Radiochemistry Expert Committee (REC)
Meeting Summary

March 26, 2014

1. Roll Call and Minutes:

Bob Shannon, Chair, called the meeting to order at 1:05pm EST on February 26, 2014. Attendance is recorded in Attachment A – there were 9 members present. Associate members: Ariana Mankerian, Brian Miller, Virgene Mulligan, Bill Ray, Carl Kircher and Reed Jeffrey.

The February 26, 2014 minutes were reviewed. A motion was made by Dave to accept the minutes. The motion was seconded by Keith. Dave and Keith accepted a friendly ammendement to add Ariana's name to the attendance list. Vote: 7 – For, 0 – Against, 1 – Abstain (Larry – Not familiar with meeting.) The motion passed.

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. Washington, DC Meeting

Bob is looking at using Friday as an additional meeting day in DC. The committee is already meeting all day on Thursday. This will be confirmed within the next couple of months depending on progress on the standard.

3. Standard

Final Text – Section 1.7.1 Backgrounds (Tom, Vas and Bob)

This section has been finalized for inclusion in the base document. Tom thanked Terry Romanko for his assistance too.

Final Section 1.7.2.2-3 and 1.7.3.2-3 – Positive and Negative Controls (Carolyn, Marty and Bob)

The changes requested in Louisville were incorporated.

Section 1.7.2 – paragraph 5: Bob will look at some additional language so labs don't need to prove they are random.

Revised Section 1.7.2.3 (Nile and Vas):

Introduction: The first paragraph was consolidated. Need to change the term sample replicates to sample duplicates.

a) Matrix Spike: Nile reviewed the updates in this section with the committee. Changes were made during discussion that changed the numbering system – these changes are referenced based on the document sent out before the meeting.

i) Change to introductory text and add last sentence: Matrix Spikes are not typically employed for methods based on non-destructive gamma spectrometry, where internal tracer or a carrier are used.

ii) Add "as" after the word "or". Make sure language surrounding the contract review process is similar to other parts of the module.

iv) Need to review the language used in this section too. Needs to be parallel with the rest of the standard.

vi) Delete last part – "and no greater than 20 times the MDA."

vii) Confirm language consistency.

viii) A section reference will change as appropriate (1.7.5.2c?).

There was concern expressed previously whether there was a second source that was traceable. This is why this section was left with some flexibility.

ix) Remove "other than gamma ray spectrometry" in the last sentence.

Richard commented that ii) is clear when an MS is needed. If it does not fall under one of these categories, it is not required. It is specified by method, regulation or determined by the client or contract review process.

Keith noted that x) and xi) also refer to frequency and perhaps they are not needed.

Bob commented that before statements were made that an MS is not needed. Now we are saying you don't need it if it is gamma spec, or if you have a carrier, etc. This implies it is a requirement. Perhaps some of the language at the end should be at the top to make it clear matrix spikes are not typically needed.

Vas does not see any contradiction. He also noted that what is included in the lab's Quality Manual needs to be considered. He thinks the text presented is fine.

Nile commented that a MS is not always included in Radiochemistry work. What is being discussed is only relevant when a MS is required. Vas emphasized that the information in

ii) needs to be in the lab Quality Manual if the lab does not do an MS. Lab's need to be held to what is in their SOPs and Quality Manual.

Larry suggested changing the word "examples" in the introductory paragraph to "options". This emphasizes that it is not a requirement unless it is required by one of the statements under ii). Vas felt strongly that his would not be appropriate – it would discourage people from ever running a MS and he feels they need to thoroughly evaluate whether a MS is required.

Vas is looking at what extra value the MS will bring to the analysis. He does not think any additional information will be gained – especially for gamma ray spectrometry.

Richard commented that matrix spikes really only relate to one single sample in the batch, not the entire batch. It is up to the client to decide how the MS results impact their data.

Bob suggested adding something about MS not typically being performed in certain circumstances. This was added to the new introduction (previously i)) – see above.

Delete x) and xi).

b) Matrix Duplicates/Matrix Spike Duplicates/LCS Duplicates

i) Change text: Duplicates are defined as <u>two</u> aliquots instead of "multiple" aliquots. Change last sentence to: Duplicate analyses provide a measure of precision when the target analyte is present in the sample chosen for duplication.

Change this section to an introduction and appropriately rename section bullets below.

ii) The language in this section needs to be consistent with the rest of the standard. Keep parallel.

iv) Bob commented that a duplicate with no activity provides valuable information about the reproducilibity of results as they approach background as long as the evaluation criteria take into account the uncertainty of the respective measurements.

v) Remove "un" in unavailable – first sentence.

c) Tracer

Nile reviewed the paragraphs.

4th paragraph: Language needs to stay consistent with the rest of the standard. Keep parallel.

d) Carrier

The language is similar to the Tracer section. Bob suggested combining these sections and using the word "and" – Tracer and Carrier.

(Callers had to hang-up and call back in due to sound issue.)

Nile and Vas will consider the comments and recommended changes. An update will be distributed for review prior to the next meeting. This will hopefully be finalized at the next meeting.

Status Section 1.7.3 (Dave, Terry, Larry)

1.7.3.1 – Negative Control

a) The word sample need to be plural – samples. The word "are" needs to be replaced with "shall be".

b) OK

d) Change "are" to "shall be".

1.7.3.2 – Positive Control

a) OK

c) and d) were combined into one bullet – b).

1.7.3.3 Sample – Specific Controls

a) Matrix Spike, Matrix Replicates, and Matrix Spike Duplicates

Replicates needs to be changed to Duplicates. Add "are" – "duplicate precision are calculated as …".

i) Add "matrix" to first sentence – "Matrix spikes and matrix duplicates …".

Need to look at whether to define "other appropriate statistical measures". Are more examples needed? RPD does not always work. Bob pointed out that some laboratories use Z_{rep} per MARLAP Chapter 18 in addition to the RPD). Additional wording will be added. Marty will forward some language he has worked on that describes the need for both. Larry will consider this during the update to this section.

Add "are" – "duplicate precision are calculated as …".

b) Tracers and Carriers

i) Second sentence: Replace "recovery" with "yield". Make similar change in last sentence in section – "%R" should be "percent yield".

ii) Instead of samples being reprocessed and reanalyzed, it should read "reprocessed and/or reanalyzed".

1.7.3.4 Evalution of Sample Results

This section still needs to be finished. Checking for internal consistency of results should be considered.

Status Section 1.7.4:

No additional comments were received after the last meeting. Bob would like Richard to review this before the next meeting.

4. Status on PT Committee Discussions

Ron Houck has joined the PTP SOP Subcommittee. He will be representing radiochemistry concerns in the re-write of the SOP on how to calculate and determine FoPT limits.

5. Collected Comments on Module 6 from Louisville Review

Bob emailed the collected comments to the committee (the sections reviewed in this meeting are included in Attachment B). Items marked in yellow are the items this committee will look at:

Section 1.3.1: Larry noted that these are defined in Module 2. Marty made a comment that a group of people from an Air Force lab are voicing concerns that batches should not be limited to ≤20 samples. Marty will send Bob the comments he received from this lab, along with a copy of an EPA document that makes reference to different acceptable batch sizes. He will decide whether it is relevant to this committee's discussions, or should be forwarded to Quality Systems Expert Committee as a more general issue.

Section 1.3.1 – Bullet 2: Bob does not think an additional definition related to non-destructive tests is needed.

Section 1.5.1 a): A suggestion for rephrasing was made. Bob had a similar suggestion:

RTS: Consider this alternate language for a)]: Prior to their acceptance and institution, methods for which data will be reported shall be validated across the range of activities

that will be encountered in samples. Where applicable, the activity range shall include zero activity.

This change will be made.

Section 1.5.1 f): Reference to MARLAP. This language does need to be reworked to make sure the intent is clear. Larry will DRAFT some language before the next meeting. "As available" should not be a "Get out of jail" card.

1.5.2: The text was broken up into individual requirements and put in order by Bob. Bob walked everyone through the changes. Need to still look at flow of section. Group detection capability requirements separately from MDA, Lc and DL need to be considered. Marty will work on this before the next meeting.

6. New Business

Upcoming Conference Calls: The group is looking at an additional meeting on Wednesday the 9th in the month of April. Bob will check with the rest of the committee by email and have this scheduled if it works for enough people. Initial response to an invitation seems to indicate that we will have sufficient participation on the proposed date.

7. Action Items

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

8. Next Meeting and Close

The next meeting will be scheduled by email.

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

The meeting was adjourned 3:01pm EST. Motion: Larry Second: Marty 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**	Wadsworth Center, NY State DOH Albany, NY	AB	518-474-6071	tms15@health.state.ny.us
Sreenivas (Vas) Komanduri **Present (Left at 2:10pm)**	State of NJ Department of Environmental Protection Trenton, NJ	AB	609-984-0855	Sreenivas.Komanduri@dep.state.nj.us
Marty Johnson **Present (2pm)**	US Army Aviation and Missile Command Nuclear Counting Redstone Arsenal, AL	Lab	865-712-0275	Mjohnson@tSC-tn.com
Dave Fauth **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 **Present (Left at 2pm)**	US EPA ORIA NAREL, Montgomery AL	Lab	334-270-3418	mccroan.keith@epa.gov
Todd Hardt **Absent**	Pro2Serve, Inc. Oak Ridge, TN	Other	865-241-6780	HardtTL@oro.doe.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 **Present**	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

Combined Comments Section 1.0-1.6

Section 1.1, Line 10: The term "Quality Assurance" was added. I believe this was intentional.

Section 1.2 Scope: Add date to MARLAP – June 2004.

Section 1.2, Lines 18-22: References to mass measurement techniques were removed.

Section 1.2, Lines 24-28: References to the SDWA, CWA and MARLAP were inserted.

Section 1.2, lines 25-27. References to the documents required.

Section 1.3.1: Additional terms and definitions were added.

Section 1.3.1: We may want to add expanded definitions for "Preparation Batch" and "Analytical Batch".

Section 1.3.1

- Delete definition for DQO? – **Will Delete**
- Add definition for analytical and prep batch that expands on concepts particularly vis-à-vis non-destructive tests.
- Add to Note 2 that for the purposes of this standard, MDA and MDC are equivalent. **[RTS – added]**

Section 1.3.2: Exclusions and Exceptions added. These address mass measurement techniques.

Section 1.5.1 a): Suggest rephrasing to read,

"Methods for which data will be reported shall be validated across the range of activities that will be encountered in samples prior to acceptance and institution. Where applicable, the activity range may include zero activity." **[RTS: I suggested very similar language] Make this change**

Section 1.5.1 b), Line 119: Insert "it" after "which". **[RTS – done]**

Section 1.5.1 b) add "it"after "…for which…"**[RTS – done]**

Section 1.5.1 d), Lines 128 – 129: Confirmed references are correct.

Section 1.5.1.d. Please, verify the reference to the latest standard. **[RTS – made note]**

Section 1.5.1 f): Do we need to refer to MARLAP? Consider rephrasing as follows: **[RTS – On rereading, this implies that labs will source QC samples – as opposed the traceable materials to create QC samples - from an outside vendor. Is this intended?]**

"As available, the laboratory shall analyze for all methods externally produced quality control samples…"

Throughout the document: There are issues with numbering of sub-levels throughout the document. This is apparent is section 1.5.1 and 1.5.2 where the sub-levels for 1.5.1 are numbered as a), b) … and the sub-levels for section 1.5.2 or are numbered as 1.5.2.1, 1.5.2.2 … This is probably best addressed by a technical editor.

Section 1.5.2: Consider breaking the paragraph into separate requirements, i.e.

Detection capability may refer to the critical value, Minimum Detectable Activity (MDA), or SDWA DL *(terms defined in Section 1.3.1)*.

a) The laboratory shall establish the detection capability for each method/matrix combination.
b) The laboratory shall document the procedure used to determine the detection capability.
c) The laboratory shall record the quality system matrix used in the initial method validation and retain all supporting documentation for the initial study in a readily retrievable format for the lifetime of the method.
d) The procedure a laboratory uses to determine the detection capability of a method must comply with the specific requirements of Sections 1.5.2.1 or 1.5.2.2.
e) Method validation documentation must also include identification of software used for detection capability calculations and the software must conform to the requirements in Module 1 Volume 2 Section 5.4.7.2.

Section 1.5.2 list a number of requirements. These should be split out and numbered so they can be referenced by auditors.

Section 1.5.2, line 152. Volume I, Module 2, and not vice versa**.[RTS – made changes]**

Section 1.5.2.1, lines 154-159. Remove reference to MDC, and keep only MDA, according to our convention in Section 1.3.1. **[RTS – done – also removed in 1.7.2.4 b)]**

Section 1.5.2.1 **[RTS – done – also removed in 1.7.2.4 b)]**

- delete “and Minimum Detectable Concentration”
- delete “/MDC” and “/MDCs”

Section 1.5.2: The critical value is not addressed.

Section 1.5.2.2, Line 179: Add “for analyses of drinking water” after methods. Otherwise this could be read as “Laboratories performing analyses for drinking water may only use approved methods (an no others).” If a laboratory performs analyses other than drinking water they are allowed to use other methods. **[RTS - done]**

STOPPED 3/26/14

Attachment C
Action Items – REC

	Action Item	Who	Target Completion	Actual Completion
37	Send January 28th meeting minutes out for an email vote.	Bob	2/27/14	3/16/14
38	Send SOP 4-101 to committee members.	Ilona	3/25/14	
39	Send updates from 2/26/14 meeting to Bob for incorporation into the standard base document.	Tom	3/14/14	3/12/14
40	Send updates from 2/26/14 meeting to Bob for incorporation into the standard base document.	Carolyn	3/14/14	3/14/14
41	Look at additional language so labs don't need to prove sample ordering is random	Bob	3/23/14	

Attachment D – Back Burner / Reminders

	Item	Meeting Reference	Comments
1	Update charter in October 2014	n/a	
2	Issue of noting modifications to methods.	1/16/13	
3	Look at batching when QC is looked at.	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	