Radiochemistry Expert Committee (REC)
Meeting Summary

March 27, 2013

1. Roll Call and Minutes:

Tom Semkow (Vice-Chair) called the meeting to order at 2pm EST. Attendance is recorded in Attachment A – there were 9 members present. Associate members present: Terry Romanko, Virgene Mulligan, and Brian Miller.

The committee tried to use the screen share option in FreeConference, but there were some difficulties that will be worked on outside of this meeting.

The minutes from the February 27, 2013 meeting were reviewed. Larry motioned to approve the minutes and the motion was seconded by Nile. The motion passed and the minutes will be finalized and posted to the TNI website.

2. Standard Review

V1M6: Section 1.2 and 1.5.1

Nile worked on language and submitted the information to the committee by e-mail (see below).

V1M6, section 1.2, second paragraph:

The essential quality control procedures applicable to radiochemistry measurements are included in the Standard. However, this does not preclude the employment of terms, definitions, and requirements from other documents, such as, the Multi-Agency Radiological Laboratory, Analytical Protocols (MARLAP) Manual, the Safe Drinking Water Act, or client specific program direction. Additional quality control requirements that are specified by method, regulation or project shall also be considered and met by laboratories depending on client directions and agreements.

Vas asked what is meant by project requirements? He thought the language was too vague and needed to be more specific. Nile commented that there is a requirement to communicate with the client and by receiving project work or program plans, project requirements would be defined in those plans. It would define QC, etc …

Tom asked if the term "directions" should be "requirement". His concern was that the client may not have enough experience to direct. Others thought the term change would make no difference. Nile commented that this would come up during the

communication/negotiation phase of the work and the lab could communicate any issues they would have with what is being requested.

Carolyn asked if the sentence could end at "… laboratories". An additional comment was to look at the term "directive". Virgene suggested the term "contract specifications".

The last sentence will be changed to include the term "contract specifications" instead "client directions and agreement".

V1M6, section 1.5.1, Validation of Methods

a) *Prior to acceptance and institution of any method for which data will be reported, all methods shall be validated. The laboratory shall document the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.*

b) *The laboratory shall validate reference methods via the procedures specified in Sections 1.5.2 and 1.5.3. For reference methods the procedures outlined in Section 1.6 can satisfy the requirements of 1.5.2.*

c) *For all non-reference methods validation must comply with Volume 1, Module 2, Sections 5.4.5.1 through 5.4.5.3. This validation must include the minimum requirements for method validation outlined here in Sections 1.5.2 through 1.5.5.*

d) *Laboratories shall participate in proficiency testing programs for both reference and non-reference methods. The results of these analyses shall be used to evaluate the ability of the laboratory to produce acceptable data.*

Carolyn commented that this language does not track with the language she wrote for section 1.5.1. Nile responded that he missed that language. It was discussed in Denver. In Denver, Bob asked why there would be different requirements between reference methods and non-method reference methods. Perhaps there could be one procedure and then some of the information available for reference methods could be used to fulfill some of the requirements for validation.

Tom suggested that Carolyn and Nile meet before the next meeting and work through the differences. They were in agreement.

Carolyn asked if proficiency testing is part of validation. Larry reminded everyone that PTs are not always available, so they can't always be a part of validation. Others look at them as a type of quality control sample and not as validation. In Carolyn's version, (f) needs to be looked at and in Nile's version (d) needs to be looked at.

V1M6: Section 1.5.2

Carolyn had reworded this section with Tom and Bob. Richard had some additional comments in Denver that he agreed to add to the revision. He is not the call today to discuss this.

Tom wanted to continue the discussion started in Denver on this section:

- From Carolyn:
  Comments on the revised Section 1.5.2 below:

  - *In the first sentence do we want to use the word "should" or "shall"? "Should" may be more appropriate since MQOs may not include Detection Capability.*

  - *Consider eliminating "Method validation" from the beginning of Larry's proposed change.*

- Larry talked about commercial software and had some suggestions for wording changes because all the documentation for software validation is not available. Change the wording to "method validation documentation must include identification of the software used for detection calculations and the software must conform with the requirements in Module 1 Volume 2 Section 5.4.7.2." Carolyn commented on whether the term "should" or "shall" should be used.

  Larry suggested that "method validation" could be removed from the sentence. Tom agreed. Since the actual wording is not available to the committee right now, the decision on using "should" or "shall" will be determined when final wording is gone through.

Activity vs Activity Concentration

Vas worked on this topic after the last meeting. He looked up the meaning of the two terms to help determine which would be most appropriate. Wherever "activity" is referred to it is discussed in terms of radioactivity. Looking at "activity concentration", there are a couple of places that reference specific activity. Vas prefers to use the term "activity".

Tom noted that IAEA associates activity concentration and specific activity according to Vas investigation. On the contrary, ISO and IUPAC associate activity concentration with volumic activity and specific activity with massic activity. The term "specific activity" is not used much in the environmental measurement field. Another committee member noted that the term is used to refer to the specific activity of a radionuclide (or mixture of radionuclides) when converting Total Uranium or U-238 from mass units to activity units. He uses the specific activity based upon the half-life of the radionuclide. This issue is not restricted uranium and is commonly encountered when someone is converting mass spectrometry results in units of radioactivity.

Other committee members agreed the term to use would be "activity" to avoid any confusion and to be consistent. Tom noted that a sentence should be added along the lines

of "other units can be substituted as needed". Bob will add this to the definition of activity.

V1M6: Section 1.5.3

Vas prepared information for this discussion that has been distributed to the committee members. He suggested the following wording changes marked in red:

1.5.3 Evaluation of Precision and Bias

The laboratory shall determine precision and bias for the method validation and prior to acceptance and institution of the method. The laboratory shall compare results of the precision and bias of measurements with criteria established by the client, given reference method or measurement quality objective established by the laboratory.

a) *The laboratory shall utilize a method that provides precision and bias for each of the analytes of interest that is appropriate and relevant for the intended use of the data. Precision shall be characterized across the range of activities that brackets those that will be encountered in samples including zero concentration.*

b) *The laboratory shall process the samples through the entire measurement system for each analyte of interest and evaluate precision and bias in each relevant quality system matrix.*

c) *The laboratory shall determine precision and bias of a method each time there is a change in the test method that affects the performance of the method, or when a change in instrumentation occurs, that affects the precision.*

~~*The laboratory shall compare results of the precision and bias of measurements with criteria established by the client, given reference method or measurement quality objective established by the laboratory.*~~

d) *Where there are no established criteria, the laboratory shall develop acceptance criteria for precision and bias based on one or more of the following:*
   a. *Intended use of the data*
   b. *Applicable regulations*
   c. *Guidelines established in publications such as MARLAP[1], The FEM document[2] and/or IUPAC[3] guidelines.*

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1. *Multi-Agency Radiological Laboratory Analytical Protocols*
2. *Validation and Peer Review of U.S. EPA Radiochemical Methods of Analysis, US EPA Document, September 2006.*
3. *Harmonized Guidelines for Single Laboratory Validation of Methods of Analysis – IUPAC Technical Report, Pure Appl. Chem., Vol. 74, No. 5, pp. 835-855, 2002.*

Carolyn commented that the section that was stricken out in C is not a repetition. After looking at the addition to the first paragraph, it was determined this strike out is appropriate.

It was asked whether the language added to the first paragraph should point to some of the language in Section 1.5.1? Carolyn commented that Section 1.5.1 (a) does address this, so a reference is not needed and perhaps the first sentence is not needed at all. After review, the committee agreed it was not needed. The sentence should be deleted.

Tom asked about how to handle footnotes in the standard. Ilona commented that the formatting will be taken care of by TNI.

V1M6: Section 1.5.4

From Carolyn:

Following is my proposed modification to Section 1.5.4.d):

d) The results of the precision evaluation in Section 1.5.3 shall be compared to the uncertainty estimates as a check on the validity of the uncertainty evaluation procedures. The experimentally observed standard deviation ~~precision, expressed as uncertainty,~~ at each testing level shall not be statistically greater than the maximum combined 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 is statistically greater than the maximum combined standard uncertainty, then the uncertainty estimate should be re-evaluated.

Larry agreed with the change proposed. Tom asked if "from the precision evaluation" needs to be added to the sentence added in the end. Other committee members did not feel it was necessary – it is clear. The addition will not be made.

Vas commented that precision and uncertainty are two different metrics that should be treated differently. There was a discussion on how different people calculate uncertainty. Tom proposed accepting the wording from Carolyn with the following changes: It should read at "any" testing level instead of "each" and change "precision" to "standard deviation".

V1M6: Section 1.5.5

The following was submitted by e-mail:

1.5.5 Evaluation of Selectivity

The laboratory shall qualitatively evaluate selectivity, if applicable, by addressing the following sample and matrix characteristics:
a) the effect of matrix composition on the ability of the method to detect analyte

b) the ability of the method to chemically separate the analyte from the interfering analytes
c) spectral and instrumental interferences.
The evaluation of selectivity may be accomplished by testing matrix blanks, spiked matrix blanks, worst-case samples, or certified reference materials. If applicable, a qualitative selectivity statement shall be included in the SOP.

Vas pointed out that selectivity would be less applicable to gross methods. Tom commented that is why he added the term "if applicable" to the sentence. After discussion, the committee determined the language proposed is sufficient.

Bob commented that "If applicable" should be removed from the last sentence. He also questioned the need for the term "qualitative". Tom noted that the EPA manual Bob recommended he review stated that there weren't quantitative methods for selectivity. After discussion, the committee agreed to delete "If applicable" and keep "qualitative". This can be revisited if comments arise.

V1M6: Section 1.7.1

Tom commented that the wording in Section 1.7.1 has been worked out by Bob, Vas and himself. Vas commented that he would like to see it one more time before it is sent to the committee.

3. Action Items

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

4. Next Meeting and Close

The next meeting is scheduled for Tuesday, April 25th at 2pm EST. *(Note: This meeting was canceled and rescheduled for May 22nd.)*

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

The meeting ended at 3:30 pm EST.

Attachment A
Participants
Radiochemistry Expert Committee

Members	Affiliation		Contact Information	
			Phone	Email
Bob Shannon (Chair) **Present – Portions of meeting.**	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**	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 **Present**	Consultant Aiken, SC	Other	803-649-5268	dj1fauth@bellsouth.net
Carolyn Wong **Present**	Lawrence Livermore National Laboratory Livermore, CA	Lab	925-422-0398	wong65@llnl.gov
Keith McCroan **Present**	US EPA ORIA NAREL, Montgomery AL	Lab	334-270-3418	mccroan.keith@epa.gov
Todd Hardt **Present**	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 **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	Actual Completion
1	Nile will prepare language for Section 1.5.1 and propose a revision to 1.2.	Nile	2-26-13	Complete
2	Richard will look at all of 1.5.2 (including 1.5.2.1) and propose some new language. He will review it with Nile before submitting to committee. (2/27/13: Carolyn and Tom also asked to review this before submission to the committee.)	Richard	2-26-13	
3	Richard will prepare language update for 1.5.3 and submit to committee.	Richard	2-26-13	
4	Tom will research terminology on activity, activity concentration, etc.	Tom	2-26-13	Complete
5	Define "activity concentration" and note that when the word activity is used, it means activity concentration. . The committee will look at changing the word "concentration" to "activity" after the definition is finalized. Circulate to committee members and Ilona.	Vas	3-21-13	Complete
6	Work on language for 1.5.3. Circulate to committee and Ilona.	Vas	3-21-13	Complete
7	Work on language for 1.5.4 d). Circulate to committee and Ilona.	Carolyn	3-21-13	Complete
8	Work on language for 1.5.5. Circulate to committee and Ilona.	Tom	3-21-13	Complete
9	Carolyn and Nile will work on combining their language for 1.5.1 and present it at the next meeting.	Carolyn Nile	5/22/13	
10	Prepare definition for "activity" based on today's conversation.	Bob	5/22/13	
11	Complete and distribute language proposed for 1.7.1.	Bob Tom Vas	5/22/13	

Attachment C

Backburner / Reminders – REC

	Item	Meeting Reference	Comments
1	Update charter in October 2013	n/a	
2	Issue of noting modifications to methods.	1/16/13	
3	Look at batching when QC is looked at.	1/16/13	