

Radiochemistry Expert Committee (REC) Meeting Summary

March 23, 2016

1. Roll Call and Minutes:

Bob Shannon, Chair, called the meeting to order at 1:0x pm Eastern on March 23, 2016 by teleconference. Attendance is recorded in Attachment A – there were 9 members present. Associate Members: Brian Miller, Matt Sowards.

2. Shawn Kassner

Shawn provided an update on the status of the PT Modules. Concern of Vas, Carolyn and Bob were addressed in the update of modules 1 and 2. No changes could be made to modules 3 and 4 although ERA and the State of NY (the two PT providers for radiochemistry) have agreed to voluntarily begin collecting uncertainty along with the reported results from labs. Collecting this data will provide a foundation upon which uncertainty can be evaluated into the radiochemistry PT evaluation process in the future.

3. Subcommittee Updates

Assessor Training

Discussion continued on the concept of annotating the Standard with the comparison document information in some way to prevent repetitiveness between these two documents. Actual text is placed into the Standard to provide helpful tips and clarification. Bob ran through examples on Webex. Bob is concerned that adding text to the actual standard may lead to people using the text as “interpretation” effectively overriding the text of the actual Standard.

Ilona noted that a copy of the Standard with additional language would be more difficult to distribute. The user would have to prove they own a copy of ISO/IEC 17025 before they could be given access to this document.

Bob opened up the summary document he prepared for the training in Tulsa. Using this document requires a copy of the TNI Standard. The summary document was originally prepared to show the differences between the old and new standard.

The committee decided to move forward in incorporating the summary document into the Standard. Bob asked for a volunteer to make this annotated version of the Standard Carolyn will start working on this. She will not have any time to work on this until May, though.

Assessor Checklist

Larry reviewed the checklist that Bob sent the committee. Larry noted that the subcommittee is halfway through the checklist. They have also gotten critical comments from Richard and Tom.

There was concern expressed that the order of the questions are not in the order of the Standard. Richard thought it was confusing. Bob noted that it is the first questions that are out of order and it makes sense. After that, it looks like it is in order. People will be able to re-sort the checklist and be able to put them in any order they want.

Question 11 of the Checklist: It was pretty much taken straight from the Standard. Tom commented that zero activity could be changed to Method Blank. Richard thinks such a change would be an issue and changing the Standard – the change should not be made.

The committee continued to review the checklist as noted in Attachment D.

4. New Business

None.

5. Action Items

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

6. Next Meeting and Close

The next meeting will be on April 27, 2016. *(Late addition: The April meeting was canceled and the next meeting is May 25, 2016).*

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

The meeting was adjourned 2:30 pm Eastern.

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	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
Nile Ludtke Absent	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
Ron Houck Present	PA DEP/Bureau of Laboratories	AB	717-346-8210	rhouck@pa.gov
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
74	Provide example of Standard with comparison document language incorporated.	Bob	3-15-16	Complete
75	Complete rough DRAFT of assessment checklist by August.	Checklist Subcommittee	8/31/2016	
76	Prepare copy of Standard annotated with summary document language.	Carolyn	Update beginning May 2016	

Attachment C – Back Burner / Reminders

	Item	Meeting Reference	Comments
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	
6	Consider preparing an impact statement on the effects of the new standard. This may be part of the “crosswalk” prepared to compare the old and new standard.	10/21/15	Ilona checked with LASEC and this is not needed. Completed.

Audit ID: _____ Laboratory: _____ Assessor: _____ Date: _____

Methods Reviewed – check as appropriate

Gross Alpha/Gross Beta	Strontium-89-90	Americium
<input type="checkbox"/> 900.0, <input type="checkbox"/> water	<input type="checkbox"/> 905.0, <input type="checkbox"/> water	<input type="checkbox"/> Am-01-RC, <input type="checkbox"/> solid
<input type="checkbox"/> 7110B, <input type="checkbox"/> water	<input type="checkbox"/> Sr-03, <input type="checkbox"/> water, <input type="checkbox"/> solid, <input type="checkbox"/> air	<input type="checkbox"/> Am-04-RC, <input type="checkbox"/> water, <input type="checkbox"/> air
<input type="checkbox"/> 9310, <input type="checkbox"/> water, <input type="checkbox"/> solid, <input type="checkbox"/> air	<input type="checkbox"/> Sr-04, <input type="checkbox"/> water	
		Plutonium Isotopes
Total Radium	Tritium	<input type="checkbox"/> Pu-01-RC, <input type="checkbox"/> air
<input type="checkbox"/> 903.0, <input type="checkbox"/> water	<input type="checkbox"/> 906.0, <input type="checkbox"/> water	<input type="checkbox"/> Pu-02-RC, <input type="checkbox"/> solid
<input type="checkbox"/> 903.1, <input type="checkbox"/> water	<input type="checkbox"/> H-02, <input type="checkbox"/> water	<input type="checkbox"/> Pu-03-RC, <input type="checkbox"/> solid
<input type="checkbox"/> 9315, <input type="checkbox"/> water, <input type="checkbox"/> solid, <input type="checkbox"/> air	<input type="checkbox"/> 7500-3H B, <input type="checkbox"/> water	
	<input type="checkbox"/> Sr-02, <input type="checkbox"/> water	Uranium
Radium-226	<input type="checkbox"/> 300 3H-04, <input type="checkbox"/> water	<input type="checkbox"/> 908.0, <input type="checkbox"/> water
<input type="checkbox"/> 903.2, <input type="checkbox"/> water		<input type="checkbox"/> 908.1, <input type="checkbox"/> water
<input type="checkbox"/> Ra-04, <input type="checkbox"/> water	Carbon-14	<input type="checkbox"/> 7500-U B <input type="checkbox"/> water
<input type="checkbox"/> 7500-Ra B, <input type="checkbox"/> water	<input type="checkbox"/> C-01, <input type="checkbox"/> water	<input type="checkbox"/> 7500-U C <input type="checkbox"/> water
<input type="checkbox"/> 7500-Ra C, <input type="checkbox"/> water		<input type="checkbox"/> U-02, <input type="checkbox"/> water, <input type="checkbox"/> solid, <input type="checkbox"/> air
<input type="checkbox"/> EMSL-19, <input type="checkbox"/> water, <input type="checkbox"/> solid, <input type="checkbox"/> air	Cesium-134/137	<input type="checkbox"/> U-04, <input type="checkbox"/> water, <input type="checkbox"/> solid, <input type="checkbox"/> air
	<input type="checkbox"/> 901.0, <input type="checkbox"/> water	
Radium-228		Gamma Emitters
<input type="checkbox"/> 904.0, <input type="checkbox"/> water	Iodine-131	<input type="checkbox"/> 901.1, <input type="checkbox"/> water
<input type="checkbox"/> Ra-05, <input type="checkbox"/> water	<input type="checkbox"/> 7500-I B, <input type="checkbox"/> water	<input type="checkbox"/> 902.0, <input type="checkbox"/> water
<input type="checkbox"/> 7500-Ra D, <input type="checkbox"/> water	<input type="checkbox"/> 7500-I C, <input type="checkbox"/> water	<input type="checkbox"/> Ga-01-R, <input type="checkbox"/> water, <input type="checkbox"/> solid, <input type="checkbox"/> air
<input type="checkbox"/> 9315, <input type="checkbox"/> water, <input type="checkbox"/> solid, <input type="checkbox"/> air		
<input type="checkbox"/> 9320, <input type="checkbox"/> water, <input type="checkbox"/> solid		

Note: Solids can include soils, sediments, sludges, vegetation, and other bulk materials

[The methods and matrices above are examples. Accreditation bodies and assessors should edit to list methods/matrices in their program.]

Assessment Checklist for Radiochemistry 3/22/2016 Draft

Audit ID: _____ Laboratory: _____ Assessor: _____ Date: _____

Item No.	Line of Inquiry		Status			Observations/Comments
			Y	N	n/a	
Standard Operating Procedures (SOPs)						
1	V1M6, 1.6.2.1 e)	Where referenced methods are required, do SOPs cite nationally accepted sources, such as EPA methods, DOE Methods Compendium, HASL 300, ASTM, etc.?				
2	V1M6, 1.5.5	Do SOPs for non-standardized methods developed by the laboratory include a qualitative statement describing the means of evaluating selectivity during method validation?				
3	V1M2, 4.2.8.5 e)	Are all methods requested for accreditation documented in SOPs?				
4	V1M2, 4.2.8.5 f)	Where modifications to the published method have been made are changes clearly described and documented?				
5	V1M2, 1.5.2.1 & 1.5.2.2	Do SOPs include the minimum elements specified in Module 2?				
6	V1M6, 1.7.2.4	Are all required QC (including tracers and carriers, as required), acceptance criteria, and corrective action procedures for QC failures clearly specified?				Note: This is to evaluate elements in SOPs. Evaluation of acceptance limits is later in cklist
7	V1M6, 1.5.2	Do laboratory SOPs describe the process and calculations used to establish detection capability?				
8	V1M6, 1.5.4	Do laboratory SOPs document the formulas for calculating measurement uncertainty and are they consistent with the Standard?				Note: Counting uncertainty for drinking water. Total uncertainty for other applications.
9	V1M6, 1.7.1.2 a)	Are calibration frequency and acceptance criteria specified in SOPs?				
10	V1M6, 1.7.1.3 c)	Are calibration verification frequency and acceptance criteria specified in SOPs?				
Method Validation						
11	V1M6, 1.5.1 a)	Does the laboratory, - Validate all methods, prior to their acceptance and institution, for which data will be reported? - Validate all methods across the range of physical and chemical parameters (e.g., density, Test Source composition, and analytical configurations) and activities that will be encountered in samples? - Include a method blank in the validation?				

Assessment Checklist for Radiochemistry 3/22/2016 Draft

Audit ID: _____ Laboratory: _____ Assessor: _____ Date: _____

Item No.	Line of Inquiry		Status			Observations/Comments	
Method Validation (continued)							
12	V1M6, 1.5.1 b), 1.5.2 through 1.5.5	Does the laboratory, <ul style="list-style-type: none">- Validate method(s) in each quality system matrix?- Demonstrate method detection capability (DL for drinking water, MDA of other applications)?- Does the validation include evaluation of the following:<ul style="list-style-type: none">- Precision- Bias- Measurement Uncertainty, and- Selectivity					
13	V1M6, 1.5.1 c)	Does the laboratory perform validation for each method for which documented data are not available to demonstrate that the above requirements are met? For reference methods, does the laboratory reference published data , if available, to satisfy method validation? Are all required QC (including tracers and carriers, as applicable), acceptance criteria, and corrective action procedures for QC failures clearly specified?					
14	V1M6, 1.5.1 d)	Does the laboratory record the quality system matrix used in the initial method validation?					
15	V1M6, 1.5.1 e)	Does the laboratory's method validations comply with the requirements at V1M2 5.4.5.1 through V1M2 5.4.5.3?					
16	V1M6, 1.5.1 f)	Does the laboratory document the results obtained and the procedures used for method validation? Does the documentation include a statement on the suitability of the method for the intended use?					
17	V1M6, 1.5.1 g)	Does the laboratory analyze, wherever available, externally-produced quality control samples from a nationally or internationally recognized source provider?					

Assessment Checklist for Radiochemistry 3/22/2016 Draft

Audit ID: _____ Laboratory: _____ Assessor: _____ Date: _____

Item No.	Line of Inquiry			Status			Observations/Comments
				Y	N	n/a	
Demonstration of Capability (DOC)							
18	V1M6, 1.6.1	Is an initial DOC conducted by individuals prior to performing any method without constant/close supervision, any time there is a significant change in instrument type, or any time that a method has not been performed by the analyst in a twelve (12) month period?					
19	V1M6, 1.6.2.1	Is documentation maintained for each initial DOC consistent with the minimum elements specified in Section 1.6.2.1?					For Committee Discussion The previous draft listed the 7 elements given in 1.6.2.1 for DOCs. Those were removed per Tom’s suggestion. Does the Committee agree?
20	V1M, 1.6.3.1	Does the laboratory have a documented procedure describing ongoing DOC demonstrating that the analyst(s) has been able to routinely meet QC requirements in the last twelve (12) month period?					
21	V1M6, 1.6.3.2	Does the on-going demonstration include one of the following: a) Acceptable performance of blank(s) and sample(s) that have known values, single blind to the analyst; b) another initial DOC; c) at least four (4) consecutive spiked samples (e.g., batch LCS) with acceptable levels of precision and accuracy. d) a documented process of analyst review using QC samples. if a) through d) are not technically feasible, then analysis of real-world samples with results within a predefined acceptance criteria (as defined by the laboratory or method) performed?					
Technical Requirements							
22	V1M6 1.7.1	Does the laboratory’s documentation address the following? -instrument set up -initial calibration -calibration verification -instrument performance checks -subtraction background -short term background checks					
23	V1M6 1.7.1	Does the procedures ensure meeting appropriate regulatory or contractual specifications and support decision making?					

Assessment Checklist for Radiochemistry 3/22/2016 Draft

Audit ID: _____ Laboratory: _____ Assessor: _____ Date: _____

Item No.	Line of Inquiry			Status			Observations/Comments
				Y	N	n/a	
Technical Requirements (continued)							
24	V1M6 1.7.1	Does the instrument QC program meet the requirements of regulation/contract and or method? When regulation/contract and or the method does not address instrument quality control program, does the laboratory incorporate MARLAP or other consensus standard guidelines?				Note: Lab must show documentation	
25	V1M6, 1.7.1.1a)	Does the laboratory maintain the instrumentation required for each method it performs or seeking accreditation? When multiple instruments (or detectors) are involved for a common method, are the results across the instruments comparable? Does the laboratory establish the configuration and operating parameters for each measurement system (or instrument)?				Note: Lab must show data for the comparability Note: Lab must show data for operating parameters	
26	V1M6 1.7.1.1b)	Does the laboratory document any specific deviations for the system configuration or operational parameters when such modifications are required or necessary for a specific method(s)? Does the laboratory document the rationale for such changes?					
27	V1M6 1.7.1.1.c)	Does the laboratory periodically verify user-maintainable values for operational parameters to ensure their consistency with values recorded at the time of initial calibration and to ensure the continued integrity of the system configuration? If the system parameters have changed, does the laboratory determine potential impact of the changes to the system configuration or operating parameters? Does the laboratory perform corrective actions as a result of changes to configuration or operating parameters since initial calibration? Does the laboratory ensure such corrective actions are adequate to ensure continued integrity of the system configuration?				Note: Lab should maintain and document historical values	

Assessment Checklist for Radiochemistry 3/22/2016 Draft

Audit ID: _____ Laboratory: _____ Assessor: _____ Date: _____

Item No.	Line of Inquiry		Status			Observations/Comments
			Y	N	n/a	
Technical Requirements (continued)						
28	V1M6, 1.7.1.2a)	<p>Does the laboratory perform radiation measurement systems calibration prior to initial use and any time the following conditions occur?</p> <p>i) following replacement of a key detector element (e.g., a photomultiplier tube, silicon barrier detector, gas proportional detector chamber, germanium crystal, etc.)</p> <p>ii) after a repair when subsequent performance checks indicate a change in performance</p> <p>iii) after modification of system parameters that affect instrument response</p> <p>iv) when instrument performance checks exceed predetermined acceptance criteria (i.e., limit of a statistical or tolerance control chart or other QC parameters) indicating a change in instrument response since the initial calibration</p> <p>v) when indicated by corrective actions</p> <p>vi) when calibration is due according to a predetermined frequency</p> <p>Does the laboratory document the criteria to initiate (re)calibration in its SOPs?</p>				

Assessment Checklist for Radiochemistry 3/22/2016 Draft

Audit ID: _____ Laboratory: _____ Assessor: _____ Date: _____

Item No.	Line of Inquiry				Status			Observations/Comments
					Y	N	n/a	
Technical Requirements (continued)								
29	V1M6 1.7.1.2b)	Due to the linear response of detection system with respect to count rate at all but the highest activity levels (i.e., where detection system dead time becomes significant), calibration curves with standards of varying activity need not be performed for radiochemical methods. However, the following techniques require multiple-point calibration curves to correlate a number of parameters other than activity. Does the laboratory perform multi-point calibration for the following? b) 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 scintillation detectors.						
30	V1M6 1.7.1.2c)	Does the instrument calibrations make use of reference standards based their on physical measurements as defined in Section 1.7.2.6.c)? Does calibration standards have the same general physical characteristics (i.e., geometry, density, composition, nuclear decay properties, etc.) that match as closely as possible those of the samples to which the calibration will be applied, except as noted in Section 1.7.1.2 d).						
31	V1M6 1.7.1.2d)	Where calibration standard characteristics do not exactly match sample characteristics, does the laboratory use empirical techniques (e.g., gamma transmission) and/or computational techniques? (e.g., Monte Carlo or efficiency modeling techniques) Does the laboratory generate correction factors that will be applied to the calibrations performed using reference standards? Does the correction factors account for minor differences between the physical characteristics of the calibration standard (i.e., geometry, density, coincidence-summing, etc.) and the samples to which the correction is to be applied?				Note: Since Monte Carlo modeling techniques are relatively recent, the lab should have thorough documentation. The modeling techniques not applicable for drinking water analysis.		

Assessment Checklist for Radiochemistry 3/22/2016 Draft

Audit ID: _____ Laboratory: _____ Assessor: _____ Date: _____

		<p>Does the laboratory document empirical or modeling techniques to</p> <ul style="list-style-type: none"> i) validate the correction method or model by physical measurement of reference standards as defined in Section 1.7.2.6.c). The validation shall span the entire range of physical characteristics observed in samples to which the correction shall be applied (i.e., geometry, density, etc.); ii) the applied correction consistently minimizes measurement bias across the range of physical characteristics; and iii) the laboratory has estimated and validated the uncertainty associated with the correction (see Section 1.5.4) and included it in the uncertainty reported with each associated sample result. 				Note: Lab should have detailed documentation.
32	V1M6 1.7.1.2e)	<p>Does the laboratory include the following essential elements for the initial instrument calibration?</p> <ul style="list-style-type: none"> i) The laboratory shall establish and document in written procedures and in records the details of the initial instrument calibration. Details shall, at a minimum, include: <ul style="list-style-type: none"> 1. the type of calibrations to be performed; 2. the number of calibration points required; 3. a description of the calibration standards required; 4. the preparation of the calibration standards; 5. the counting of the calibration standards; 6. the maximum permissible uncertainty for calibration measurements (e.g., a maximum relative combined uncertainty of the calibration parameter or a minimum number of counts collected); and 7. all calculations. ii) The laboratory shall establish criteria, appropriate to the calibration technique, for the acceptance of an initial instrument calibration in written procedures. iii) If the initial instrument calibration results are outside established acceptance criteria, the laboratory shall perform corrective actions. iv) The laboratory shall retain sufficient raw data records to permit reconstruction of the initial instrument calibration. v) 				

Assessment Checklist for Radiochemistry 3/22/2016 Draft

Audit ID: _____ Laboratory: _____ Assessor: _____ Date: _____

Item No.	Line of Inquiry			Status			Observations/Comments
				Y	N	n/a	
Technical Requirements (continued)							
33	V1M6 1.7.1.2f)	Does the laboratory quantitate sample results only from the initial instrument calibrations unless otherwise allowed by regulation, method, or contract?					
34	V1M6, 1.7.1.3 a) & c)	Are initial instrument calibrations verified with either: a) a second set of calibration measurements compared to the first, or b) a standard obtained from a second manufacturer or lot, if the lot from the manufacturer can be demonstrated as prepared independently from other lots? Does the laboratory have a procedure stating the acceptance criteria, and were those criteria met?				For Committee Discussion Tom's Comment: This is an example of repeating the standard. I would put it: Does the laboratory have procedure for instrument calibration verification? Does the laboratory have procedures for accepting calibration verification and corrective action when it fails?	
35	V1M6, 1.7.1.3 b)	Does the laboratory have a procedure that specifies the maximum permissible uncertainty for calibration verification, which could be expressed as the minimum number of counts for each measurement?				Tom: Delete text in red?	
36	V1M6, 1.7.1.4 a)	Are instrument performance checks conducted using appropriate check sources and monitored with control charts or tolerance charts to ensure that the instrument is operating properly, the detector response has not significantly changed, and therefore the instrument calibration has not changed?				Tom: No need to outline why performance checks are conducted.	
37	V1M6, 1.7.1.4 a)	Does the laboratory have a procedure for corrective actions to be taken when results for the performance check are outside of acceptance criteria, and when results were outside those criteria were appropriate corrective actions taken?					
38	V1M6, 1.7.1.4 a)	Do the performance check sources provide adequate counting statistics for a relatively short count time, and is the activity level of the performance check decay corrected where significant?					
39	V1M6, 1.7.1.5 a)	Are performance check sources sealed or encapsulated to prevent loss of activity and contamination of the instrument and laboratory personnel?					

Assessment Checklist for Radiochemistry 3/22/2016 Draft

Audit ID: _____ **Laboratory:** _____ **Assessor:** _____ **Date:** _____

Item No.	Line of Inquiry	Status			Observations/Comments
		Y	N	n/a	
Technical Requirements (continued)					
40	V1M6, 1.7.1.4 (b)	Are performance checks conducted at least as frequently as required in Section 1.7.1.4 b) c)?			For Committee Discussion
					Tom: this is a repetition of the standard
		For gamma spectrometry systems, are detector efficiency, energy calibration, and peak resolution checked:			
		- Semiconductor detector: twice weekly on non-consecutive days, or on day of use if the detector is not used continuously			
		- Scintillation detector (e.g., sodium iodide): each day of use?			
		For alpha spectrometry systems:			
41	V1M6, 1.7.1.4 d)	- Energy calibration checked weekly			
		- Detector efficiency checked monthly			
		For gas-proportional and semiconductor alpha/beta detectors:			
		- Alpha and beta efficiency checked each day of use			
		For liquid scintillation detectors:			
		- Calibration at frequency recommended by the manufacturer?			
42	V1M6, 1.7.1.5 d)	- Efficiency with unquenched ³ H and ¹⁴ C standards: each day of use			
		For solid-state scintillation detectors (e.g. zinc sulfide):			
		- Efficiency checked each day of use?			
		Note: Test Sources (e.g., samples) may be tested without interruption on systems with automated sample changers to complete a batch (preparation batch or radiation measurement batch) for a period longer than the intervals listed above, as long as the period between checks is not > 7 days, checks are done at the beginning and end of the batch, and the checks meet acceptance criteria.			
		When detector systems are powered off between performance checks, are performance checks counted prior to the next Test Source measurement?			
		Does the laboratory have procedures for performing and evaluating subtraction background measurements that include the following:			
43	V1M6, 1.7.1.5 e)	- Frequency and length of measurements?			
		- Count times ≥ longest associated sample counting time			
		- Use of control or tolerance charts and acceptance criteria?			
		- Corrective action steps to be taken when acceptance criteria are not met?			
		When are the acceptance criteria checked?			
		When are the acceptance criteria updated?			

semkow 3/18/2016 2:25 PM

Deleted: the following

Assessment Checklist for Radiochemistry 3/22/2016 Draft

Audit ID: _____ Laboratory: _____ Assessor: _____ Date: _____

Item No.	Line of Inquiry			Status			Observations/Comments
				Y	N	n/a	
Technical Requirements (continued)							
43	V1M6, 1.7.1.5 a)	Are subtraction background measurements performed and evaluated separately for each detector? Are background checks being collected before and after any counting chamber changes are made (i.e., cleaning, liner replacement, or instrument modification)?					
44	V1M6, 1.7.1.5 a)	Are subtraction background measurements conducted at least as frequently <u>as required in Section 1.7.1.5 c)?</u> <ul style="list-style-type: none">- Before and after each batch of Test Source measurements (a batch could be as small as a single sample), or- Measurements performed at a fixed frequency depending on the detector technology:<ul style="list-style-type: none">- Gamma spectrometry: monthly- Alpha spectrometry: monthly- Gas-proportional and semiconductor alpha/beta detectors: Quarterly.- Liquid scintillation detectors.<ul style="list-style-type: none">• Individual quenched background: Once per Preparation Batch.• Quenched background curve: According to frequency specified in laboratory procedures.- Solid-state scintillation detectors (e.g., zinc sulfide) for non-spectrometric measurements: Each day of use				Tom: No need to repeat the standard	
45	V1M6, 1.7.1.5 a)	Is the duration of the subtraction background measurement sufficient to quantify contamination that may affect routine sample measurements (the count time for the background measurement shall be at least as long as the sample count time.)?					
46	V1M6, 1.7.1.5	Are the counting rates from the subtraction background measurements being subtracted from the total measured counting rates in Test Sources?				Larry: Will it be obvious to auditors that the phrase “Test Sources” includes sample unknowns?	
47	V1M6, 1.7.1.6	Short-Term Background Checks – Marty to complete?					
48	V1M6, 1.7.1.7	Contamination Monitoring – Marty to complete?					

semkow 3/18/2016 2:44 PM

Deleted: the following

Assessment Checklist for Radiochemistry 3/22/2016 Draft

Audit ID: _____ Laboratory: _____ Assessor: _____ Date: _____

Item No.	Line of Inquiry			Status			Observations/Comments
				Y	N	n/a	
Quality Control for Radiochemistry – General							
49	V1M6, 1.7.2.1a)	<p>Does the laboratory follow a documented QC program that monitors and assesses the performance of the laboratory's analytical systems?</p> <p>Does the laboratory, at a minimum, incorporate the QA program imposed by regulation, method(s) and this Standard?</p> <p>Does the laboratory follow the imposed regulations when the regulations are more stringent than this Standard? (see Module 2, Section 5.9.3.c).</p> <p>If it is not apparent which requirement is more stringent, does the laboratory follow the requirements of the regulation or the mandated method?</p> <p>Does the laboratory establish requirements in its quality system based on the guidelines of MARLAP Manual or other similar consensus standard organizations when there are no established guidelines?</p>					
50	V1M6 1.7.2.1b)	<p>Does the laboratory process batch and sample-specific quality controls to provide empirical evidence that demonstrates that the analytical system is in control?</p> <p>Does the laboratory use the results for these controls to assess the data quality of sample results produced by the analytical system?</p>					
51	V1M6 1.7.2.1c)	<p>Does the laboratory employ either a sample Preparation Batch or a RMB to determine the grouping of samples and assignment of batch QC?</p>					
52	V1M6 1.7.2.1c)i)	<p>Does the laboratory initiate a Preparation Batch for samples that involves physical or chemical processing which affects the outcome of the test?</p> <p>Does the laboratory prepare the QC samples together with the associated preparation batch using the same process, personnel, and lot(s) of reagents?</p>					

Assessment Checklist for Radiochemistry 3/22/2016 Draft

Audit ID: _____ Laboratory: _____ Assessor: _____ Date: _____

Item No.	Line of Inquiry		Status			Observations/Comments
			Y	N	n/a	
Quality Control (continued)						
53	V1M6 1.7.2.1c)ii)	Does the laboratory initiate an RMB in lieu of preparation batch where sample processing does not involve physical or chemical processing of the samples? (e.g., non-destructive gamma spectrometry, alpha/beta counting of air filters, or swipes on gas proportional detectors). Does the samples and associated QC in the RMB are similar in physical and chemical parameters, and analytical configurations? (e.g., analytes, geometry, calibration, and background correction).				
54	V1M6 1.7.2.1c)iii)	Does the laboratory keep open the RMB for adding samples for a period not exceeding 14 calendar days from the start of the first sample counting or until twenty (20) environmental samples have been counted, whichever occurs first?				
55	V1M6 1.7.2.1c)iv)	Does the laboratory combine only such samples and associated QC within an RMB that share a range of physical and chemical parameters, and analytical configurations (e.g., analytes, geometry, calibration, density) that conform to the ranges of physical and chemical parameters, and analytical configurations demonstrated by method validation studies (see Section 1.5)? Does the laboratory documented procedures for RMB that include how method validation is performed, and how corrections are applied to physical calibration? (e.g., for efficiency, density, cascade summing, and background)				
56	V1M6 1.7.2.1d)	Does the laboratory's QC program document the frequency required for quality controls?				
57	V1M6 1.7.2.1e)	Does the laboratory process all batch QC samples together with and under the same conditions as the associated samples, and use the same processes and procedures for preparation, analysis, data reduction and reporting of results? <i>Note:</i> Although samples in a Preparation Batch must be prepared together, they need not be analyzed concurrently on a single detection system, rather they may be analyzed on different detection systems as long as the detection systems are calibrated for the technique in question and instrument quality controls indicate that the systems are in control.				

Assessment Checklist for Radiochemistry 3/22/2016 Draft

Audit ID: _____ Laboratory: _____ Assessor: _____ Date: _____

Item No.	Line of Inquiry			Status			Observations/Comments
				Y	N	n/a	
Quality Control (continued)							
58	V1M6 1.7.2.1f)	Does the laboratory not use systematically or preferentially specific detectors, equipment or glassware for the analysis of QC samples? <i>Note:</i> This should not preclude laboratories from segregating detectors, equipment, or glassware to minimize the risk of cross-contamination of samples or equipment as long as the criteria for segregation applies equally to batch QC samples and samples.					
59	V1M6 1.7.2.1g)	Does the laboratory's QC program document acceptance criteria for batch QC samples, sample-specific QCs, and for the evaluation of long-term trends and the methods used to establish these criteria?					
60	V1M6 1.7.2.1h)	Does the laboratory assess the results of the QC samples against acceptance criteria documented in the QC program? Does the laboratory develop acceptance criteria consistent with guidelines in MARLAP ³ or other consensus standards, or other criteria such as statistical control charts developed by the laboratory where there are no established criteria in regulations, the method, or contract?					
61	V1M6 1.7.2.1i)	Does the laboratory track and trend the results of batch QC samples using statistical or tolerance control charts?					
62	V1M6 1.7.2.1j)	Does the laboratory investigate the cause when results do not meet acceptance criteria and take corrective actions to eliminate the source or minimize the magnitude of the problem? Does the laboratory consider samples associated with a failed QC parameter as suspect and shall, wherever possible, reprocess such samples? Does the laboratory report results with appropriate data qualifiers when reprocessing is not possible? Does the laboratory note the occurrence of a failed QC sample and any associated actions in the laboratory report?					