Radiochemistry Expert Committee (REC)
Meeting Summary

January 16, 2013

1. Roll Call and Minutes:

Bob Shannon (chair) called the meeting to order at 1:30 pm MT in Denver, CO. Attendance is recorded in Attachment A – there were 10 members present. Vas (NJ DEP) and Fauth (Consultant) were present by phone. Associate members present: Pardue, Romanko, Cha, Patton.

The previous meeting minutes were approved by e-mail and have been posted on the website.

2. General

This is a new expert committee responsible for Volume 1 - Module 6. This group previously met as a subcommittee under the Quality Systems Expert Committee.

The committee make-up is required to be a balance of ABs, Labs and Others.

3. Standard Review

The committee has started review of the 2009 standard (that includes the changes proposed by the Quality Systems Committee). The changes being made are to make it consistent with what the committee feel is needed for radiochemistry. The first four sections have been reviewed.

Section 1.5 Method Validation:

This is a large change.

Section 1.5.1: Carolyn read through the changes recommended in this section. Should a reference to MARLAP be made? There is a comment in the DOD manual that is at the top of Module 6. A similar statement could be made at the top of this section. Richard said the committee should be very careful about pointing to additional documents because of copyright issues. Nile will provide the language and send it out to the committee. He will propose a revision to 1.2.

This committee would prefer to come up with its own definitions and not just refer elsewhere. If a document is referenced, it makes it difficult for someone to pull all the documents together to assess the standard. It should be avoided where possible.

Section 1.5.1 e):

Comment 1: Include a statement to the extent that the method shall not be used outside scope – or that results must be qualified if the method is used outside scope? Larry thinks this is covered in Module 2. Scope is defined there.

Need to be careful that the language does not lead to having to validate every possible soil type. (5.4.2 is a useful reference here.) It is a performance based method and it is up to the assessor what is and is not accepted. Don't want to have to validate every possible matrix. The scope of the method has to meet the customer's needs.

Comment 2:

What about modified methods – should these be named modified, or should lab-modified, lab-developed methods be referred to using the laboratory's SOP ID. Larry commented that it is very difficult to determine what a modified method is. You can pick-up HASL 300 and no one does it verbatim. Are these all modifications?

Larry reminded everyone that Module 2 does require that SOPs need to state any modifications if they are referring to a specific method. If it is a true performance based method, it would have a unique name. It has been validated.

Larry noted that this is a problem, but this may not be the best place to put it in the standard. This will be remembered, but the discussion was tabled at this time.

Carolyn asked people about the removal of exceptions for grandfathered methods or reference methods. She is suggesting that all methods have to be validated. Richard noted this is much more stringent than what is in the rest of the standard. He would prefer not to support a more stringent requirement.

There is a difference between a demonstration of capability and a validation of the method. Labs demonstrate capability of reference methods, but they don't go through a formal validation procedure. A DOC does not look at precision and bias. In other parts of the TNI standard, precision and bias is looked at as being assessed through an LCS. Many members of the committee did not feel this was adequate for radiochemistry methods and how they are used and results are reported.

The standard does state that measurement of uncertainty must be available and reported where required. Module 6 will make it a requirement. Does this make validation make more sense?

Bob noted that there are difficult questions. Does a lab need to validate every matrix? It might make sense, instead, to point to NELAC defined matrices and then leave it up to the lab beyond that. .

Section 1.5.1 f):

Richard: There are some issues with this wording.

The 2009 standard has some new PT language from what was originally in the 2003 standard. Does a PT have to come from a TNI approved PT Provider?

Suggested Rewording of 1.5.1 (f):

~~For all methods, laboratories shall participate in proficiency testing programs.~~ The results of these analyses ~~shall~~ **may** be used as one of the criteria to evaluate the ability of the laboratory to produce acceptable data.

Conference Break

Ilona was asked to check with Jerry about standard distribution. *1-18-13: The standard, including the ISO language, can be distributed to associate members if the associate member shows proof of ownership of the ISO standard.*

Review after Break:

Suggested language: All methods need to have documented performance data.

Tom Patton requested that more information be given about what validation means?

Carolyn reminded everyone that existing QC data may be used to calculate the information needed to validate the method.

Section 1.5.2:

Larry commented on the language in Section 1.5.2 that states that all procedures used to determine method detectable activity shall be documented. The concern is that the laboratory does not always have the exact details or source code for commercial software used for determining detectability. The committee agreed to revise this section to include a cross reference to software validation requirements in V1M2 Section 5.4.7.2.

DL should not be used. It has a different meaning in other parts of the standard. “DL” will be removed and it will be spelled out.

Suggested language change:

The Detection Capability should be established by the applicable measurement quality objectives and may refer to one (or more) of the following terms ... This section should make it clear this needs to be done for each method. Richard noted that this needs to be written in an active voice and “should” is not appropriate. He will reword this and send it to the committee for consideration.

Section 1.5.2.1:

Project program planning process instead of MQO.

The Request and Tenders part of Module 2 is relevant.

The standard has to be more generic and general because of all the different matrices.

Richard noted that there is a need to rewrite this section. It needs to be rearranged. Need to put in requirements, not develop a teaching document. Richard will edit the section and get it back to the committee (2 weeks.) He will look at the entire 1.5.2 section. He will send a first draft to Nile and then finalize the DRAFT to go the committee.

Section 1.5.3:

MQO reference needs to be revised.

a) Need to decide on one term – activity, activity concentration, or concentration. Use of the term bracket is also an issue – if it includes zero … does this mean there are negative numbers too?

   Nearly every result is a concentration, not activity. Concentration is also more generic. Concentration will be used.

   There was a question about what "characterized" means. The subcommittee felt this was an appropriate term and will be left as is. Richard proposed language that he will write up and distribute to the commmittee for use.

b) Add: Additional specific analytes may be required in clients request and requirement.

c) No changes.

d) It is more than just comparing it. It needs to meet some type of criteria.

e) These were already in the standard. It is useful, but does not make sense to have in the standard.

   Look at adding examples and ideas to the Quality Manual Template or white papers.

   Section (e) should be deleted.

4. Other Business:

   - Tom wanted to talk about batching. He was voted down on the batches. He feels that radiochemistry techniques are different than chemistry and suggested that someone else could come out with a proposal. If someone is in a hurry and has to analyze one sample - 4 QC are needed. There are two spiked samples and additional radioactive waste is created.

He is concerned that no action will be taken on this and that this will reflect badly on the committee. Bob said they were not completely done with the topic and it would be looked at again when the committee looks at QC.

- Tom also wanted to express his concerns about the generic use of the term “concentration”. (4:56) An example was given that it can be mass concentration and activity concentration if you leave it more generic. Tom is concerned that concentration is going to be assumed to be mass concentration. This will be further discussed at the next meeting.

5. Action Items

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

6. Next Meeting and Close

The next meeting is scheduled for Tuesday, February 26th at 2pm EST.

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

A motion to dismiss the meeting was made by Nile. The motion was seconded by Marty and unanimously approved.

Attachment A
Participants
Radiochemistry Expert Committee

Members	Affiliation	Balance	Contact Information	
			Phone	Email
Bob Shannon (Chair) **Present**	QRS, LLC	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 - Phone**	State of NJ Department of Environmental Protection Trenton, NJ	AB	609-984-0855	Sreenivas.Komanduri@dep.state.nj.us
Marty Johnson **Present**		Lab	865-712-0275	Mjohnson@tSC-tn.com
Dave Fauth **Present - Phone**	Consultant	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 **Not 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
Ilona Taunton (Program Administrator) **Present**	The NELAC Institute	n/a	828-712-9242	Ilona.taunton@nelac-institute.org
Richard Sheibley	Sheibley Consulting, LLC Hummelstown, PA	Other	651-485-1875	RHSHEIB111@yahoo.com

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	
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.	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	
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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.	1/6/13	