered per ISO. Since the langauge has been restored. Larry moved that the comment be deemed non-persuasive, Richard seconded. The motion was approved by unanimous vote,	4
2	1.2, 1.3.2, 1.5.3, 1.5.4, 1.6.2.2.e, 1.6.3.1, 1.6.3.2.d more?	The term "quality management plan" (QMP) shows up. I checked the other technical modules and Module 2, and I did not see that term show up as it appears here. What do you all think the QMP is? Is it the overall Quality System? Is it (just) the Quality Manual? Is it really a combination of the Quality Manual and the test method SOPs? Is a definition for "Quality Management Plan" needed for Module 6? Whatever the QMP is, it needs to be clear that the plan has to be a documented plan.	Paul: The term Quality Management Plan is no longer used as a universal identifier for the quality system. Instead, quality system is the most general term. When referring to documentation, Paul recommends language along the lines of "as documented or referenced in the laboratory's quality manua+D14l". Editorial - Bob will review the standard and make chnaged consistent with these guidelines, throughout.	4

#	Section/ Clause No.	Comments	Comment Resolution. P = Persuasive NP = Non-Persuasive	
3	1.3.1	*Detection Limit (DL) for Safe Drinking Water Act (SDWA) Compliance: Laboratories that analyze drinking-water samples for SDWA compliance monitoring must use methods that provide sufficient detection capability to meet the detection limit requirements established in 40 CFR 141. The SDWA DL for radioactivity is defined in 40 CFR Part 141.25(c) as the radionuclide concentration, which can be counted with a precision of plus or minus 100% at the 95% confidence.* Comment: per ECLS-R-GA, Revision 8, the confidence has been changed from 95% (1.96) to 90% (1.65). This revision also states that these calculations must be used for all Safe Drinking Water Act (SDWA) Compliance samples being analyzed (ref: page 22 of 26 of Revision 8). Using 1.65 and the new SDWA DL is in conflict with other US EPA 900 series Test Methods. Can you please address this conflict ?	Nile moves that this is a regulatory requirement that lies beyond the scope of the TNI standard and that it be deemed non-persuasive. Marty seconds. The motion passed by unanimous vote. *Note in clarification to the commenter: The TNI standard requires that the laboratory review all work that it intends to accept to determine whether it can conform to requirements. If the laboraotry cannot comply with a requirement, it must notifiy the client (or regulator) of the issue and come to an agreement about whether it can accept work.*	3
4	1.5.1.f	The language implies that the lab can get its PTs from either a TNI accredited PT Provider, accredited ISO 17043 PT Provider, accredited ISO/IEC Guide 34 provider, or ANSI N42.22 compliant provider. However, the language in Volume 1, Module 1 will over-ride and supersede these options of the lab wants to be accredited under NELAP. The TNI PT Program has made available Fields of Proficiency Testing for radionuclides in the Drinking Water matrix (as posted on the TNI internet site), so the laboratory's ONLY option for these FoPTs is to run the PTs from the TNI accredited PT Providers. If there are no such accredited providers available, then the lab is free to select from the other options (but that is NOT the case for DW Radiochem. FoPTs). As long as the labs are aware of this, then I am fine with the language as stated. If you think that it will not be clear to the labs to get the DW PTs specifically from the TNI-accredited sources, then please revise the language in this section.	Larry moved that this comment be deemed non-persuasive since the section is addressing method validation and not ongoing proficiency testing. It addresses the reality that standards needed to validate a method may not be routinely available from a TNI provider but using traceable materials is important for validation. Richard seconded the motion. The motion passed by unanimous vote.	4

#	Section/ Clause No.	Comments	Comment Resolution. P = Persuasive NP = Non-Persuasive	
5	1.5.4.c	I have a follow up question with regard to uncertainty calculation. Suppose that one only calculates the counting error, and not the total propagated uncertainty (TPU). If one must adhere to section 1.54(c), then the TPU could significantly exceed the counting error, and the experimental standard deviation could exceed the counting error, especially if the samples are counting for long periods of time, say until 10,000 counts are collected. For Safe Drinking Water Act (SDWA) samples, must one adhere to 1.54(c) ? If so, this would seem to be a problem. Also, I don't think I've ever seen a data set that conforms to a Gaussian distribution in any statistical test (like the skewness, kurtosis, or omnibus tests). Some have significant tails that would tend to increase the standard deviation. At this point, if one doesn't arbitrarily discard the data points in the tail, it seems that one would have to use an alternate set of statistics and would have to justify this to a NELAC auditor. Is this correct?	Editorial. The committee updated section 1.5.4 c) and added i) and ii) as follows: i) T*he experimentally-observed standard deviation from the initial precision evaluation at any testing level shall not be statistically greater than the maximum standard uncertainty of the measurement results at that level , although it may be somewhat less. If the experimentally-observed standard deviation at each testing level statistically exceeds the standard uncertainty, then the uncertainty estimate should be re-evaluated.* *ii) The comparison of the experiementally-observed precision evaluation need not be performed for measurements that are required to be reported only with counting uncertainty per 1.5.4 a) ii).*	2
6	1.6.3.2.a	For some reason, the term "samples single blind to the analyst" has become unclear and problematic to me. Technically, all submitted client samples are single-blind to the analyst. Are blanks and non-detect samples thus going to be okay for an on-going demonstration of capability? At a minimum, I would recommend that the "samples" have known or accepted or verified non-zero Assigned Values and then be submitted single-blind to the analyst(s) for capability demonstrations.	Editorial - Nile moves to add language to clarify: a) as follows: "and sample(s) that have known, accepted value(s), single blind to the analyst" Marty seconds. Motion passes by unianimous vote	4
7	1.7.1.2.b.	Perhaps the wording should be "Several examples where varying activity is not required are:"	Text updated (editorial) Some techniques may require multiple-point calibration curves to correlate a number of parameters other than activity. i) channel-energy calibration of alpha or gamma spectrometers; ii) energy-efficiency calibration of gamma spectrometers; iii) mass-efficiency (mass-attenuation) calibration of gas-flow proportional or x-ray detectors; iv) quench-efficiency calibration of liquid scintillation detectors; v) mass-crosstalk calibration of gas-flow proportional; and vi) quench-crosstalk calibration of liquid	1

#	Section/ Clause No.	Comments	Comment Resolution. P = Persuasive NP = Non-Persuasive	
			scintillation detectors.	
8	1.7.1.2.d.i	For the empirical and/or computational techniques, is the "documented validation of the corrected method or model" a one-time test? Or does this validation need to be verified at some frequency? Does the validation have to be performed again after the occurrence of any of the Section 1.7.1.2(a) conditions? (My opinion is to come with and require some frequency for verification).	No action requested. In answer to the commenter's question: this refers to method validation and not calibration. As long as the lab has documented validation, and the method itself has not changed, a second validation is not required.	4
9	1.7.1.4.c.ii and 1.7.1.6.b.ii	Are there any potential conflicts between the RMB batch maximum measurement period of 14 days and the 7 days specified here for the performance checks and short-term background checks? It's fine with me if this is the language you intended. I am reading this as, during a 14-day RMB batch: (a) Performance Check & short-term Background check, then (b) 7 days of counting samples, then (c) another Performance Check & short-term Background Check, then (d) 7 more days of counting samples, and (e) a concluding Performance Check & short-term Background Check. If more samples need to be counted, then the lab must do another "beginning" Performance Check and short-term Background Check to start another RMB batch before the additional samples can be counted. Am I correct in ALL of the interpretations described above? If yes, then the standards are good-to-go in these sections.	No action requested. To confirming the commenter's question: all of the assumptions are correct and we are "good-to-go".	4

#	Section/ Clause No.	Comments	Comment Resolution. P = Persuasive NP = Non-Persuasive	
10	1.7.2.1.a.	1.7.2.1.a) states "laboratory shall incorporate guidelines established in MARLAP or other consensus - etc" I think we have or should have established quality control program requirements in this section and should not refer to another document. If we haven't done that, we have failed to meet our 1st objective in our charter is "Ensure that the Standard will produce data of known and documented quality"	Editorial - Nile moved to change to "Where there are no established requirements, the laboratory may reference guidelines consistent with MARLAP or other consensus standard organizations in its quality management system." Vas seconded. The motion was passed by unanimous vote. Bob will look for similar langauge throughout the rest of the module and make changes, if appropriate.	1
11	1.7.2.1.c.iv	As I read more into your descriptions of RMB (Radiation Measurements Batch), I think I need a lot more clarification. Exactly which Radiochemistry methods would qualify to be treated as a RMB rather than as a Preparation Batch. If I consider just the promulgated SDWA methods, ONLY EPA 901.1, SM 7120 B, et. al. would be processed as RMB and ALL the other SDWA methods would be treated as Preparation Batches (for QC purposes). Am I correct? Also, would I be correct in assuming that any one Radiochemistry method can be associated with EITHER a Preparation Batch or a RMB, but NOT BOTH?	Yes - the commenter's observation is correct. No changes needed.	4
12	1.7.2.2.b.i and 1.7.2.3.b.i	I am totally lost here. Are you saying that I can use DI water as a method blank for Biological Tissue samples? Can I just use some point-source in bare air as the LCS for water samples? Do your considerations of "geometry, size, and OTHER factors" preclude the mis-matching of sample matrices with inappropriate QC types? Who makes the call as to what will "significantly affect" results? Is it the lab? Can the AB over-ride the lab? And, by the way, what is a "method blank test source" and a "LCS test source"? Can you give an example of each that would be applicable to DW, NPW, SCM, BT, and AE samples? I am wearing my Lab. Accreditation System EC hat on this comment, and I am informing you that the NELAP laboratory accreditation system is currently matrix-method-analyte. I therefore, DISAGREE strongly with your proposed deletions of "the same quality system matrix as samples" for the method blank and the LCS. It will likely not survive the LASEC deliberations as it is not at all clear how laboratory conformance to this standard can be assessed so that clients can be confident of test results obtained.	The committee believes that the standard adequately addresses this question. There is no need to make changes here. Carl's will withdraws this question. Ilona will add this to issues to be dealt with in the future	4

#	Section/ Clause No.	Comments	Comment Resolution. P = Persuasive NP = Non-Persuasive	
13	1.7.2.3	What is the purpose of the LCS?	The purpose of the LCS is clearly addressed in 1.7.2.3. No need for any changes	5
14	1.7.2.3.a	I am not clear on the last sentence of this section. Is the CCV/LCS analysis in the RMB batch in ADDITION to the performance check that is performed?	Yes - the commenter is correct in their reading of the language. No changes needed here.	4
15	1.7.2.3.b.ii	The term "surrogate matrix" appears here, and I am concerned that the usage will not be consistent with the use of "surrogate" as used in the Chemistry Module (Module 4). I recommend changing the term to "quality system matrix" (along with retaining the original language about method blanks and LCS being in the same quality system matrix as associated samples).	The committee consulted Webster's dictionary for the definition of "surrogate". We believe that the choice of the word is appropriate and in that we are not talking about mass spectrometry, there is little concern that this will be confusing. The sentence does need an editorial tweak since surrogate is mentioned twice. The first one is redundant and can be deleted.	4
16	1.7.2.3.c	What is the correct reference from 1.7.2.3.c? The text points to 1.7.2.2.e below - should it be 1.7.2.3.e?	Comment 18 also impacts this section - the following statement was deleted: The laboratory may use a calibration source for the LCS if the source is independent of the source used for calibration of the measurement system (see 1.7.2.23.. e)) below).	1
17	1.7.2.3.e	There is a reference to Section 1.7.6.2(c) that does not exist; should be 1.7.2.6(c).	This section was deleted. See comment 18 on 1.7.2.3.e.	4
18	1.7.2.3.e and 1.7.2.4.a.vii	When the statements appear for the LCS and MS to be from a source independent from the calibration source, what about the "performance check" source? Can the same source for the performance check be used as the LCS and MS? Should the sources for calibration, performance checks, and LCS & MS QC samples all be independent of each other (i.e., 3 independent sources needed)? I know you are trying to separate performance checks from the typical chemistry calibrations, but this confusion is arising as a result. If I can express an opinion, I think it might be okay to use the same source for the LCS, MS, and mass-quench calibrations (to use one example), but the performance check (or efficiency check) standard needs to be from a different source.	The commenter appears to be confusing performance checks with calibrations and batch QC samples. There is no requirement that the performance check sources be prepared from traceable material. Therefore, the material used has not impact on calibrations. This intiated discussion about 1.7.2.3 e). See forther discussion under number item #30.	4
19	1.7.2.3.f.ii)	The Section 1.7.2.2(d) reference points to a method blank section, rather than LCS. Instead, should the reference be Section 1.7.2.3(e)?	The commenter is correct - the sections have been renumbered, however, due to other comments - the final corrected section number is: 1.7.2.3.d)	4

#	Section/ Clause No.	Comments	Comment Resolution. P = Persuasive NP = Non-Persuasive	
20	1.7.2.4.a.v	How does the fact that sample matrix spikes may not be required relate to this standard to note lack of sample to perform the matrix spike on test reports? Probably should add language at the beginning of the clause to say: "For test methods, regulatory compliance, or client specifications where analysis of sample Matrix Spikes is required, the lack of sufficient sample aliquot …"	Following discussion, this editorial change was not needed.	4
21	1.7.2.4.b	Matrix Spike/LCS Section: Based on specific project or program requirements or when there is insufficient sample available, the laboratory may choose to analyze a LCS in duplicate in place of a MD. The LCS and its duplicate will provide a measure of analytical precision. However, they will not provide information on matrix effects. Comment: 1. The EPA Drinking Water Certification Manual requires one duplicate for a batch of 10 samples or fewer. 2. The requirement to analyze one duplicate for a batch of 10 or less is burdensome on a commercial laboratory. As an example, if 11 samples are received, 2 LCS duplicates must be performed in addition to other laboratory QC/LCS sample requirements per NELAC. Can you please clarify these requirements?	Marty moved that this be deemed non-persuasive since the details of specific EPA requirements for drinking water analysis are beyond the scope of this module. Larry seconded; the motion was passed with a uninimous vote and 1 abstention *Note in clarification to the commenter: The TNI standard, and this module specifically, require that the laboratory review requirements in advance, and comply with all regulatory or contractual requirements associated with work it performs under the TNI standard. In this case, if the laboratory were to accept this work, it would have to meet requirements that exceed the defaults specified in the module.*	3
22	1.7.2.6.c.i	Is ANSI N42.22 an accreditation standard against which providers are accredited? I do not think this standard is used for accreditation. Therefore, I do not think we should include this reference to non-existent accreditation. We may need to add - where relevant and available. The information in ii appears to be correct.	Marty moved and Nile seconded making an editorial change to the last sentence of this section which would read as "Alternatively, reference standards may be obtained from an ISO/IEC Guide 34 accredited provider or an ANSI N42.22 reference material provider." The motion passed with a unanimous vote.	1
23	1.7.2.6.c.i	For section 1.7.2.6.c)i) - is ANSI N42.22 an accreditation standard against which providers are accredited? I do not think this standard is used for accreditation. Therefore, I do not think we should include this reference to non-existent accreditation. We may need to add - where relevant and available. The information in ii appears to be correct.	This comment duplicates comment 22.	1
24	1.7.3	1.7.3: Using greater than 5x blank concentration criteria is too much as there are too many ways we could have problems that are not investigated.	RRMC workshop comment The committee discussed this and felt that there was no need to make a change.	5

#	Section/ Clause No.	Comments	Comment Resolution. P = Persuasive NP = Non-Persuasive	
25	1.7.3.1.b	The reference to Section 1.7.2.1 may be incorrect (i.e., to the general QC section?); should change it to Section 1.7.2.2.	This had already been identified and corrected	4
26	1.7.3.2.b	The reference to Section 1.7.2.2 may be incorrect (i.e., LCS acceptance criteria pointing to the method blank section?); should change it to Section 1.7.2.3.	This had already been identified and corrected	4
27	1.7.3.5.a (by reference to 5.10)	Section 1.7.3.5.a (by reference to 5.10) requires reports meet customer requirements and 1.7.3.5.c requires reporting negative numbers, etc. So reporting requirements (SDWA for example) define the report format and may not accept negative numbers. This will cause problems with labs that are required to report results directly to regulatory authorities (like in PA). I think we can fix this simply by moving f) higher up in the list.	We discussed this in the committee. Richard's suggestion would have been to move the exception in f) to the first bullet. Since we have clearly allowed project or client specific requirements to override the requirement to report net results, there is no impact and Richard was satisfied that a change would not be necessary.	1
28		The EuraChem guide to method validation is now the 2014 edition. Not sure what changed.	The comment is correct - The correction was made.	1
29		The Rad prep batch definition is changed and is now a combination of the original TNI definition of prep and analytical batch. The problem is if we keep just prep batch definition, we will have prepared samples but then have no definition to describe how the prepared samples are analyzed. I think we need to recognize this and make a change. As written in the WDS, since the definition includes BOTH prep and analysis AND states the batch must be completed within 24 hours, this could mean that prep AND analysis must be complete within 24 hours OR that each step gets a 24 hour window.	We discussed this in detail. Two sentences in the original definition of preparation batch were combined to one without changing any content. The concern about 24 hours is not warranted - as written, the 24 hour restriction affects only the starting of the preparation batch and not completion. The only concern remaining is with language about samples being "analyzed together". Depending on how an assessor reads this, it might impact labs since where it is common practice to analyze samples on different instruments and if the requirement were not read carefully, could result in misinterpretation. The note under 1.7.2.1 e) makes this clear. To further underscore this, however, the decision was made to delete "and or analyzed" from the definition of preparation batch.	1

#	Section/ Clause No.	Comments	Comment Resolution. P = Persuasive NP = Non-Persuasive	
30		I just noticed that the LCS, MS, and MSD require independent sources. This generally not required in chemistry and may be an unnecessary expense for labs. I am surprised the labs didn't push back on this one.	A similar concern was raised while discussing comment 18. Requiring QC samples to be prepared from standards independent from those used for calibration is a new requirement. Since there is already a requirement that calibration verifications be performed with independent material, requiring idenpendence of batch quality controls is redundant and provides no added value, but is associated with additional overhead and cost. Larry moved that the text addressing independent standards in 1.7.2.3 e) and 1.7.2.4 a) viii) be stricken. Tom seconded. The motion passed unianimously with Marty abstaining. While updating the comments matrix after the meeting, Bob noted that this same concern impacts the final sentence in 1.7.2.3.c) He has deleted this as well. Approval of these minutes will act as approval of the deletion.	1
31		I have a question on a proposed NELAC rule. In the NELAC Radiochemistry Working Draft Standard, it's clear that counting error can be reported for SWDA work. (I would agree that it would be best to report the total propagated uncertainty.) Here's my question: If counting error is quoted for SWDA work, does the report have to state this.	No action needed. *In answer the commentor's question: Yes – the type of uncertainty estimate and the confidence interval or coverage factor) are required per 1.7.3.5 (as specified in 1.5.4.b). The information would not necessarily need to be included in the column header or on report forms, but must be specified somewhere "in the report".*	2
32		Does a simple transfer of samples to new containers fall into the category of preparation batch?	No action needed. *RRMC workshop question for committee consideration:* The definition of batch, the note after preparation batch definiton, and section 1.7.2.1 all address this. If the transfer affects the outcome of the test, the batch would be considered to be a preparation batch. No action needed.	5
33		What defines terms like method variance, technical equivalency, comparing methods, and alternate test protocol?	No action needed. *RRMC workshop question for committee consideration:* These terms are not used in the standard so there is no concern.	5

#	Section/ Clause No.	Comments	Comment Resolution. P = Persuasive NP = Non-Persuasive	
34		Have we over-specified the number of samples needed for DOC of the analyst?	No action needed. *RRMC workshop question for committee consideration:* No – this comes from Quality Systems Expert Committee – it is standard across TNI (i.e., for the most part not in our control).	5
35		How should we validate modeling methods (for calibration)?	No action needed. *RRMC workshop question for committee consideration:* There is no prescribed method as long as you comply with section 1.7.1.2.d)	5
36		Need to state the time period for LSC performance checks.	No action needed. *RRMC workshop question for committee consideration:* This is defined in the section on LSC	5
37		Comparing result to CSU: Is there better criteria? ANSI validation standard specifies critical level	No action needed. *RRMC workshop question for committee consideration:* This was already addressed with Tom and Mike's comments on validation of uncertainty	5
38		Should we expect a project engineer to understand LCS test source characteristics?	No action needed. *RRMC workshop question for committee consideration*	5
39		Solid Source control samples are not geometry independent	No action needed. *RRMC workshop question for committee consideration*	5
40		Reporting criteria of method sensitivity should be a customer requirement	No action needed. *RRMC workshop question for committee consideration:* The standard clearly requires that contractual, regulatory or other client specified concerns be taken into account by the lab.	5
41		How do you handle validation from a customer specification limit to zero activity?	No action needed. *RRMC workshop question for committee consideration:* It is not clear what zero means - this would have to be defined. That notwithstandaing, the module addresses requirements for validation of methods and points to references that address concerns about absolute bias. While the exact approach used is not prescribed (i.e., the laboratory has flexibility to meet different requirements), the module does provide several references that could be used to answer such a question.	5
Comments added after meeting				

#	Section/ Clause No.	Comments	Comment Resolution. P = Persuasive NP = Non-Persuasive	
42	1.7.2.2 b) ii)	Should size be quantity?	Made editorial change to: ii) The sample aliquot used for the method blank shall be similar to that of routine samples. If the sample aliquot in a Preparation Batch varies (e.g., due to differences in sample density or restrictions on the activity or mass residue that may be processed), the laboratory shall use acceptance criteria that compensate for differing aliquot sizes (e.g., z-score per MARLAP, Vol. 3, Chapter 18, Section 18.4.1).	6
43	1.7.2.3 b) iii)	Should size be quantity?	Made editorial change to: iii) The aliquot used for the LCS shall be similar to that of routine samples. If the sample aliquot in a Preparation Batch varies (e.g., due to restrictions on the activity or mass residue that may be processed), the laboratory shall use acceptance criteria for samples that compensate for differing aliquot sizes (e.g., z-score per MARLAP, Vol. 3, Chapter 18, Section 18.4.3).	6
44	throughout	Need to state acronyms at first use of the term.	After the meeting, Tom went through and updated first references/acronyms throughout the standard to make this consistent.	6
45	throughout	References needs to be udated to use a more formal and consistent format throughout the module. Is there an accepted format that is used across the standard?	Ilona is not aware of a formalized requirement - she will make some inquiries regarding this. Although this editorial concern would presumably be addressed during editing of the module, since there are no formal requirements at the current time, she recommends that we address the concern before we send this for final editing (after balloting). Resolution: This will be done down the road, hopefully after Ilona finds out if there is some format that we should follow.	6

#	Section/ Clause No.	Comments	Comment Resolution. P = Persuasive NP = Non-Persuasive	
45	1.7.2.2.b.i and 1.7.2.3.b.i	Following up on questions from Carl and Tom, and based on continuing concern from Bob. Originally when I (Bob) proposed this language, the thought was to tie it to a specific statement of applicable matrix in the scope and applicability statement of the SOP. This turned out to be too burdensome and I never followed up on it. When I look at the first sentence in 1.7.2.2.b.i. and at 1.7.2.3.b.i., each of these sentences appears to be saying the same thing as b) above (i.e., matrix QC is required). The sentences, however, go beyond requiring matrix QC and may unintentionally open the door to having assessors challenge QC samples requiring a lab to prove that their QC samples match the chemical and physical properties of associated samples (which change from sample to sample). I propose that we delete these sentences. They are redundant and losing them does not eliminate the requirement for matrix QC. It does minimize the liklihood that these sections will be misinterpreted by assessors.	Resolution: Sentences deleted.	4, 5